Clinical Study Report

Drug substance: quetiapine fumarate

Study code: D1447C00135

Date: 01 December 2005

A Confirmatory Multicenter, Double-blind, Randomized, Placebo-controlled Study of the Use of Quetiapine Fumarate (SEROQUEL) in the Treatment of Patients with Bipolar Depression

Study dates: First patient enrolled: 30 June 2004
Last patient completed: 26 August 2005

Phase of development: Therapeutic confirmatory (IIIb)

Sponsor's Responsible Medical Officer: Martin Brecher, MD, DMSc

This study was performed in compliance with Good Clinical Practice.

Drug product:	SEROQUEL	**SYNOPSIS**	
Drug substance(s):	quetiapine fumarate		
Study code:	D1447C00135		
Date:	01 December 2005		

A Confirmatory Multicenter, Double-blind, Randomized, Placebo-controlled Study of the Use of Quetiapine Fumarate (SEROQUEL) in the Treatment of Patients with Bipolar Depression

Study center(s)

This study was conducted in 42 centers in the USA

Publications

None

Study dates

First patient enrolled 30 June 2004

Last patient completed 26 August 2005

Phase of development

Therapeutic confirmatory (IIIb)

Objectives

Primary:

To evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

1. The change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score
2. The percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment
3. The change from baseline to each assessment in the MADRS total score

4. The change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, the Clinical Global Impression – Severity (CGI-S), and the Clinical Global Impression – Improvement (CGI-I)[1]

Secondary:

1. To evaluate the incidence of treatment-emergent mania[2] compared to placebo by comparing the percentage of patients with a score of ≥16 points on the Young Mania Rating Scale (YMRS) at 2 consecutive visits or at the Week 8

2. To evaluate the superiority of quetiapine compared to placebo in treatment of anxiety symptoms by the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

3. To evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression

4. To demonstrate that quetiapine is superior to placebo in improving patient's overall quality of life by the change from baseline (day 1, visit 2) in the Quality of Life Enjoyment Satisfaction Questionnaire (Q-LES-Q)[3]

5. To demonstrate that quetiapine is superior to placebo in improving patient's productive days at work, their family and social lives by the change from baseline (Day1, Visit 2) in Sheehan Disability Score (SDS)

Study design

This study was a randomized, multicenter, double-blind, placebo-controlled, parallel group, fixed-dose comparison of quetiapine vs placebo in the treatment of bipolar depression. This study was stratified by diagnosis (bipolar I and bipolar II), and monitored to obtain an overall ratio of 2:1, respectively.

Target patient population and sample size

Outpatients, aged 18 to 65 years inclusive, with a diagnosis of bipolar I or bipolar II disorder with a current major depressive episode of duration less than 1 year but greater than 4 weeks from the screening visit will be enrolled in the study. The HAM-D (17-item scale) score must be ≥20, the HAM-D item 1 (depressed mood) score must be ≥2, and the YMRS score must be ≤12 at both Visit 1 and Visit 2 (randomization) to be eligible for entry into the study. Approximately 540 patients were expected to be enrolled in the study to obtain 504 evaluable patients.

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[1] The abbreviation for the CGI Global Improvement scale was changed from "CGI-C" as used in the protocol to "CGI-I" to be consistent with the clinical literature.
[2] Modified to include adverse events as defined in the statistical analysis plan.
[3] For this study, Q-LES-Q was designated as a secondary endpoint of particular interest.

Investigational product and comparator(s): dosage, mode of administration and batch numbers

Quetiapine fumarate was increased in a blinded manner to a total daily dose of 300 mg/day by Day 4 in the 300-mg/day treatment group and to a total daily dose of 600 mg/day by Day 8 (Week 1) in the 600 mg/day treatment group. Thereafter, oral doses of the study drug were administered in a blinded fashion once daily at bedtime in a dose of 300 or 600 mg/day. One-time dose reductions for intolerability of 100 mg/day in all treatment groups were allowed at the discretion of the investigator after Day 8 (Week 1). The resulting dose for patients with reduced dosing would be 200 mg/day, 500 mg/day, or no dosing change for placebo (3 tablets/dose rather than 4 in all treatment groups). Placebo was administered once daily with tablets matching in number and appearance to blinded quetiapine dosing. Study treatment was given in tablets of the following doses (lot #): quetiapine 25 mg (6500J), quetiapine 100 mg (6510J, 6514J), quetiapine 200 mg (7542F, 0215K), placebo 25 mg match (7553F), placebo 100 mg match (1011C, 7550F, ST70142-015-FA02), placebo 200 mg match (1509C, 1510C).

Duration of treatment

Patients received double-blind treatment for up to 8 weeks (56 days), following an initial washout period of between 7 to 28 days (depending on the medications involved) and came in to the clinic on Day 57 (Week 8) for final assessments.

Criteria for evaluation (main variables)

Efficacy and pharmacokinetics

- **Primary variable**: Montgomery-Asberg Depression Rating Scale (MADRS) total score change from baseline at last assessment

- **Secondary variables**: MADRS response (>=50% reduction from baseline; MADRS remission (total score <=12), change from baseline for the following: MADRS total score at each visit, MADRS Item scores, Hamilton Rating Scale for Depression (HAM-D) total score, HAM-D Item 1, Clinical Global Impression Severity of Illness (CGI-S), Hamilton Rating Scale for Anxiety (HAM-A) total score, Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q), Sheehan Disability Scale (SDS); and Clinical Global Impression Improvement (CGI-I) response (very much improved or not very much improved) at each visit.

Safety

Safety assessments included: adverse events, patient withdrawal due to adverse events, adverse events of special interest (EPS, diabetes mellitus, mania/hypomania, suicidality, QT prolongation, neutropenia/agranulocytosis), treatment emergent mania/hypomania (composite based on AE and Young Mania Rating Scale [YMRS] total score), hematology and chemistry findings, vital signs, Simpson-Angus Scale (SAS), the Barnes Akathisia Rating Scale (BARS) and specific inquiries of relevant data for metabolic syndrome risk factors, cardiac function, neutropenia/agranulocytosis and thyroid function.

Statistical methods

All statistical tests were 2-sided. The primary analyses used last observation carried forward (LOCF) for the time period of interest. A Bonferonni parallel gatekeeping strategy was employed to control for multiple comparisons. Bonferonni adjustments were made for the 2 comparisons with placebo for the MADRS and Q-LES-Q change from baseline assessments. The primary variable MADRS change from baseline test served as a gatekeeper, with testing of Q-LES-Q as a secondary outcome variable of particular interest dependent on at least 1 comparison for MADRS reaching statistical significance. Analysis of Covariance (ANCOVA) was used for comparative analysis of continuous variables with the baseline score as the covariate and including treatment and diagnosis strata as fixed effects and center as a random effect in the model. Cochran-Mantel-Haenszel Chi square tests (CMH) were used for categorical comparisons. Descriptive statistics were provided for all safety assessments with statistical analyses performed and presented for safety variables predefined in the Statistical Analysis Plan.

Subject population

Baseline patient characteristics are shown in Table S1.

Table S1 Patient population and disposition

		Quetiapine 300 mg	Quetiapine 600 mg	Placebo
Demographic characteristics (ITT population)				
N		155	151	161
Sex (n and % of patients)	Male	69 (44.5)	68 (45.0)	64 (39.8)
	Female	86 (55.5)	83 (55.0)	97 (60.2)
Age (years)	Mean (SD)	37.2 (10.53)	38.2 (11.01)	37.7 (11.75)
	Minimum	18	18	18
	Maximum	64	64	63
Race; n (%)	Caucasian	107 (69.0)	115 (76.2)	138 (85.7)
	Black	25 (16.1)	21 (13.9)	11 (6.8)
	Oriental	3 (1.9)	0	1 (0.6)
	Other	20 (12.9)	15 (9.9)	11 (6.8)
Baseline disease characteristics (ITT population)				
N		155	151	161
DSM-IV diagnosis [n and (%)]				
Bipolar I disorder		104 (67.1)	101 (66.9)	110 (68.3)
Bipolar II disorder		51 (32.9)	50 (33.1)	51 (31.7)
Baseline MADRS	Mean (SD)	31.1 (5.7)	29.9 (5.6)	29.6 (5.4)
Screening HAM-D	Mean (SD)	24.8 (3.39)	24.5 (3.06)	24.3 (3.27)

Table S1 Patient population and disposition

		Quetiapine 300 mg	Quetiapine 600 mg	Placebo
Baseline HAM-A	Mean (SD)	19.1 (5.98)	18.4 (5.78)	18.2 (5.69)
Screening YMRS	Mean (SD)	5.8 (3.30)	5.4 (2.79)	5.8 (3.00)
Baseline CGI-S	Mean (SD)	4.5 (0.56)	4.4 (0.57)	4.4 (0.55)
Baseline Q-LES-Q	Mean (SD)	35.4 (7.77)	37.5 (7.51)	37.8 (6.90)
Disposition (all enrolled)				
N safety[a]		171	168	167
N efficacy ITT[b]		155	151	161
N efficacy PP		139	133	150
N (randomized)	Completed	101	90	110
	Discontinued	71	79	58

[a] Number of patients who received at least 1 dose of study drug
[b] Number of patients who took at least 1 dose of study treatment and had at least 1 data point after dosing.
CGI-S Clinical Global Impression Severity scale; MADRS Montgomery-Asberg Depression Rating Scale, HAM-A Hamilton Rating Scale for Anxiety, HAM-D Hamilton Rating Scale for Depression; Q-LES-Q Quality of Life Enjoyment Satisfaction Questionnaire; ITT Intention to treat; N Number; PP Per-protocol.

The 3 groups were well-matched as to number and demographic and baseline disease characteristics. Subject not willing to continue was the main reason for withdrawal across the 3 treatment groups.

Efficacy results

In patients with bipolar disorder, quetiapine at a dose of either 300 mg once daily or 600 mg once daily was demonstrated to be superior to placebo in reducing the level of depressive symptoms as early as Day 8 (Week 1) and for up to 8 weeks of treatment, as assessed by the change from baseline in the total MADRS score. In addition, both bipolar I and bipolar II patients treated with 300 mg or 600 mg of quetiapine showed greater improvements in MADRS total score compared to patients treated with placebo. Patients receiving quetiapine 300 mg reported statistically superior improvements (p=0.034) compared to placebo in change from baseline in Q-LES-Q total score at 8 weeks. Patients receiving quetiapine 600 mg reported numerically greater improvements (p=0.068) than placebo in change from baseline in Q-LES-Q total score at 8 weeks. Analysis of other secondary outcome variables also supported the superiority of quetiapine 300 mg or 600 mg over placebo in the treatment of depression in patients with bipolar disorder. For most secondary outcome variables the treatment advantage for both doses of quetiapine was apparent by Day 8 (Week 1) and continued through Day 57 (Week 8). The proportion of patients showing ≥50% reduction in MADRS total score (responders) was statistically significantly higher for the quetiapine 300 mg group and the quetiapine 600 mg group compared to the placebo group by Day 15 and

continued to end of treatment. Likewise, the proportion of patients showing a MADRS total score ≤12 (remitters) was statistically significantly higher for the quetiapine 300 mg group and the quetiapine 600 mg group compared to the placebo group by Day 22 and continued to end of treatment. Quetiapine, at a dose of either 300 mg or 600 mg once daily, also improved a broad range of symptoms, including core symptoms of depression and suicidal thoughts, as assessed by the item analysis of the MADRS.

Table S2 Efficacy results at final assessment (LOCF, ITT population)

Outcome variable	Quetiapine 300 mg (N=155)		Quetiapine 600 mg (N=151)		Placebo (N=161)	
	Day 8	Day 57	Day 8	Day 57	Day 8	Day 57
MADRS LS mean change from baseline	-9.42[a]	-16.94[a]	-9.14[a]	-16.00[a]	-6.10	-11.93
Proportion with ≥50% MADRS response	20.3%	60.0%[b]	21.8%	58.3%[c]	14.9%	44.7%
Proportion with MADRS remission (total score <=12)	15.0%	51.6%[c]	16.3%	52.3%[b]	11.2%	37.3%
HAM-D LS mean change from baseline	-8.02[a]	-13.81[a]	-7.88[a]	-12.97[a]	-5.66	-9.92
HAM-D Item 1 LS mean change from baseline	-0.7	-1.76[a]	-0.7	-1.57[c]	-0.6	-1.29
Q-LES-Q total score LS mean change from baseline	NA	9.86[c]	NA	9.19	NA	7.12
CGI-S LS mean change from baseline	-0.6[b]	-1.68[a]	-0.5[b]	-1.59[a]	-0.3	-1.12
Proportion improved on CGI-I	18%	61%[a]	20%[c]	60%[a]	12%	39%

Note: For the analyses of MADRS and Q-LES-Q change from baseline, p-values were adjusted and compared with α=0.05 using the Bonferonni procedure within the parallel gatekeeping strategy.

[a] p<0.001 comparison with placebo

[b] p<0.01 comparison with placebo

[c] p<0.05 comparison with placebo

CGI-S Clinical Global Impression Severity scale; CGI-I Clinical Global Impression Improvement scale; MADRS Montgomery-Asberg Depression Rating Scale, HAM-D Hamilton Rating Scale for Depression; Q-LES-Q Quality of Life Enjoyment Satisfaction Questionnaire; LOCF Last observation carried forward; ITT Intention to treat; NA Not applicable; LS Least square.

Safety results

Both the 300 mg and 600 mg once-daily doses of quetiapine were generally well tolerated. Analysis of adverse events indicated that nervous system and gastrointestinal events predominated, with dry mouth, sedation, somnolence, dizziness, and constipation occurring at higher rates with quetiapine compared to placebo. Most adverse events were mild to moderate. Larger proportions of patients in the quetiapine dose groups discontinued due to an AE than did patients in the placebo group. No deaths occurred in the study. SAEs were infrequent in all treatment groups. Treatment-emergent mania and hypomania were lower in incidence in the quetiapine treatment groups compared to placebo with a significantly lower rate in the quetiapine 300 mg treatment group compared to placebo. The incidences of individual EPS-related AEs were low in each treatment group with the majority of these AEs reported as mild to moderate for all groups. An increase in the incidence in the composite of AEs related to EPS was noted for both groups of quetiapine-treated patients (300 mg: 12.3%; 600 mg: 10.1%) compared to the placebo group (6.6%). The incidence of AEs related to suicidality was low in all treatment groups. There were 3 cases of clinically important shifts to low values ($\leq 1.5 \times 10^9$/L) in neutrophils reported during the study: 2 in the quetiapine 300 mg treatment group and 1 in the placebo group. There were no cases of agranulocytosis ($\leq 0.5 \times 10^9$ cells/L) reported during the study. The incidence of shift from baseline to reference ranges identified for metabolic risk factors was higher for quetaipine-treated patients compared to placebo in triglycerides, BMI, and blood pressure while differential shifts to either increased HDL or fasting glucose were lower in the quetiapine treatment groups compared to the placebo group.

Table S3 Adverse event overview (safety population)

Category of adverse event	Number (%) of subjects who had an adverse event in each category[a]					
	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
Any adverse events	155	90.6	151	89.9	138	82.6
Serious adverse events	3	1.8	7	4.2	1	0.6
Serious adverse events leading to death	0		0		0	
Discontinuations of study treatment due to adverse events	14	8.2	19	11.3	2	1.2

[a] Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.

Table S4 Adverse event incidence of at least 5% sorted by decreasing order within the quetiapine 300 mg group (safety population)

MedDRA Preferred term	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
	n	(%)	n	(%)	n	(%)
Dry mouth	73	42.7	79	47.0	30	18.0
Sedation	55	32.2	46	27.4	17	10.2
Somnolence	51	29.8	50	29.8	8	4.8
Dizziness	24	14.0	27	16.1	9	5.4
Fatigue	16	9.4	19	11.3	13	7.8
Headache	15	8.8	14	8.3	28	16.8
Constipation	14	8.2	17	10.1	5	3.0
Increased appetite	13	7.6	7	4.2	7	4.2
Nausea	13	7.6	18	10.7	22	13.2
Dyspepsia	12	7.0	11	6.5	8	4.8
Extrapyramidal disorder	11	6.4	10	6.0	4	2.4
Lethargy	9	5.3	2	1.2	3	1.8
Vomiting	9	5.3	9	5.4	10	6.0
Back pain	8	4.7	3	1.8	13	7.8
Upper respiratory tractiInfection	7	4.1	10	6.0	14	8.4
Weight increased	7	4.1	9	5.4	3	1.8
Nasopharyngitis	6	3.5	11	6.5	10	6.0
Insomnia	5	2.9	3	1.8	12	7.2
Nasal congestion	5	2.9	10	6.0	6	3.6
Diarrhea	4	2.3	8	4.8	11	6.6
Orthostatic hypotension	4	2.3	10	6.0	3	1.8
Dysarthria	3	1.8	9	5.4	1	0.6

Note: This table uses a cut-off of 5% in any group. Data are ordered by descending incidence in the quetiapine 300 mg group.
MedDRA Medical Dictionary for Regulatory Affairs.

Conclusion(s)

- Quetiapine, at doses of either 300 mg or 600 mg once daily, was superior to placebo in treating depression in patients with either bipolar I or bipolar II disorder.
- The antidepressant effect of quetiapine treatment was observed as early as 7 days following treatment initiation and was maintained throughout the 8-week treatment

course in patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine, at doses of either 300 mg or 600 mg once daily, was superior to placebo in treating anxiety symptoms in patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine, at a dose of 300 mg once daily, was superior to placebo in improving the quality of life for patients with bipolar disorder who were experiencing a depressive episode. A numerically greater improvement in quality of life was also seen with quetiapine 600 mg compared to placebo.

- Quetiapine at a dose of 300 mg or 600 mg once daily showed numerically greater reduction compared to placebo in disability in the SDS total scale score, reaching statistical significance for the quetiapine 600 mg dose. Quetiapine at a dose of 300 mg daily or 600 mg daily was statistically superior to placebo in reducing the number of unproductive days, as measured by the SDS Days Unproductive scale.

- Quetiapine, at a dose of either 300 mg or 600 mg once daily, was generally safe and well-tolerated in patients with bipolar disorder who were experiencing a depressive episode. A higher rate of discontinuation due to AEs, most of which started within the first 7 days of study treatment, was seen with the quetiapine treatment groups compared to placebo. The most common adverse events associated with quetiapine treatment were dry mouth, somnolence, sedation, dizziness and constipation.

- Treatment emergent mania and hypomania were lower in incidence in the quetiapine treatment groups compared to placebo with a significantly lower rate in the quetiapine 300 mg treatment group compared to placebo.

Date of the report

01 December 2005

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

The following abbreviations and special terms are used in this study report.

Abbreviation or special term	Explanation
AE	Adverse event (see definition in Section 5.5.7.2).
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
AST	Aspartate aminotransferase
BARS	Barnes Akathisia Rating Scale
BID	twice daily
BMI	Body Mass Index
CGI-I	Clinical Global Impression Improvement scale
CGI-S	Clinical Global Impression Severity of Illness scale
CHM	Cochran-Mantel-Haenzel test
CRF	Case report form
CRO	Contract research organization
DM	Diabetes mellitus
DSM-IV	Diagnostic and Statistical Manual of the American Psychiatric Association, ed. IV-TR
ECG	Electrocardiogram
EPS	Extrapyramidal symptoms
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HAM-A	Hamilton Rating Scale for Anxiety
HAM-D	Hamilton Rating Scale for Depression
HbA1c	Glycated hemoglobin
HCG	Human Chorionic Gonadotropin
$HOMA_R$	Homeostatic Model Assessment of insulin resistance
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
ITT	Intention to treat
IVRS	Interactive voice recognition system
LLN	Lower limit of normal

Abbreviation or special term	Explanation
LOCF	Last observation carried forward
LRA	Lineberry Research Associates
MADRS	Montgomery-Asberg Depression Rating Scale
MMRM	Mixed Model Repeated Measures
MedDRA	Medical Dictionary for Regulatory Affairs
NA	Not applicable
OC	Observed cases
OFC	Olanzapine-fluoxetine combination
PP	Per-protocol
PR	P-R interval
PRO	Patient-reported outcomes
qd	once daily
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QUICKI	Quantitative Insulin Sensitivity Check Index
QRS	Q-R-S interval
QT	Q-T interval
QT_C	Q-T interval with Fridericia correction
RBC	Red blood cell count
SAE	Serious adverse event (see definition in Section 5.5.7.2)
SAP	Statistical analysis plan
SAS	Simpson-Angus Scale
SCID	Structured Clinical Interview for DSM-IV TR
SDS	Sheehan Disability Scale
T3RU	Triiodothyronine resin uptake
T4	Thyroxine
TID	Three times daily
TSH	Thyroid stimulating hormone
ULN	Upper limit of normal
WBC	White blood cell count
YMRS	Young Mania Rating Scale

1. ETHICS

1.1 Ethics review

The study protocol was approved by the Institutional Review Board (IRB) for each study site. There were no amendments made to the protocol.

Names and addresses of each of the IRBs for each of the centers is provided in Appendix 12.1.3.

1.2 Ethical conduct of study

The study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with ICH/Good Clinical Practice and applicable regulatory requirements and the AstraZeneca policy on Bioethics.

1.3 Patient information and consent

Patients gave written, informed consent before screening. The master version of the consent form is included in Appendix 12.1.2.

2. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

2.1 Staff at investigational sites

Participating personnel at study sites are listed in Appendix 12.1.4.1.

2.2 AstraZeneca study personnel

Participating AstraZeneca study personnel at study sites are listed in Table 1 and Appendix 12.1.4.2.

Table 1 AstraZeneca study personnel

Name	Position	Role in study
Nadine Everett	Principal Statistical Programmer	Team SAS programmer
Frank Hubbard, PhD	Principal Medical Communication Scientist	Clinical study report author
Wayne Macfadden, MD	Director, Clinical Research	Team physician
Margaret Minkwitz, PhD	Biostatistics Leader – Neurology (CNS)	Team statistician
William Chang, PhD	Principal Statistician	Statistician
Joy Russo	Senior Statistical Programmer	Statistical programmer
Julie Cashon	Clinical Study Leader	Clinical Study Team Leader

2.3 Other participants

2.3.1 Non-sponsor organizations or individuals

Monitoring of study sites, clinical data base administration, and safety reporting services were provided by Lineberry Research Associates, Inc (LRA). A complete list of participating LRA personnel is included in Appendix 12.1.4.4.

ECG scoring and interpretation was performed by eResearch Technology, Inc. A complete list of participating eResearch Technology personnel is included in Appendix 12.1.4.4.

Covance Laboratories served as the central laboratory for this study. A complete list of participating Covance Laboratories personnel is included in Appendix 12.1.4.4.

Pharmastar trained investigators in the administration of the Montgomery-Asberg Depression Rating Scale (MADRS), the Hamilton Rating scale for Depression (HAM-D), the Hamilton Rating scale for Anxiety (HAM-A) and the Young Mania Rating Scale (YMRS). A complete list of participating Pharmastar personnel is included in Appendix 12.1.4.4.

Randomization of treatment assignments was provided by ICON Clinical Research. A complete list of participating ICON personnel is included in Appendix 12.1.4.4.

2.3.2 Study committee(s)

No study committees were utilized for this study.

3. INTRODUCTION

Quetiapine fumarate (SEROQUEL®, quetiapine) is a dibenzothiazepine derivative approved in more than 78 countries, including the United States and the European Union, for the treatment of psychosis/schizophrenia and for treatment of acute manic episodes associated with bipolar disorder. Quetiapine fumarate is designated chemically as bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl) piperazin-1-yl]ethoxy)ethanol] fumarate.

The bipolar disorders are psychiatric disorders in which a disturbance in mood is the predominant feature. Bipolar I disorder is characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes. Bipolar II disorder is characterized by one or more major depressive episodes accompanied by at least 1 hypomanic episode. Bipolar depression refers to the major depressive episodes that occur with bipolar I and II disorder.

The lifetime prevalence of bipolar spectrum disorder, including both bipolar I and bipolar II types, is estimated to be 3.7% (95% confidence interval: 3.6% to 3.8%), evenly divided between men and women (Hirschfeld et al 2003). Even with treatment, bipolar patients have been found to be symptomatic for an average of almost half of a year with manic symptoms approximately 11% and depressed symptoms approximately 33% of the time – depressive symptoms severe enough to be associated with dysfunction were manifested approximately 17% of the year (Post et al 2003). Mortality is high among bipolar patients due to increased risk-taking behavior, comorbidity with other psychiatric illnesses, and suicide. Suicide risk among bipolar patients is estimated to be 0.4% per year compared to the general population average of 0.017% per year (Baldessarini and Tondo 2003).

There is no currently approved single-agent compound (monotherapy) for use in bipolar depression, although recently published data have reported that the combination of fluoxetine and olanzapine may be effective in the treatment of bipolar disorder (Tohen et al 2003). The use of antidepressants as monotherapy for bipolar depression requires careful clinical monitoring to avoid a “switch” into hypomania or mania from depression, or increase in cycle acceleration.

The current label for schizophrenia (twice daily [bid] or three times daily [tid]) and acute mania specifies bid dosing. However, efficacy and tolerability using once-daily dosing were recently demonstrated in a study using quetiapine monotherapy for bipolar depression (Study 5077US/0049). In the current study, quetiapine fumarate was to be administered once daily at bedtime and seeks to confirm the findings from Study 5077US/0049.

4. STUDY OBJECTIVES

4.1 Primary objectives

The primary objectives of the study were to evaluate the efficacy of quetiapine compared to placebo in the treatment for a major depressive episode in patients with bipolar disorder after receiving treatment for up to 8 weeks as assessed by comparing

1. The change from baseline to final assessment in the Montgomery-Asberg Depression Rating Scale (MADRS) total score

2. The percentage of patients with a ≥50% reduction from baseline in the MADRS total score at final assessment

3. The change from baseline to each assessment in the MADRS total score

4. The change from baseline to each assessment in the Hamilton Rating scale for Depression (HAM-D), HAM-D Item 1, the Clinical Global Impression – Severity (CGI-S), and the Clinical Global Impression – Improvement (CGI-I)

4.2 Secondary objectives

The secondary objectives of the study were:

1. To evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients with a score of ≥16 points on the Young Mania Rating Scale (YMRS)[4] at 2 consecutive visits or at the Week 8

2. To evaluate the superiority of quetiapine compared to placebo in treatment of anxiety symptoms by the change from baseline to final assessment in the Hamilton Rating Scale for Anxiety (HAM-A) total score

3. To evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression

4. To demonstrate that quetiapine is superior to placebo in improving patient's overall quality of life by the change from baseline (day 1, visit 2) in the Quality of Life Enjoyment Satisfaction Questionnaire (Q-LES-Q)[5]

5. To demonstrate that quetiapine is superior to placebo in improving patient's productive days at work, their family and social lives by the change from baseline (Day 1, Visit 2) in Sheehan Disability Score (SDS)

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[4] Modified to include adverse events as defined in the statistical analysis plan.
[5] For this study, Q-LES-Q was designated as a secondary endpoint of particular interest.

5. STUDY PLAN AND PROCEDURES

The overall study design and plan are presented and discussed in Section 5.1 and Section 5.2, respectively. The study population and its relationship to the intended target population are defined in Section 5.3. Study treatments and dosing regimens are described in Section 5.4. Study measurements and variables are described and justified in Section 5.5, and measures taken to ensure the quality of study data are described in Section 5.6. Statistical methods and presentation of the data are detailed in Section 5.7. Any changes to the planned conduct of the study, or planned statistical analyses, are presented in Section 5.8.

5.1 Overall study design

This multicenter, double-blind, randomized, placebo-controlled, parallel group study consisted of a washout period (from 7 to 28 days depending on the medications involved) followed by 8 weeks of treatment to evaluate the efficacy, safety, and tolerability of quetiapine fumarate in the treatment of a major depressive episode in adult patients with bipolar disorder. A total of approximately 840 patients were to be screened to obtain 530 enrolled patients to yield 504 evaluable patients at approximately 40 centers, with a target enrollment of 13 patients per center (maximum 50). Patients were required to have a HAM-D (17-item scale) score of ≥20, a HAM-D item 1 (depressed mood) of ≥2, and a YMRS of ≤12 at screening baseline (Visit 1) and randomization (Visit 2).

The study comprised the following 2 periods:

- Washout period
  Patients underwent HAM-D, SCID, YMRS, and safety evaluations at screen (Visit 1) and if they qualified to participate they commenced a washout of psychoactive medications. The number of days for washout depended upon the medication they were taking. These medications had to be discontinued for a period of at least 7 days prior to randomization (Day 1, Visit 2), with the exception of fluoxetine which had to be discontinued for a period of 14 days prior to randomization (Day 1, Visit 2) and depot injections of haloperidol decanoate or fluphenazine decanoate which required 28 days washout before randomization. If the patient was not taking any medications that required washout, the patient may have been randomized once all the inclusion/exclusion criteria were met.

- 8-week double-blind randomized treatment period (Weeks 1 to 8)
  Eligible patients were randomized on Day 1 (Visit 2) to 1 of 3 treatment groups: quetiapine 300 mg/day, quetiapine 600 mg/day, or placebo. The randomization used a stratification based on a diagnosis of bipolar I or bipolar II disorder. Treatment was administered once daily at bedtime for 8 weeks (Days 1 - 56). Patients did not receive medication on Day 57 (Visit 10), which was only for final assessments. If a patient discontinued from the study early for any reason, then final assessments (Day 57, Visit 10) were to be performed. Doses were titrated to achieve target doses of 300 mg/day within 4 days or 600 mg/day within 8 days. A one-time dose reduction of 100 mg was allowed to improve patient tolerance in

each treatment group. The patient was to remain at the reduced dose for the remainder of the study. MADRS assessments (used to evaluate the primary efficacy variable) were performed at Days 1, 8, 15, 22, 29, 36, 43, 50, and 57.

Table 2 summarizes the study procedures and assessments conducted at each time point.

Table 2 Study plan

	Screen	Washout[a]	Double-blind treatment phase Weeks 1 through 8								
Days			**1**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57[b]**
Visits	**1**		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Informed consent	√										
Medical history	√										
Risk factors for diabetes	√										
Concurrent medications	√		√	√	√	√	√	√	√	√	√
Inclusion/Exclusion criteria	√		√								
Structured Clinical Interview for DSM-IV (SCID)	√										
Physical examination, height, weight[c]	√										√
Urine toxicology screen	√										√
Pregnancy tests (females)	√										
Vital signs[d]	√		√	√	√	√	√	√	√	√	√
12-lead electrocardiogram	√		√e								√
Fasting clinical chemistry and hematology	√		√e				√f				√
Hamilton Rating Scale for Depression (17-item)	√		√	√	√	√	√	√	√	√	√
Montgomery-Asberg Depression Rating Scale			√	√	√	√	√	√	√	√	√
Young Mania Rating Scale	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression - Severity	√		√	√	√	√	√	√	√	√	√
Clinical Global Impression -Improvement				√	√	√	√	√	√	√	√
Hamilton Rating Scale for Anxiety			√	√			√				√
Barnes-Akathisia Rating Scale			√								√
Simpson-Angus Scale			√								√
Quality of Life Enjoyment Satisfaction Questionnaire[g]			√				√				√
Sheenan Disability Scale (SDS)[g]			√				√				√
Dispense study medication			√	√	√	√	√	√	√	√	
Adverse events	√	√	√	√	√	√	√	√	√	√	√

[a] Washout of antidepressants, antipsychotics, mood stabilizer for 7 to 28 days depending on the medications involved.
[b] Study completion or withdrawal from the study.
[c] Height and weight on screen and weight on Day 57. Physical exam included ophthalmoscopic exam on screen.
[d] Blood pressure obtained in supine and standing positions.
[e] Repeated laboratory tests and ECG only if results outside of normal range and clinically significant at Screening. Acceptable repeat results were to be obtained before randomization.
[f] Fasting plasma glucose, fasting insulin and CBC with differential count only.
[g] Q-LES-Q was to be done before the SDS.

5.2 Rationale for study design, doses and control groups

This study was designed as a double-blind, placebo-controlled evaluation of quetiapine as monotherapy in bipolar depression. At the time of study initiation there was no currently approved compound for use in bipolar depression, although a fixed combination tablet containing olanzapine and fluoxetine recently received marketing approval in the US for use in this patient population. Conventional antidepressants are not commonly used as monotherapy because of the need for close clinical monitoring to avoid the induction of manic symptoms.

In a randomized clinical study of 539 patients treated with quetiapine monotherapy or placebo for bipolar depression (Study 5077US/0049), clinically relevant efficacy and superiority to placebo, as defined by the MADRS change from baseline, were demonstrated in both treatment arms of 300 mg/day and 600 mg/day following 8 weeks of treatment. Based on these data, both 300 mg/day and 600 mg/day are appropriate treatment arms that exhibit efficacy with adequate tolerability and compliance. Also, there is a high placebo response rate of approximately 30% in bipolar depression studies, justifying the use of a placebo treatment arm for comparison.

This study seeks to confirm these findings. As such, it is designed as a fixed-dose evaluation in order to provide information about dose range not possible in flexible dose studies.

A period of 7 to 28 days is adequate for washout of most psychoactive medications including antidepressants, antipsychotics (including depot agents), and mood stabilizers to ensure that patients are not experiencing residual psychotropic effects from any such medications they were taking before randomization. The double-blind treatment period of 8 weeks is consistent with the time period that is generally accepted to be required to see a clinically meaningful response in depressive symptoms.

The MADRS is a standardized, well-validated measure of depressive symptoms that is sensitive to treatment effects in depressed outpatients.

5.3 Selection of study population

5.3.1 Inclusion criteria

For inclusion in the study, patients had to fulfill all of the following criteria prior to randomization:

1. Documented ability to provide informed consent before beginning any study-specific procedures

2. Male and female patients between 18 and 65 years of age, inclusive

3. Females of childbearing potential must have had a negative pregnancy test at enrollment and were to use a reliable method of contraception. Reliable methods included hormonal contraceptives (eg, oral contraceptive or long-term injectable or

implantable hormonal contraceptive), double-barrier methods (eg, condom and diaphragm, condom and foam, condom and sponge), intrauterine devices, and tubal ligation

4. Met DSM-IV criteria for bipolar disorder I or bipolar II, most recent episode depressed (296.5x and 296.89)

5. Outpatient status

6. HAM-D (17-item) total score of ≥20 at Visit 1 (Screen) and Visit 2 (randomization)

7. HAM-D item 1 (depressed mood) score ≥2 at Visit 1 (Screen) and Visit 2 (randomization)

8. YMRS total ≤12 at Visit 1 (Screen) and Visit 2 (randomization)

5.3.2 Exclusion criteria

Any of the following was regarded as a criterion for exclusion from the study:

1. Cycled into a manic or hypomanic episode between Visit 1 (Screen) and 2 (randomization)

2. Had more than 8 mood episodes in the past year from screen (Visit 1)

3. A current Axis I disorder other than bipolar disorder within 6 months of screening

4. Current episode of depression that exceeded 12 months or was less than 4 weeks from screen

5. History of non-response, in the opinion of the investigator, to an adequate treatment (approximately 6 weeks) of more than 2 classes of antidepressants during their current episode

6. Patients were to be excluded if they satisfied DSM-IV criteria for substance abuse within 3 months or dependence for any substance except nicotine, within 12 months of screening or had not been in remission for at least 1 year before study start. Patients with a positive urine toxicology screen were to be excluded if they satisfied the DSM-IV criteria for abuse or dependence.

7. Failure to discontinue the use of potent P450 inhibitors and inducers (see Section 5.4.5, Table 10)

8. Failure to discontinue all psychoactive medications (excluding prn zolpidem tartrate or lorazepam, see Section 5.4.5, Table 10), including antidepressants, antipsychotics, and mood stabilizer, at least 7 days prior to randomization and consistent with the pharmacokinetics of the drug

- Failure to discontinue fluoxetine or extended-release risperidone for at least 14 days prior to randomization.

- Failure to discontinue haloperiodol decanoate or fluphenazine decanoate for 28days prior to randomization.

9. Would require initiation of psychotherapy during the study period in the investigator's judgement. If a patient had been in ongoing psychotherapy for a minimum of 3 months, the therapy may have continued.

10. Posed a current or future suicidal or homicidal risk in the investigator's judgement

11. A HAM-D item 3 score of 3 or greater or a suicide attempt within the past 6 months of screen

12. Clinically significant or unstable medical condition in the opinion of the investigator

13. A patient with diabetes mellitus (DM) who fulfilled 1 of the following criteria:

    - Unstable DM defined as glycated hemoglobin (HbA1c) >8.5% at enrollment

    - Admitted to hospital for treatment of DM or DM related illness in past 12 weeks.

    - Not under the care of a physician responsible for patient's DM care

    - Physician responsible for patient's DM care had indicated that patient's DM was not controlled

    - Physician responsible for patient's DM care had not approved patient's participation in the study

    - Had not been on the same dose of oral hypoglycemic drug(s) and/or diet for the 4 weeks prior to randomization. For thiazolidinediones (glitazones) this period should not have been less than 8 weeks

    - Took insulin at a daily dose on 1 occasion in the past 4 weeks that was more than 10% above or below their mean dose in the preceding 4 weeks

Note: If a diabetic patient met 1 of the above criteria, the patient was to be excluded even if the treating physician believed that the patient was stable and could participate in the study.

14. Patients with clinically significant abnormal laboratory findings in the investigators judgement

15. An ANC (absolute neutrophil count) of $\leq 1.0 \times 10^9$ per liter

16. Renal impairment (serum creatinine ≥1.5 mg/dL) or hepatic impairment (ALT or AST 3 times the upper limit of normal)

17. A thyroid-stimulating hormone (TSH) concentration higher than 10% above the upper limit of the normal range of the laboratory used for sample analysis whether or not the patient was being treated for hypothyroidism. Patients maintained on thyroid medication were to be euthyroid for a period of at least 3 months before Visit 1.

18. ECG considered to show clinically significant abnormality at enrollment that would have put the patient at risk

19. Women who had a positive human chorionic gonadotropin (HCG) pregnancy test at Visit 1 or who were lactating or planning to become pregnant during the course of the study

20. Participation in a clinical drug study within 3 months before screen

21. In the investigator's judgement, would have been non-compliant with the visit schedule or study procedures

22. Orthostatic hypotension or conditions that would have predisposed them to hypotension (eg dehydration, hypovolemia)

23. History of intolerance, hypersensitivity, or lack of response to quetiapine or any of the components of quetiapine tablets, as judged by the investigator

24. Prescribed greater than 50 mg/day of quetiapine within 1 year of screen (Visit 1)

25. Contraindications to quetiapine as detailed in country-specific prescribing information for quetiapine

26. Previous participation in this study or Study 5077US/0049

5.3.3 Restrictions

Patients were required to adhere to the following special restrictions:

1. Use of any psychoactive drugs including antidepressants, hypnotics (with the exceptions noted in Section 5.4.5), mood stabilizing drugs, and antipsychotics was not permitted for 7-28 days (14 days for fluoxetine and extended-release risperidone and 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization and throughout the study.

2. Use of cytochrome P450 3A4 inducers and potent inhibitors were not permitted from 14 days prior to randomization to end of study (see Table 10)

5.3.4 Discontinuation of patients from treatment or assessment

5.3.4.1 Criteria for discontinuation

Patients could be discontinued from study treatment and assessments at any time, at the discretion of the investigator. Specific reasons for discontinuing a patient from this study were:

1. Voluntary discontinuation by the patient who was at any time free to discontinue their participation in the study, without prejudice to further treatment
2. Safety reasons as judged by the investigator and/or AstraZeneca
3. Severe non-compliance to protocol as judged by the investigator and/or AstraZeneca
4. Use of excluded psychotropic medications at any time during the double-blind treatment period
5. Incorrect enrollment or randomization of the patient
6. Pregnancy at any time during the double-blind treatment period
7. If a patient had an ANC < 1.0×10^9 per liter, the test was to be repeated within 24 hours. If it remained < 1.0×10^9 per liter, the drug was to be discontinued. The investigator was to make the final determination of the reason for discontinuation.

5.3.4.2 Procedures for discontinuation

All study procedures required at Day 57 (Week 8) were to be conducted when a patient discontinued from the study (See Table 2).

5.4 Treatments

5.4.1 Investigational products

The details of the investigational product and any study treatment are given in Table 3.

Table 3 Details of investigational product and any other study treatments

Investigational product or other treatment	Dosage form and strength	Manufacturer	Formulation number	Lot number
Quetiapine	tablet, 25 mg	AstraZeneca	F12804	6500J
Quetiapine	tablet, 100 mg	AstraZeneca	F12689	6510J, 6514J
Quetiapine	tablet, 200 mg	AstraZeneca	F12690	7542F, 0215K
Placebo	tablet, 25 mg	AstraZeneca	F12636	7553F
Placebo	tablet, 100 mg	AstraZeneca	F12637	1011C, 7550F, ST70142-015-FA02
Placebo	tablet, 200 mg	AstraZeneca	F12638	1509C, 1510C

All investigational products were to be kept in a secure place under appropriate storage conditions.

5.4.2 Doses and treatment regimens

Quetiapine and placebo for each study center were packaged in blister cards. The 8-week supply consisted of 8 double-blind blister cards that were packaged in patient-specific cartons.

Study medication was provided for each patient in an 8-card carton that contained the following:

- 1-week titration double-blind treatment cards for Days 1-7
- Seven 1-week double-blind treatment cards for Days 8-56, with individual cards provided for treatment Days 8-14, 15-21, 22-28, 29-35, 36-42, 43-49, and 50-56. Each one-week blister card included a 2-day treatment overage to accommodate visit schedules.

The Week 1 titration card consisted of 25 mg tablets, 100-mg tablets, and 200-mg tablets or matching placebo for each of the 300 mg/day and 600 mg/day treatment groups and placebo treatment group (Table 4, Table 6, Table 8).

Blister cards for Weeks 2 through 8, for each treatment group, consisted of 9 days of dosing with the same number of pills for each group (300-mg, 600-mg, and placebo) respectively. The cards for each treatment group consisted of 2 yellow tablets (quetiapine 100 mg or matching placebo) and 2 white tablets (quetiapine 200 mg or matching placebo) per day at bedtime (Table 5, Table 7, Table 9).

Quetiapine or placebo was administered once a day at bedtime without regard to meals with dose titration designed to reach a target dose of 300 mg/day by Day 4 in the 300-mg/day

treatment group and 600 mg/day by Day 8 (Week 1) in the 600-mg/day treatment group. Patients were instructed to take all the tablets in the row of the blister pack for the corresponding day of treatment.

Table 4 Week 1 blister pack for 300 mg/day quetiapine group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 5 Week 2-8 300 mg/day quetiapine blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
2	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
3	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
4	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
5	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
6	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
7	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo
Extra Day	100-mg quetiapine	100-mg placebo	200-mg quetiapine	200-mg placebo

Table 6 Week 1 600 mg/day quetiapine blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg quetiapine	25-mg quetiapine		
2	100-mg quetiapine			
3	200-mg quetiapine			
4	100-mg quetiapine	200-mg quetiapine		
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 7 Week 2-8 600 mg/day quetiapine blister pack

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
2	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
3	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
4	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
5	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
6	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
7	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine
Extra Day	100-mg quetiapine	100-mg quetiapine	200-mg quetiapine	200-mg quetiapine

Table 8 Week 1 blister pack for placebo group

Day	Column 1	Column 2	Column 3	Column 4
1	25-mg placebo	25-mg placebo		
2	100-mg placebo			
3	200-mg placebo			
4	100-mg placebo	200-mg placebo		
5	100-mg placebo	100-mg placebo	200-mg placebo	
6	100-mg placebo	100-mg placebo	200-mg placebo	
7	100-mg placebo	100-mg placebo	200-mg placebo	
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Table 9 Week 2-8 blister pack for placebo group

Day	Column 1	Column 2	Column 3	Column 4
1	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
2	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
3	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
4	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
5	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
6	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
7	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo
Extra Day	100-mg placebo	100-mg placebo	200-mg placebo	200-mg placebo

Dose reduction

Dose reductions for intolerability were allowed after Day 8 (Week 1) in all treatment groups. Dose reductions of 100 mg/day were achieved by reducing the bedtime dose by one 100-mg tablet. After Day 8 (Week 1), a one-time dose reduction of 100 mg/day was achieved by elimination of the tablet in the first column of the blister pack. Placebo blister packs contained an inactive tablet in order to maintain the blind. Once the dose was reduced, it was to be maintained at that level for the remainder of the study participation.

5.4.3 Method of assigning patients to treatment groups

This study utilized a non-center-specific labeling randomization which was stratified in a 1:1:1 ratio for treatment group within bipolar diagnosis (bipolar I vs bipolar II). Randomization to study treatment was done via an Interactive Voice Response System (IVRS) at ICON ICOPhone on Day 1 (Visit 2) in balanced blocks (block size of 6) within each bipolar stratum in order to ensure relative balance in total number of patients among treatment groups and strata. The randomization schedule was created under the auspices of AstraZeneca Quantitative Decision Sciences Group and allocated patient numbers to the treatment regimens. Clinical supplies contained a 4-digit kit number. A separate randomization was used to assign kits of packaged drugs to the sites. The IVRS system at ICON ICOPhone allocated a kit number at the site for the treatment assigned through the stratified randomization.

5.4.4 Blinding and procedures for unblinding the study

5.4.4.1 Methods for ensuring blinding

All packaging of treatments was identical with placebo and active tablets identical in size and color. The number of tablets dispensed on each card was identical across all treatment arms.

The randomization for the kit assignments were generated by an AstraZeneca randomization staff member and provided directly to packaging with a copy going to the IVRS Clinical Supplies Management Group. The stratified randomization was generated by an AstraZeneca randomization staff member not associated with the study and was provided directly to the IVRS group for incorporation into the IVRS system. No member of the study team in AstraZeneca, at investigational sites or the CRO organization handling data had access to the randomization scheme during the conduct of the study.

5.4.4.2 Methods for unblinding the study

Treatment codes, indicating the treatment randomization for each randomized patient, were available to the investigators or pharmacists at the study center. The treatment code was not to be broken except in medical emergencies when the appropriate management of the patient necessitated knowledge of the treatment randomization. The investigator was to document and report to AstraZeneca any breaking of the treatment code. AstraZeneca retained the right to break the code for serious adverse events that were causally related to treatment and potentially required expedited reporting to regulatory authorities and, in exceptional circumstances, for other safety reasons. Treatment codes were not to be broken for the planned analyses of data until all decisions on patient populations and data exclusions were made and documented.

There were no treatment codes broken prior to database lock in this study.

5.4.5 Pre-study, concomitant, and post-study treatments

Nonpsychotropic medication, including over-the counter medications, taken by the patient before entry into the study could be continued during the study. Medications required to treat illnesses or complaints that occur during the study could be used at the discretion of the

investigator. Use of cytochrome P450 inducers and potent inhibitors was restricted (see Table 10, below).

Women who entered the study with an intrauterine device in place, using oral contraceptives, or using injectable or implantable hormonal agents designed to prevent pregnancy could continue these treatments throughout the study.

The use of psychoactive drugs other than those specifically allowed during the study (ie, lorazepam and zolpidem tartrate) was restricted. Medications specifically prohibited or restricted, and those permitted during the study are listed in Table 10.

Table 10 Permitted, restricted and prohibited medications

Use category	Type of medication
Permitted	Previous medications for medical, nonpsychiatric illnesses Oral contraceptives and contraceptive devices
Restricted	Zolpidem tartrate 5-10 mg at bedtime for insomnia Lorazepam 1-3 mg per day for severe anxiety These drugs could be prescribed during the first 3 weeks of the study as long as they did not interfere with any assessments
Prohibited	Potent cytochrome P450 3A4 inducers (including but not limited to barbiturates, carbamazepine, rifampin, and St John's Wort) Potent cytochrome P450 3A4 inhibitors (including but not limited to ketoconazole, itraconazoole, fluconazole, erythromycin, clarithromycin, troleandomycin, indinavir, nelfinavir, ritonavir, and saquinavir) Antipsychotic medications (including but not limited to phenothiazines, risperidone, olanzapine, ziprasidone, clozapine, loxapine, thiothixene, molindone) Use of any psychoactive drugs including antidepressants, hypnotics, mood stabilizing drugs, and antipsychotics from a period of 7 to 28 days depending on the medications involved (eg. 28 days for haloperidol decanoate and fluphenazine decanoate) prior to randomization to end of study. Fluoxetine had to be discontinued at least 14 days prior to randomization.

Other medication considered necessary for the patient's safety and well being could be given at the discretion of the investigators. The administration of all medication (including investigational products) was recorded in case report forms (CRFs).

5.4.6 Treatment compliance

Compliance was assessed by returned tablet counts. Compliance was calculated as the number of tablets taken (dispensed - returned) divided by the prescribed number of tablets (number of days times number of tablets per day) expressed as a percent. Based on this calculation a patient with at least 80% compliance with study medication during study participation was classified as compliant.

If, in the opinion of the investigator, there were any significant irregularities in compliance the patient was to be withdrawn from the study.

5.5 Measurements of study variables and definitions of outcome variables

5.5.1 Primary variable

The primary outcome variable was the change from baseline to final assessment in the MADRS total score. This outcome variable was the basis for the sample size calculation (Section 5.7.5).

5.5.2 Screening and demographic measurements

The following data were collected at screening:

- date of birth, sex and race. Race was defined by the geographic origin of the patient's family. Caucasian was used for family origins in Europe, India, Pakistan, Afghanistan, Arabia, North Africa, Middle East countries, and Asia Minor. Black was used for Africa but not North Africa. Oriental was used from Asia (except for Asian countries classified as Caucasian) and for Greenland. Other was used for mixed races and for Aboriginal, Maori, Melanesian, Pygmean, and Tamil.
- vital signs, height, weight
- supine and standing blood pressure and pulse
- significant medical history (including current adverse events)
- risk factors for diabetes
- physical examination including ophthalmoscopic exam
- 12-lead electrocardiogram
- fasting clinical chemistry and hematology
- urine toxicology screen
- pregnancy test (if female of childbearing potential)
- HAM-D assessment
- YMRS
- CGI-S
- DSM-IV diagnosis, based on SCID assessment

- psychiatric history
- concurrent medications

5.5.3 Efficacy measurements and variables

5.5.3.1 Summary of efficacy objectives and variables

Table 11 summarizes the efficacy variables of this study, and shows how they relate to the study objectives.

Table 11 Efficacy objectives, and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including timepoint and population)
Primary	**Primary outcome variable**
Evaluate the superiority of quetiapine compared to placebo in the treatment of a major depressive episode in subjects with bipolar disorder after receiving treatment for up to 8 weeks	Change from baseline to Week 8 in the MADRS total score in the Intention-to-treat (ITT) population
	Secondary outcome variables
	Percentage of patients in the ITT population showing a ≥50% reduction from baseline in MADRS total score (responders) at each assessment and at final assessment
	Percentage of patients in the ITT population showing a MADRS total score ≤12 (remitters) at each assessment and at final assessment
	Change from baseline to each assessment for the MADRS total score in the ITT and PP populations
	Change from baseline to each assessment in the total HAM-D total score in the ITT population
	Change from baseline to each assessment in the HAM-D Item 1 score in the ITT population
	Change from baseline to each assessment and at final assessment for the CGI-S in the ITT population
	CGI-I score at each assessment and at final assessment in the ITT population
	Percentage of patients in the ITT population showing a CGI-I score of ≤2 (much or very much improved; responders) at each assessment and at final assessment
Secondary	**Secondary outcome variables**
Evaluate the superiority of quetiapine compared to placebo on symptoms of anxiety	Change from baseline to final assessment in the HAM-A total score in the ITT population

CGI-S Clinical Global Impression Severity scale; CGI-I Clinical Global Impression Improvement scale -, MADRS Montgomery-Asberg Depression Rating Scale, HAM-A Hamilton Rating Scale for Anxiety, HAM-D Hamilton Rating Scale for Depression, ITT Intent to treat.

The timings of the efficacy assessments are presented in the study plan in Section 5.1. The methods for collecting efficacy data are presented below.

5.5.3.2 Primary variable: MADRS total score change from baseline at last assessment

(a) Methods of assessment

The MADRS is a 10-item instrument that was used to rate the patient's depressive symptoms for the preceding week (Montgomery and Asberg 1979). Scoring for each of the items was made on a 0- to 6-point scale, with higher scores indicating more severe depression (maximum score of 60).

(b) Calculation or derivation of outcome variable

The MADRS total score was calculated by summing the scores from each of its 10 items. Change from baseline in the MADRS total score was calculated by subtracting the baseline total score from the visit score. Alleviation of depressive symptoms was thus indicated by a negative change score.

5.5.3.3 Secondary variable: MADRS response

(a) Methods of assessment

As specified in Section 5.5.3.2.

(b) Calculation or derivation of outcome variable

Response at a visit was defined as a decrease from baseline MADRS total score of ≥50% at the given visit. No criterion for sustained response across visits was applied.

5.5.3.4 Secondary variable: MADRS remission

(a) Methods of assessment

As specified in Section 5.5.3.2.

(b) Calculation or derivation of outcome variable

Remission at a visit was defined as a MADRS total score ≤12 at the given visit. No criterion for sustained remission across visits was applied.

5.5.3.5 Secondary variable: MADRS total score change from baseline at each assessment

As specified in Section 5.5.3.2 for each visit.

5.5.3.6 Secondary variable: change from baseline in HAM-D total score

(a) Methods of assessment

The HAM-D is a 17-item instrument that was used to rate the patient's depressive symptoms for the preceding week (Hamilton 1960). The items are scored on a 0- to 2-, 0- to 3-, or 0- to

4-point scale, with higher scores indicating more severe depression. The maximum score is 53.

(b) Calculation or derivation of outcome variable

The HAM-D total score was calculated by summing the scores from each of its 17 items. Change from baseline in the HAM-D total score was calculated by subtracting the baseline total score from the visit score. Alleviation of depressive symptoms was thus indicated by a negative change score.

5.5.3.7 Secondary variable: change from baseline in HAM-D Item 1 score

(a) Methods of assessment

Item 1 of the HAM-D is a 0- to 4-point rating of depressed mood.

(b) Calculation or derivation of outcome variable

Change from baseline in the HAM-D Item 1 score was calculated by subtracting the baseline score from the visit score. Alleviation of depressed mood was thus indicated by a negative change score.

5.5.3.8 Secondary variables: change from baseline in CGI

The CGI is a three-item scale used to assess treatment response in psychiatric patients (Guy 1976). Only Items 1 and 2 were recorded on the CRF and evaluated in this study. They are: Severity of Illness (CGI-S) and Global Improvement (CGI-I)[6]. Item 1 is rated on a seven-point scale (1=normal to 7=extremely ill) and item 2, on a seven-point scale (1=very much improved to 7=very much worse).

(a) Methods of assessment – CGI-S

The Severity of Illness item requires the clinician to rate the severity of the patient's illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis. Considering total clinical experience, a patient is assessed on severity of mental illness at the time of rating according to: normal (not at all ill); borderline mentally ill; mildly ill; moderately ill; markedly ill; severely ill; or extremely ill.

(b) Calculation or derivation of outcome variable

Change from baseline of the CGI-S was calculated by subtracting the baseline score from the visit score. Alleviation of symptom severity was thus indicated by a negative change score.

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[6] The abbreviation for the CGI Global Improvement scale was changed from "CGI-C" as used in the protocol to "CGI-I" to be consistent with the clinical literature.

(c) Methods of assessment – CGI-I

The Improvement item requires the clinician to rate how much the patient's illness has improved or worsened relative to a baseline state. Compared to condition at baseline, a patient's illness is compared to change over time, and rated according to: very much improved; much improved; moderately improved; minimally improved; no change; minimally worse; moderately worse; much worse; or very much worse.

(d) Calculation or derivation of outcome variable

For the CGI-I, symptomatic improvement (response to treatment) was indicated as a score of 2 or less.

5.5.3.9 Secondary variable: change from baseline in HAM-A

(a) Methods of assessment

The HAM-A is a 14-item instrument that was used to rate the patient's anxiety symptoms for the preceding week (Hamilton 1959). Scoring for each of the items was made on a 0- to 4-point scale of increasing severity.

(b) Calculation or derivation of outcome variable

Change from baseline in the HAM-A score was calculated by subtracting the baseline score from the visit score. Alleviation of anxiety symptoms was thus indicated by a negative change score.

5.5.4 Patient-Reported Outcomes (PROs) measurements and variables

5.5.4.1 Summary of PRO objectives and variables

Table 12 shows how the efficacy outcome variables of this study relate to the study objectives.

Table 12 Quality of life objectives and outcome variables relating to each objective

Secondary objective	Summary secondary outcome variables for analysis (including time point and population)
To demonstrate that quetiapine is superior to placebo in improving the patient's overall quality of life	Change from baseline (Visit 2) to final assessment in the Quality of Life Enjoyment Satisfaction Questionnaire (Q-LES-Q)[a] – Short form total score
To demonstrate that quetiapine is superior to placebo in improving the patient's productive days at work and their family and social lives	Change form baseline (Visit 2) to final assessment in the Sheehan Disability Scale (SDS) domains of work/school, social life/leisure, and family life/home responsibility

[a] The Q-LES-Q variable was a secondary endpoint of particular interest for this study.

The methods of collecting quality of life data are described below.

5.5.4.2 Change from baseline in the Q-LES-Q

(a) Methods of assessment

The Q-LES-Q is a quality of life questionnaire assessing physical health, patient feelings, leisure activities, social relationships, and medication and life satisfaction (Endicott et al 1993).Higher scores indicate better quality of life. The Q-LES-Q short form consisting of the 16-item "General Activities" scale of the Q-LES-Q long form was used. The items are scored on a 5-point scale.

(b) Calculation or derivation of outcome variable

To put the Q-LES-Q total score into a generally accepted 0-100% frame of reference (noted as percent maximum) for reporting and clinical interpretation, the Q-LES-Q total score was rescaled from 14 - 70 to 0 - 100%. The change from baseline was calculated for both the original scale and the transformed scale at each assessment (observed cases) and final assessment in the Q-LES-Q by subtracting the baseline score from the visit score. A positive change score thus indicated improvement in quality of life.

5.5.4.3 Change from baseline in the SDS

(a) Methods of assessment

The Sheehan Disability Scale (SDS) uses a discretized visual analog scale to measure 3 items to assess symptom impact on overall disability, reviewing the last week (Sheehan 1983). The instrument evaluates symptom impact and impairment in the domains of work/school, social life/leisure, and family life/home responsibility.

The SDS was utilized to evaluate the level of functioning between mood events in the patient population.

(b) Calculation or derivation of outcome variable

Each 1 of the 3 domains is rated from 0-10 (no impairment to most severe impairment) with evaluation of not at all (0), mild (1-3), moderate (4-6), marked (7-9) and extreme (10) disability. A total score was calculated. A score of 30 indicated most severe impairment.

5.5.5 Health Economics measurements and variables

Not applicable.

5.5.6 Pharmacokinetic measurements and variables

Not applicable.

5.5.7 Safety measurements and variables

5.5.7.1 Summary of safety objectives and variables

Table 13 summarizes the safety variables assessed in this study, and shows how they relate to the study objectives.

Table 13 Safety objectives and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including time point and population)
Evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	Incidence and severity of adverse events during double-blind treatment Incidence of drug-related adverse events during double-blind treatment Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment
	Incidence of patient discontinuation due to adverse events
	Clinical laboratory assessments change from baseline to Day 57 in the safety population
	Incidence of potentially clinically important changes in clinical laboratory assessments
	Change in glucose and insulin data from baseline to Day 57 by diabetic risk groups in the safety population
	Change in weight and body mass index (BMI) from baseline to Day 57 in the safety population
	Change in vital signs from baseline to Day 57 in the safety population
	Incidence of potentially clinically important changes in vital signs
	Electrocardiogram (ECG)
	Incidence of potentially clinically important changes in ECG
	Change in the SAS total score from baseline to final assessment
	Change in BARS Global Assessment score from baseline to final assessment

Table 13 Safety objectives and outcome variables relating to each objective

Objective	Summary outcome variables for analysis (including time point and population)
Evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients with a score of ≥16 points on the YMRS at 2 consecutive visits or at Week 8	Proportion of patients exhibiting a YMRS total score ≥16 on 2 consecutive assessments or at final assessment or having an AE report of treatment-emergent mania or hypomania. Change from baseline to each assessment and to final assessment in the YMRS total score in the ITT population

SAS Simpson-Angus Scale; BARS Barnes Akathisia Rating Scale; YMRS Young Mania Rating Scale.

The timings of the safety assessments are presented in the study plan in Section 5.1. The methods for collecting safety data are described below.

5.5.7.2 Adverse events

(a) Definitions

An adverse event was defined as the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product, whether or not considered causally related to the product. This definition included events in any screening period or during any follow-up period specified in the study protocol. An undesirable medical condition could be symptoms (eg, nausea, chest pain), signs (eg, tachycardia, enlarged liver) or the abnormal results of an investigation (eg, laboratory findings, electrocardiogram).

A serious adverse event was defined as an AE occurring during any study phase (ie, run-in, treatment, washout, follow-up), and at any dose of the investigational product, comparator or placebo, that fulfilled one or more of the following criteria:

- resulted in death
- was immediately life-threatening
- required in-patient hospitalization or prolonged existing hospitalization
- resulted in persistent or significant disability or incapacity
- was a congenital abnormality or birth defect
- was an important medical event that might have jeopardized the patient or might have required medical intervention to prevent 1 of the outcomes listed above.

Study drug abuse was to be considered an SAE, even when there are no symptoms or additional AEs. Misuse of study drug was considered to be an AE but was not considered an SAE unless accompanied by serious sequelae.

All overdoses, with or without associated symptoms, were to be reported as AEs.

Suicide and attempted suicide, irrespective of the method, but occurring in connection with the use of study drug, was to be reported as AEs (serious or non-serious). The event was to be identified as suicide or attempted suicide, and the method of the suicide or attempt was to be provided. If an attempted suicide meets the criteria for an SAE, the event was to be reported as such.

(b) Recording of adverse events

All AEs that occur before, during treatment, or within 30 days following the cessation of treatment, whether or not related to the study drug, had to be recorded on the CRF provided by the sponsor.

A description of the event, its intensity, duration, action taken and outcome were to be recorded, along with the investigator's causality assessment of the relationship of the event to the study drug. If a diagnosis of the patient's condition was made, then the diagnosis was to be recorded as the AE. However, if a diagnosis of the patient's condition had not been made, or if the individual symptoms were not well-recognized, then the individual symptoms were to be recorded separately.

AstraZeneca personnel coded AEs according to the MedDRA dictionary.

In general, abnormal laboratory tests or vital signs were not to be reported as AEs unless they fulfilled the criteria for an SAE or lead to discontinuation. If an abnormal laboratory test result or vital sign was associated with clinical signs and symptoms, the sign or symptom was reported to be an AE, and the associated test result or vital sign was to be recorded on the CRF.

Any detrimental change in the patient's condition after the patient entered the study was to be discussed with the investigator. Where the detrimental change was considered by the investigator to constitute a progression or relapse of bipolar depression or a lack of efficacy, the change was not considered to be an AE event where hospitalization was necessitated or prolonged. If it was believed that study medication contributed to deterioration, it was recorded as an AE. If it was not believed that the study medication contributed to deterioration, it was recorded as lack of efficacy.

Signs & symptoms noted in patient reported outcome instruments (SDS and Q-LES-Q) were not reported as AEs.

Pregnancy in itself was not regarded as an adverse event unless there was a suspicion that the investigational product under study may have interfered with the effectiveness of a

contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) was to be followed up and documented even if the patient was discontinued from the study. All reports of congenital abnormalities, birth defects and spontaneous miscarriages were to be recorded as SAEs. Elective abortions without complications were not to be considered as adverse events. All outcomes of pregnancy were to be reported to AstraZeneca on the pregnancy outcomes report form.

(c) Reporting of serious adverse events

All SAEs were to be reported, whether or not they were considered causally related to the investigational product. When an investigator became aware of an SAE during the course of the study, the SAE was to be reported to the local monitor or other AstraZeneca representative in accordance with the AstraZeneca study protocol. If any SAEs were recorded during the 30-day follow-up period, all concomitant medications taken during the 30-day follow-up were also to be recorded on the CRF.

5.5.7.3 Incidence of treatment-emergent mania -- YMRS

(a) Methods of assessment

The YMRS is an 11-item instrument that was used to rate the patient's mania symptoms for the preceding week (Young et al 1978). Scoring for the items was made on a 0- to 4-point scale for 7 of the items and on a 0- to 8-point scale for the remaining 4 items. Reports of investigator-diagnosed cases of treatment-emergent mania or hypomania were compiled from adverse events reports.

(b) Calculation or derivation of outcome variable

Treatment-emergent mania for a patient was scored if the patient's YMRS total score was ≥16 at any 2 consecutive visits or final visit or if they received an AE report of mania or hypomania from the investigator. Change from baseline in the YMRS score was calculated by subtracting the baseline score from the visit score. The primary variable, the change from baseline in YMRS, was defined as the YMRS total score at Day 57 (Week 8) or final assessment minus the YMRS total score at baseline. An increase in mania or hypomania symptoms was thus indicated by a positive change score.

5.5.7.4 Laboratory safety measurements and variables

Laboratory safety variables assessed in this study are summarized in Table 14.

Table 14 Laboratory safety variables

Type of assessment	Variables
Fasting hematology	Hemoglobin
	Hematocrit
	Red blood cell count (RBC)
	White blood cell count (WBC)
	Differential white blood cell count (% and absolute)
	Platelet count
Fasting clinical chemistry	
Hepatic function	Alanine transaminase (ALT)
	Aspartate transaminase (AST)
	Alkaline phosphatase
	Total bilirubin
Renal function	Creatinine
Lipids	Total cholesterol
	low-density lipoprotein cholesterol
	high-density lipoprotein cholesterol
	triglycerides
Electrolytes	Sodium
	Potassium
	chloride
	bicarbonate
Thyroid function	Thyroid stimulating hormone (TSH)
	Triiodothyronine resin uptake (T3RU)
	Free thyroxine (T4)
Other	Glycated hemoglobin (HbA1c)
	Insulin
	Glucose

Laboratory results were converted to standard units according to conversion factors listed in Table 11.3.7.1.1.1 and Table 11.3.7.1.2.1, Section 11.3. Change from baseline (the final test value minus the screening test value) was derived for all patients who had a screening

laboratory test and a final laboratory test. Abnormal laboratory findings were identified as outside the normal range according to local laboratory criteria or as clinically important according to the criteria presented in Table 15, which presents criteria specified in the Statistical Analysis Plan (SAP) and the criteria that were adopted as the safety analysis proceeded. The criteria for clinically important changes were revised to reflect changes in medical standards and to insure consistency across the Seroquel programs as defined in 2005 and agreed with regulatory authorities.

Table 15 Definition of clinically important clinical laboratory values

Laboratory assessment	Units	Low	High
Hematology			
Hematocrit (males)	vol fraction	≤0.37	≥0.55
Hematocrit (females)	vol fraction	≤0.32	≥0.50
Hemoglobin (males)	g/dL	≤11.5	≥18.5
Hemoglobin (females)	g/dL	≤10.5	≥16.5
RBC	10^{12} cells/L	≤3	≥6
Platelet count	10^{9} cells/L	≤100	≥600
WBC	10^{9} cells/L	≤3.0	≥16.0
Neutrophils			
proportion	%	None	None
Absolute (neutropenia)	10^{9} cells/L	≤1.5[a]	≥10
Absolute (agranulocytosis)	10^{9} cells/L	≤0.5[b]	NA
Eosinophils			
proportion	%	NA	None
absolute	10^{6} cells/L	NA	≥1000
Basophils			
proportion	%	NA	None
absolute	10^{9} cells/L	NA	≥0.5
Lymphocytes			
proportion	%	None	None
absolute	10^{9} cells/L	≤0.5	≥6
Monocytes			
proportion	%	NA	None
absolute	10^{9} cells/L	NA	≥1.4

Table 15 Definition of clinically important clinical laboratory values

Laboratory assessment	Units	Low	High
Chemistry			
ALT	ULN	NA	≥3
AST	ULN	NA	≥3
Alkaline phosphatase	ULN	NA	≥3
Total bilirubin	ULN	NA	≥1.5
Creatinine	mg/dL	NA	≥1.58
Sodium	mmol/L	≤132	≥152
Potassium	mmol/L	≤3.0	≥5.5
Bicarbonate (CO_2)	mmol/L	≤18	≥30
Chloride	mmol/L	≤90	≥120
Free T4	LLN/ULN	<0.8	>1.2
TSH	mIU/L	NA	>5
Total cholesterol	mg/dL	NA	≥240
HDL	mg/dL	≤40	None
LDL	mg/dL	None	≥160
Triglycerides	mg/dL	NA	≥200
HbA1c	%	NA	>7.5
Insulin C-peptide	ng/ml	≤0.5	≥2
Glucose (fasting)	mg/dL	≤45	≥126

[a] Criterion for neutropenia
[b] Criterion for agranulocytosis
LLN Lower limit of normal; ULN Upper limit of normal; HbA1c Glycosylated hemoglobin; NA Not applicable.

5.5.7.5 Vital signs measurement

Vital signs included supine and standing pulse, and systolic and diastolic blood pressure. Changes from baseline at each visit for each of these variables were calculated. Differences in supine and standing scores were also computed.

Vital signs assessed are shown in Table 16, along with criteria for potentially clinically important values.

Table 16 Definitions of potentially clinically important vital signs by FDA criteria

Vital sign	Criterion value	Change from baseline
Pulse	>120 bpm	increase ≥15 bpm
	<50 bpm	decrease ≥15 bpm
Systolic blood pressure	≥180 mm Hg	increase ≥20 mm Hg
	≤90 mm Hg	decrease ≥20 mm Hg
Diastolic blood pressure	≥105 mm Hg	increase ≥30 mm Hg
	≤50 mm Hg	decrease ≥20 mm Hg
Orthostatic changes		
Systolic blood pressure or	decrease ≥20 mm Hg from supine to standing after 1 min	
Diastolic blood pressure	decrease ≥20 mm Hg from supine to standing after 1 min	
Pulse	increase ≥20 bpm from supine to standing after 1 min	
Combined	Decrease ≥20 mm Hg in systolic BP and increase ≥20 bpm in pulse rate	

bpm beats per minute

5.5.7.6 ECG safety measurements and variables

Twelve-lead ECGs were performed at screening and on Day 57 (Week 8). ECGs for patients at all study sites were acquired at the site using an approved unit and were transmitted to eResearch Technology. Quality assurance of the ECG waveform and patient demographics was conducted by a central laboratory operator at eResearch Technology. ECGs were processed through a computer interpretation program and then reviewed first by an ECG analyst and then by a board-certified cardiologist. QTc intervals were calculated using the Fridericia formula (Puddu et al 1988). ECG parameters are shown in Table 17, along with criteria for clinically important values.

Table 17 Definition of clinically important electrocardiogram parameters

ECG parameter	Criterion value	Change from baseline
Heart rate	>120 bpm	increase ≥15 bpm
	<50 bpm	decrease ≥15 bpm
PR	≥210 msec	NA
QRS	≤50 msec	NA
	≥120 msec	NA
QT	≥500 msec	Increase ≥60 msec
	≤200 msec	NA
QT_C (Fridericia Correction)	≥450 msec	Increase ≥60 msec
PQ	≥200 msec	NA
	≤120 msec	NA

PR P-R interval; QRS Q-R-S interval; QT Q-T interval; QT_c Q-T interval with Fridericia correction; PQ P-Q interval; NA Not applicable.

5.5.7.7 Weight and Body Mass Index (BMI)

Patient weight data were also explored as change in BMI. Patients were stratified by BMI category to determine changes within and across categories.

Body mass index was calculated using the following formula:

BMI = weight in kilograms ÷ (height in meters)^2

For cross tabulation the following categorization was used:

Category	BMI (kg/m^2)
Underweight	Under 18.5
Normal weight	18.5 – <25
Overweight	25 – <30
Obese	30 – <40
Severely Obese	40 and over

BMI Body mass index.

Changes in body weight and BMI were computed as Day 57 (OC) and Day 57 (LOCF) measurement minus the baseline measurement. The key endpoint for weight change was whether a patient gained ≥7% over baseline. Weight loss of ≥7% has been presented as well.

5.5.7.8 Physical examination

Physical examination including height and weight were assessed at the screen visit. A brief physical exam with weight only was assessed at Day 57 (Week 8) or on the day a patient voluntarily discontinued treatment. New positive findings on last-visit physical examination were to be reported as adverse events.

5.5.7.9 Simpson-Angus Scale (SAS)

The SAS (Simpson and Angus 1970) is the sum of a 10-item scale that is used to rate the presence and intensity of extrapyramidal motor symptoms, with the score for each item ranging from 0 to 4. The investigator could also enter each item as "not ratable." Items rated as "not ratable" were scored as a "9" in the database and were treated as missing data and not included in the total score (see the SAP, Appendix 12.1.9, for further detail). Increases from baseline in total score thus indicated an increase in extrapyramidal motor symptoms.

5.5.7.10 Barnes-Akathisia Rating Scale (BARS)

The BARS (Barnes 1989) has 4 items and is used to assess objective and patientive attributes of akathisia. Only 1 item of the BARS, the Global Assessment of Akathisia, with a score ranging from 0 to 5 was analyzed (see the SAP, Appendix 12.1.9 for further detail). Increases from baseline in the global assessment item score thus indicated an increase in akathisia.

5.6 Data management and quality assurance

The quality of study data was assured through monitoring of investigational sites, provision of appropriate training for study personnel, and use of data management procedures, as detailed below.

AstraZeneca's quality assurance and internal quality control procedures provide reassurance that the clinical study program was carried out in accordance with GCP guidelines. AstraZeneca undertakes a GCP audit program to ensure compliance with its procedures and to assess the adequacy of its quality control measures. Audits, by a Global Quality Assurance group operating independently of the study monitors and in accordance with documented policies and procedures, are directed towards all aspects of the clinical study process and its associated documentation.

5.6.1 Monitoring

An investigator's meeting was held before the start of the study. During the study, the LRA monitors had regular contact with the investigational sites; these contacts included visits to confirm that the facilities remained acceptable, that the investigational teams were adhering to the protocol, that data were being accurately recorded in the CRF and to provide information and support to the investigator. The monitor ensured that drug accountability was being carried out. Source data verification (a comparison of the data in the CRF with the hospital and other records at the investigational site) was also performed. The monitors or other LRA personnel were available between visits to provide any information or advice required by the investigator.

5.6.2 Training

Investigational personnel were trained and tested on the administration of the MADRS, the HAM-D, the HAM-A and the YMRS at an investigators meeting in Chicago, Illinois from 11 June 2004 to 13 June 2004. Testing standards were set at ±2points for each test item. If trainees failed to meet this standard for ≥3 items, or if their total test score was deviant by 4 points or more, they were required to repeat the test using a new test videotape. Training but no testing was also provided by Michael B First, MD, Columbia University for the SCID.

In addition, all site personnel were given a refresher course on study procedures by a mid-study webcast meeting on 9 December 2004. The refresher course also covered known points of difficulty based upon experience in the study to date.

5.6.3 Data management

Case report forms were provided for recording of data. The forms were printed in triplicate on carbonless paper. Data were to be recorded directly and legibly onto the case report forms with black ink, preferably with black ball-point pen. If any data were not available, omissions were to be indicated on the case report forms. Corrections were to be made legibly and be initialed and dated by approved personnel; the reasons for significant changes had to be provided. Correction fluid or covering labels could not be used. The top 2 sheets were collected and returned to LRA, and transferred periodically to AstraZeneca Pharmaceuticals. The 3rd sheet was retained by the investigator.

Data from the completed CRFs were entered into a Microsoft ACCESS database version 97 at LRA and transferred to AstraZeneca as SAS datasets. The process was documented in the Data Management Plan and the Data Management Validation Guidelines and the validation performed under the direction of the responsible Data Manager. Centrally collected ECG data were sent from eResearch Technology in an electronic format to be loaded by batch process.

Clinical laboratory data were transferred to AstraZeneca from Quintiles Laboratories as SAS datasets.

Data management activities (ie, cleaning of data) were performed using the ACCESS database version 97. Any data queries raised following validation were dealt with using data query sheets. The distribution of copies was as for the CRFs.

5.7 Statistical methods and determination of sample size

5.7.1 Statistical evaluation

The statistical evaluation of study data was performed by the Biostatistics Group of the AstraZeneca Biostatistics Section using SAS® Version 8.2.

5.7.2 Description of outcome variables in relation to objectives and hypotheses

Definitions of efficacy outcome variables are given in Section 5.5.3. Definitions of patient-reported outcome variables are given in Section 5.5.4. Definitions of safety outcome variables are given in Section 5.5.7.

The null hypotheses of no difference between quetiapine once daily (300 mg and 600 mg respectively) and placebo with respect to the primary outcome variable, the change from baseline at Day 57 (Week 8) in the MADRS total score, were tested in favor of the alternative hypotheses that treatment with quetiapine 300 mg once daily or with quetiapine 600 mg once daily would have superior efficacy to placebo in treating depressive symptoms. Similar null hypotheses were tested for the following secondary efficacy, exploratory efficacy and safety outcome variables:

- Change from baseline at each assessment of MADRS total score
- Patient response, showing a ≥50% reduction from baseline in MADRS total score (responders) at each assessment and at final assessment
- Patient remission, a MADRS total score ≤12 (remitters) at each assessment and at final assessment
- Change from baseline to each assessment in the total HAM-D total score
- Change from baseline to each assessment in the HAM-D Item 1 score
- Change from baseline to each assessment and at final assessment for the CGI-S score
- CGI-I score at each assessment and at final assessment (response, much improved or very much improved in CGI-I)
- Change from baseline to each assessment and at final assessment for the Q-LES-Q score (secondary endpoint of particular interest)
- Change from baseline to each assessment and at final assessment for the SDS score
- Change from baseline to each assessment and at final assessment for the YMRS score
- Percentage of patients with an increase in total SAS score from baseline at final assessment
- Percentage of patients with an increase in total BARS score from baseline at final assessment

Analysis of the secondary outcome variables of response to treatment (≥50% reduction in MADRS total score from baseline) and remission (achievement of MADRS total score ≤12) following treatment tested the hypotheses that treatment with quetiapine 300 mg once daily or with 600 mg once daily would produce a larger proportion of patients that met criteria within either of the treatment groups compared to the placebo group.

Analysis of the secondary outcome variables of change from baseline to each assessment and to final assessment in the HAM-A total score tested the hypotheses that treatment with quetiapine 300 mg once daily or with quetiapine 600 mg once daily would produce similar or larger reductions than would treatment with placebo.

5.7.3 Description of analysis sets

Data analysis was based on the following 3 patient populations:

- The safety population included all enrolled patients classified according to treatment actually received. Randomized patients who did not receive treatment were excluded.

- The intention-to-treat (ITT) population included all evaluable patients in the safety population, classified according to the assigned randomized treatment. It included all enrolled patients who took study medication and who had a baseline MADRS and at least 1 valid post baseline MADRS assessment. The ITT population was used to assess the primary efficacy outcome variable.

- The per-protocol (PP) population excluded patients from the ITT population with protocol violations and deviations that were regarded as interfering with an accurate efficacy assessment (see the SAP, Appendix 12.1.9 for further detail).

5.7.4 Methods of statistical analysis

5.7.4.1 General principles

All statistical tests were 2-sided. The primary analyses used last observation carried forward (LOCF) for the time period of interest. A supportive secondary analysis was also performed to assess sensitivity to drop outs, this was an observed cases (OC) analysis in the ITT population.

This study employed a central randomization with a stratification based on diagnosis (bipolar 1 and bipolar 2); therefore diagnosis (not center) was included as a stratification variable in the analysis models. Center was included in the ANCOVA model as a random effect.

Modification in the protocol specified method to control the experiment wise error was made in order to control the error rate for multiple comparisons hypothesis testing in both the primary analysis and secondary analysis of particular interest, 4 hypothesis tests rather than 2.

A parallel gatekeeping procedure, which strongly controlled the family wise error rate (α), was employed to handle the multiple comparisons. Using the Bonferonni procedure as defined in the parallel gatekeeping strategy (Dmitrienko et al, 2003), p-values were adjusted and compared with α=0.05. In this gatekeeper strategy, the first gate allowed one to proceed to test the secondary hypotheses only if at least 1 primary hypothesis was rejected. Details of the hypotheses are detailed in the SAP, Appendix 12.1.9.

The primary analysis was the MADRS change from baseline at week 8 (LOCF) and the secondary endpoint of particular interest was the Q-LES-Q change from at week 8 (LOCF).

All secondary analyses were conducted at the nominal significance level of 0.05, with no adjustment for multiple comparisons.

The primary analysis of efficacy was performed on the ITT population. An analysis on the PP population was also conducted for the primary efficacy variable to assess sensitivity of results.

Patients who were randomized but subsequently were never dosed were excluded from both efficacy and safety analyses.

5.7.4.2 Testing of covariates

In general, the baseline value for a given score was included as a covariate in an analysis of change from baseline for that score. Because randomization was stratified by diagnosis, diagnosis stratum was also included as a covariate where appropriate.

Center was included and evaluated as a random variable in the models. It was not expected that all centers would contribute patients to all strata. Thus imbalances were expected both in terms of number randomized and in the distribution across the strata.

5.7.4.3 Efficacy analysis methods

Efficacy analysis methods are summarized below. Changes from the original SAP are described in Section 5.8.2.

Primary analysis for MADRS

The primary analysis of change from baseline to final assessment (LOCF) in MADRS total scores tested the superiority of each dose level of quetiapine using an Analysis of Covariance (ANCOVA) with the baseline MADRS total score as the covariate and including treatment and diagnosis strata as fixed effects in the model. The p-values from the primary analyses were adjusted using the weights defined in Section 5.7.4.1.

A supportive secondary analysis model in the ITT population, using a mixed model repeated measures (MMRM) approach, utilized a REML estimation and the Toeplitz estimator for the covariance matrix. This model was employed to further characterize the treatment effects across 8 weeks of treatment with an estimate of the effect at the end of study. This approach assumed that missing observations were missing at random (MAR), and utilized all available data.

The MADRS score change from baseline used the ITT population as the primary analysis with a secondary analysis performed on the PP population to assess sensitivity of results to population assessed.

The effect size, a measure of treatment differences adjusted for the variability, was calculated for the MADRS change from baseline using the MMRM approach. The numerator was the

LS mean difference compared to placebo, and the variability used in the denominator was based on the relevant error terms in the analysis model.

Secondary efficacy analysis

All secondary analyses were made in order to yield supportive evidence that quetiapine was more effective than placebo. These analyses used the ITT population and mainly have been presented as point estimates with associated 95% confidence intervals for the treatment effects and the difference between groups. The confidence levels and p-values displayed are nominal with no adjustment for multiplicity.

Descriptive statistics for the primary variable are presented for both the ITT and PP populations to support the analyses of this variable.

MADRS

Descriptive statistics are presented for MADRS total score, MADRS Item scores, change from baseline for MADRS total score and change from baseline MADRS Item scores by visit and final assessment (LOCF). The ANCOVA model was used with baseline as a covariate and treatment and diagnosis strata as fixed effects in the item score analysis.

HAM-D

Descriptive statistics are presented for HAM-D total score, HAM-D Item scores, change from baseline for HAM-D total score and change from baseline HAM-D Item scores by visit and final assessment (LOCF). The ANCOVA model was used with baseline as a covariate and treatment and diagnosis strata as fixed effects.

HAM-A

Descriptive statistics are presented for HAM-A total score, HAM-A Item scores, change from baseline for HAM-A total score and change from baseline HAM-A Item scores by visit and final assessment (LOCF). The ANCOVA model was used with baseline as a covariate and treatment and diagnosis strata as fixed effects in the item score analysis.

Q-LES-Q

For this study, Q-LES-Q was a secondary endpoint of particular interest. Descriptive statistics are presented for the Q-LES-Q total score, %Maximum total score, Q-LES-Q item scores, change from baseline for Q-LES-Q total score, change from baseline %Maximum total score, and change from baseline Q-LES-Q item scores by visit and final assessment. The ANCOVA model was used with baseline as a covariate and treatment and diagnosis strata as fixed effects in the model. The p-values were adjusted using a Bonferroni procedure defined in Section 5.7.4.1.

CGI

Descriptive statistics are presented for the CGI-S, CGI-Change from baseline in CGI-S by visit and final assessment.

Two approaches to analysis were evaluated; 1 approach handled the data as if it were continuous. The Change from baseline CGI-S used an ANCOVA model with baseline CGI-S as a covariate and treatment and diagnosis strata as fixed effects. The CGI change score used an ANOVA model with treatment and diagnosis strata as fixed effects.

The second approach dichotomized the ratings into response /non-response where response was defined as (very much or much improved) for the CGI-C; the categorized response was analyzed using the Cochran-Mantel-Haenszel Chi square test across diagnosis strata. To support response, the response based on the CGI-C was used (Response on Depression Scales).

Response on the MADRS

Analysis of the MADRS response (presence of a ≥50% reduction from baseline) tested the differences between treatment and placebo in response rates at each visit assessment and final assessment (LOCF) using a Cochran-Mantel-Haenszel Chi square test across diagnosis strata. Summary statistics (number and % in each treatment group responding) are presented along with the p-values and estimated relative risk with 95% confidence interval. The model was fitted using the PROC FREQ procedure in SAS®. The Breslow Day statistic was used to evaluate homogeneity of response across the bipolar diagnosis strata.

Additional criteria of response were evaluated using descriptive statistics at the Week 8 time point to determine sensitivity to the choice of criteria, levels for consideration included reductions from baseline at the following levels: ≥30%, 40%, and 60%.

Remission on the MADRS

Analysis of the MADRS remission (presence of a total score ≤12) tested the differences between treatment and placebo in response rates at each visit assessment and final assessment (LOCF) using a Cochran-Mantel-Haenszel Chi square test across diagnosis strata. Summary statistics (number and % in each treatment group responding) are presented along with the p-values and estimated relative risk with 95% confidence interval. The model was fitted using the PROC FREQ procedure in SAS®. The Breslow Day statistic was used to evaluate homogeneity of response across the bipolar diagnosis strata.

Additional criteria of remission were evaluated using descriptive statistics at the Week 8 time point to determine sensitivity to the choice of criteria, levels for consideration included MADRS total scores of ≤8 and 10.

YMRS total score

Descriptive statistics are presented for the YMRS total score and the change from baseline in YMRS total score by visit and at final assessment. The ANCOVA model was used with the YMRS baseline as a covariate and treatment and diagnosis strata as fixed effects.

Patient reported outcomes – SDS

Descriptive statistics are presented for the SDS total (sum of 3 domains), the individual domains (work/school, social life, and family life) and productivity measures (days lost and days unproductive). The ANCOVA model was used for SDS change from baseline for both raw total score and the individual domains to each assessment and final visit with the appropriate baseline SDS score as a covariate and treatment and diagnosis strata as fixed effects.

5.7.4.4 Safety analysis methods

All safety analyses were based on the safety population, but where change from baseline was the primary focus of the analysis, only patients with both baseline and post baseline data were included.

Treatment emergent mania

Tolerability of the treatment in Bipolar patients included an assessment of treatment emergent mania. The presence/absence of the criteria (defined in the SAP, Appendix 12.1.9) assessed the safety population using a Cochran-Mantel-Haenszel Chi square test across diagnosis strata. Summary statistics (number and % in each treatment group responding) are presented along with the p-values and estimated relative risk with 95% confidence interval. The model was fitted using the PROC FREQ procedure in SAS®. The Breslow Day statistic was used to evaluate homogeneity of response across the bipolar diagnosis strata.

Movement disorders

Modified SAS total score and BARS global assessment score, including changes from baseline for each variable, are summarized by visit using descriptive statistics. A logistic regression analysis was run on the dichotomized change from baseline: 1=worsened (increase in the total score ≥1), and 0= did not worsen (change of 0 or a reduction in the score).

Study withdrawals

Differences between treatment groups in overall rate of withdrawal and category of withdrawal were tested using a CMH test stratified by diagnosis. Withdrawals on or before Day 8 (Week 1) were examined as part of the consideration of balance between treatment groups due to early withdrawal.

For each visit (week of study) withdrawals are summarized in total and by reason for withdrawal using descriptive statistics.

Adverse events

Adverse events were classified using MedDRA system of nomenclature. System organ class and preferred term were used to tabulate the number of events and crude event rates. An event that occurred 1 or more times in a patient after randomized treatment counted as 1 event in the numerator of the crude event rate, the denominator was the number at risk in the group.

Events were classified as prior to treatment, during treatment, during follow up period. Tabulation of events included all events during treatment and events reported within 30 days of the last dose of study medication. All other events appeared only in patient listings.

Adverse events have the primary assessment by treatment arm and a secondary reporting by treatment and diagnosis strata.

Incidence rates are tabulated and presented for the following categories: all adverse events, serious adverse events, drug related adverse events, adverse events leading to death, and adverse events leading to withdrawal of patients from the study.

An additional analysis included an assessment of events during titration, that is an event that started on Day 1-8 of study treatment. This descriptively assessed the impact of the once daily dosing with relatively rapid titration.

Other adverse events of interest included the disease state events suicidality and switch to mania or hypomania, as well as EPS symptom events, neutropenia/agranulocytosis events, QT prolongation events, and diabetic events, which were summarized by treatment group to explore level of risk in the population and potential dose response effects in these events. Search criteria for these events are found in the SAP, Appendix 12.1.9.

Patients identified through this review for neutropenia/agranulocytosis, QT prolongation and diabetic events had a listing prepared of the relevant laboratory assessments in order to facilitate the identification of patients for full discussion in the relevant laboratory section.

No formal statistical testing was planned for adverse events.

Adverse event summaries based on all events by SOC and preferred term are provided for subgroups including age categories, sex, race, and bipolar diagnosis.

Weight analysis

Descriptive statistics at baseline are tabulated by sex.

Descriptive statistics were used to assess changes in weight and was assessed without regard to sex. No formal analysis was planned, but the change from baseline in weight and BMI is reported as are shift table summary statistics for the number and percentage of patients shifting into a new category (see Section 5.5.7.7).

Laboratory data

The clinical laboratory data included only those patients with both a baseline and post baseline assessment for summary tables, all data appear in the listings. The clinical laboratory summary data presented include the value at the baseline, final visit and change from baseline to final assessment for the following variables: total bilirubin, alkaline phosphatase, AST, ALT, sodium, potassium, chloride, glucose, insulin, bicarbonate, total cholesterol, HDL and LDL cholesterol, triglycerides, thyroid functioning (TSH, T3RU, T4), creatinine, hemaglobin,

hematocrit, RBC, WBC, differential %, ANC, platelets. These test results are tabulated using descriptive statistics by treatment group. Shift tables are provided using the criteria defined in Quetiapine project agreed extended normal ranges to identify potentially clinically significant changes (Table 15).

Fasting state was assessed through the following methods:

- For patients with the fasting flag on the laboratory file reported as 'Y'
- Calculated difference between date and time of lab draw and date and time of last meal is > 8 hours - create meal confirmed fasting flag
- Time of laboratory draw was between 0600 and 1200 hours- create time fasting flag

A patient was defined as confirmed fasting in 2 ways:

- Fasting flag was "Y" and meal confirmed fasting was "Y"
- All 3 flags were "Y"

A separate analysis of lipids, glucose and insulin data and derived glucose regulation variables (HOMA-R and QUICKI) was done for the subset of patients with data at baseline and post baseline which was collected in the confirmed fasting state by both definitions. In addition, descriptive statistics are provided for the following 3 subgroups based on risk factors for diabetes: patients with diabetes at study entry (subgroup defined as diabetic, based on history or current diagnosis of diabetes mellitus or baseline glucose of ≥126 mg/dl); patients at risk for diabetes at study entry (subgroup defined as diabetic at risk, with risk factors of either gestational diabetes or baseline BMI ≥35 or impaired baseline glucose [≥100-<126 mg/dl]); and those patients without impaired glucose or risk factors at study entry (subgroup defined as non-diabetic).

Insulin resistance, assessed by HOMA-R calculated as (insulin value (mU/ml) x glucose value (mmol/l)) divided by 22.5, are summarized.

Insulin sensitivity, assessed by QUICKI calculated as 1 divided by the following value ($\log_{10}$(insulin value (μU/ml)) + $\log_{10}$(glucose value (mg/dl))), are summarized.

Vital signs

Vital signs were measured at each visit in both supine and standing position. The data are summarized using descriptive statistics by visit and as change from baseline at each visit and final assessment for the following variables: supine pulse, diastolic and systolic blood pressure, standing pulse, diastolic and systolic blood pressure, and change in pulse, diastolic and systolic blood pressure related to change in position.

Shift tables of the data as related to the extended normal range defined in Table 16 are provided for the supine blood pressure values at baseline and final assessment by treatment

group. A patient was considered to have had a shift if at least 30% of the post baseline assessments were outside the extended range.

For each visit, the number and percentage of patients with changes meeting the criteria for an orthostatic change was calculated for each treatment group also defined in Table 16. A patient was considered to have had a shift if at least 30% of the post baseline assessments met the definition of orthostatic change.

ECG data

The ECG variables were summarized for those patients with both a baseline and final assessment. All ECG assessments are listed. The ECG summary tables included ventricular heart rate, PR interval, QRS interval, QT interval and Fridericia QTc interval at baseline, final assessment and change from baseline to final assessment.

Descriptive statistics are presented for each treatment group.

Shift tables of the interval data based on the criteria found in Table 17 quetiapine project specific agreed extended ranges, will be provided for baseline and final assessment by treatment group.

Metabolic syndrome categorization

Metabolic syndrome risk factors were evaluated by determining which patients had relevant medical history at baseline or who exhibited combinations of the following findings:

- BMI ≥30 kg/m^2
- Supine systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥85 mmHg averaged over the last 2 assessments
- Triglycerides ≥150 mg/dL
- HDL <40 mg/dL for men or <50 mg/dL for women
- Fasting glucose ≥110 mg/dL

Patients who met an aggregate of at least 3 metabolic syndrome risk factors were considered to be at risk for metabolic syndrome. Patients were classified as meeting or not meeting each individual criterion at baseline and at final assessment. The number and proportion of patients shifting from meeting 0, 1, or 2 criteria to meeting either fewer than 3 vs 3 or more criteria at final assessment were determined. The contribution of each criterion factor to the meeting of 3 or more criteria was evaluated within the population meeting aggregate risk criteria by determining the proportion of patients who shifted from not meeting to fulfilling each individual criterion. A presentation of the methods used for analyzing metabolic syndrome risk factors is included in Appendix 12.1.9.

5.7.4.5 Study medication compliance

Patients were classified by the nominal dose for the treatment group to which they were assigned.

The number and percentage of patients who had a dose reduction was tabulated. Compliance was checked versus the number of tablets expected for the period of active treatment (adjusted as appropriate).

Compliance was calculated for the study based on tablet counts. For each patient the overall compliance was assessed as the total number of tablets taken divided by the total number expected to be taken (adjusted for those with the dose reduction). The patient was then classified as fully compliant (≥80%), partially compliant (≥70% and <80%), or non-compliant <70%.

Descriptive statistics are provided by category of compliance by treatment group and diagnosis.

5.7.4.6 Concomitant medication use

Descriptive statistics were used to summarize the number and percent of patients using concomitant medications by generic drug classification. Rescue medication use, lorazepam, and sleep medication use, zolpidem tartrate, were identified from this summary table.

5.7.5 Determination of sample size

The sample size estimation was based on achieving a clinically relevant moderate effect size of 0.36. This was equivalent to a 3.6-point difference from placebo in the MADRS total score with a common standard deviation of 10.

Sample size was estimated using a Bonferroni correction for the 2 comparisons with placebo. A clinically meaningful 3.6-point difference between quetiapine treatment and placebo was used to estimate the effect size (with 3.1 points considered a minimally effective and detectable difference). The variability used for calculation was 10 units, the variability seen in the Study 5077US/0049. A sample size of 168 patients/arm (504 patients total) provided 85% power for 2-sided pair-wise comparisons with placebo at α=0.025 which provides an overall experiment wise type I error rate of 0.05. Therefore, 840 patients were to be screened and approximately 530 patients randomized (allowing for a 5% early drop out rate), to insure 504 patients with post baseline data available for analysis (ITT analysis population).

5.7.6 Interim analyses

There were no interim analyses for this study.

5.7.7 Data and safety monitoring board

There were no data or safety monitoring boards for this study.

5.8 Clinical study protocol amendments and other changes in the conduct of the study or planned analyses

5.8.1 Changes in the conduct of the study

There were no changes in the conduct of this study.

5.8.2 Changes to planned analyses

There were no changes to the planned analyses. Re-evaluation of the sample size requirements was done using a difference between active and placebo of 4 units rather than 3.6 units. This was a reasonable assumption, since the prior study (5077US0049, BOLDER I) had demonstrated a difference of > 5 units. The decision was made to terminate the study at the original planned 1-year recruitment point if the number randomized was between 505 and 510 patients. With this change in expected number randomized, the study would maintain at least 85% power to detect a 4-unit difference from placebo.

In addition, although the SAP states that odds ratios were to be reported for binary variables, the actual analyses performed used the relative risks compared to placebo rather than the odds ratios. The normal Bonferonni procedure instead of the weighted procedure was used for the parallel gatekeeping strategy.

6. STUDY SUBJECTS

A summary of the patient population is given in Section 6.1. Thereafter, the following aspects of the study population are considered: disposition (Section 6.2), adherence to the study protocol (Section 6.3), populations analyzed (Section 6.4), demography and other baseline characteristics (Section 6.5), and treatment compliance and use of concomitant medication (Section 6.6). Conclusions on the suitability of the patient population with respect to the overall purpose of the study are given in Section 6.7.

6.1 Summary of patients

In total, 788 patients were screened and 509 patients with either bipolar I disorder and bipolar II disorder exhibiting moderate to severe depression were randomly assigned to receive quetiapine 300 mg daily, quetiapine 600 mg daily or placebo. Bipolar I patients made up 67.5% of the total and bipolar II patients, 32.5% of the ITT population. Approximately 31% of all patients had rapid cycling courses (≥4 mood episodes in past year). The first patient was enrolled on 30 June 2004 and the last patient completed the study on 26 August 2005. Of the 509 patients recruited, 506 received treatment and were included in the safety population, of whom 467 were analyzed for efficacy in an intention-to-treat analysis set and 422 in a per-protocol analysis set. The 3 groups were well-matched in number and demographic and baseline disease characteristics. The mean patient age was approximately 38 years, and approximately 58% of the patients were female. Approximately 69% to 86% of patients in each treatment group were Caucasian, and most of the remainder were Black. Within the safety population, 59% of quetiapine 300 mg

patients, 54% of quetiapine 600 mg patients and 66% of placebo patients completed the protocol. "Subject not willing to continue" and "patient lost to follow-up" were the main reasons for discontinuation for both quetiapine-treated and placebo-treated patients.

Table 18 shows where the data supporting this section are presented.

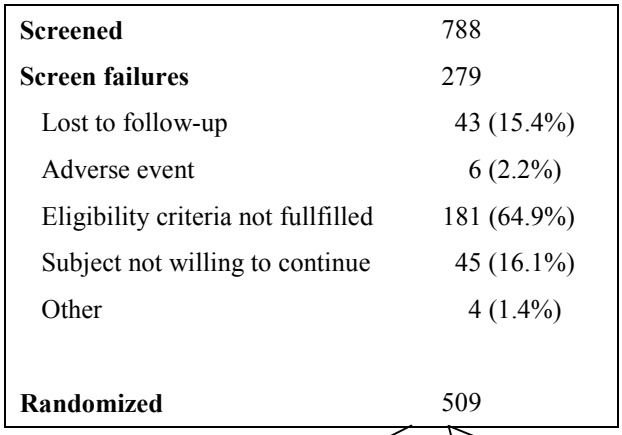
Table 18 Location of supporting data on study patients

Data	Location	
	Summary tables (Section 11.1)	**Individual patient data (Appendix 12.2)**
Subject disposition	Table 11.1.1.1 to Table 11.1.4.5	Appendix 12.2.1.1 to Appendix 12.2.2
Discontinued patients	Table 11.1.4.1 to Table 11.1.4.2 and Table 11.1.4.5	Appendix 12.2.1.2
Patients completing the study	Table 11.1.4.3 to Table 11.1.4.5	Appendix 12.2.1.2
Patients for whom the treatment code was prematurely broken	None	None
Protocol deviations	Table 11.1.3.1 and Table 11.1.3.2	Appendix 12.2.2
Patients and data excluded from efficacy analyses	Table 11.1.3.1 and Table 11.1.3.2	Appendix 12.2.2
Demographic and baseline characteristics	Table 11.1.5.1.1 to Table 11.1.6.5	Appendix 12.2.4.1, to Appendix 12.2.4.4,
Prior medication use	Table 11.1.7.1 to Table 11.1.7.5	Appendix 12.2.10.6
Concomitant medication use	Table 11.1.7.6 to Table 11.1.7.10	Appendix 12.2.10.7
Treatment compliance	Table 11.3.1.4 to Table 11.3.1.6	Appendix 12.2.5

6.2 Disposition

The disposition of study patients is summarized in Figure 1.

Figure 1 Subject disposition (completion or discontinuation)



	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
Randomized	**172**	**169**	**168**
Not treated[a]	1	1	1
Received drug	**171 (99.4%)**	**168 (99.4%)**	**167 (99.4%)**
Discontinued study treatment			
Lost to follow-up	21 (12.2%)	19 (11.2%)	14 (8.3%)
Adverse event	14 (8.1%)	19 (11.2%)	2 (1.2%)
Development of study-specific discontinuation criteria	7 (4.1%)	6 (3.6%)	8 (4.8%)
Subject not willing to continue	26 (15.1%)	30 (17.8%)	19 (11.3%)
Lack of therapeutic response	3 (1.7%)	5 (3.0%)	13 (7.7%)
Eligibility criteria not fulfilled	0	0	2 (0.4%)
Other	0	0	0
Completed study	**101 (58.7%)**	**90 (53.3%)**	**110 (65.5%)**

[a] Patients not treated are also included in the discontinued from study treatment population due to development of study-specific discontinuation criteria

Data derived from Table 11.1.1.1, Table 11.1.2.1 and Table 11.1.4.1

Rates of study completion (safety population) were 59.1% for quetiapine 300 mg patients, 53.6% for quetiapine 600 mg patients and 65.9% for placebo-treated patients (quetiapine 300 mg vs placebo: p = 0.194; quetiapine 600 mg vs placebo: p = 0.022; see Table 11.1.4.5, Section 11.1).

Among all patients assigned to treatment, those treated with quetiapine had higher rates of withdrawal than did those treated with placebo due to being lost to follow-up, "subject not willing to continue" and adverse events. Lack of therapeutic response was cited as the reason for withdrawal of more placebo-treated patients than quetiapine-treated patients (see Table 11.1.4.1, Section 11.1). Of all patients randomly assigned to treatment, 58.3% of Bipolar I patients and 60.8% of Bipolar II patients completed the protocol (see Table 11.1.4.2, Section 11.1).

6.3 Protocol violation and deviations leading to exclusion from the PP population

The number of patients with protocol violations or deviations in each treatment group that lead to exclusion from the PP population are summarized in Table 19.

Table 19 Protocol violations and deviations leading to exclusion from the PP population

Protocol deviation or violation	Number (%) of ITT patients		
	Quetiapine 300 mg N=155	Quetiapine 600 mg N=151	Placebo N=161
Protocol violators and deviators[a]	16	18	11
HAM-D total score <20 at screen or baseline visit	0	0	3
Greater than 8 mood episodes in the past year	2	0	1
History of substance dependence	3	3	2
Lorazepam use after Week 3	0	1	1
Potent P450 inducer use	0	1	0
Potent P450 inhibitor use	1	1	0
Antipsychotic use during study	0	1	0
Antidepressants, hypnotics, mood stabilizers use during study	2	4	0
Patients who received less than 70% of prescribed doses	2	4	0

Table 19 Protocol violations and deviations leading to exclusion from the PP population

Protocol deviation or violation	Number (%) of ITT patients		
	Quetiapine 300 mg N=155	Quetiapine 600 mg N=151	Placebo N=161
Patients who received ≤8 days of study therapy	10	12	6
MADRS assessment collected >4 days after last dose of study medication	0	5	0
No post-baseline assessment after data exclusions	0	2	0

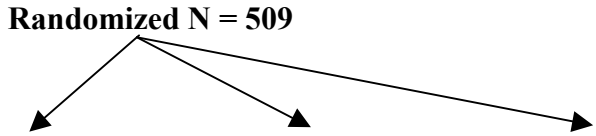
[a] Patients in this category may have multiple reasons listed below
Data derived from Table 11.1.3.2, Section 11.1 and include only items with counts.

Patients were excluded from the PP population in slightly greater proportion for quetiapine-treated patients but for similar causes among the 3 treatment groups overall. Exclusion for receiving less than 9 days of treatment was the most common reason for all treatment groups.

6.4 Subject populations analyzed (analysis sets)

The analysis sets and the number of patients in each analysis set are summarized in Figure 2. Definitions of the analysis sets are given in Section 5.7.3.

Figure 2 Analysis sets



	Quetiapine 300 mg n = 172	Quetiapine 600 mg n = 169	Placebo n = 168
Excluded from safety population			
Not treated	1	1	1
Safety population	171	168	167
Excluded from ITT population			
No valid baseline or post-baseline MADRS score	16	17	6
Intent-to-treat population	155	151	161
Excluded from PP population	16	18	11
see Table 19 for reasons			
PP population	139	133	150

Data derived from Table 11.1.2.1, Table 11.1.3.1 and Table 11.1.3.2, Section 11.1.

All decisions on the inclusion or exclusion of patients from analyses were made while the data were blinded.

Protocol deviations and violations leading to exclusion of quetiapine-treated patients from the ITT population were restricted to missing MADRS data that made computation of change from baseline impossible. With 1 exception, patients excluded from the ITT analysis did not return for the Day 8 (Week 1) assessment, and therefore, had no post-baseline MADRS data. One patient was excluded because (s)he did not have a valid post-baseline MADRS. Altogether, 16 of the 171 patients treated with quetiapine 300 mg, 17 of the 168 patients treated with quetiapine 600 mg and 6 of the 167 patients treated with placebo were excluded

from the ITT population (see Table 11.1.3.1). Exclusions from the PP population are described in Section 6.3.

6.5 Demographic and other patient characteristics

6.5.1 Sex, age, race and weight

The demographic and key baseline characteristics of study patients in the ITT population are summarized in Table 20. Data for the safety population are presented in Table 11.1.5.1.1 and Table 11.1.5.2.1, Section 11.1.

Table 20 Demographic and baseline characteristics of the ITT population

Demographic or baseline characteristic		Treatment group		
		Quetiapine 300 mg (N=155)	Quetiapine 600 mg (N=151)	Placebo (N=161)
Demographic characteristics				
Sex: n (%)	Male	69 (44.5)	68 (45.0)	64 (39.8)
	Female	86 (55.5)	83 (55.0)	97 (60.2)
Age (years)	Mean (SD)	37.2 (10.53)	38.2 (11.01)	37.7 (11.75)
	Minimum	18	18	18
	Maximum	64	64	63
Age distribution: n (%)	18-39 years	92 (59.4)	78 (51.7)	88 (54.7)
	40-65 years	63 (40.6)	73 (48.3)	73 (45.3)
Race: n (%)	Caucasian	107 (69.0)	115 (76.2)	138 (85.7)
	Black	25 (16.1)	21 (13.9)	11 (6.8)
	Oriental	3 (1.9)	0	1 (0.6)
	Other	20 (12.9)	15 (9.9)	11 (6.8)
Baseline characteristics				
Weight (kg)	Mean (SD)	87.0 (22.0)	87.7 (23.7)	82.7 (21.6)
	Minimum	36	36	44
	Maximum	159	172	155
BMI: n (%)	<18.5 kg/m^2	2 (1.3)	5 (3.3)	3 (1.9)
	18.5 to <25 kg/m^2	38 (24.5)	29 (19.3)	48 (29.8)
	25 to <30 kg/m^2	47 (30.3)	46 (30.7)	53 (32.9)
	30 to <40 kg/m^2	53 (34.2)	54 (36.0)	44 (27.3)
	≥40 kg/m^2	15 (9.7)	16 (10.7)	13 (8.1)

Data derived from Table 11.1.5.1.2 and Table 11.1.5.2.2, Section 11.1.

The safety and PP populations were similar to the ITT population in distribution of demographic and baseline characteristics. The lower mean weight for the placebo group may have been due to the larger proportion of females in that group who also weighed a mean of 5 to 7 kg less compared to females in the quetiapine groups. The treatment groups were well-matched in all analysis populations (see Tables 11.1.5.1.1, and 11.1.5.1.2 and Tables 11.1.5.2.1 and 11.1.5.2.2, Section 11.1).

6.5.2 Baseline disease characteristics

Baseline disease characteristics for the ITT population are displayed in Table 21. Baseline disease characteristics for the safety population are presented in Table 11.1.6.1 and Table 11.1.6.2, Section 11.1).

Table 21 Baseline disease characteristics (ITT population)

	Quetiapine 300 mg (N=155)		Quetiapine 600 mg (N=151)		Placebo (N=161)	
DSM-IV diagnosis: n (%)						
Bipolar I disorder [a]	104	(67.1)	101	(66.9)	110	(68.3)
Bipolar II disorder	51	(32.9)	50	(33.1)	51	(31.7)
Baseline MADRS total score						
Mean (SD)	31.1	(5.68)	29.9	(5.61)	29.6	(5.44)
Range – Minimum, maximum	17,	46	14,	46	17,	44
Screening HAM-D score						
Mean (SD)	24.8	(3.39)	24.5	(3.06)	24.3	(3.27)
Range – minimum, maximum	20,	39	20,	39	15,	33
Baseline HAM-A score						
Mean (SD)	19.1	(5.98)	18.4	(5.78)	18.2	(5.69)
Range – minimum, maximum	5,	34	6,	33	6,	36
Screening YMRS score						
Mean (SD)	5.8	(3.30)	5.4	(2.79)	5.8	(3.00)
Range – minimum, maximum	0,	12	0,	12	0,	12
Baseline CGI-S score						
Mean (SD)	4.5	(0.56)	4.4	(0.57)	4.4	(0.55)
Range – minimum, maximum	4,	6	3,	6	3,	6
Baseline Q-LES-Q score						
Mean (SD)	35.4	(7.77)	37.5	(7.51)	37.8	(6.90)
Range – minimum, maximum	14,	52	19,	57	21,	55

Table 21 Baseline disease characteristics (ITT population)

	Quetiapine 300 mg (N=155)		Quetiapine 600 mg (N=151)		Placebo (N=161)	
Years since first depressed episode						
Mean (SD)	18.0	(10.3)	19.5	(10.3)	17.6	(10.6)
Range – minimum, maximum	2,	46	2,	47	1,	47
Depressed episodes over lifetime						
Mean (SD)	18.2	(19.7)	18.8	(21.1)	18.9	(24.5)
Range – minimum, maximum	2,	100	1,	108	1,	99
Depressed episodes over past year						
Mean (SD)	1.7	(0.9)	1.9	(1.1)	1.9	(1.0)
Range – minimum, maximum	1,	8	1,	6	1,	6
Years since first manic or hypomanic episode						
Mean (SD)	15.4	(10.0)	15.9	(9.4)	15.2	(9.9)
Range – minimum, maximum	2,	46	1,	39	1,	45
Manic or hypomanic episodes over lifetime						
Mean (SD)	15.0	(29.6)	13.5	(18.9)	15.0	(19.6)
Range – minimum, maximum	1,	272	1,	108	1,	99
Manic or hypomanic episodes over past year						
Mean (SD)	1.1	(1.1)	1.2	(1.1)	1.3	(1.2)
Range – minimum, maximum	0,	5	0,	4	0,	6
Mood episodes over the past year: n (%)						
<4	111	(71.6)	105	(69.5)	108	(67.1)
≥4	44	(28.4)	46	(30.5)	53	(32.9)

[a] Includes patients with and without psychotic features.
Data derived from Table 11.1.6.1, Table 11.1.6.3, Table 11.1.6.5, Table 11.2.1.1.1, Table 11.2.2.1.1, Table 11.2.3.1.1, Table 11.2.5.1.1, Table 11.2.6.1, Table 11.3.8.1.7.1, Section 11.1.

MADRS total scores at baseline ranged from 14 to 46; the mean MADRS total score was between 30 and 31 in the 3 groups within the ITT population. The PP population was similar to the ITT population with respect to baseline MADRS scale scores (see Table 11.2.1.1.1 and Table 11.2.1.1.3, Section 11.2). HAM-D total scores at screening ranged from 15 to 39; the

mean HAM-D total score was between 24 and 25 in the 3 groups within the ITT population. CGI-S scores at screening ranged from 3 to 6 with means of 4.4 to 4.5 for the 3 groups.

Descriptive parameters for years since first depressed episode, for the number of depressed episodes over lifetime and for the number of manic or hypomanic episodes over lifetime were similar for the 3 treatment groups (see Table 21).

The ITT population comprised approximately two-thirds Bipolar I and one-third Bipolar II patients, with similar proportions for each treatment group (see Table 11.1.6.1, Section 11.1). Bipolar I patients tended to have slightly higher severity ratings for their bipolar disorder than did Bipolar II patients. Bipolar I patients exhibited baseline mean MADRS scores of 30 to 32 points, mean screening HAM-D scores of approximately 25 points, and CGI-S scores of 4.5 to 4.6 points Bipolar II patients exhibited baseline mean MADRS scores of 27 to 30 points, mean screening HAM-D scores of approximately 24 points, and CGI-S scores of 4.2 to 4.3 points (see Table 11.2.1.4.1, Table 11.2.2.4.1 and Table 11.2.3.4.1, Section 11.1). Patients with a rapid cycling course (≥4 mood episodes in the past year) made up 31% of patients in all 3 treatment groups combined (see Table 11.1.6.5, Section 11.1).

6.6 Treatment compliance and use of concomitant medication

6.6.1 Treatment compliance

Compliance was uniform and high within the entire safety population for the 3 treatment groups. One hundred sixty seven quetiapine 300 mg patients (97.7%), 163 quetiapine 600 mg patients (97.0%) and 167 placebo patients (100%) were classified as being compliant on the basis of tablet counts that were consistent with at least 80% consumption of doses (see Table 11.3.1.4, Section 11.1). It is recognized that these estimates err to the high end because patients lost to follow-up who did not return study medication were counted as having taken their full dose.

6.6.2 Concomitant medication

6.6.2.1 Use of medication at study entry

The use of psychoactive medications at Visit 1 (screening) in the ITT population is summarized in Table 11.1.7.2, Section 11.1. Approximately 15% to 23% of patients in the safety population were taking an antidepressant before Visit 1 (screening); 3% to 5% were taking an antipsychotic, and 2% to 4% were taking both an antipsychotic and an antidepressant (see Table 11.1.7.5, Section 11.1). The treatment groups were well-matched with respect to recent medication history.

6.6.2.2 Use of concomitant medication after randomization

The use of psychoactive medications after study entry in the ITT population is summarized in Table 11.1.7.7, Section 11.1. Lorazepam use was noted for 1.3% of quetiapine 300 mg patients, 4.0% of quetiapine 600 mg patients and 3.1% of placebo patients. Zolpidem use was noted for 1.3% of quetiapine 300 mg patients, 2.0% of quetiapine 600 mg patients and 2.5%

of placebo patients. Deviations from the protocol list of excluded medications were recorded for a small number of patients in the safety population (see Table 19).

Anticholinergic use for any indication was low (<8% at any week) for all treatment groups (see Table 11.1.7.10, Section 11.1). One patient treated with quetiapine 300 mg, 2 patients treated with quetiapine 600 mg and 1 patient treated with placebo were given anticholinergic medication to treat akathisia or EPS symptoms. Other anticholinergic medications were given for other indications such as allergy symptoms (see Appendix 12.2.10.7).

6.7 Conclusions on study patients

The 509 patients with either bipolar I disorder or bipolar II disorder exhibiting moderate to severe depression who participated in this study provided an adequate number to meet the design requirements for statistical power. The patients were representative of the general patient population -- bipolar I patients made up 67% of the total, and 31% of all patients had rapid cycling courses. The 3 treatment groups were well-matched in number and demographic and baseline disease characteristics. The mean patient age was approximately 38 years, and approximately 58% of the patients were female. Approximately 69% to 86% of patients in each treatment group were Caucasian, and most of the remainder were Black. Within the safety population, 59% of quetiapine 300 mg patients, 54% of quetiapine 600 mg patients and 66% of placebo patients completed the study. "Subject not willing to continue" was the main reason for withdrawal in both quetiapine-treated and placebo-treated patients. Patients lost to follow-up comprised the second-largest count of discontinued patients for both quetiapine-treated and placebo-treated patients.

7. EFFICACY RESULTS

A summary of the efficacy results is given in Section 7.1. Full results are given in following sections, and any issues potentially affecting these results are discussed in Section 7.6. Conclusions on efficacy are given in Section 7.7.

7.1 Summary of efficacy results

In patients with bipolar disorder, quetiapine at a dose of either 300 mg once daily or 600 mg once daily was demonstrated to be superior to placebo in reducing the level of depressive symptoms as early as Day 8 (Week 1) and for up to 8 weeks of treatment, as assessed by the change from baseline in the total MADRS score. In addition, both bipolar I and bipolar II patients treated with 300 mg or 600 mg of quetiapine showed greater improvements in MADRS total score compared to patients treated with placebo. Patients receiving quetiapine 300 mg reported statistically superior improvements (p=0.034) compared to placebo in change from baseline in Q-LES-Q total score at 8 weeks. Patients receiving quetiapine 600 mg reported numerically greater improvements (p=0.068) than placebo in change from baseline in Q-LES-Q total score at 8 weeks. Analysis of other secondary outcome variables also supported the superiority of quetiapine 300 mg or 600 mg over placebo in the treatment of depression in patients with bipolar disorder. For most

secondary outcome variables the treatment advantage for both doses of quetiapine was apparent by Day 8 (Week 1) and continued through Day 57 (Week 8). The proportion of patients showing ≥50% reduction in MADRS total score (responders) was statistically significantly higher for the quetiapine 300 mg group and the quetiapine 600 mg group compared to the placebo group by Day 15 and continued to end of treatment. Likewise, the proportion of patients showing a MADRS total score ≤12 (remitters) was statistically significantly higher for the quetiapine 300 mg group and the quetiapine 600 mg group compared to the placebo group by Day 22 and continued to end of treatment. Quetiapine, at a dose of either 300 mg or 600 mg once daily, also improved a broad range of symptoms, including core symptoms of depression and suicidal thoughts, as assessed by the item analysis of the MADRS.

Table 22 shows where the data supporting this section are presented.

Table 22 Location of supporting data on efficacy

Data	Location	
	Summary tables (Section 11.2)	**Individual patient data (Appendix 12.2.6)**
Primary variable		
MADRS total score	Table 11.2.1.1.1 to Table 11.2.1.2.6, Table 11.2.1.4.1 to Table 11.2.1.4.4, Table 11.2.1.6 to Table 11.2.1.10.10; Table 11.2.1.17 Figure 11.2.1.3.1 to Figure 11.2.1.3.6, Figure 11.2.1.5.1 to Figure 11.2.1.5.4	Appendix 12.2.6.1
Secondary variables		
MADRS response	Table 11.2.1.11 to Table 11.2.1.12.6, Table 11.2.1.14 Figure 11.2.1.13	Appendix 12.2.6.1
MADRS remission	Table 11.2.1.14, Table 11.2.1.15.1 to Table 11.2.1.15.2 Figure 11.2.1.16	Appendix 12.2.6.1
HAM-D	Table 11.2.2.1.1 to Table 11.2.2.2.2, Table 11.2.2.4.1 to Table 11.2.2.5.2 Figure 11.2.2.3.1 to Figure 11.2.2.3.6	Appendix 12.2.6.2
HAM-D Item 1	Table 11.2.2.5.1 to Table 11.2.2.6.2	Appendix 12.2.6.2
CGI-S	Table 11.2.3.1.1 to Table 11.2.3.2.2, Table 11.2.3.4.1 to Table 11.2.3.6 Figure 11.2.3.3.1 to Figure 11.2.3.3.3	Appendix 12.2.6.3

Table 22 Location of supporting data on efficacy

Data	Location	
	Summary tables (Section 11.2)	**Individual patient data (Appendix 12.2.6)**
CGI-I	Table 11.2.4.1.1 to Table 11.2.4.2.4, Table 11.2.4.4.1, Table 11.2.4.4.2 Figure 11.2.4.3	Appendix 12.2.6.3
HAM-A	Table 11.2.5.1.1 to Table 11.2.5.2.2, Table 11.2.5.4.1 to Table 11.2.5.5.14 Figure 11.2.5.3.1 to Figure 11.2.5.3.3	Appendix 12.2.6.5

7.2 Efficacy results

7.2.1 Primary variable: MADRS total score change from baseline at last assessment

Results of the analysis of Day 57 (Week 8) change from baseline in MADRS total score are shown in Table 23.

Table 23 MADRS total score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline mean (SD)**	**LS mean change or difference**	**95% CI**	**p-value[a]**
Quetiapine 300 mg	155	31.1 (5.68)	-16.94	-18.91, -14.98	
Quetiapine 600 mg	151	29.9 (5.61)	-16.00	-18.00, -13.99	
Placebo	161	29.6 (5.44)	-11.93	-13.89, -9.96	
Quetiapine 300 mg vs placebo			-5.02	-7.31, -2.72	<0.001
Quetiapine 600 mg vs placebo			-4.07	-6.37, -1.77	0.001

[a] p-values were adjusted and compared with α=0.05 using the Bonferonni procedure within the parallel gatekeeping strategy.

Data derived from Table 11.2.1.2.1 and Table 11.2.1.17, Section 11.2.

For the ITT population, MADRS total scores (LOCF) decreased for both quetiapine and placebo-treated patients, but the decrease was significantly greater for the quetiapine-treated patients (see Table 23). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 5.02 points larger decrease than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 4.07 points larger decrease than did placebo-treated patients (quetiapine 300mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p=0.001$; see Table 23). The same general magnitude of mean difference between treatments was also seen in the PP patients in the ITT population in which quetiapine 300 mg patients had a least square mean of 4.94 points larger decrease than did placebo-treated patients and quetiapine 600 mg patients had a least square mean of 4.85 points larger decrease than did placebo-treated patients (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$; see Table 11.2.1.2.3, Section 11.2). The OC analysis of the ITT population revealed that patients treated with quetiapine 300 mg had a least square mean of 5.06 points larger decrease than placebo-treated patients and those treated with quetiapine 600 mg had a least square mean of 4.52 points larger decrease than placebo-treated patients at Day 57 (Week 8) (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p=0.001$; see Table 11.2.1.2.2, Section 11.2).

Analysis using the MMRM technique supported the primary analysis findings (see Table 11.2.1.2.5 and Table 11.2.1.2.6, Section 11.2).

Table 24 MADRS change from baseline at Day 57 by bipolar diagnosis (LOCF, ITT population)

	QTP 300		QTP 600		Placebo	
	N	Mean change	N	Mean change	N	Mean change
Bipolar I	104	-17.6	101	-16.0	110	-12.1
Bipolar II	51	-17.0	50	-15.6	51	-10.5

Data derived from Table 11.2.1.4.1, Section 11.2.

Bipolar I and bipolar II patients treated with either 300 mg or 600 mg of quetiapine showed greater improvements in MADRS total score compared to patients treated with placebo. The magnitude of the difference compared to placebo was similar for the 2 diagnostic groups (see also Figure 11.2.1.5.1 and Figure 11.2.1.5.2, Section 11.2).

In general, descriptive statistics of MADRS data including change from baseline classified by race, age or sex revealed improvement with quetiapine treatment over placebo for all of these subgroups (see Tables 11.2.1.6 through 11.2.1.8, Section 11.2).

Comparison of quetiapine treatment groups to the placebo treatment group for MADRS individual item changes from baseline at Day 57 (Week 8) is shown in Table 25.

Table 25 MADRS item comparisons at Day 57 (LOCF, ITT population)

	Quetiapine 300 mg		Quetiapine 600 mg	
MADRS item	**LS mean difference from placebo**	**p-value**	**LS mean difference from placebo**	**p-value**
1. Apparent sadness	-0.32	0.058	-0.28	0.097
2. Reported sadness	-0.58	<0.001	-0.41	0.018
3. Inner tension	-0.39	0.008	-0.42	0.005
4. Reduced sleep	-1.24	<0.001	-1.11	<0.001
5. Reduced appetite	-0.20	0.127	-0.27	0.043
6. Concentration difficulties	-0.43	0.008	-0.55	<0.001
7. Lassitude	-0.50	0.004	-0.32	0.064
8. Inability to feel	-0.44	0.009	-0.35	0.037
9. Pessimistic thoughts	-0.43	0.005	-0.19	0.227
10. Suicidal thoughts	-0.24	0.014	-0.10	0.311

Data derived from Table 11.2.1.10.1 through Table 11.2.1.10.10, Section 11.2.

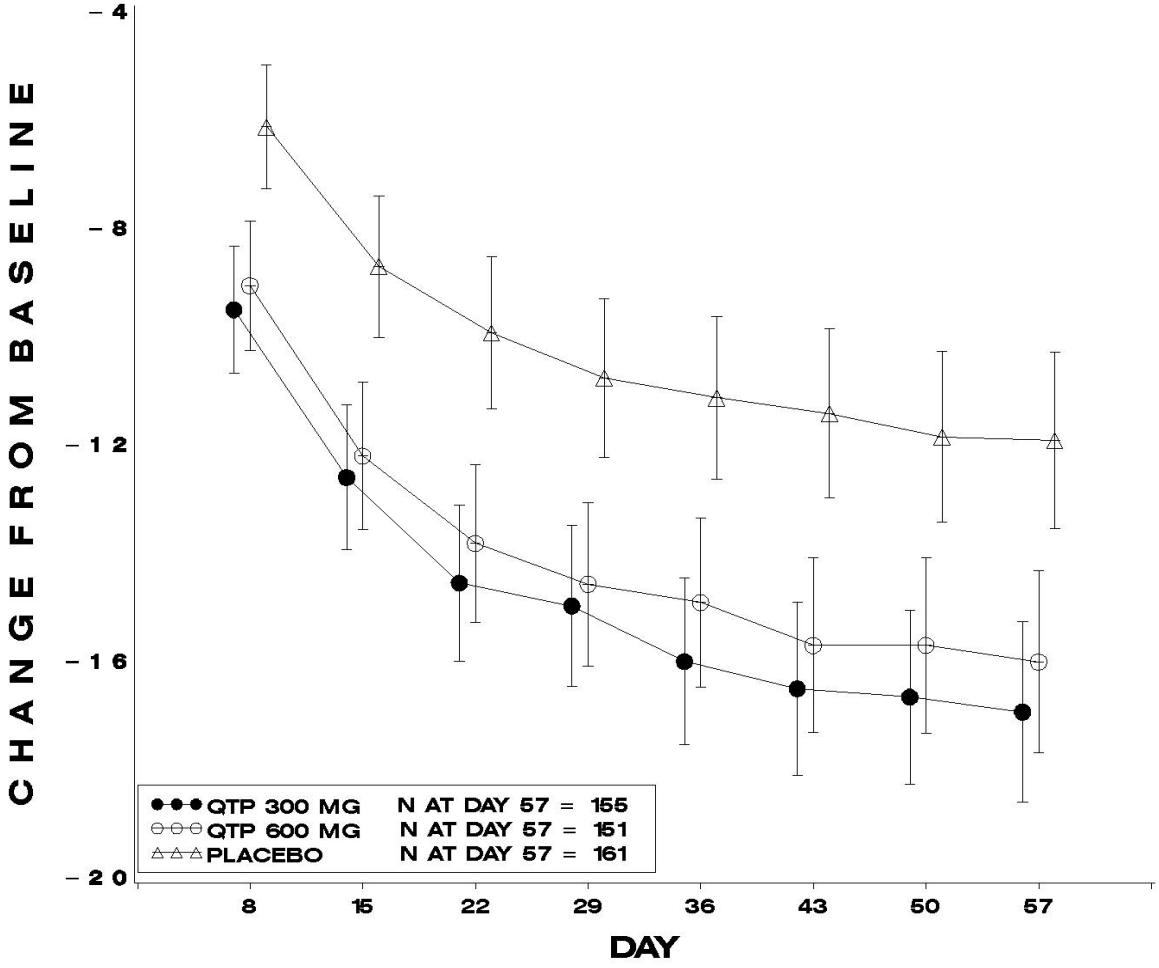
All of the 10 individual MADRS item scores, including suicidal thoughts, were reduced more by quetiapine treatment than by placebo treatment. Statistically significant separation from placebo was observed in 6 of 10 MADRS items in the quetiapine 600 mg dose group and 8 of 10 in the quetiapine 300 mg dose group.

7.2.2 Secondary variables

7.2.2.1 Change from baseline to each assessment for the MADRS total score

Changes from baseline in the MADRS total score at each visit for ITT patients are shown in Figure 3.

Figure 3 **MADRS total score change from baseline – LS mean (95% CI) (LOCF, ITT population)**

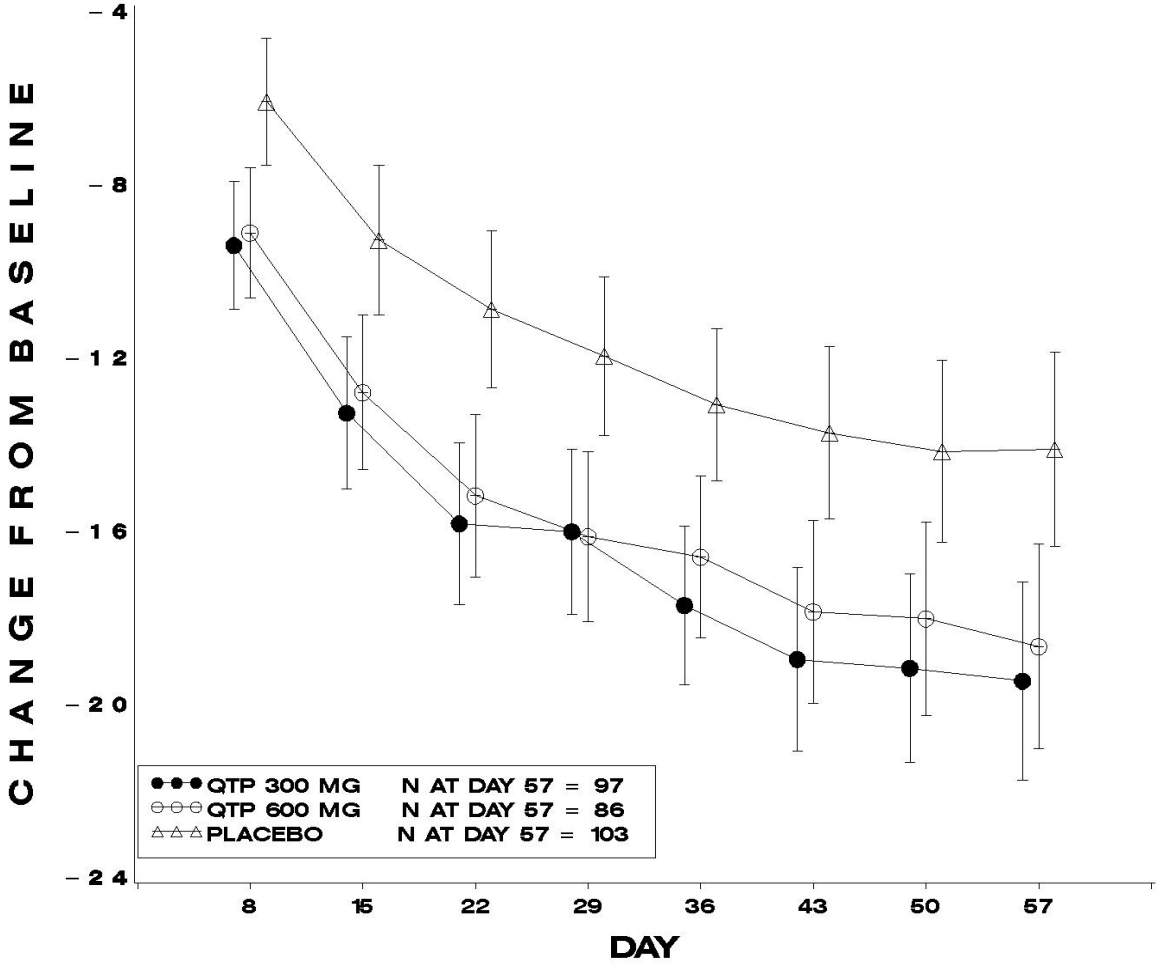


Replication of Figure 11.2.1.3.5, Section 11.2

Baseline MADRS values were similar for the 3 groups. The change from baseline for both quetiapine treatment groups was significantly better than placebo at Day 8 (Week 1) (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$) and continued to be superior to placebo at all subsequent assessments (see Table 11.2.1.2.1, Section 11.2).

Changes from baseline in the MADRS total score at each visit for observed cases in the ITT population are shown in Figure 4.

Figure 4 **MADRS total score change from baseline – LS mean (95% CI) (OC, ITT population)**



Replication of Figure 11.2.1.3.6, Section 11.2

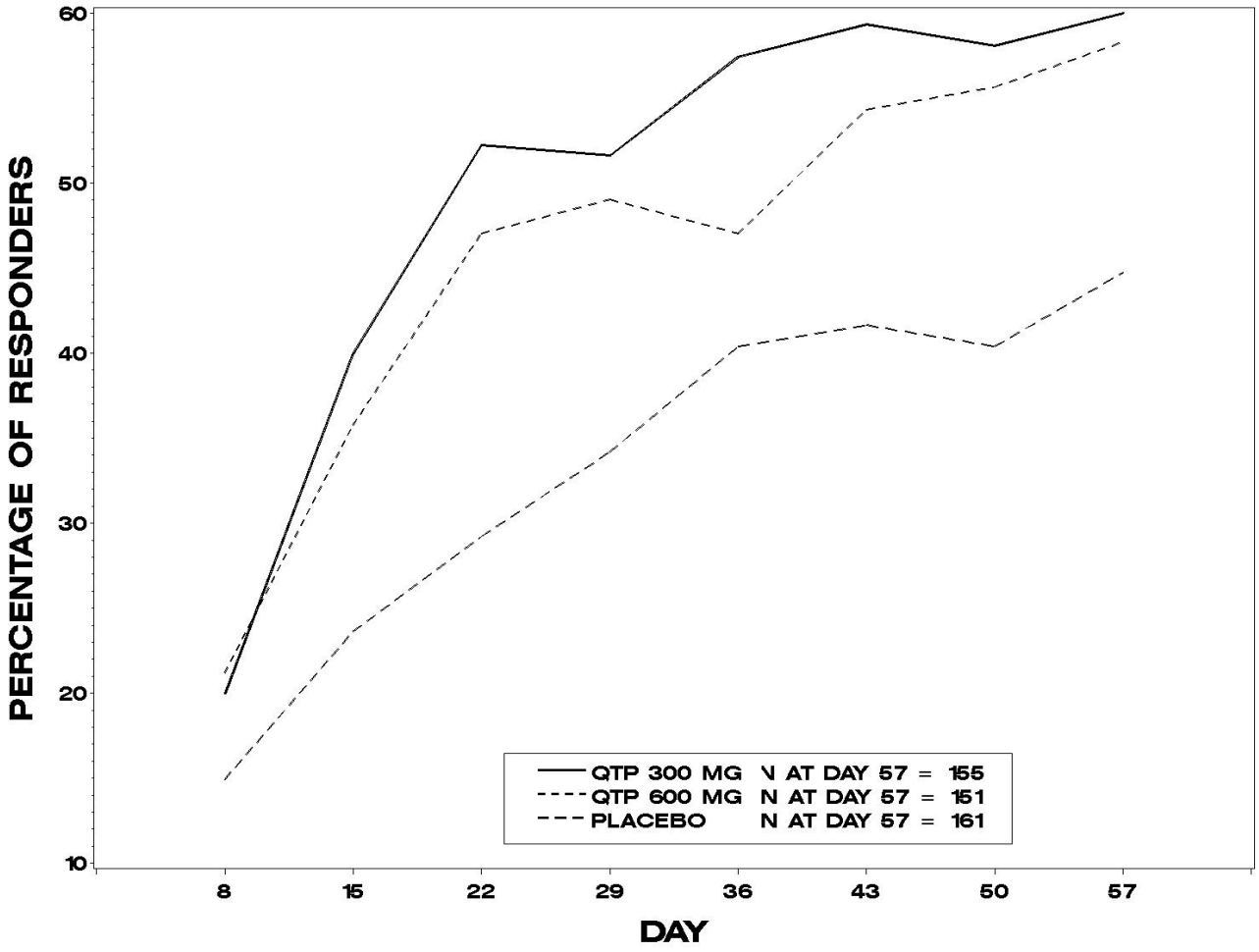
Changes from baseline in MADRS score for observed cases showed statistical separation from placebo for the 2 quetiapine treatment groups at Day 8 (Week 1) and continued to be superior to placebo at all subsequent assessments (see also Table 11.2.1.2.2, Section 11.2).

Throughout the course of treatment, OC data revealed that bipolar I and bipolar II patients treated with either 300 mg or 600 mg of quetiapine showed greater improvements in MADRS total score compared to patients treated with placebo (see Figure 11.2.1.5.3 and Figure 11.2.1.5.4, Section 11.2).

7.2.2.2 MADRS response

The percentage of patients showing a MADRS response, at least a 50% improvement from baseline in MADRS total score, is shown for each visit in Figure 5.

Figure 5 **MADRS response (≥50% score reduction) – percent of patients responding by visit day (LOCF, ITT population)**



Replication of Figure 11.2.1.13, Section 11.2

At final assessment, 60% of quetiapine 300 mg patients, 58.3% of quetiapine 600 mg patients and 44.7% of placebo patients had achieved a status of MADRS responder (quetiapine 300 mg vs placebo: p=0.007; quetiapine 600 mg vs placebo: p=0.017; see Table 11.2.1.12.1, Section 11.2). The statistically significant differential between quetiapine and placebo groups was established by Day 15 for both the quetiapine 300 mg group (p<0.001) and the quetiapine 600 mg group (p=0.017) and continued to be superior to placebo at most subsequent assessments for both quetiapine groups (see Table 11.2.1.12.2, Section 11.2). Similar results were observed in patients who completed eight weeks of treatment (see Table 11.2.1.12.2, Section 11.2), and similar comparisons of the 3 treatment groups were noted when criteria for response were varied from 30% to 70% (see Table 11.2.1.12.3, Section 11.2).

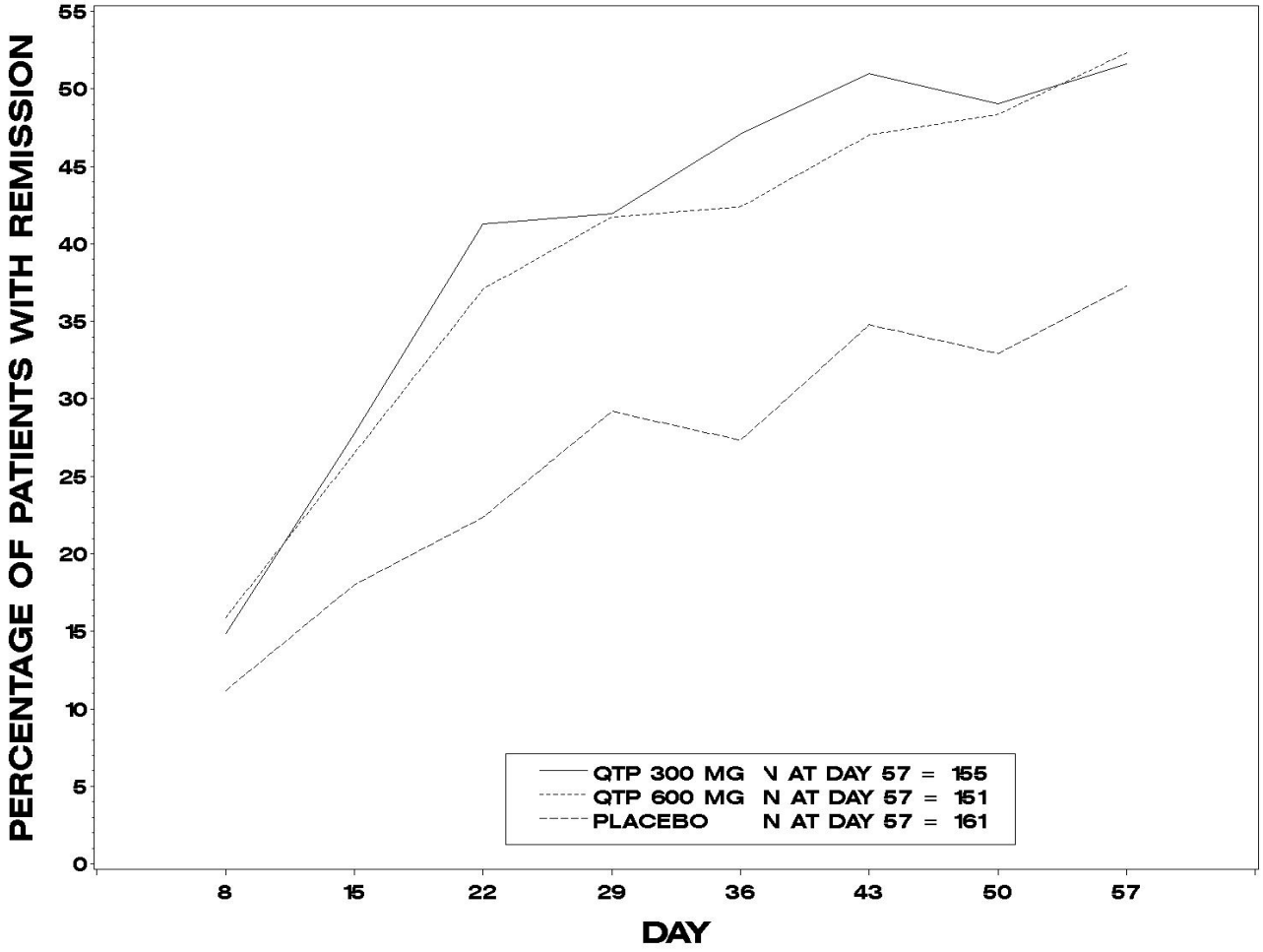
Within the Bipolar I population at Day 57 (Week 8), 59.6% of quetiapine 300 mg patients, 58.4% of quetiapine 600 mg patients and 44.5% of placebo patients had achieved a status of

MADRS responder. For Bipolar II patients, the response rates were 60.8% for quetiapine 300 mg patients, 58.0% for quetiapine 600 patients and 45.1% for placebo patients (see Table 11.2.1.12.1, Section 11.2).

7.2.2.3 MADRS-defined remission

The percentage of patients showing a reduction in MADRS score to ≤12, is shown for each visit in Figure 6.

Figure 6 MADRS-defined remission (MADRS score ≤12) – percent of patients by visit day (LOCF, ITT population)



Replication of Figure 11.2.1.16, Section 11.2

At last assessment, 51.6% (80 of 155 patients)of quetiapine 300 mg patients, 52.3% (79/151) of quetiapine 600 mg patients and 37.3% (60/161) of placebo patients had achieved a MADRS score of ≤12 and were regarded as being in remission (quetiapine 300 mg vs placebo: p=0.011; quetiapine 600 mg vs placebo: p=0.008; see Table 11.2.1.15.1, Section 11.2). The statistically significant difference between quetiapine and placebo groups was established by

Day 15 for the quetiapine 300 mg group (p=0.041) and by Day 22 for the quetiapine 600 mg group (p=0.004) and continued to be superior to placebo at all subsequent assessments (see Table 11.2.1.15.1, Section 11.2). Similar results were observed in patients who completed eight weeks of treatment (see Table 11.2.1.15.2, Section 11.2).

7.2.2.4 Change from baseline to each assessment for the HAM-D total score

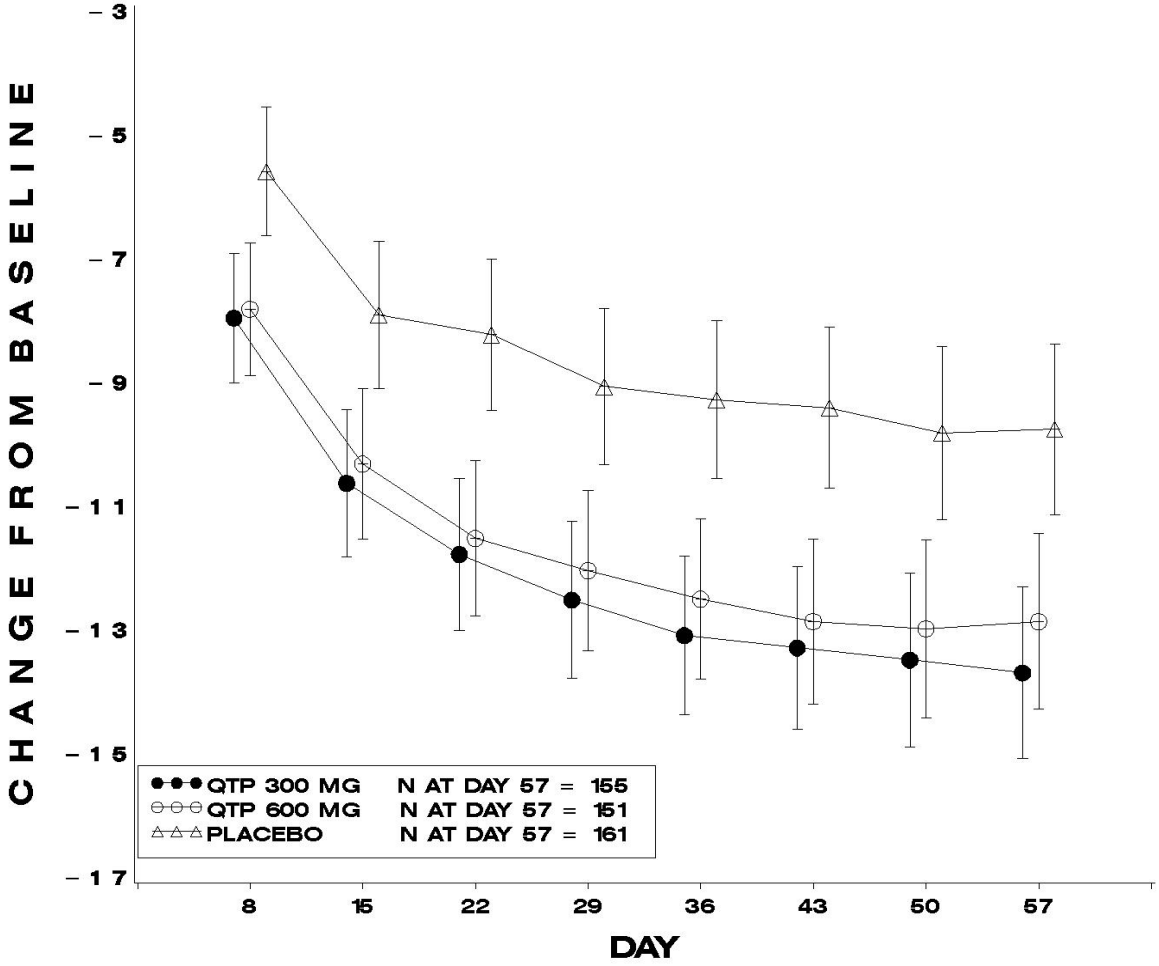
Results of the analysis of Day 57 (Week 8) change from baseline in HAM-D total score are shown in Table 26. Changes from baseline in the HAM-D total score at each visit for ITT patients are shown in Figure 7.

Table 26 HAM-D total score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**95% CI**	**p-value**
Quetiapine 300 mg	155	24.9 (3.35)	-13.81	-15.18, -12.44	
Quetiapine 600 mg	151	24.3 (3.27)	-12.97	-14.37, -11.57	
Placebo	161	24.3 (3.09)	-9.92	-11.29, -8.55	
Quetiapine 300 mg vs placebo			-3.89	-5.50, -2.28	<0.001
Quetiapine 600 mg vs placebo			-3.05	-4.68, -1.43	<0.001

Data derived from Table 11.2.2.2.1, Section 11.2

Figure 7 **HAM-D total score change from baseline – LS mean (95% CI) (LOCF, ITT population)**



Replication of Figure 11.2.2.3.5, Section 11.2

Baseline HAM-D values were similar for the 3 groups. The improvement for both quetiapine treatment groups was significantly better than placebo at Day 8 (Week 1) (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$) and continued to be superior to placebo at all subsequent assessments (see Figure 7 above and Table 11.2.2.2.1, Section 11.2). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 3.89 points larger decrease than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 3.05 points larger decrease than did placebo-treated patients (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p<0.001$; see Table 26). Similar results were noted for patients who completed eight weeks of treatment (see Table 11.2.2.2.2, Section 11.2).

Change from baseline in mean individual HAM-D item scores were lower for quetiapine-treated patients compared to those for placebo-treated patients at Day 57 (Week 8), with the

largest treatment differences in Depressed Mood, Anxiety Psychic, Work and Activities and the 3 insomnia items (see Table 11.2.2.5.1 and Table 11.2.2.5.2, Section 11.2).

7.2.2.5 Change from baseline to each assessment for the HAM-D Item 1 (depressed mood) score

Results of the analysis of Day 57 change from baseline in HAM-D Item 1 (depressed mood) score are shown in Table 27.

Table 27 HAM-D Item 1 score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**95% CI**	**p-value**
Quetiapine 300 mg	155	3.0 (0.50)	-1.76	-1.96, -1.55	
Quetiapine 600 mg	151	3.0 (0.45)	-1.57	-1.79, -1.36	
Placebo	161	3.0 (0.45)	-1.29	-1.50, -1.08	
Quetiapine 300 mg vs placebo			-0.47	-0.72, -0.21	<0.001
Quetiapine 600 mg vs placebo			-0.28	-0.54, -0.03	0.030

Data derived from Table 11.2.2.6.1, Section 11.2

Baseline HAM-D Item 1 values were similar for the 3 groups. The improvement for both quetiapine treatment groups was significantly better than placebo at Day 15 (quetiapine 300 mg vs placebo: p=0.016; quetiapine 600 mg vs placebo: p=0.042) and continued to be superior to placebo at most visits (see Table 11.2.2.6.1, Section 11.2). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 0.47 points larger decrease than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.28 points larger decrease than did placebo-treated patients (quetiapine 300 mg vs placebo: p<0.001; quetiapine 600 mg vs placebo: p=0.030; see Table 27). Similar results were noted for patients who completed eight weeks of treatment (see Table 11.2.2.6.2, Section 11.2).

7.2.2.6 Change from baseline to each assessment for the CGI-S score

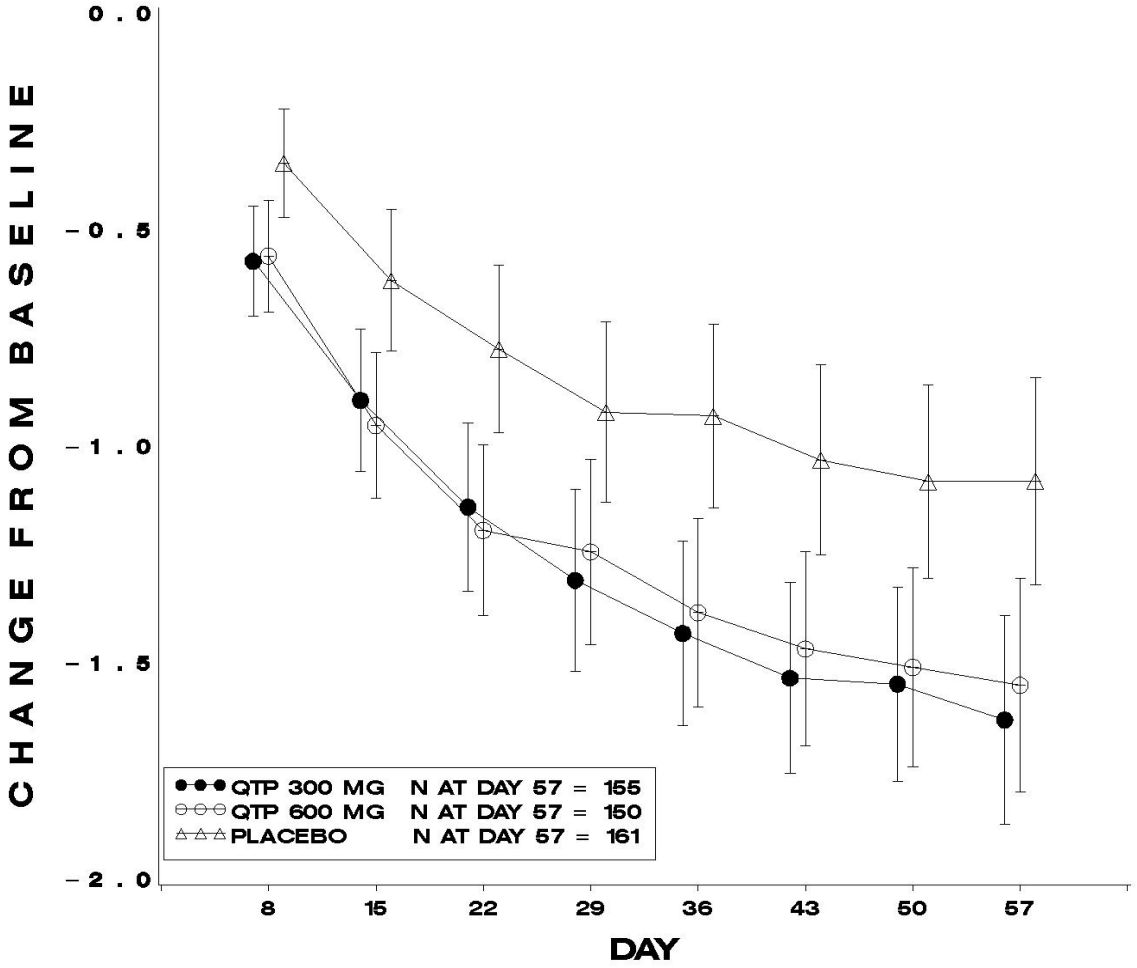
Results of the analysis of Day 57 (Week 8) change from baseline in CGI-S score are shown in Table 28. Changes from baseline in the CGI-S score at each visit for ITT patients are shown in Figure 8.

Table 28 CGI-S score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**95% CI**	**p-value**
Quetiapine 300 mg	155	4.6 (0.62)	-1.68	-1.91, -1.44	
Quetiapine 600 mg	150	4.4 (0.55)	-1.59	-1.83. –1.35	
Placebo	161	4.5 (0.56)	-1.12	-1.36, -0.89	
Quetiapine 300 mg vs placebo			-0.55	-0.82, -0.29	<0.001
Quetiapine 600 mg vs placebo			-0.46	-0.73, -0.20	<0.001

Data derived from Table 11.2.3.2.1, Section 11.2

Figure 8 **CGI-S score change from baseline – LS mean (95% CI) (LOCF, ITT population)**



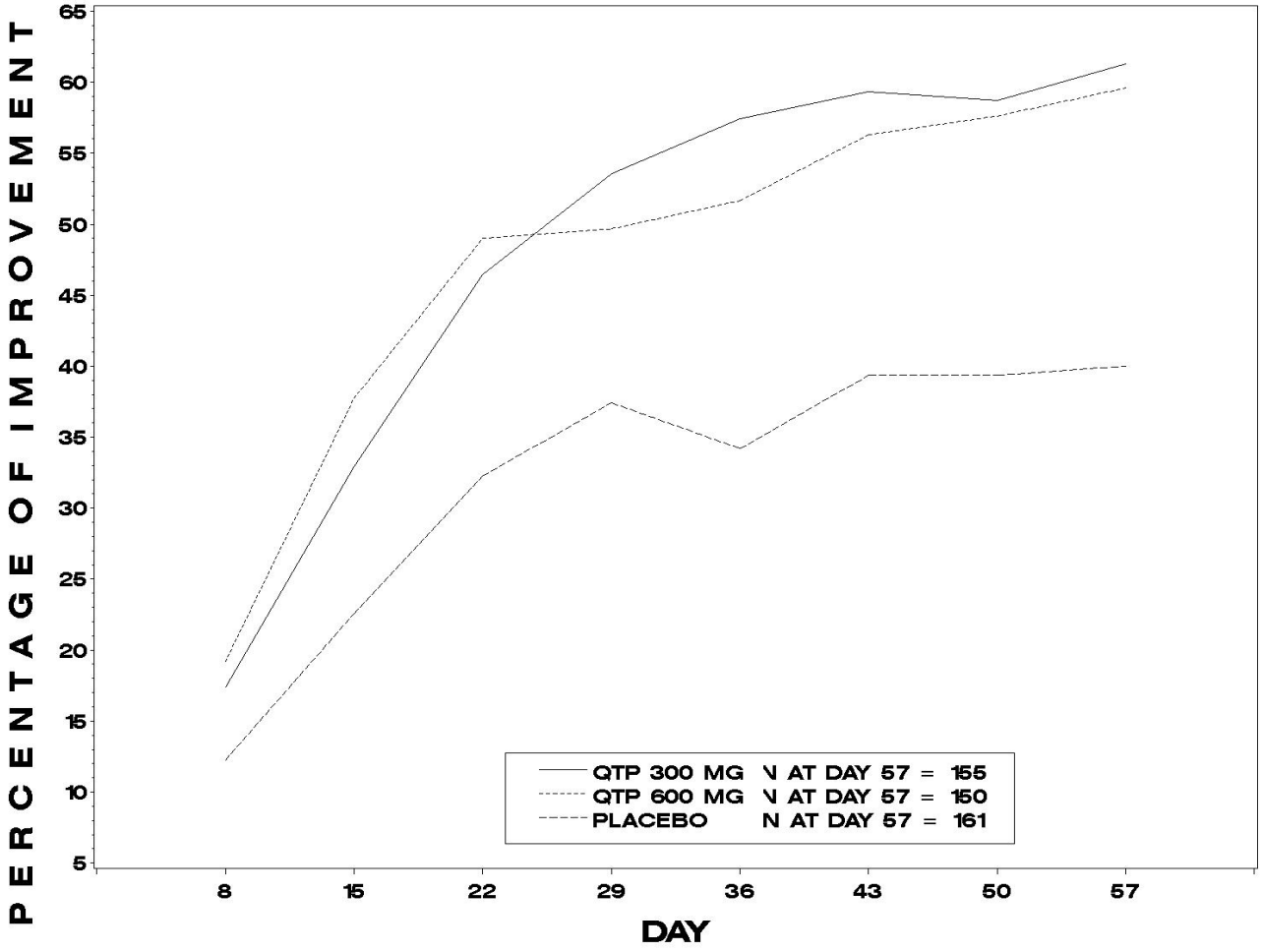
Replication of Figure 11.2.3.3.3, Section 11.2

Baseline CGI-S values were similar for the 3 groups within the ITT population. The improvement for both quetiapine treatment groups was significantly better than placebo at Day 8 (Week 1) (quetiapine 300 mg vs placebo: p=0.003; quetiapine 600 mg vs placebo: p=0.005) and continued to be superior to placebo at all visits (see Figure 8 above and Table 11.2.3.2.1, Section 11.2). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a least square mean of 0.55 points larger decrease than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.46 points larger decrease than did placebo-treated patients (quetiapine 300 mg vs placebo p<0.001; quetiapine 600 mg vs placebo p<0.001; see Table 28). Similar results were noted for patients who completed eight weeks of treatment (see Table 11.2.3.2.2, Section 11.2).

7.2.2.7 CGI-I

The percent of patients rated as "much improved" or "very much improved" on the CGI-I at each visit is presented in Figure 9.

Figure 9 CGI-I scale – patients Much Improved or Very Much Improved (LOCF, ITT population)



Replicated from Figure 11.2.4.3, Section 11.2.

At last observation, 61% of quetiapine 300 mg patients, 60% of quetiapine 600 mg patients and 39% of placebo patients were rated as "much improved" or "very much improved" in the CGI-I (quetiapine 300 mg vs placebo: p <0.001; quetiapine 600 mg vs placebo: p<0.001; see Table 11.2.4.2.3, Section 11.2). The differentiation between quetiapine and placebo treatment was apparent at earlier assessments and persisted to the final assessment. At Day 15, 33% of quetiapine 300 mg patients, 39% of quetiapine 600 mg patients and 22% of placebo patients had shown global improvement in the CGI-I (quetiapine 300 vs placebo: p=0.024; quetiapine 600 mg vs placebo: p<0.001; see Table 11.2.4.2.3, Section 11.2). Similar results were noted for patients who completed eight weeks of treatment (see Table 11.2.4.2.4, Section 11.2).

Results of the ANCOVA of Day 57 (Week 8) CGI-I scores are shown in Table 29.

Table 29 CGI-I score at Day 57 (LOCF, ITT population)

		ANCOVA results		
	N	CGI-I LS mean or difference	95% CI	p-value
Quetiapine 300 mg	155	2.28	2.07, 2.48	
Quetiapine 600 mg	150	2.29	2.08, 2.50	
Placebo	161	2.88	2.67, 3.08	
Quetiapine 300 mg vs placebo		-0.60	-0.86, -0.34	<0.001
Quetiapine 600 mg vs placebo		-0.59	-0.85, -0.33	<0.001

Data derived from Table 11.2.4.2.1, Section 11.2.

The CGI-I score for both quetiapine treatment groups was significantly better than placebo at Day 8 (Week 1) (quetiapine 300 mg vs placebo: $p<0.001$; quetiapine 600 mg vs placebo: $p=0.001$) and continued to be superior to placebo at all visits (see Table 11.2.4.2.1). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a CGI-I least square mean of 0.60 points lower than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 0.59 points lower than did placebo-treated patients (quetiapine 300 mg vs placebo $p<0.001$; quetiapine 600 mg vs placebo $p<0.001$; see Table 29). Similar results were noted for patients who completed eight weeks of treatment (see Table 11.2.4.2.2, Section 11.2).

7.2.2.8 Change from baseline to each assessment for the HAM-A total score

Results of the analysis of Day 57 (Week 8) change from baseline in HAM-A total score are shown in Table 30. Changes from baseline in the HAM-A score at each visit for ITT patients are shown in Figure 10.

Table 30 HAM-A score change from baseline at Day 57 (LOCF, ITT population)

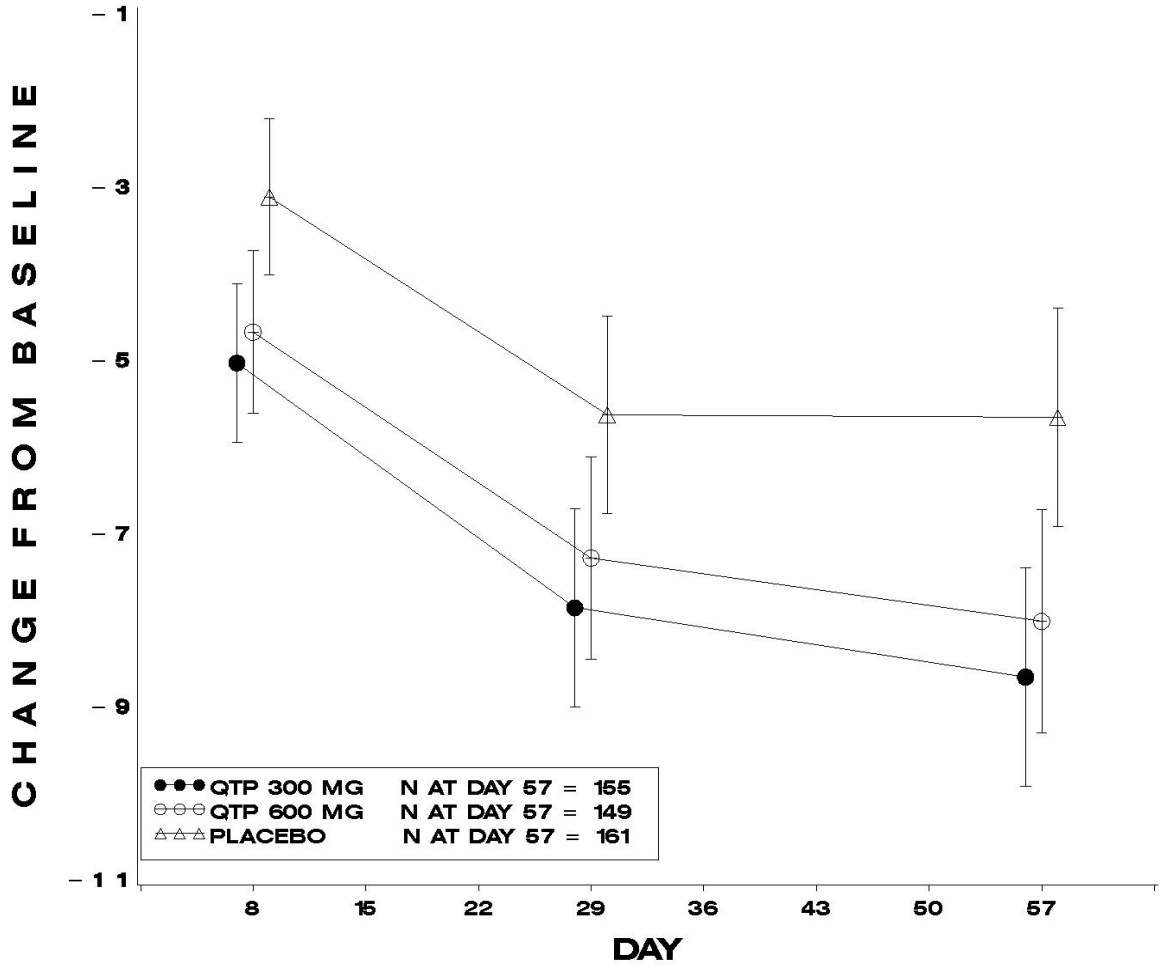
				ANCOVA results	
	N	Baseline Mean (SD)	LS mean change or difference	95% CI	p-value
Quetiapine 300 mg	155	19.1 (5.98)	-8.78	-10.07, -7.49	
Quetiapine 600 mg	149	18.3 (5.74)	-8.15	-9.47, –6.83	
Placebo	161	18.2 (5.69)	-5.80	-7.09, -4.51	

Table 30 **HAM-A score change from baseline at Day 57 (LOCF, ITT population)**

	N	Baseline Mean (SD)	ANCOVA results		
			LS mean change or difference	95% CI	p-value
Quetiapine 300 mg vs placebo			-2.98	-4.36, -1.60	<0.001
Quetiapine 600 mg vs placebo			-2.35	-3.75, -0.96	0.001

Data derived from Table 11.2.5.2.1, Section 11.2.

Figure 10 **HAM-A score change from baseline – LS mean (95% CI) (LOCF, ITT population)**



Replicated from Figure 11.2.5.3.3, Section 11.2

The improvement in the HAM-A score for both quetiapine treatment groups was significantly better than placebo at Day 8 (Week 1) (quetiapine 300 mg vs placebo: p<0.001; quetiapine 600 mg vs placebo: p=0.007) and continued to be superior to placebo at all visits (see Figure 10 and Table 11.2.5.2.1, Section 11.2). At the end of the 8-week course of treatment, quetiapine 300 mg patients in the ITT population had a HAM-A least square mean of 2.98 points larger decrease than did placebo-treated patients, and quetiapine 600 mg patients in the ITT population had a least square mean of 2.35 points larger decrease than did placebo-treated patients (quetiapine 300 mg vs placebo: p<0.001; quetiapine: 600 mg vs placebo p=0.001; see Table 30). Similar results were noted for patients who completed eight weeks of treatment (see Table 11.2.5.2.2, Section 11.2).

Individual items of the HAM-A that most differentiated quetiapine-treated patients from placebo patients were Tension, Intellectual, Depressed Mood, Somatic-Muscular, Cardiovascular Symptoms, Behavior at Interview and Insomnia (see Table 11.2.5.5.1 through Table 11.2.5.5.14, Section 11.2).

7.3 Patient Reported Outcomes

7.3.1 Summary of patient reported outcomes

Table 31 shows where the data supporting this section are presented.

Table 31 Location of supporting data on patient reported outcomes

Data	Location	
	Summary tables (Section 11.2)	**Individual patient data (Appendix 12.2.6)**
Q-LES-Q	Table 11.2.6.1 to Table 11.2.6.7; Table 11.2.1.17	Table 12.2.6.7
SDS	Table 11.2.7.1 to Table 11.2.7.3, Table 11.2.7.4.1 Table 11.2.7.4.2, Table 11.2.7.5.1 to Table 11.2.7.5.5	Table 12.2.6.6

Q-LES-Q Quality of Life Enjoyment and Satisfaction Questionnaire; SDS Sheehan Disability Scale.

7.3.2 Patient reported outcomes results

7.3.2.1 Secondary variable of particular interest: Q-LES-Q total score change from baseline at final assessment

Results of the analysis of Day 57 (Week 8) change from baseline in Q-LES-Q total mean score are shown in Table 32 while results of the analysis of Day 57 change from baseline in % of maximum Q-LES-Q total score are presented in Table 11.2.6.4 and Table 11.2.1.17, Section 11.3.

Table 32 Q-LES-Q total score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	Baseline Mean (SD)	LS mean change or difference	95% CI	p-value[a]
Quetiapine 300 mg	129	35.6 (7.69)	9.86	8.01, 11.71	
Quetiapine 600 mg	131	37.7 (7.54)	9.19	7.34, 11.03	
Placebo	150	37.8 (7.06)	7.12	5.37, 8.88	
Quetiapine 300 mg vs placebo			2.74	0.50, 4.98	0.034
Quetiapine 600 mg vs placebo			2.06	-0.15, 4.28	0.068

[a] p-values were adjusted and compared with α=0.05 using the Bonferonni procedure within the parallel gatekeeping strategy.
Note: Q-LES-Q refers to the 16-item general activities section of the Q-LES-Q-SF.
Data derived from Table 11.2.6.2 and Table 11.2.1.17, Section 11.2.

At Day 57 (Week 8), patients treated with quetiapine 300 mg daily reported superior improvements (P=0.034) in quality of life enjoyment and satisfaction as assessed by a mean change from baseline in Q-LES-Q score compared to patients treated with placebo. For patients in the quetiapine 600 mg group, supportive improvements (P=0.68) were also seen compared to placebo-treated patients.

This advantage over placebo for quetiapine 300 mg daily was 2.74 points. Patients treated with 600 mg of quetiapine also showed greater improvements in quality of life enjoyment and satisfaction than placebo (2.06 point advantage).

The mean percent-of-maximum Q-LES-Q score at final assessment for quetiapine 300 mg patients was 57.1 % and for 600 mg patients was 57.7 %, compared to 54.4 % for placebo patients (see Table 11.2.6.3, Section 11.2).

7.3.2.2 SDS

Results of the analysis of Day 57 (Week 8) change from baseline in SDS total score are shown in Table 33.

Table 33 SDS total score change from baseline at Day 57 (LOCF, ITT population)

			ANCOVA results		
	N	**Baseline Mean (SD)**	**LS mean change or difference**	**95% CI**	**p-value**
Quetiapine 300 mg	129	18.5 (6.42)	-7.30	-8.81, -5.78	
Quetiapine 600 mg	132	17.7 (6.38)	-7.87	-9.38, -6.35	
Placebo	149	18.0 (6.21)	-6.03	-7.49, -4.57	
Quetiapine 300 mg vs placebo			-1.27	-2.98, 0.44	0.146
Quetiapine 600 mg vs placebo			-1.84	-3.54, -0.13	0.035

Data derived from Table 11.2.7.2, Section 11.2.

The SDS scale score for both quetiapine treatment groups showed numerically greater reduction in disability at final assessment compared to placebo but reached statistical significance only for the quetiapine 600 mg group (quetiapine 300 mg vs. placebo: p=0.146; quetiapine: 600 mg vs. placebo p=0.035; see Table 33). Similar results were noted for patients who completed 8 weeks of treatment (see Table 11.2.7.2, Section 11.2).

Of the 3 individual items (work/school, social life, and family life/home responsibilities) that form the SDS scale score, the social item had statistically significant reduction at final visit for the quetiapine 600 mg group compared to the placebo group (quetiapine 300 mg vs placebo: p=0.332; quetiapine 600 mg vs placebo: p=0.043; see Table 11.2.7.5.2, Section 11.2).

At the end of 8-week course of treatment, statistically significant reductions over the placebo treated patients were noted among the quetiapine 300 mg group and the quetiapine 600 mg group in the Days Underproductive item (quetiapine 300 mg vs placebo: p=0.022; quetiapine 600 mg vs placebo: p=0.027; see Table 11.2.7.5.5, Section 11.2). By Week 8, patients receiving quetiapine 300 mg or 600 mg reported significantly fewer unproductive days (>0.60 fewer unproductive days) than placebo (see Table 11.2.7.5.5, Section 11.2).

7.4 Health Economics results

Not applicable.

7.5 Pharmacokinetic results

Not applicable.

7.6 Potential issues affecting efficacy results

No potential issues affecting efficacy results have been identified.

7.7 Conclusions on efficacy results

The linkage between these conclusions, the specific efficacy and pharmacokinetic objectives of the study, and the study variables selected to address each objective, is presented in Table 34.

Table 34 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
Primary	**Primary**	
Evaluate the superiority of quetiapine compared to placebo in the treatment of a major depressive episode in subjects with bipolar disorder after receiving treatment for up to 8 weeks	Change from baseline to Week 8 in the MADRS total score in the Intention-to-treat (ITT) population	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline on the MADRS total score.
	Secondary	
	Percentage of patients in the ITT population showing a ≥50% reduction from baseline in MADRS total score (responders) at each assessment and at final assessment	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a 50% reduction in MADRS total score. Superiority was evident for both quetiapine treatment groups on Day 15 of treatment and was maintained at most subsequent assessments to Day 57 (Week 8) of treatment.

Table 34 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
	Change from baseline to each assessment for the MADRS total score in the ITT and PP population	Superiority of quetiapine at a dose of 300 mg daily or 600 mg over placebo was evident in MADRS total score change from baseline on Day 8 (Week 1) of treatment in patients with bipolar depression and was maintained at each subsequent assessment to Day 57 (Week 8) of treatment.
	Percentage of patients showing a MADRS total score ≤12 (remitters) at each assessment and at final assessment	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the percentage of patients achieving a MADRS total score ≤12 on Day 15 (quetiapine 300 mg) or Day 22 (quetiapine 600 mg) of treatment and was maintained at each subsequent assessment to Day 57 (Week 8) of treatment.
	Change from baseline to each assessment in the HAM-D total score in the ITT population	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily in patients with bipolar depression was superior to placebo in reducing the level of depressive symptoms as measured by the change from baseline on Day 8 (Week 1) of treatment and was maintained at each subsequent assessment to Day 57 (Week 8) of treatment.
	Change from baseline to each assessment in the HAM-D Item 1 score in the ITT population	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing the level of depressed mood as measured by the change from baseline on the HAM-D Item 1 on Day 15 of treatment and was maintained at most subsequent assessments to Day 57 (Week 8) of treatment.

Table 34 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
	Change from baseline to each assessment and at final assessment for the CGI-S in the ITT population	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing the severity of illness as measured by the change from baseline on the CGI-S on Day 8 (Week 1) of treatment and was maintained at each subsequent assessment to Day 57 (Week 8) of treatment.
	CGI-I score at each assessment and at final assessment in the ITT population	Quetiapine fumarate at a dose of 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in improving the patient's clinical status as measured by the CGI-I by Day 8 (Week 1) of treatment and was maintained at each subsequent assessment to Day 57 (Week 8) of treatment.
Secondary	**Secondary**	
Evaluate the superiority of quetiapine compared to placebo on symptoms of anxiety	Change from baseline to each assessment and to final assessment in the HAM-A total score in the ITT population	Quetiapine at a dose of 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression was superior to placebo in reducing anxiety symptoms as measured by change from baseline in the HAM-A total score on Day 8 (Week 1) of treatment and was maintained at each subsequent assessment to Day 57 (Week 8) of treatment.
To demonstrate that quetiapine is superior to placebo in improving the patient's overall quality of life	Change from baseline (Visit 2) to final assessment in the Quality of Life Enjoyment Satisfaction Questionnaire (Q-LES-Q) – Short form total score	Patients receiving quetiapine 300 mg daily reported superior improvements compared to placebo in total mean Q-LES-Q score at 8 weeks. Patients receiving quetiapine 600 mg daily reported numerically greater improvements than placebo at 8 weeks.

Table 34 Efficacy objectives, variables, and conclusions

Objective	Variables	Conclusions
To demonstrate that quetiapine is superior to placebo in improving the patient's productive days at work and their family and social lives	Change form baseline (Visit 2) to final assessment in the Sheehan Disability Scale (SDS) domains of work/school, social life/leisure, and family life/home responsibility	Quetiapine at a dose of 600 mg daily for up to 8 weeks was statistically superior in improving the patient's productive days at work and their family and social lives as measured by the SDS total score. Patients receiving quetiapine 300 mg daily reported numerically greater improvements than placebo at 8 weeks. Quetiapine at a dose of 300 mg daily or 600 mg daily for up to 8 weeks was statistically superior to placebo in reducing the number of unproductive days, as measured by the SDS Days Unproductive scale.

CGI-S Clinical Global Impression Severity scale; CGI-I Clinical Global Impression Improvement scale; MADRS Montgomery-Asberg Depression Rating Scale; HAM-A Hamilton Rating Scale for Anxiety; HAM-D Hamilton Rating Scale for Depression; ITT Intent to treat.

8. SAFETY RESULTS

Safety data in this report are presented under the following headings:

- Summary of safety (Section 8.1)
- Exposure (Section 8.2)
- Adverse events (Section 8.3)
- Deaths, serious adverse events, discontinuations due to adverse events, and other significant adverse events (Section 8.4)
- Clinical laboratory evaluation (Section 8.5)
- Vital signs, ECG, physical findings and other observations related to safety. (Section 8.6).

8.1 Summary of safety

Both the 300 mg and 600 mg once-daily doses of quetiapine were generally well tolerated. Analysis of adverse events indicated that nervous system and gastrointestinal events predominated, with dry mouth, sedation, somnolence, dizziness, and constipation occurring at higher rates with quetiapine compared to placebo. Most adverse events were mild to moderate. Larger proportions of patients in the quetiapine dose groups discontinued due to an AE than did patients in the placebo group. No deaths occurred in the study. SAEs were infrequent in all treatment groups. Treatment-emergent mania and hypomania were lower in incidence in the quetiapine treatment groups compared to placebo with a significantly lower rate in the quetiapine 300 mg treatment group compared to placebo. The incidences of individual EPS-related AEs were low in each treatment group with the majority of these AEs reported as mild to moderate for all groups. An increase in the incidence in the composite of AEs related to EPS was noted for both groups of quetiapine-treated patients (300 mg: 12.3%; 600 mg: 10.1%) compared to the placebo group (6.6%). The incidence of AEs related to suicidality was low in all treatment groups. There were 3 cases of clinically important shifts to low values (≤1.5 X 10^9/L) in neutrophils reported during the study: 2 in the quetiapine 300 mg treatment group and 1 in the placebo group. There were no cases of agranulocytosis (≤0.5 X 10^9 cells/L) reported during the study. The incidence of shift from baseline to reference ranges identified for metabolic risk factors was higher for quetiapine-treated patients compared to placebo in triglycerides, BMI, and blood pressure while differential shifts to either increased HDL or fasting glucose were lower in the quetiapine treatment groups compared to the placebo group.

Table 35 identifies where the data that support this section can be found.

Table 35 Location of supporting data on safety

Data	Location	
	Summary tables (Section 11.3)	**Individual patient data (Appendix 12.2)**
Treatment compliance (extent of exposure)	Table 11.3.1.1 to Table 11.3.1.6	Appendix 12.2.5
Adverse events	Table 11.3.2.1 to Table 11.3.2.8	Appendix 12.2.7.1, Appendix 12.2.7.2, Appendix 12.2.7.3
Deaths	none	none
Serious adverse events, discontinuation due to adverse events, and other significant adverse events	Table 11.3.4.1.1 to Table 11.3.6.2	Appendix 12.2.7.1
Treatment emergent mania	Table 11.3.8.1.7.1 to Table 11.3.8.1.7.4, Table 11.3.8.1.7.8 to Table 11.3.8.1.7.13 Figure 11.3.8.1.7.5 to Figure 11.3.8.1.7.7	Appendix 12.2.6.4, Appendix 12.2.7.1
Clinical laboratory evaluations	Table 11.3.7.1.1.1 to Table 11.3.7.1.1.3.4, Table 11.3.7.1.2.1 to Table 11.3.7.1.2.3.14, Table 11.3.7.2.1.1 to Table 11.3.7.2.2.6 Figure 11.3.7.1.1.4.1 to Figure 11.3.7.1.1.4.10, Figure 11.3.7.1.2.4.1 to Figure 11.3.7.1.2.4.12	Appendix 12.2.8.1 to Appendix 12.2.8.2.7
Weight, vital signs, ECG, physical findings and other observations related to safety	Table 11.3.8.1.1.1 to Table 11.3.8.1.2.1, Table 11.3.8.1.2.3 to Table 11.3.8.1.3.5 Figure 11.3.8.1.2.2, Figure 11.3.8.1.3.6	Appendix 12.2.9.1, Appendix 12.2.9.2 (vital signs), Appendix 12.2.9.3 to Appendix 12.2.10.2 (other safety data)
Metabolic syndrome	Table 11.3.8.1.4.1, Table 11.3.8.1.4.4	Appendix 12.2.10.3
SAS	Table 11.3.8.1.5.1 to Table 11.3.8.1.5.3 Figure 11.3.8.1.5.4	Appendix 12.2.10.4

Table 35 Location of supporting data on safety

Data	Location	
	Summary tables (Section 11.3)	Individual patient data (Appendix 12.2)
BARS	Table 11.3.8.1.6.1 to Table 11.3.8.1.6.3 Figure 11.3.8.1.6.4	Appendix 12.2.10.5

8.2 Extent of exposure

A total of 506 of 509 patients who were randomized into the study received at least 1 dose of double-blind treatment and were included in the safety analysis set. Patient 0011014, a 62-year-old female who was randomized to receive quetiapine 300 mg, Patient 0025021, a 34-year old female who was randomized to receive quetiapine 600 mg, and Patient 0022008, a 59-year old female who was randomized to receive placebo, were excluded from the safety analysis set because they did not take study medication (Appendix 12.2.2).

The mean overall exposure, in terms of days of double-blind treatment, was similar between the 2 quetiapine treatment groups, with a higher exposure for the placebo group relative to the active treatments. These results are consistent with overall discontinuation rates, which were higher for the quetiapine 300 mg (41.3%) and quetiapine 600 mg (46.7%), relative to the placebo group (34.5%) (see Table 11.1.4.1, Section 11.1). The size of the study population and the duration of overall study drug exposure were adequate to draw safety conclusions.

An overview of exposure, in terms of duration of treatment and doses received, is presented in Table 36. Supporting data on the numbers of patients who completed or discontinued the study are presented in Table 37.

Table 36 Overview of exposure in the safety population

		Quetiapine 300 mg (N=171)	Quetiapine 600 mg (N=168)	Placebo (N=167)
Exposure by duration of treatment (days)	Mean	41.8	39.8	46.0
	Minimum	1	1	1
	Maximum	62	63	65
Mean daily dose (mg) over study[a]	Median	281.7	528.7	0
	Minimum	25	10	0
	Maximum	291	562	0
Cumulative dose (mg) over study	Mean	11793.3	21191.7	0
	Minimum	50	50	0

Table 36 Overview of exposure in the safety population

		Quetiapine 300 mg (N=171)	Quetiapine 600 mg (N=168)	Placebo (N=167)
	Maximum	17450	33800	0
Patients with dose reduction	n (%)	43 (25.1)	37 (22.0)	8 (4.8)

[a] Median computed over days in study rather than days of dosing.
Data derived from Table 11.3.1.1 and Table 11.3.1.3, Section 11.3.

Approximately 26% of quetiapine-treated patients had their dose reduced. Of the 88 patients who had dose reductions, 29 (67.4%) of the quetiapine 300 mg patients, 22 (59.5%) of the quetiapine 600 mg patients, and 6 (75.0%) of the placebo patients completed the study (Table 11.3.1.3, Section 11.3). For all patients who had a dose reduction regardless of whether they completed the study or not, the median time to dose reduction for the quetiapine 300 mg treatment group was 14 days, the 600 mg treatment group 13 days, and the placebo group 8.5 days (Appendix 12.2.1.2 and Appendix 12.2.5).

8.3 Adverse events

This section gives an overview of the adverse events reported in the study.

8.3.1 Categories of adverse events

A summary of adverse events in each category is presented in Table 37.

Table 37 Patients who had an adverse event in any category (safety population)

Category of adverse event	Number (%) of patients who had an adverse event in each category[a]					
	Quetiapine 300 mg (n=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
Any adverse events[a]	155	90.6	151	89.9	138	82.6
Serious adverse events	3	1.8	7	4.2	1	0.6
Serious adverse events leading to death	0		0		0	
Study drug-related adverse events	149	87.1	134	79.8	94	56.3
Discontinuations of study treatment due to adverse events	14	8.2	19	11.3	2	1.2

[a] Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.
Data derived from Table 11.3.2.1, Section 11.3.

Quetiapine-treated patients exhibited an overall adverse event rate of approximately 90% to 91%, approximately 7 percentage points higher than the rate for the placebo group. SAEs were more common (4.2%) in the quetiapine 600 mg group than in either the quetiapine 300 mg (1.8%) or placebo (0.6%) groups. Approximately 11% of quetiapine 600 mg patients, 8% of quetiapine 300 mg patients and 1% of placebo patients discontinued treatment due to adverse events.

Categories of adverse events are shown for bipolar I and bipolar II patients in Table 11.3.2.2, Section 11.3.

8.3.2 Most common adverse events

The most common adverse events in the study, summarized by system organ class, are shown in Table 38.

Table 38 Adverse events by system organ class, sorted by decreasing order of incidence (safety population)

System organ class	Quetiapine 300 mg (n=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
	n	(%)	n	(%)	n	(%)
Nervous system	129	75.4	123	73.2	68	40.7
Gastrointestinal	98	57.3	95	56.5	72	43.1
General disorders and administration site conditions	40	23.4	37	22.0	31	18.6
Psychiatric	36	21.1	31	18.5	34	20.4
Infections & infestations	29	17.0	33	19.6	47	28.1
Musculoskeletal & connective tissue	28	16.4	25	14.9	27	16.2
Respiratory, thoracic & mediastinal	21	12.3	22	13.1	18	10.8
Metabolism & nutrition	18	10.5	12	7.1	12	7.2
Eye	12	7.0	11	6.5	5	3.0
Investigations	12	7.0	13	7.7	8	4.8
Cardiac	11	6.4	9	5.4	2	1.2
Injury, poisoning and procedural complications	10	5.8	11	6.5	8	4.8
Vascular	10	5.8	12	7.1	9	5.4
Renal & urinary	8	4.7	3	1.8	9	5.4
Reproductive system & breast	5	2.9	6	3.6	11	6.6
Ear & labyrinth	3	1.8	4	2.4	4	2.4
Skin & subcutaneous tissue	3	1.8	3	1.8	13	7.8
Immune system	2	1.2	1	0.6	2	1.2
Endocrine	1	0.6	1	0.6	0	
Surgical & medical procedures	1	0.6	0		2	1.2
Blood & lymphatic	0		1	0.6	0	

Note: Data are ordered by descending incidence in the quetiapine 300 mg group.
Data derived from Table 11.3.2.3, Section 11.3.

Quetiapine treatment was associated with a greater incidence of adverse events in the nervous and gastrointestinal systems. The quetiapine 300 mg and 600 mg groups showed similar rates of adverse events in these 2 systems, with a difference in incidence of 34.7 percentage points between the quetiapine 300 mg and the placebo groups, and 32.5 percentage points between

the quetiapine 600 mg and placebo groups, for the nervous system events and one of approximately 14.2 percentage points (quetiapine 300 mg vs placebo) and 13.4 percentage points (quetiapine 600 mg vs placebo) for the gastrointestinal system events. The incidences of adverse events in the infections, reproductive system, and in the skin classifications were higher for the placebo group than for either of the quetiapine groups.

The incidence of adverse events by system organ class is presented for bipolar I and bipolar II patients in Table 11.3.2.4, Section 11.3.

The most common adverse events, as summarized by MedDRA preferred term, are shown in Table 39.

Table 39 Patients with commonly reported adverse events, sorted by decreasing order of frequency (safety population)

MedDRA preferred term	Quetiapine 300 mg (n=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
	n	(%)	n	(%)	n	(%)
Dry mouth	73	42.7	79	47.0	30	18.0
Sedation	55	32.2	46	27.4	17	10.2
Somnolence	51	29.8	50	29.8	8	4.8
Dizziness	24	14.0	27	16.1	9	5.4
Fatigue	16	9.4	19	11.3	13	7.8
Headache	15	8.8	14	8.3	28	16.8
Constipation	14	8.2	17	10.1	5	3.0
Increased appetite	13	7.6	7	4.2	7	4.2
Nausea	13	7.6	18	10.7	22	13.2
Dyspepsia	12	7.0	11	6.5	8	4.8
Extrapyramidal disorder	11	6.4	10	6.0	4	2.4
Lethargy	9	5.3	2	1.2	3	1.8
Vomiting	9	5.3	9	5.4	10	6.0
Back pain	8	4.7	3	1.8	13	7.8
Upper respiratory tract infection	7	4.1	10	6.0	14	8.4
Weight increased	7	4.1	9	5.4	3	1.8
Nasopharyngitis	6	3.5	11	6.5	10	6.0
Insomnia	5	2.9	3	1.8	12	7.2
Nasal congestion	5	2.9	10	6.0	6	3.6
Diarrhea	4	2.3	8	4.8	11	6.6

Table 39 Patients with commonly reported adverse events, sorted by decreasing order of frequency (safety population)

MedDRA preferred term	Quetiapine 300 mg (n=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
	n	(%)	n	(%)	n	(%)
Orthostatic hypotension	4	2.3	10	6.0	3	1.8
Dysarthria	3	1.8	9	5.4	1	0.6

Note: This table uses a cut-off of 5% in any group. Data are ordered by descending incidence in the quetiapine 300 mg group.
MedDRA Medical Dictionary for Regulatory Affairs.
Data derived from Table 11.3.2.5, Section 11.3.

The most commonly reported AE for the quetiapine-treated groups was dry mouth reported for 73 (42.7%) quetiapine 300 mg patients, 79 (47.0%) quetiapine 600 mg patients, and 30 (18.0%) placebo patients. The onset of dry mouth in quetiapine-treated patients most often occurred in the first 8 days of treatment (see Table 11.3.2.7, Section 11.3). Mild to moderate dry mouth was reported for 65 of 73 (89%) quetiapine 300 mg patients, 74 of 79 (94%) quetiapine 600 mg patients and all 30 (100%) placebo patients. Severe dry mouth was reported for 8 quetiapine 300 mg patients, 5 quetiapine 600 mg patients and no placebo patients (see Table 11.3.2.6, Section 11.3). Most of the dry mouth AEs were judged to be drug related in each treatment group (see Table 11.3.2.8, Section 11.3).

Sedation and somnolence were more often seen in the quetiapine treatment groups than in the placebo group. The onset of sedation and somnolence in quetiapine-treated patients most often occurred in the first 8 days of treatment (see Table 11.3.2.7, Section 11.3), and sedation was the most often cited event in association with discontinuation (see Section 8.4.3). Mild to moderate sedation was reported for 46 of 55 (84%) quetiapine 300 mg patients, 42 of 46 (91%) quetiapine 600 mg patients and all 17 (100%) placebo-treated patients (see Table 11.3.2.6, Section 11.3). Nine quetiapine 300 mg patients, 4 quetiapine 600 mg patients and no placebo-treated patients experienced severe sedation. Most sedation AEs were judged to be related to study treatment in all treatment groups (see Table 11.3.2.8, Section 11.3). Mild to moderate somnolence was reported for 44 of 51 (86%) quetiapine 300 mg patients, 47 of 50 (94%) quetiapine 600 mg patients, and all 8 (100%) placebo patients. Seven quetiapine 300 mg patients, 3 quetiapine 600 mg patients and no placebo-treated patients experienced severe somnolence (see Table 11.3.2.6). Most somnolence AEs were judged to be related to study treatment in all treatment groups (see Table 11.3.2.8, Section 11.3). Four patients had sedation and somnolence, 3 in the quetiapine 300 mg treatment group and 1 in the quetiapine 600 mg treatment group (Appendix 12.2.7.1).

Dizziness was more often seen in the quetiapine treatment groups than in the placebo group. Mild to moderate dizziness was reported for all 24 (100%) quetiapine 300 mg patients, 24 of 27 (89%) quetiapine 600 mg patients, and all 9 (100%) placebo-treated patients. Only

3 patients, all in the quetiapine 600 mg group, reported severe dizziness (see Table 11.3.2.6, Section 11.3) while most dizziness AEs were judged related to study treatment across all treatment groups (see Table 11.3.2.8, Section 11.3).

Headache was more often seen in the placebo treatment group than in the quetiapine treatment groups. Mild to moderate headache was reported for all 15 (100%) quetiapine 300 mg patients, 13 of 14 (93%) quetiapine 600 mg patients, and 25 of 28 (89%) placebo patients. Severe headache was reported for no quetiapine 300 mg patients, 1 quetiapine 600 mg patient, and 3 placebo patients. Headache was judged study treatment-related in 11 quetiapine 300 mg patients, 11 quetiapine 600 mg patients and 17 placebo patients (see Table 11.3.2.8, Section 11.3).

The most frequently occurring gastrointestinal system adverse event was constipation. Most of these events were mild to moderate for all groups (see Table 11.3.2.6, Section 11.3). Constipation was attributed to study medication for approximately 5% to 8% of quetiapine-treated patients and 2% of placebo-treated patients (see Table 11.3.2.8, Section 11.3).

Orthostatic hypotension was more often seen in the quetiapine 600 mg treatment groups than in the quetiapine 300 mg or placebo groups. Mild to moderate orthostatic hypotension was reported for 4 quetiapine 300 mg patients, 8 quetiapine 600 mg patients and 3 placebo-treated patients. Only 2 patients, both in the quetiapine 600 mg group, reported severe orthostatic hypotension (see Table 11.3.2.6, Section 11.3) while most orthostatic hypotension AEs were judged related to study treatment across all treatment groups (see Table 11.3.2.8, Section 11.3). The majority of orthostatic hypotension events occurred in patients aged 50 years old or less. Most orthostatic hypotension events occurred before Day 4 when the dose in the 2 quetiapine treatment groups was the same (3 of 4 patients in the quetiapine 300 mg group; 6 of 10 patients in the quetiapine 600 mg group; Appendix 12.2.7.1).

Extrapyramidal disorder AEs occurred with higher incidence (6.2%) in the quetiapine-treated groups than in the placebo-treated group (2.4%). Most of these events were mild to moderate in intensity with only 2 severe cases reported, 1 in each quetiapine treatment group, and occurred within the first 4 days of study treatment (Tables 11.3.2.6 and 11.3.2.7, Section 11.3 and Appendix 12.2.7). EPS-related findings are discussed in detail in Section 8.4.4.1.

Mild to moderate (as reported by the investigator) weight increase was noted in 7 quetiapine 300 mg patients, 9 quetiapine 600 mg patients and 3 placebo patients. No patients experienced severe weight gain (see Table 11.3.2.6, Section 11.3). Study treatment-related weight increase was judged in 7 of quetiapine 300 mg patients, 8 quetiapine 600 mg patients and 3 placebo patients (see Table 11.3.2.8, Section 11.3).

8.3.3 Discussion of common adverse events

In general, the known adverse event profile for quetiapine was reported in patients with bipolar depression. The most common AEs occurring in the quetiapine treatment groups, dry mouth, sedation, somnolence, dizziness, and constipation, were classified within the central nervous system and the gastrointestinal system. Dry mouth, somnolence and sedation were

most often reported as mild to moderate. Across the 3 treatment groups, most AEs, including dry mouth, headache, and sedation, occurred within the first 8 days of study treatment.

8.4 Deaths, serious adverse events, discontinuation due to adverse events, and other significant adverse events

8.4.1 Deaths

No patient deaths were reported in this study.

8.4.2 Serious adverse events other than deaths

Patients who had a serious adverse event other than death are listed in Table 40. Serious adverse events are summarized by system organ class and preferred term in Table 11.3.4.1.1, Section 11.3.

Table 40 Patient listing of serious adverse events other than death (safety population)

Treatment, dose regimen and bipolar diagnosis	Subject code[a]	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Intensity	Duration of AE (if resolved)	Action taken with respect to investigational product	Causality (as assessed by the investigator)
Quetiapine 300 mg daily Bipolar I	0015008	M	37	Suicidal ideation	Suicidal ideation with plan	9	Sev	7	Permanently stopped	No
	0033007	M	39	Mitral valve prolapse	Mitral valve prolapse worsening	55	Sev	2	None	No
	0034010	F	58	Bipolar I disorder	Worsening of bipolar I disorder, mixed with associated psychotic features	4	Sev	7	None[b]	No
Quetiapine 600 mg daily Bipolar I	0015005	F	42	Syncope	Syncope not due to orthostatic hypotension	11	Mil	1	None	Yes
	0020032	M	33	Convulsion	Seizure with associated aspiration/bronchospasm	33	Sev	4	Permanently stopped	Yes
	0020037	F	30	Suicidal ideation	Suicidal ideation with plan	22	Sev	9	None	No
	0027016	F	21	Suicidal ideation	Suicidal ideation	61	Mil	36	None	No
	0028013	M	26	Accidental overdose	Suspected unintentional overdose of study drug	36	Sev	2	Permanently stopped	No
	0046012	M	60	Acute myocardial infarction	Acute inferior wall myocardial infarction	2	Sev	16	Permanently stopped	No
Quetiapine 600 mg daily Bipolar II	0025045	F	24	Suicide attempt	Suicide attempt, intentional overdose non-study drug	2	Sev	2	Permanently stopped	No
Placebo Bipolar I	0014020	F	20	Tonsillitis	Tonsillitis associated with strep infection	37	Sev	8	None	No

[a] Subject code includes study center number in left-most 4 digits and a patient number for that study center in the right-most 3 digits.
[b] Patient E0034010 stopped taking study drug on her own with no subsequent investigator action against study drug.

Mil=mild; Mod=moderate; Sev=severe; Unk=unknown
Data derived from Table 11.3.4.2, Section 11.3.

A total of 11 patients reported 11 SAEs. Three of the 11 patients with SAEs were treated with quetiapine 300 mg, 7 with quetiapine 600 mg and 1 with placebo. Serious psychiatric disorders were observed in 2 patients treated with quetiapine 300 mg, 3 patients treated with quetiapine 600 mg and no patients treated with placebo. Two of 3 SAEs for quetiapine 300 mg treatment, 4 of 7 SAEs for quetiapine 600 mg treatment and no SAEs for placebo treatment were associated with withdrawal from the study.

Serious adverse events for bipolar I and bipolar II patients are described in Table 11.3.4.1.2, Section 11.3.

8.4.3 Discontinuations due to adverse events

Discontinuations due to adverse events are summarized by system organ class and preferred term in Table 41. All patients who were discontinued from study treatment due to an adverse event are listed in Table 42.

Table 41 Incidence of discontinuations due to adverse events by system organ class (safety population)

		Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
System organ class	**Preferred term**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Any event leading to discontinuation		14	8.2	19	11.3	2	1.2
Nervous system	Total	10	5.8	10	6.0	0	
	Akathisia	1	0.6	0		0	
	Convulsions	0		1	0.6	0	
	Dizziness	1	0.6	2	1.2	0	
	Extrapyramidal disorder	0		1	0.6	0	
	Hypersomnia	0		1	0.6	0	
	Hypoaesthesia	0		1	0.6	0	
	Sedation	8	4.7	6	3.6	0	
	Somnolence	0		1	0.6	0	
Gastrointestinal	Total	2	1.2	1	0.6	0	
	Dry mouth	0		1	0.6	0	
	Nausea	2	1.2	0		0	
General disorders and administration site conditions	Total	1	0.6	4	2.4	0	
	Chest discomfort	0		1	0.6	0	
	Fatigue	0		3	1.8	0	
	Lethargy	1	0.6	0		0	
Psychiatric	Total	4	2.3	1	0.6	0	
	Bipolar I disorder	1	0.6	0		0	

Table 41 Incidence of discontinuations due to adverse events by system organ class (safety population)

		Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
System organ class	**Preferred term**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
	Dissociation	1	0.6	0		0	
	Hypomania	1	0.6	0		0	
	Panic attack	1	0.6	0		0	
	Suicidal ideation	1	0.6	0		0	
	Suicide attempt	0		1	0.6	0	
Skin and subcutaneous tissue disorders	Total	0		1	0.6	1	0.6
	Rash	0		1	0.6	1	0.6
Eye	Total	0		1	0.6	0	
	Vision blurred	0		1	0.6	0	
Vascular	Total	0		1	0.6	0	
	Hypertension	0		1	0.6	0	
Injury, poisoning and procedural complications	Total	0		1	0.6	0	
	Accidental overdose	0		1	0.6	0	
Cardiac	Total	0		2	1.2	0	
	Acute myocardial infarction	0		1	0.6	0	
	Tachycardia	0		1	0.6	0	
Blood and lymphatic system	Total	0		1	0.6	0	
	Anemia	0		1	0.6	0	
Infections and infestations	Total	0		0		1	0.6
	Tonsillitis	0		0		1	0.6

Data derived from Table 11.3.5.1.1, Section 11.3.

Patients discontinuing from the study due to AEs totalled 14 (8.2%) of the quetiapine 300 mg group, 19 (11.3%) of the quetiapine 600 mg group, and 2 (1.2%) of the placebo group. Nervous system disorders constituted the largest portion of the DAEs, with a total of 10 (5.8%) patients in the quetiapine 300 mg group, 10 (6.0%) patients in the quetiapine 600 mg group, and none in the placebo group. Sedation was noted as associated with discontinuation in 8 (4.7%) quetiapine 300 mg patients, 6 (3.6%) quetiapine 600 mg patients, and no placebo patients. Dizziness was listed for 1 (0.6%) quetiapine 300 mg patient, 2 (1.2%) quetiapine 600 mg patients, and no placebo patients (see Table 41). Somnolence was noted as associated with discontinuation in only 1 patient (quetiapine 600 mg).

The majority of AEs that led to discontinuation started within the first 7 days of study treatment (see Table 42). Adverse events leading to discontinuation are displayed by bipolar I and bipolar II diagnosis in Table 11.3.5.1.2, Section 11.3.

Table 42 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
Quetiapine 300 mg daily Bipolar I	0008009	F	34	Sedation	Sedation	2	6	No	Yes
	0008010	F	31	Nausea	Nausea	2	6	No	Yes
				Sedation	Sedation	2	6	No	Yes
	0010017	M	29	Sedation	Sedation	2	17	No	Yes
				Dissociation	Intermittent dissociation	3	10	No	Yes
				Panic attack	Intermittent panic attack	3	13	No	Yes
	0013006	F	36	Sedation	Sedation	1	4	No	Yes
	0014010	M	45	Sedation	Early morning sedation	2	34	No	Yes
	0015008	M	37	Suicidal ideation	Suicidal ideation with plan	9	7	Yes	No
	0034010	F	58	Bipolar I disorder	Worsening of bipolar I disorder, mixed with associated psychotic features	4	7	Yes	No
	0039023	F	35	Sedation	Sedation	1	9	No	Yes
Quetiapine 300 mg daily Bipolar II	0007002	F	35	Sedation	Sedation	1	9	No	Yes
	0008007	F	34	Sedation	Sedation	1	7	No	Yes
	0011024	M	22	Dizziness	Dizziness not due to orthostatic hypotension	2	2	No	Yes
				Nausea	Nausea	2	2	No	Yes
	0014005	M	42	Lethargy	Lethargy	1	UNK	No	Yes
	0030023	F	31	Hypomania	Hypomania	2	UNK	No	No
	0037021	M	54	Akathisia	Akathisia	6	3	No	Yes

Table 42 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
Quetiapine 600 mg daily Bipolar I	0006017	F	51	Hypertension	Hypertension	8	UNK	No	Yes
	0012004	M	43	Anemia	Worsening anemia	30	UNK	No	No
	0014023	F	39	Vision blurred	Blurred vision	23	UNK	No	Yes
	0020032	M	33	Convulsion	Seizure with associated aspiration/bronchospasm	33	4	Yes	Yes
	0020037	F	30	Rash	Diffuse rash	3	26	No	Yes
	0028013	M	26	Accidental overdose	Suspected unintentional overdose of study drug	36	2	Yes	No
	0030016	M	56	Hypoesthesia	Numbness in fingers	2	UNK	No	Yes
				Chest discomfort	Tightness in chest not due to EPS	2	3	No	Yes
				Dizziness	Dizziness not due to orthostatic hypotension	2	3	No	Yes
	0032010	F	55	Sedation	Sedation	2	19	No	Yes
				Dry mouth	Dry mouth	3	18	No	Yes
				Hypersomnia	Oversleeping	11	10	No	Yes
	0042020	F	43	Dizziness	Dizziness due to EPS not due to orthostatic hypotension	6	1	No	Yes
				Extrapyramidal disorder	Involuntary tongue movement due to EPS	6	1	No	Yes
				Extrapyramidal disorder	Muscle aches due to EPS	6	1	No	Yes
				Extrapyramidal disorder	Muscle stiffness due to EPS	6	1	No	Yes
				Extrapyramidal disorder	Slurred speech due to EPS	6	1	No	Yes

Table 42 Patient listing for study treatment discontinuation due to an adverse event (safety population)

Treatment and dose regimen	Subject number	Sex (M/F)	Age (year)	Adverse event (preferred term)	Adverse event (investigator text)	Time from start of treatment to onset of AE (days)	Duration of AE (if resolved)[a]	Reported as a serious adverse event (yes/no)	Causality (as assessed by the investigator)
				Tachycardia	Tachycardia	6	1	No	Yes
	0042021	F	33	Somnolence	Drowsiness	14	UNK	No	Yes
	0046012	M	60	Acute myocardial infarction	Acute inferior wall myocardial infarction	2	16	Yes	No
Quetiapine 600 mg daily Bipolar II	0010011	M	54	Sedation	Sedation	3	UNK	No	Yes
	0011006	F	38	Sedation	Sedation	6	2	No	Yes
	0011013	F	32	Sedation	Sedation	3	3	No	Yes
	0012003	F	34	Fatigue	Fatigue	2	11	No	Yes
				Sedation	Sedation	2	11	No	Yes
	0014009	F	22	Sedation	Sedation	3	UNK	No	Yes
	0025002	M	24	Fatigue	Fatigue	2	4	No	Yes
	0025032	F	30	Fatigue	Fatigue	1	2	No	Yes
	0025045	F	24	Suicide attempt	Suicide attempt – intentional overdose (non-study drug)	2	2	Yes	No
Placebo Bipolar I	0008011	F	24	Rash	Rash	37	UNK	No	No
	0014020	F	20	Tonsillitis	Tonsillitis associated with strep infection	37	8	Yes	No

[a] Events of unknown duration were ongoing at the time of discontinuation.
EPS Extrapyramidal symptoms; UNK Unknown.
Data from Table 11.3.5.2, Section 11.3.

8.4.4 Adverse events of special interest

8.4.4.1 Adverse events related to EPS

The AE cluster of terms identified as related to EPS (see SAP, Appendix 12.1.9) are summarized by system organ class and preferred term in Table 43 and Table 11.3.6.2, Section 11.3.

Table 43 Adverse events coded to EPS (safety population)

	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
Preferred term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total[a]	21	12.3	17	10.1	11	6.6
Extrapyramidal disorder	11	6.4	10	6.0	4	2.4
Akathisia	5	2.9	2	1.2	2	1.2
Tremor	2	1.2	5	3.0	3	1.8
Dyskinesia	2	1.2	0		1	0.6
Dystonia	1	0.6	1	0.6	0	
Restlessness	1	0.6	1	0.6	2	1.2

[a] Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.
Note: Data are ordered by descending incidence in the quetiapine 300 mg group.
Data derived from Table 11.3.6.1, Section 11.3.

The incidences of individual EPS-related AEs were low in each treatment group. Most AEs related to EPS were reported as mild to moderate for all groups (Table 11.3.6.2, Section 11.3). The most commonly reported individual AE related to EPS was extrapyramidal disorder, which had a higher incidence in the quetiapine 300 mg (6.4%) and 600 mg (6.0%) treatment groups compared to the placebo (2.4%) group. Akathisia was noted in quetiapine-treated patients with an incidence of 2.1% compared to 1.2% in placebo-treated patients. There were 8 EPS-related symptoms with severe intensity: 5 in the quetiapine 300 mg treatment group; 2 in the quetiapine 600 mg treatment group; and 1 in the placebo group. One of these 8 patients discontinued study treatment with the event ongoing at the time of withdrawal. The majority of EPS-related symptoms occurred within the first 8 days of study treatment (Table 11.3.2.7, Section 11.3). The composite of MedDRA-encoded AEs related to EPS were reported for 12.3% of quetiapine 300 mg patients, 10.1% of quetiapine 600 mg patients and 6.6% of placebo patients.

If an AE was reported that coded to one of the terms identified by AstraZeneca as a possible EPS-related symptom, the investigator was asked whether or not they judged this AE as being due to EPS. A summary of adverse events coded as extrapyramidal adverse events by

MedDRA as shown in Table 43 with the exclusion of those considered by the investigators to not be extrapyramidal symptoms is shown in Table 44.

Table 44 Adverse events coded as EPS and not excluded as EPS by investigators (safety population)

	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
Preferred term	**n**	**(%)**	**n**	**%**	**n**	**%**
Total[a]	17	9.9	12	7.1	6	3.6
Extrapyramidal disorder	11	6.4	10	6.0	4	2.4
Akathisia	5	2.9	2	1.2	2	1.2
Dystonia	1	0.6	1	0.6	0	
Restlessness	0		0		1	0.6

[a] Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.

Data derived from Table 11.3.6.2, Section 11.3.

After EPS-coded adverse events specified by investigators as not being due to EPS were removed from those reported in Table 43, the remaining data (reported in Table 44) contained reports of EPS-related AEs for 9.9% of patients in the quetiapine 300 mg group, 7.1% of patients in the quetiapine 600 mg group and 3.6% of patients in the placebo group.

8.4.4.2 Adverse events related to QT prolongation

No adverse events encoded to the MedDRA terms of "long QT syndrome," "electrocardiogram QT corrected interval prolonged," "electrocardiogram QT prolonged," "long QT syndrome congenital," "torsades de pointes," "cardiac arrest," "cardio-respiratory arrest," "cardiac death," "electromechanical dissociation" or "sinus arrest" were reported for patients in any of the 3 treatment groups (Table 11.3.2.6, Section 11.3).

8.4.4.3 Adverse events related to neutropenia and agranulocytosis

No adverse events encoded to the MedDRA terms of "band neutrophil count decreased," "band neutrophil percentage decreased," "febrile neutropenia," "neutropenia," "neutropenic infection," "neutropenic sepsis," "neutrophil count decreased," "neutrophil percentage decreased," "granulocyte count decreased," "granulocytopenia," "idiopathic neutropenia," "neutrophil count abnormal," "neutrophil percentage abnormal" or "agranulocytosis" were reported for patients in any of the 3 treatment groups (Table 11.3.2.6, Section 11.3).

Three cases of neutropenia were identified based on clinical laboratory hematology data and are further discussed in Section 8.5.1.3.

8.4.4.4 Adverse events related to treatment-emergent mania and hypomania

Criteria, including AEs, related to treatment-emergent mania and hypomania are summarized in Table 45.

Table 45 Treatment-emergent mania and hypomania (LOCF, safety population)

Criteria	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
	n	(%)	n	(%)	n	(%)
All[a]	3	1.8	6	3.6	11	6.6
YMRS alone[b]	2	1.2	5	3.0	9	5.4
Adverse events alone	2	1.2	1	0.6	5	3.0

[a] Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.
[b] YMRS >16 at 2 consecutive visits or at final visit
LOCF last observation carried forward; YMRS Young Mania Rating Scale.
Data derived from Table 11.3.8.1.7.12, Section 11.3.

The rates of treatment-emergent mania were lower in the quetiapine treatment groups compared to placebo. There was a statistically significant difference in treatment-emergent mania rates between quetiapine 300 mg and placebo (p=0.027) but not between quetiapine 600 mg and placebo (p=0.211; see Table 11.3.8.1.7.13, Section 11.3).

Both quetiapine-treated groups showed greater improvement in YMRS scores compared to placebo at end of treatment (quetiapine 300: mean change from baseline compared to placebo= -1.18; p=0.006; quetiapine 600: mean change from baseline compared to placebo= -0.63; p=0.141; see Table 11.3.8.1.7.3, Section 11.3).

8.4.4.5 Adverse events related to diabetes mellitus

Six cases of adverse events possibly related to diabetes (see SAP, Appendix 12.1.9 for search terms) were identified: 5 cases were "increased thirst" while the remaining case was "hyperglycemia". None of increased thirst cases showed signs or symptoms that would indicate diabetes mellitus (see Tables 11.3.6.1 and 11.3.6.2, Section 11.3). Three of the cases (patients E0012020, E0021008, and E0037028) were treated with quetiapine 300 mg daily. One patient (E0021008) had an AE of hyperglycemia. However, this patient had a meal approximately 30 minutes prior to his blood draw on Visit 6 (glucose value at Visit 6: 161.0 mg/dL; see Appendices 12.2.7.1, 12.2.8.2.1, and 12.2.8.2.4) and subsequent assessments were within normal limits (Visit 6 retest glucose value = 104.0 mg/dL and Visit 10 glucose value = 103.0 mg/dL).

8.4.4.6 Adverse events related to suicidality

Adverse events related to suicidality are summarized by system organ class and preferred term in Table 46.

Table 46 Adverse events related to suicidality incidence (safety population)

	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
Preferred term	**n**	**%**	**n**	**%**	**n**	**%**
Total[a]	1	0.6	3	1.8	0	
Suicidal ideation	1	0.6	2	1.2	0	
Suicide attempt	0		1	0.6	0	

[a] Patients with multiple events in the same category are counted only once in that category. Patients with events in more than 1 category are counted once in each of those categories.

Data derived from Table 11.3.6.1, Section 11.3.

There were 4 adverse events related to suicidality reported in quetiapine-treated patients and none in placebo-treated patients (see narratives for these patients in Section 11.3.4.3, Section 11.3).

8.4.5 Discussion of deaths, serious adverse events, discontinuation due to adverse events, and other significant adverse events

There were no deaths reported in this study, and serious adverse events were infrequent in all 3 treatment groups. More quetiapine-treated patients discontinued the study due to adverse events than did placebo-treated patients. Sedation, most often occurring in the first 8 days of treatment, was the adverse event most-frequently associated with discontinuation after administration of quetiapine.

Adverse events of special interest included a composite of AEs related to EPS, diabetes, QT prolongation, neutropenia/agranulocytosis, treatment-emergent mania/hypomania and suicidality. The incidences of individual EPS-related AEs were low in each treatment group with the majority of these AEs reported as mild to moderate for all groups. An increase in the incidence in the composite of AEs related to EPS was noted for both groups of quetiapine-treated patients compared to the placebo group. Few individual EPS-related AEs led to discontinuation. The incidence of treatment-emergent mania/hypomania was higher in the placebo treatment group than the quetiapine groups. Four cases of AEs related to suicidality were reported in the quetiapine treatment groups and none in the placebo group. No AEs of QT prolongation or neutropenia/agranulocytosis were reported.

8.5 Clinical laboratory evaluation

Clinical laboratory results are presented separately for hematology and clinical chemistry variables. Within each of these categories, results are examined in 3 ways: changes in mean values over time, changes in individual patients over time, and individual clinically important abnormalities. The results for all clinical laboratory evaluations are discussed collectively in Section 8.5.3.

8.5.1 Hematology

8.5.1.1 Changes in mean values over time in hematology

Changes in hematology from baseline to Day 57 (Week 8) are shown in Table 47.

Table 47 Hematology changes from baseline (LOCF, safety population)

	Quetiapine 300 mg (N=171)			Quetiapine 600 mg (N=168)			Placebo (N=167)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Hematocrit (vol fraction)	138	-0.01	0.03	138	-0.01	0.03	154	-0.01	0.03
Hemoglobin (g/dL)	138	-0.31	0.89	138	-0.45	0.83	154	-0.23	0.75
Total RBC count (10^{12}/L)	138	-0.09	0.31	138	-0.13	0.29	154	-0.06	0.26
Platelet count (10^9/L)	137	-12.55	49.03	137	-9.80	51.12	154	-3.23	35.44
Total WBC count (10^9/L)	138	-0.40	1.99	138	-0.73	1.75	154	-0.20	1.65
Neutrophils (10^9/L)	138	-0.20	1.80	138	-0.52	1.54	154	-0.16	1.47
Eosinophils (10^9/L)	138	0.01	0.07	138	0.02	0.12	154	-0.00	0.07
Basophils (10^9/L)	138	-0.00	0.03	138	-0.01	0.03	154	-0.00	0.03
Lymphocytes (10^9/L)	138	-0.20	0.50	138	-0.21	0.47	154	-0.03	0.47
Monocytes (10^9/L)	138	-0.01	0.14	138	-0.01	0.12	154	-0.00	0.11

Data derived from Table 11.3.7.1.1.2, Section 11.3.

There were no clinically relevant differences between treatment groups in mean change from baseline for any hematology assessments.

8.5.1.2 Changes in individual patients over time in hematology

The number of patients within each treatment group with positive findings of categorical shifts to out-of-range hematology abnormalities are summarized in Table 48. Complete shift analyses for hematology assessments are presented in Table 11.3.7.1.1.3.1, Section 11.3 (see also Figure 11.3.7.1.1.4.1 through Figure 11.3.7.1.1.4.10, Section 11.3).

Table 48 Hematology shifts exceeding laboratory norms - incidence (safety population)

	Shift to low (%)			Shift to high (%)		
	Quetiapine 300 mg (N=171)	Quetiapine 600 mg (N=168)	Placebo (N=167)	Quetiapine 300 mg (N=171)	Quetiapine 600 mg (N=168)	Placebo (N=167)
Hematocrit	1.5	1.5	0.0	0.0	0.0	0.0
Hemoglobin	2.3	3.1	1.3	0.7	0.0	0.0
Total RBC count	2.2	5.9	2.0	0.7	0.0	0.6
Platelet count	0.0	2.2	0.0	3.1	1.6	1.4
Total WBC count	1.5	3.6	0.7	5.3	3.1	0.7
Neutrophils	2.3	3.7	2.0	6.2	3.2	2.8
Eosinophils	0.0	0.0	0.0	0.7	0.7	2.0
Basophils	0.0	0.0	0.0	0.0	0.0	0.0
Lymphocytes	0.0	0.7	0.0	0.0	0.0	0.7
Monocytes	0.0	0.7	0.0	0.0	0.7	0.0

Incidence (%) of cases with out-of-normal range findings at final visit in the population of patients who did not have out-of-normal range findings at baseline are noted in each cell. Normal ranges are shown in Table 11.3.7.1.1.1, Section 11.3.
NA Not applicable
Data derived from Table 11.3.7.1.1.3.2, Section 11.3.

There were no clinically relevant differences between treatment groups in hematology shifts to out of normal range values.

8.5.1.3 Individual clinically important abnormalities in hematology

The number of patients within each treatment group with positive findings of categorical shifts to clinically important hematology abnormalities is summarized in Table 49. Complete shift analyses for clinically important hematology assessments are presented in Tables 11.3.7.1.1.3.3 and 11.3.7.1.1.3.4, Section 11.3 (see also Figure 11.3.7.1.1.4.1 through Figure 11.3.7.1.1.4.10, Section 11.3).

Table 49 Hematology shifts to clinically important values - incidence (safety population)

	Shift to low (%)			Shift to high (%)		
	Quetiapine 300 mg (N=171)	Quetiapine 600 mg (N=168)	Placebo (N=167)	Quetiapine 300 mg (N=171)	Quetiapine 600 mg (N=168)	Placebo (N=167)
Hematocrit	1.5	0.0	0.0	0.0	0.0	0.0
Hemoglobin	1.5	1.5	0.0	0.7	0.0	0.0
Total RBC count	0.7	0.0	0.0	0.0	0.0	0.0
Platelet count	0.0	0.0	0.0	0.0	0.0	0.0
Total WBC count	0.0	0.7	0.6	0.0	0.0	0.0
Neutrophils[a]	1.5	0.0	0.6	0.7	0.0	0.0
Neutrophils (agranulocytosis)[b]	0.0	0.0	0.0	NA	NA	NA
Eosinophils	NA	NA	NA	0.0	0.7	0.0
Basophils	NA	NA	NA	0.0	0.0	0.0
Lymphocytes	0.0	0.0	0.0	0.0	0.0	0.0
Monocytes	NA	NA	NA	0.0	0.0	0.0

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell. Clinically important criteria are shown in Table 15.

[a] Clinically important value = $\leq 1.5 \times 10^9$ cells/L or $\geq 10 \times 10^9$ cells/L.

[b] Clinically important value = $\leq 0.5 \times 10^9$ cells/L.

RBC Red blood cell; WBC White blood cell; NA Not applicable.

Data derived from Table 11.3.7.1.1.3.4, Section 11.3.

There were no clinically relevant differences between treatment groups in hematology shifts to clinically important abnormalities. Two quetiapine 300 mg patients (Patients E0004029 and E0020020) and 1 placebo-treated patient (Patient E0001013) had their neutrophil values shift from normal or low at baseline to potentially clinically important low values at final assessment (Appendix 12.2.8.1.2). None of these cases were reported as adverse events (Appendix 12.2.7.1). Patient E0004029 had a normal neutrophil value at baseline (2.39×10^9/L) but potentially clinically important low values at Visit 6 (1.27×10^9/L) and end of treatment (1.30×10^9/L). Patient E0020020 had a low neutrophil value at baseline (1.79×10^9/L) but potentially clinically important low values at Visit 6 (1.41×10^9/L; retested at Week 5, 1.61×10^9/L) and end of treatment (1.43×10^9/L). Patient E0001013 had a normal neutrophil value at baseline (2.38×10^9/L) but potentially clinically important low values at her final assessment (Week 4, Visit 6) (0.80×10^9/L). This patient discontinued from the study on Day 23 due to development of study-specific discontinuation criteria (Appendix 12.2.1.2). There were no signs of clinical infection in these patients.

8.5.2 Clinical chemistry

8.5.2.1 Changes in mean values over time in clinical chemistry

Changes in chemistry assessments from baseline to Day 57 (Week 8) are shown in Table 50.

Table 50 Clinical chemistry changes from baseline (LOCF, safety population)

	Quetiapine 300 mg (N=171)				Quetiapine 600 mg (N=168)				Placebo (N=167)			
	n	Mean	SD	Median	n	Mean	SD	Median	n	Mean	SD	Median
AST (U/L)	125	1.62	13.00	1.0	128	3.07	11.98	1.5	139	0.09	9.70	-1.0
ALT (U/L)	127	-0.26	14.60	-1.0	129	4.88	21.10	2.0	142	0.03	15.89	-1.0
Alkaline phosphatase (U/L)	127	1.31	9.65	0.0	129	7.36	21.99	6.0	142	-1.95	10.19	-1.0
Total bilirubin (mg/dL)	114	0.01	0.24	0.0	112	-0.07	0.23	0.0	132	-0.04	0.19	0.0
Creatinine (µmol/L)	127	0.01	0.13	0.0	129	0.01	0.11	0.0	142	-0.00	0.13	0.0
Glucose (mg/dL)	139	6.02	22.35	3.0	137	7.38	24.96	3.0	154	2.90	15.95	1.0
Insulin (pmol/L)	136	31.05	112.96	4.1	136	26.27	86.26	5.3	153	2.61	72.44	5.6
HbA1c	126	0.03	0.48	0.0	127	0.07	0.27	0.1	141	0.03	0.27	0.0
Sodium (mEq/L)	127	-0.72	2.74	-1.0	129	-0.22	2.78	0.0	142	-0.92	2.68	-1.0
Potassium (mEq/L)	127	-0.08	0.37	0.0	128	-0.05	0.47	0.0	142	-0.03	0.49	-0.1
Chloride (mEq/L)	127	-0.06	2.70	0.0	129	0.50	3.08	1.0	142	-0.15	2.67	0.0
Bicarbonate (mEq/L)	127	0.17	3.40	0.4	129	0.46	2.96	0.7	142	0.81	3.15	0.6

Table 50 Clinical chemistry changes from baseline (LOCF, safety population)

	Quetiapine 300 mg (N=171)				Quetiapine 600 mg (N=168)				Placebo (N=167)			
	n	Mean	SD	Median	n	Mean	SD	Median	n	Mean	SD	Median
Triglycerides (mg/dL)	127	40.08	128.08	15.0	129	6.74	96.75	7.0	142	1.76	85.89	-4.0
Total cholesterol (mg/dL)	127	1.43	32.99	-2.0	129	-1.83	31.74	4.0	142	-6.15	25.93	-5.0
HDL (mg/dL)	123	-0.71	7.42	-2.0	129	-0.43	8.39	0.0	141	-0.69	7.58	-1.0
LDL (mg/dL)	116	-4.46	22.69	-3.0	120	0.17	26.37	2.0	140	-5.25	22.19	-4.0
TSH (mIU/L)	127	0.20	1.54	0.0	129	0.37	1.78	0.1	140	0.00	0.86	0.0
Total T4 (pmol/L)	127	-0.92	2.40	-1.3	129	-1.12	2.28	-1.3	142	0.21	1.83	0.0

HbA1c Glycated hemoglobin.
Data derived from Table 11.3.7.1.2.2.1, Section 11.3.

Kidney function and electrolyte test changes from baseline were similar for the 3 treatment groups. For liver function tests, a slightly higher change from baseline for AST and ALT was seen in the quetiapine 600 mg group compared to quetiapine 300 mg and placebo. In addition, alkaline phosphatase exhibited a slight increase with quetiapine treatment.

Triglycerides exhibited higher mean increases from baseline for the quetiapine-treated patients than for the placebo-treated patients. Triglyceride median changes from baseline were higher for the treatment groups quetiapine 300 mg and quetiapine 600 mg than the corresponding mean for placebo while the standard deviations for change from baseline were large compared to the means. Triglyceride standard deviations for final assessment were larger than those for baseline assessments for all 3 treatment groups. There were no clinically relevant differences between the 3 treatment groups in change from baseline in total cholesterol, LDL, or HDL.

Mean glucose levels increased slightly for all 3 treatment groups, with higher increases in the quetiapine groups. However, the data were highly variable, with the variability increasing as the mean increased. Median changes from baseline for glucose were generally lower than mean changes. Part of the variability of glucose concentration could be explained by the variation in blood sampling time of day as many samples were collected past morning (>50%) (see Figure 11.3.7.1.2.4.11 and Figure 11.3.7.1.2.4.12). For this reason, information on the last meal was collected to assist in identifying samples where the patient had fasted at least 8 hours (confirmed fasting). While there was less variability observed in confirmed fasting glucose values with fewer patients, the same trend was seen with mean and median changes from baseline in glucose, and median changes were generally lower than mean changes (see Table 11.3.7.1.2.3.11, Section 11.3).

Mean insulin levels increased for all 3 treatment groups, with higher increases in the quetiapine groups. However, the data were highly variable, with the variability increasing as the mean increased. Median changes from baseline for insulin were generally lower than mean changes except for the placebo group with no differences in median changes across the 3 treatment groups. While there was less variability observed in confirmed fasting insulin values with fewer patients, the same trend was seen with mean and median changes from baseline in insulin, and median changes were generally lower than mean changes except for the placebo group (see Table 11.3.7.1.2.3.11, Section 11.3).

There were no clinically meaningful changes from baseline in HbA1c values across the 3 treatment groups.

Separate analyses of patients with pre-existing diabetes, patients with risk for diabetes and non-diabetic patients (see Section 5.7.4.4) were performed. The mean and median changes from baseline to end of treatment in glucose, insulin and HbA1c laboratory data for patients with diabetes, patients at risk for diabetes, and patients with no known diabetic risk is summarized by randomized treatment group in Table 51.

Table 51 Glucose, insulin and HbA_{1C} change from baseline, diabetic subgroups (safety population)

		QTP 300 (N=139)				QTP 600 (N=137)				PLA (N=154)			
Parameter		N[a]	Mean	SD	Median	N[a]	Mean	SD	Median	N[a]	Mean	SD	Median
Glucose, fasting (mg/dL)	Diabetic	9	32.89	58	8.0	5	23.40	35.95	5.0	9	17.33	37.24	1.0
	Diabetic risk	38	-1.26	13.00	-4.0	43	12.67	39.75	2.0	43	1.49	19.41	0.0
	Non diabetic	92	6.40	17.07	4.0	89	3.92	10.45	3.0	102	2.22	9.96	1.0
HbA1c (%)	Diabetic	7	0.83	1.64	0.3	5	0.44	0.51	0.2	8	-0.01	0.56	-0.1
	Diabetic risk	35	-0.02	0.32	0.0	39	0.08	0.19	0.1	37	0.05	0.28	0.0
	Non diabetic	84	-0.02	0.24	0.0	83	0.04	0.26	0.0	96	0.03	0.23	0.0
Insulin (pmol/L)	Diabetic	8	4.41	4.06	2.7	5	9.37	10.84	4.9	9	-2.98	16.11	-1.7
	Diabetic risk	37	1.67	11.54	-0.4	43	6.18	18.97	0.8	43	-0.25	16.59	0.5
	Non diabetic	91	5.62	18.38	1.2	88	2.29	7.31	0.7	101	0.94	5.25	0.9
HOMA-R	Diabetic	8	3.19	5.50	1.1	5	3.14	2.62	2.6	9	2.69	6.50	0.1
	Diabetic risk	35	-0.04	1.03	-0.2	42	2.41	5.88	0.7	42	0.33	3.11	0.3
	Non diabetic	85	1.55	4.35	0.3	84	0.57	1.81	0.1	101	0.26	1.27	0.2
QUICKI	Diabetic	8	-0.0242	0.0164	-0.0192	5	-0.0536	0.0610	-0.0306	9	-0.0049	0.0340	-0.0031
	Diabetic risk	35	0.0028	0.0300	0.0049	42	-0.0143	0.0495	-0.0128	42	-0.0046	0.0383	-0.0058
	Non diabetic	85	-0.0236	0.0545	-0.0161	84	-0.0119	0.0414	-0.0173	101	-0.0085	0.0432	-0.0108

[a] Number of patients with an assessment at baseline and at least one after baseline.
PLA Placebo. QTP Quetiapine. N Number of patients in treatment group.
Note: Diabetics defined as having baseline glucose ≥126 mg/dL at baseline or a history of diabetes. Diabetic risk defined as having a history of gestational diabetes or a BMI of ≥35 or impaired glucose≥100 to <126 mg/dL; Non-diabetic defined as not meeting criteria for diabetes or diabetic risk.
Data derived from Tables 11.3.7.1.2.3.9, Section 11.3

Changes from baseline in glucose- and insulin-related lab variables were generally higher for the quetiapine-treated patients compared to placebo-treated patients for all diabetic subgroups. The standard deviations for these measures across the 3 treatment groups were high indicating a large variability in results. Due to the small number of patients with pre-existing diabetes the diabetic subgroup results should be interpreted with caution.

Changes from baseline in $HOMA_R$, an estimator of insulin resistance, and QUICKI, an estimator of insulin sensitivity, are shown in Table 52.

Table 52 Insulin resistance and sensitivity change from baseline (safety population)

	Quetiapine 300 mg (N=139)			Quetiapine 600 mg (N=137)			Placebo (N=154)		
	n	Median change	Mean (SD) change	n	Median change	Mean (SD) change	n	Median change	Mean (SD) change
$HOMA_R$	128	0.2	1.21 (3.90)	131	0.3	1.26 (3.75)	152	0.2	0.42 (2.50)
QUICKI	128	-0.0089	-0.0164 (0.0486)	131	-0.0161	-0.0143 (0.0452)	152	-0.0076	-0.0072 (0.0412)

N Number of patients in dose group; n Number of patients in analysis subset.
Data derived from Table 11.3.7.1.2.3.9, Section 11.3.

The changes from baseline to final assessment in the $HOMA_R$ estimate of insulin resistance and the QUICKI estimate of insulin sensitivity were highly variable with relatively small deviations from no change. Patients who completed the study and thus received exposure to treatment for the full 8 weeks, as well as patients whose fasting status was confirmed, showed similar patterns of response (see Table 11.3.7.1.2.3.10 and Table 11.3.7.1.2.3.12, Section 11.3). Examination of data for quetiapine-treated and placebo-treated patients with diabetes or diabetes risk factors at baseline did not reveal systematic differences for $HOMA_R$ or QUICKI assessments (see Table 11.3.7.1.2.3.9 and Table 11.3.7.1.2.3.10, Section 11.3).

Quetiapine-treated patients exhibited a greater mean decrease in total thyroxine than did the placebo-treated patients. Mean change from baseline in TSH concentrations were slightly higher for the quetiapine treatment groups compared to placebo (Table 50).

8.5.2.2 Changes in individual patients over time in clinical chemistry

The number of patients within each treatment group with findings of categorical shifts to out-of-range chemistry abnormalities is summarized in Table 53. Complete shift analyses for chemistry parameters are presented in Table 11.3.7.1.2.3.1, Section 11.3 (see also Figure 11.3.7.1.2.4.1 through Figure 11.3.7.1.2.4.10, Section 11.3).

Table 53 Clinical chemistry shifts exceeding laboratory norms - incidence (safety population)

Parameter	Shift to low (%)			Shift to high (%)		
	Quetiapine 300 mg	Quetiapine 600 mg	Placebo	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
AST	0.0	0.0	0.0	7.9	13.4	6.3
ALT	0.0	0.0	0.7	10.4	13.2	6.0
Alkaline phosph.	0.0	0.0	0.0	1.7	5.7	1.5
Total bilirubin	0.0	0.0	0.0	1.8	0.0	0.8
Creatinine	0.0	0.0	0.0	1.6	0.0	0.0
Glucose	2.9	1.5	1.3	6.0	5.2	2.7
Insulin	1.6	2.3	2.0	8.1	12.9	4.1
Sodium	0.0	0.0	0.0	0.8	0.0	0.0
Potassium	0.0	0.0	0.7	0.8	0.0	2.1
Chloride	0.0	0.0	0.0	0.0	0.0	0.0
Bicarbonate	0.0	0.8	0.0	0.8	0.0	0.7
Triglycerides	0.0	1.6	3.5	9.4	8.6	5.0
Total cholesterol	2.5	4.5	1.5	3.6	5.2	2.4
HDL	7.9	4.0	3.0	4.3	0.8	2.3
LDL	2.8	6.2	3.8	2.8	8.1	2.3
TSH	0.8	0.8	1.4	2.4	3.9	2.2
Total T4	2.4	11.0	0.0	0.0	0.0	0.0

Incidences (%) of cases with out-of-normal range findings at final visit in the population of patients who did not have out-of-normal range findings at baseline are noted in each cell. Normal ranges are shown in Table 11.3.7.1.2.1, Section 11.3.
Data derived from Table 11.3.7.1.2.3.2, Section 11.3.

Patients treated with quetiapine 600 mg who had low or normal baseline liver function tests showed more shifts to out-of-range high results after treatment compared to placebo-treated patients. However, the incidence across AST, ALT and alkaline phosphatase shifts was fewer than 10 percentage points over placebo for either quetiapine group. Insulin showed a 4% to 13% incidence of shift to high concentrations for all 3 treatment groups with a greater incidence of shift in the quetiapine groups. Triglycerides, total cholesterol and LDL concentrations shifted to out-of-normal-range concentrations for quetiapine-treated patients with incidences that were approximately 1 to 6 percentage points higher compared to placebo-treated patients. HDL concentrations shifted to out-of-range lower concentrations for quetiapine-treated patients with incidences that were 1 to 5 percentage points higher compared to placebo-treated patients. In patients whose fasting was confirmed, shifts in clinical chemistry parameters, including glucose, insulin, triglycerides, and total cholesterol, were

generally similar with slightly reduced incidences of shifts (Table 11.3.7.1.2.3.6, Section 11.3).

8.5.2.3 Individual clinically important abnormalities in clinical chemistry

The number of patients within each treatment group with positive findings of categorical shifts to potentially clinically important clinical chemistry abnormalities are summarized in Table 54. Complete shift analyses for potentially clinically important chemistry results are presented in Table 11.3.7.1.2.3.3, Section 11.3 (see also Figure 11.3.7.1.2.4.1 through Figure 11.3.7.1.2.4.10, Section 11.3). Complete shift analyses for potentially clinically important chemistry results for confirmed fasting patients are also presented in Table 11.3.7.1.2.3.7, Section 11.3.

Table 54 Clinical chemistry shifts to clinically important values - incidence (safety population)

	Shift to low (%)			Shift to high (%)		
	Quetiapine 300 mg	Quetiapine 600 mg	Placebo	Quetiapine 300 mg	Quetiapine 600 mg	Placebo
AST	NA	NA	NA	0.8	0.8	0.0
ALT	NA	NA	NA	0.0	1.6	1.4
Alkaline phosphatase	NA	NA	NA	0.0	0.0	0.0
Total bilirubin	NA	NA	NA	0.9	0.0	0.0
Creatinine	NA	NA	NA	0.0	0.0	0.0
Glucose (fasting)	0.0	0.0	0.0	3.7	3.7	2.0
HbA1c	NA	NA	NA	0.8	0.0	0.7
Sodium	0.0	0.0	0.0	0.0	0.0	0.0
Potassium	0.0	0.0	0.0	0.8	0.0	2.1
Chloride	0.0	0.0	0.0	0.0	0.0	0.0
Bicarbonate	0.0	0.8	0.7	1.7	1.6	2.2
Triglycerides	NA	NA	NA	15.8	8.2	9.9
Total cholesterol	NA	NA	NA	11.5	7.9	5.9
HDL	11.9	13.4	13.8	0.0	0.0	0.0
LDL	NA	NA	NA	5.9	7.2	5.0
TSH	NA	NA	NA	2.4	3.9	2.2
Total T4	1.6	2.3	0.0	0.0	0.0	0.0

Incidences (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell. Clinically important criteria are shown in Table 15.
HbA1c Glycated hemoglobin; NA Not applicable.
Data derived from Table 11.3.7.1.2.3.4, Section 11.3.

Quetiapine 300 mg-treated patients showed a 5.9-percentage-point-higher incidence of clinically important elevated triglyceride concentration and a 5.6-percentage-point-higher incidence of clinically important elevated total cholesterol concentration than did placebo-treated patients. The incidence of clinically important low concentration of HDL was similar for quetiapine-treated patients compared to placebo-treated patients. In patients whose fasting status was confirmed, similar trends in shifts to clinically important values were observed including glucose, triglycerides, and total cholesterol (Table 11.3.7.1.2.3.8, Section 11.3).

A higher shift to out-of-range low T4 concentrations was seen with patients treated with quetiapine 600 mg compared to placebo. More quetiapine 600 mg-treated patients with normal baseline TSH concentrations showed a slightly higher shift to out-of-range high results after treatment compared to placebo-treated patients.

There were 2 cases of treatment-emergent hypothyroidism identified during the study based on clinically important high TSH values in combination with clinically important low T4 values with both cases in the quetiatpine 300 mg group. Two patients (Patients E0020044 and E0021022) had high TSH and low T4 shifts to potentially clinically important values at end of treatment (Week 8, Visit 10). However, 1 of these patients had a prior diagnosis of hypothyroidism (E0021022) and received concomitant levothyroxine sodium medication throughout the study. This patient had normal TSH and T4 values at baseline but developed an increase in TSH (11.53 mU/L) and a decrease in T4 (6.44 nmol/L) during the study (at Week 8). The other patient (E0020044) had normal values at baseline but developed an increase in TSH (6.31 mU/L) and a decreased T4 (6.44 nmol/L) at Week 8. However, these values had normalized at retesting 4 weeks after discontinuing study treatment (see Appendix 12.2.4.2 and Appendix 12.2.8.2.7). Neither of these patients experienced an AE of hypothyroidism.

In addition, there were 2 patients who had an AE of hypothyroidism reported during the study (Patient E0039010, quetiapine 300 mg; Patient E0042023, quetiapine 600 mg) (see Table 11.3.2.3, Section 11.3) although they did not have clinically important increases in TSH with clinically important decreases in T4. One of these 2 events was considered treatment-emergent (Patient E0042023, quetiapine 600 mg; see Appendix 12.2.7.2). This patient completed the study with an ongoing hypothyroidism of moderate intensity at study end. The patient had normal TSH and T4 values at baseline and a potentially clinically important TSH concentration (20.92 mU/L) and a lower than the lower limit of normal range value for T4 (7.72 nmol/L) at end of treatment (Visit 10). An AE of hypothyroidism was reported on Day 66 (Appendix 12.2.7.1) and the patient was subsequently given a concomitant medication (levothyroxine sodium). Upon retesting, the TSH concentration remained potentially clinically important but the T4 concentration was within the normal range (Appendix 12.2.8.2.7). This case was thought to be related to study drug (see Appendix 12.2.7.1). Patient E0039010 did not have a history of hypothyroidism but had a clinically important high value of TSH at baseline (6.30 mIU/L, retest: 5.49 mIU/L). An AE of hypothyroidism was reported on Day 37 (Appendix 12.7.1) and the patient was initiated on levothyroxine on Day 37 (Week 4: TSH 7.93 mU/L, T4 11.58 nmol/L).

8.5.2.4 Metabolic syndrome risk factors

Shifts in metabolic syndrome risk factors using criteria for fasting glucose elevations (see Table 15) are presented in Table 55. A summary of individual risk factors for shifting to meeting criteria for metabolic syndrome for patients who did not meet risk criteria at baseline is presented in Table 11.3.8.1.4.1, Section 11.3. Shifts in metabolic syndrome risk factors using criteria for fasting glucose elevations are presented in Table 11.3.8.1.4.2 through Table 11.3.8.1.4.4, Section 11.3 with proportions calculated as a percentage of all patients with baseline and post-baseline data.

Table 55 Metabolic syndrome risk factors, shift from baseline (safety population)

		Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
Factor	**Shift criteria**	**N at risk**	**n (%) shifting**	**N at risk**	**n (%) shifting**	**N at risk**	**N (%) shifting**
Metabolic syndrome risk (fasting glucose criterion)	≥3 risk factors	98	18 (18.4)	105	17 (16.2)	121	11 (9.1)

Note: Patients classified as "at risk" in each treatment group did not meet criteria for the specific risk factor at baseline. The proportion (%) who shifted to meeting 3 or more risk factors is computed from the "at risk" population within each treatment group.
Data derived from Table 11.3.8.1.4.2, Section 11.3.

Quetiapine-treated patients showed a 7- to 9-percentage-point-higher rate of shift than did placebo patients to meeting criteria for an aggregate of 3 metabolic syndrome risk factors. The most pronounced differential shifts to meeting criteria among quetiapine-treated patients compared to placebo-treated patients were observed for increases in triglycerides, while the least pronounced were for BMI (see Table 11.3.8.1.4.2, Section 11.3). Differential shifts to either increased HDL or fasting glucose were lower in the quetiapine treatment groups compared to the placebo group (see 11.3.8.1.4.5, Section 11.3). For those patients whose fasting was confirmed, quetiapine-treated patients showed an approximate 5 to 7 percentage point higher rate of shift than did placebo patients to meeting criteria for an aggregate of 3 metabolic syndrome risk factors (Table 11.3.8.1.4.5, Section 11.3).

The incidence of meeting aggregate metabolic syndrome risk factors after the criterion for triglyceride elevation has been removed is shown in Table 56.

Table 56 Metabolic syndrome risk factors without triglyceride criterion, shift from baseline (safety population)

Factor	Shift criteria	Quetiapine 300 mg (N=171)		Quetiapine 600 mg (N=168)		Placebo (N=167)	
		N at risk	n (%) shifting	N at risk	n (%) shifting	N at risk	N (%) shifting
Metabolic syndrome risk (fasting glucose criterion)	≥3 risk factors	114	4 (3.5)	122	13 (10.7)	141	7 (5.0)

Note: Patients classified as "at risk" in each treatment group did not meet criteria for the specific risk factor at baseline. The proportion (%) who shifted to meeting 3 or more risk factors is computed from the "at risk" population within each treatment group.
Data derived from Table 11.3.8.1.4.3, Section 11.3.

When the criteria for triglyceride elevation was excluded, patients treated with placebo showed a 2-percentage point higher rate of shift from baseline than did patients treated with quetiapine 300 mg to meeting criteria for an aggregate of 3 or more metabolic syndrome risk factors. Patients treated with quetiapine 600 mg showed a 6-percentage-point-higher rate of shift than did placebo-treated patients. Similarly, when triglyceride elevation data were excluded and fasting was confirmed, a 4-percentage point higher rate was seen in the quetiapine 600 mg treatment group compared to placebo (Table 11.3.8.1.4.6, Section 11.3).

8.5.3 Discussion of clinical laboratory results

In this study, the clinical laboratory results for patients treated with quetiapine were consistent with the clinical laboratory profile that has been well-characterized in previous studies in patients treated with quetiapine for other disorders.

Decreases in the concentrations of thyroxine without accompanying increases in TSH, and increases in transaminases were seen in this population. The increases in triglycerides seen in this study are previously observed effects of quetiapine, although the increase in triglycerides may have been somewhat exaggerated by possible non-fasting assessments for some patients. The distribution of blood sampling times-of-day suggests that many samples were likely drawn from non-fasting patients. The distributions of data for triglycerides, glucose and insulin were skewed and highly variable, with markedly higher concentrations detected for some patients but not for others. The variability and difference between mean and median for these assessments were somewhat reduced for patients who confirmed their fasting status at blood sampling, but showed the same trend for higher triglyceride and glucose concentrations for quetiapine-treated patients compared to placebo-treated patients. The skewed results may suggest that some patients are affected by quetiapine administration more than others but do not reveal the underlying etiology.

When shifts in metabolic syndrome risk factors were explored taking into account blood pressure, quetiapine-treated patients showed a higher proportion of patients shifting to meet

aggregate criteria for risk for metabolic syndrome. Such a shift is predictable, given the known effects of quetiapine on body weight and blood triglyceride concentrations. In this study, the mean BMI at baseline was close to the criterion value for metabolic syndrome. Triglycerides appeared to be the most common risk factor shifting in the quetiapine 300 mg group and, when triglycerides were excluded from the criteria, there were no differences to placebo in that group.

Shifts to the aggregate criteria for metabolic syndrome would suggest that decreases in insulin sensitivity might occur. The $HOMA_R$, an index of insulin resistance, was statistically significantly higher in the quetiapine 600 mg group at last visit compared to placebo. However, the reciprocal estimator of insulin sensitivity, QUICKI, was not statistically significantly different and did not confirm the $HOMA_R$ results. Eight weeks of treatment may be insufficient to understanding the long-term effects of quetiapine on glucose regulation.

Examination of clinical laboratory data for patients with pre-existing diabetes showed no clinically relevant findings to suggest that progression of diabetes had occurred. Examination of data for patients considered to be at-risk for diabetes showed no clinically relevant findings to suggest that diabetes was emergent in these patients. These data were in accord with the lack of adverse events that might suggest the development of diabetic symptoms. No differential effect for quetiapine compared to placebo was noted for glycated hemoglobin concentrations, suggesting that glycemic control was not impaired by quetiapine administration in this acute study.

Examination of hematology data revealed the development of neutropenia in 2 patients treated with quetiapine 300 mg and 1 patient treated with placebo. No patient developed agranulocytosis, and there were no adverse event reports of those conditions.

8.6 Vital signs, ECG, physical findings and other observations related to safety

Results for vital signs and ECG are grouped together. In the vital signs and ECG section, results are examined in 2 ways: trends or group changes over time and individual potentially clinically important abnormalities. The results for all vital signs, ECG and other physical findings are discussed collectively in Section 8.6.4.

8.6.1 Changes in vital signs and ECG over time

Changes in vital sign and ECG parameters from baseline to Day 57 (Week 8) are shown in Table 57. Tables 11.3.8.1.1.1 and 11.3.8.1.1.3, Section 11.3 include presentation of standing blood pressure and orthostatic changes.

Table 57 Vital signs and ECG parameters change from baseline (LOCF, safety population)

	Treatment								
	Quetiapine 300 mg (N=171)			Quetiapine 600 mg (N=168)			Placebo (N=167)		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Vital signs									
Supine pulse (bpm)	160	3.4	9.95	154	4.3	10.18	162	-0.2	9.65
Supine systolic BP (mmHg)	160	1.2	11.49	154	1.2	13.51	162	-0.3	11.19
Supine diastolic BP (mmHg)	160	1.9	9.40	154	2.6	10.08	162	1.2	9.31
ECG									
Heart rate (bpm)	125	4.21	11.38	128	7.91	13.21	140	3.28	12.07
PR interval (msec)	125	-0.26	13.62	124	-0.37	13.21	136	0.82	11.57
QRS interval (msec)	125	1.38	7.88	128	-2.01	8.20	140	-0.87	8.29
QT interval (msec)	125	-8.08	24.70	128	-14.38	30.48	140	-8.46	26.02
Fridericia corrected QTC interval (msec)	125	-0.26	17.65	128	-0.61	19.99	140	-2.45	16.09

Data derived from Table 11.3.8.1.1.3 and Table 11.3.8.1.2.1, Section 11.3.

There were no clinically relevant differences in mean changes from baseline to end of treatment in vital sign or ECG data between patients treated with quetiapine and placebo. Higher mean increases in supine pulse were observed in quetiapine-treated patients (3.4 bpm in the quetiapine 300 mg group and 4.3 bpm in the quetiapine 600 mg group) compared with placebo-treated patients (-0.2 bpm). Higher mean increases in heart rate were observed in quetiapine-treated patients (mean change: 4.2 bpm in the quetiapine 300 mg group, 7.9 bpm in the quetiapine 600 mg group) compared to the placebo group (3.3 bpm). There was no indication of an increase in the QTC interval in any treatment group.

8.6.2 Individual clinically important abnormalities in vital signs and ECG

Patients within each treatment group with positive findings of categorical shifts to clinically important vital sign abnormalities are summarized in Table 58. Complete shift analyses for clinically important vital sign results are presented in Table 11.3.8.1.1.4 and Table 11.3.8.1.1.5, Section 11.3 and for ECG results in Table 11.3.8.1.2.4 and Table 11.3.8.1.2.5, Section 11.3 (also see Figure 11.3.8.1.2.2 and Table 11.3.8.1.2.3, Section 11.3). A summary of clinically important of shifts in orthostatic changes is presented in Table 59.

Table 58 Vital signs and ECG shifts to potentially clinically important values - incidence (safety population)

Parameter	Shift to low			Shift to high		
	Quetiapine 300 mg %	Quetiapine 600 mg %	Placebo %	Quetiapine 300 mg %	Quetiapine 600 mg %	Placebo %
Vital signs						
Supine pulse	0	0	0.6	0	0	0
Supine systolic BP	0.6	0	0.6	0.6	0.6	0
Supine diastolic BP	0	0	0.6	0.6	2.0	0.6
ECG						
Heart rate	1.7	0	3.0	0	0	0
PR interval	NA	NA	NA	0.8	0	0
QRS interval	0	0	0	0	0.8	0.7
QT interval	0	0	0	0	0	0
Fridericia corrected QTC interval	NA	NA	NA	2.4	0.8	1.4

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell.
NA not applicable.
Data derived from Table 11.3.8.1.1.5 and Table 11.3.8.1.2.5, Section 11.3.

Table 59 Orthostatic change shifts to clinically important values - incidence (safety population)

Orthostatic change	Shift to positive findings		
	Quetiapine 300 mg %	Quetiapine 600 mg %	Placebo %
Pulse	4.0	2.0	3.9
Systolic BP	1.9	0.7	0.6
Diastolic BP	0.6	0.7	0
Combined pulse & SBP	0	0	0

Incidence (%) of cases with clinically important findings at final visit in the population of patients who did not exhibit clinically important findings at baseline are noted in each cell
BP Blood pressure; SBP Systolic blood pressure.
Data derived from Table 11.3.8.1.1.6, Section 11.3.

While an apparent dose-response for an increased pulse rate change upon standing with quetiapine administration was noted (see Table 11.3.8.1.1.3, Section 11.3), combined criteria for orthostatic changes did not show any differential effect of quetiapine administration compared to placebo.

Shifts in ECG assessments did not show any differential effect of quetiapine administration compared to placebo.

8.6.3 Physical findings and other observations related to safety

8.6.3.1 Physical examinations

Abnormal findings from physical examination, indicating a clinical change from baseline, were to be reported as adverse events.

8.6.3.2 Weight and BMI

At end of treatment, quetiapine 300 mg patients showed a mean gain of 1.4 kg of body weight, quetiapine 600 mg patients showed a mean gain of 1.3 kg, and placebo patients showed a mean gain of 0.3 kg (see Table 11.3.8.1.3.1.1, Section 11.3). Among patients who completed the protocol, quetiapine 300 mg patients showed a gain of 1.4 kg; quetiapine 600 mg patients showed a gain of 1.8 kg; and placebo patients, a gain of 0.4 kg (see Table 11.3.8.1.3.1.2, Section 11.3). Changes in body weight and BMI from baseline to final visit are shown in Table 60 for patients categorized by baseline BMI classification.

Table 60 Body weight (kg) and BMI (kg/m^2) change from baseline by BMI category (LOCF, safety population)

		Quetiapine 300 mg (N=171)			Quetiapine 600 mg (N=168)			Placebo (N=167)		
BMI category		**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**
≤18.49										
	Weight	0	NA	NA	3	1.0	1.00	1	-1.0	NA
	BMI	0	NA	NA	3	0.3	0.30	1	-0.4	NA
18.5 to 24.9										
	Weight	32	1.3	2.77	23	1.1	2.50	42	0.4	1.77
	BMI	32	0.5	0.98	23	0.4	0.91	42	0.2	0.65
25 to 29.9										
	Weight	35	1.3	2.39	41	1.6	3.99	46	-0.2	2.03
	BMI	35	0.5	0.84	41	0.5	1.38	46	-0.1	0.64
30 to 39.9										
	Weight	47	1.9	4.52	46	1.2	4.91	42	0.4	2.36
	BMI	47	0.7	1.58	46	0.4	1.83	42	0.1	0.82

Table 60 Body weight (kg) and BMI (kg/m^2) change from baseline by BMI category (LOCF, safety population)

BMI category		Quetiapine 300 mg (N=171) N	Mean	SD	Quetiapine 600 mg (N=168) N	Mean	SD	Placebo (N=167) N	Mean	SD
>40										
	Weight	14	-0.2	1.72	15	1.2	5.66	11	1.9	4.64
	BMI	14	-0.1	0.62	15	0.5	1.85	11	0.7	1.75

BMI Body mass index.
Data derived from Table 11.3.8.1.3.2, Section 11.3.

No consistent pattern of differential weight gain dependent upon baseline BMI was noted. At end of treatment, 4 (4.0%) quetiapine 300 mg patients, 10 (11.2%) quetiapine 600 mg patients, and 4 (3.7%) placebo patients showed a weight gain ≥7% (see Table 11.3.8.1.3.5, Section 11.3).

8.6.3.3 SAS

At the end of treatment, quetiapine 300 mg patients showed a mean SAS total score of 0.33 (SD=0.87), quetiapine 600 mg patients showed a mean total score of 0.49 (SD=1.67) and placebo patients, a mean score of 0.13 (SD=0.48). The 3 treatment groups were similar in mean change in the SAS total score at end of treatment (quetiapine 300 mg: 0.08 [SD=1.08]; quetiapine 600 mg: 0.19 [SD=1.58]; placebo: -0.28 [SD=1.05]; see Table 11.3.8.1.5.1, Section 11.3).

The distribution of patients whose SAS score improved, worsened or stayed the same by the end of treatment is shown in Table 61.

Table 61 SAS categorical change from baseline to end of treatment (LOCF, safety population)

	Quetiapine 300 mg (N=171) n	%	Quetiapine 600 mg (N=168) n	%	Placebo (N=167) n	%
Improved	17	13.1	13	10.0	28	19.6
No change	100	76.9	105	80.8	110	76.9
Worsened	13	10.0	12	9.2	5	3.5
Total	130	100.0	130	100.0	143	100.0

SAS Simpson-Angus Scale; LOCF last observation carried forward; N Number of patients in dose group. n Number of patients in analysis subset.
Data derived from Table 11.3.8.1.5.3, Section 11.3.

In each treatment group, most patients had no change. More patients had improved SAS scores by end of study treatment than had worsened SAS scores. There was a statistically significant difference between the quetiapine 300 mg treatment group and placebo in the number of patients showing increases (worsened) from baseline in SAS score (p=0.0.32). This difference approached statistical significance between the quetiapine 600 mg treatment group and placebo (p=0.054; see Table 11.3.8.1.5.2, Section 11.3).

8.6.3.4 BARS

At the end of treatment, quetiapine 300 mg patients showed a mean BARS Global Assessment score of 0.21 (SD=0.62), quetiapine 600 mg patients showed a mean score of 0.13 (SD=0.47) and placebo-treated patients, a mean score of 0.15 (SD=0.44). The 3 treatment groups were similar in mean change in the BARS Global Assessment score at the end of treatment (quetiapine 300 mg: 0.04 (SD=0.60); quetiapine 600 mg: -0.11 (SD=0.71); placebo: -0.11 (SD=0.61); see Table 11.3.8.1.6.1, Section 11.3).

The distribution of patients whose BARS score improved, worsened or stayed the same is shown in Table 62.

Table 62 BARS Global Assessment categorical change from baseline (LOCF, safety population)

	Quetiapine 300 (N= 171)		Quetiapine 600 (N = 168)		Placebo (N= 167)	
	n	%	n	%	n	%
Improved	7	5.4	20	15.5	23	16.1
No change	116	89.2	103	79.8	109	79.2
Worsened	7	5.4	6	4.7	11	7.7
Total	130	100.0	129	100.0	143	100.0

BARS Barnes Akathisia Rating Scale; N Number of patients in dose group; n Number of patients in analysis subset.
Data derived from Table 11.3.8.1.6.3, Section 11.3.

In each treatment group, most patients had no change. More patients treated with either quetiapine 600 mg or placebo had improved BARS scores by end of study treatment than worsened BARS scores, while the same number of patients treated with quetiapine 300 mg had improved or worsened BARS scores. There was no statistically significant difference between either quetiapine treatment group and placebo in the number of patients showing increases from baseline in BARS score (quetiapine 300 mg vs placebo: p=0.412; quetiapine 600 mg vs placebo: p=0.300; see Table 11.3.8.1.6.2, Section 11.3).

8.6.4 Discussion of vital signs, ECG, physical findings and other observations related to safety

The small increases in heart rate and body weight are consistent with known effects of quetiapine in other populations. Most patients within each treatment group did not experience any change in their SAS or BARS total scores. There was a statistically significant difference between quetiapine 300 mg and placebo treatment groups for patients with worsened SAS scores (with quetiapine 600 mg vs placebo approaching statistical significance). However, BARS assessments were not statistically significantly different for quetiapine-treated patients compared to placebo-treated patients.

8.7 Conclusions on safety results

Treatment of patients with a depressive episode in bipolar disorder with either quetiapine 300 mg or quetiapine 600 mg daily was generally safe and well tolerated. Most adverse events and clinical findings seen in these patients have been previously identified in patients treated with quetiapine for other disorders. Sedation was the adverse event most often associated with discontinuation in quetiapine-treated patients.

The linkage between these conclusions, the specific safety objectives of the study, and the study variables selected to address these objectives, is presented in Table 63.

Table 63 Safety objectives, variables and conclusions

Objective	Variables	Conclusions
Evaluate the safety and tolerability of quetiapine in the treatment of patients with bipolar depression	Incidence and severity of adverse events during double-blind treatment	The most common AEs associated with quetiapine administration were dry mouth, sedation, somnolence, and dizziness. Suicidality-associated adverse events occurred in 4 quetiapine treated patients and none in placebo-treated patients.
	Incidence of drug-related adverse events during double-blind treatment	AEs most often attributed to quetiapine administration were dry mouth, sedation, somnolence, dizziness, and constipation.
	Incidence rate of adverse events related to extrapyramidal symptoms during double-blind treatment.	The incidences of individual AEs possibly related to EPS were low in all treatment groups with the majority of these AEs reported as mild to moderate for all groups. An increase in the incidence in the composite of AEs related to EPS was noted for both groups of quetiapine-treated patients compared to the placebo group.
	Incidence of patient discontinuation due to adverse events	Sedation was the most common adverse event associated with discontinuation. Higher rates of discontinuation due to adverse events were associated with the quetiapine treatment groups compared to placebo.

Table 63 Safety objectives, variables and conclusions

Objective	Variables	Conclusions
	Clinical laboratory assessments change from baseline to Day 57 in the safety population	There were no clinically relevant hematology findings for quetiapine-treated patients in comparison with placebo-treated patients.
	Incidence of potentially clinically important changes in clinical laboratory assessments	Decreases in the concentrations of thyroxine without accompanying increases in TSH, and increases in transaminases were consistent with those seen in other patient populations. The incidence of shift from baseline to reference ranges identified for metabolic risk factors was higher for quetaipine-treated patients compared to placebo in triglycerides, BMI, and blood pressure while differential shifts to either increased HDL or fasting glucose were lower in the quetiapine treatment groups compared to the placebo group.
	Change in glucose and insulin data from baseline to Day 57 by diabetic risk groups in the safety population	There were no clinically relevant findings to suggest that progression of diabetes had occurred or, in patients considered to be at-risk for diabetes, that diabetes was emergent in these patients. No differential effect for quetiapine compared to placebo was seen for glycated hemoglobin concentrations.
	Change in weight and body mass index (BMI) from baseline to Day 57 in the safety population	Quetiapine-treated patients showed a slight increase in body weight consistent with findings in other patient populations.
	Vital signs from baseline to Day 57 in the safety population	Small mean increases in pulse and heart rate were observed in quetiapine patients.
	Incidence of clinically significant changes in vital signs	An apparent dose-response for an increased pulse rate change upon standing with quetiapine administration was noted, but combined criteria for orthostatic changes did not show any differential effect of quetiapine administration compared to placebo.
	Electrocardiogram (ECG)	There was no indication of an increase in the QT_C interval in any treatment group.
	Incidence of potentially clinically important changes in ECG	Shifts in ECG assessments did not show any differential effect of quetiapine administration compared to placebo.
	Change in the SAS total score from baseline to final assessment	In each treatment group, most patients had no change in SAS total score. More patients had improved SAS scores by end of study treatment than had worsened

Table 63 Safety objectives, variables and conclusions

Objective	Variables	Conclusions
		SAS scores.
	Change in BARS Global Assessment score from baseline to final assessment	Most patients within each treatment group did not experience any change in their BARS total scores. There was no statistically significant difference between either quetiapine treatment group and placebo in the number of patients showing increases from baseline in BARS score.
Evaluate the incidence of treatment-emergent mania compared to placebo by comparing the percentage of patients with a score of ≥16 points on the YMRS at 2 consecutive visits or at Week 8	Proportion of patients exhibiting a YMRS total score ≥16 on 2 consecutive assessments or at final assessment or having an AE report of treatment-emergent mania or hypomania.	Rates of treatment-emergent mania or hypomanic symptoms as measured by YMRS total score or an adverse event of mania were lower in quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment in patients with bipolar depression compared to placebo with a statistically significant difference favoring quetiapine 300 mg compared to placebo.
	Change from baseline to each assessment and to final assessment in the YMRS total score in the ITT population	Both quetiapine-treated groups showed greater improvement in mean change from baseline for YMRS scores compared to placebo at end of treatment.

9. DISCUSSION AND OVERALL CONCLUSIONS

9.1 Discussion

In total, 788 patients were screened and 509 patients with either bipolar I disorder or bipolar II disorder, with or without a rapid cycling course, exhibiting moderate to severe depression were randomly assigned to receive quetiapine 300 mg daily, quetiapine 600 mg daily or placebo. Of the 509 patients recruited, 506 received treatment and were included in the safety population, of whom 467 were analyzed for efficacy in an intention-to-treat analysis set and 422 in a per-protocol analysis set. The 3 treatment groups were well-matched in number and demographic and baseline disease characteristics and were representative of the general population of patients with bipolar disorder.

The study was well-conducted and high levels of compliance with study drug administration were inferred from tablet counts. Study completion rates were within the expected ranges for bipolar depression studies. Within the safety population, 59% of quetiapine 300 mg patients, 54% of quetiapine 600 mg patients and 66% of placebo patients completed the study. "Subject not willing to continue" and "patient lost to follow-up" were the main reasons for discontinuation in both quetiapine-treated and placebo-treated patients.

The primary objective for this study was to evaluate the efficacy of quetiapine compared to placebo in the treatment of a major depressive episode in patients with bipolar disorder for up to 8 weeks. The comparison of change from baseline in total MADRS score supported the hypothesis that quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment of a depressive episode in patients with bipolar disorder was superior to placebo in reducing the level of depressive symptoms. A small numerical advantage in treatment effect for MADRS change from baseline was seen for the quetiapine 300 mg group compared to the quetiapine 600 mg group. Treatment advantages for both quetiapine groups over placebo were statistically significant by Day 8 (Week 1) and continued to be so through Day 57 (Week 8). The superiority for both doses of quetiapine over placebo in MADRS total score was due to improvements across all 10 of the MADRS items, each evaluating different symptoms of depression.

The demonstration that quetiapine is superior to placebo in improving patients' overall quality of life was a secondary objective of special interest that was tested using the Q-LES-Q, subjected to a statistical gate-keeping strategy to guard against Type I error. The improvements in Q-LES-Q score from baseline values were superior for patients treated with quetiapine 300 mg daily compared to placebo-treated patients, indicating that quetiapine-treated patients judged that their quality of life had improved over placebo levels. In addition, patients receiving quetiapine 600 mg daily reported numerically greater improvements than placebo at 8 weeks.

Analysis of secondary outcome variables also supported the superiority of quetiapine over placebo in the treatment of depression in patients with bipolar disorder. This treatment advantage was apparent by Day 8 (Week 1) and continued through Day 57 (Week 8) for most of the secondary outcome variables. The proportion of patients showing ≥50% reduction in MADRS total score (responders) was statistically significantly higher for both the quetiapine 300 mg group and the quetiapine 600 mg group compared to the placebo group by Day 15, and continued through study completion for both quetiapine groups. Likewise, the proportion of patients showing a MADRS total score ≤12 (remitters) was statistically significantly higher for the quetiapine 300 mg group and the quetiapine 600 mg group compared to the placebo group by Day 15 and continued to end of treatment. The changes from baseline in HAM-D total score and CGI-S were statistically significantly greater for the quetiapine groups compared to the placebo groups by Day 8 (Week 1), with greater differential effect compared to placebo to Day 57 (Week 8). The changes from baseline in HAM-D Item 1 were statistically significantly greater for the quetiapine groups compared to the placebo groups by Day 22, and continued to be so at most assessments to the end of the study. The CGI-I comparisons of quetiapine groups to placebo were also statistically significant by Day 15 and continued to be significant through Day 57 (Week 8). The changes from baseline in HAM-A were superior for the quetiapine groups compared to the placebo groups by Day 8 (Week 1), and continued for up to 8 weeks of treatment. As with the MADRS change from baseline, secondary outcome variables exhibited a more pronounced numerical advantage for quetiapine 300 mg compared to quetiapine 600 mg for patients.

Bipolar I and bipolar II patients showed greater improvement in MADRS change from baseline with either dose of quetiapine than with placebo. The change from baseline in MADRS score was similar for bipolar I patients as for bipolar II patients, but the study was not designed for statistical comparison of bipolar I vs bipolar II subgroups or for either diagnostic subgroup vs placebo. In general, subgroups categorized by sex, race and age also showed a therapeutic advantage for quetiapine treatment compared to placebo.

The evaluation of the effect of quetiapine on anxiety in bipolar patients with depression was a secondary objective of the study. The comparison of change from baseline in total HAM-A score supported the hypothesis that quetiapine at a dose of either 300 mg daily or 600 mg daily for up to 8 weeks of treatment of a depressive episode in patients with bipolar disorder was superior to placebo in reducing the level of anxiety symptoms. Treatment advantages for both quetiapine groups over placebo were statistically significant by Day 8 (Week 1) and continued to be so through Day 57 (Week 8).

Demonstration that quetiapine is superior to placebo in improving patients' productive days at work as well as their family and social lives was a secondary objective of the study. Assessment of these outcomes using the SDS showed superiority for the overall rating only in the quetiapine 600 mg group. By Week 8, patients receiving quetiapine 300 mg or 600 mg reported significantly fewer unproductive days (>0.60 fewer unproductive days) than placebo.

The evaluation of the safety and tolerability of quetiapine in the treatment of bipolar patients with depression was a secondary objective of the study. Analysis of adverse events indicated that nervous system and gastrointestinal events predominated, with dry mouth, sedation, somnolence, dizziness and constipation occurring at higher rates with quetiapine treatment compared to placebo treatment. Most adverse events were mild to moderate. No deaths occurred during the study. Serious adverse events were reported for 3 quetiapine 300 mg patients, 7 quetiapine 600 mg patients and 1 placebo patient. Adverse events leading to discontinuation were more numerous for the quetiapine-treated groups than for the placebo-treated group and were highest in the quetiapine 600 mg group.

The evaluation of treatment-emergent mania/hypomania was a secondary objective of the study. Treatment-emergent mania was not associated with quetiapine treatment; there was a lower incidence in the quetiapine treatment groups compared to placebo with a significantly lower rate in the quetiapine 300 mg treatment group compared to placebo. Consistent with these findings, the decrease in YMRS scores at final assessment showed a statistically significant advantage for the quetiapine 300 mg treatment group compared to placebo.

Safety events of special interest included a composite of AEs related to EPS, QT prolongation, neutropenia/agranulocytosis; weight changes, metabolic syndrome, diabetes and suicidality.

Low rates of individual AEs related to EPS were observed across all 3 treatment groups with a lower incidence occurring in the placebo group. Most EPS-related events were mild to moderate and not-often associated with discontinuation and occurred within the first 8 days of study treatment. An increase in the incidence in the composite of AEs related to EPS was noted for both groups of quetiapine-treated patients compared to the placebo group.

There were no ECG reports of QT prolongation reported during the study. There were 3 patients (2 quetiapine 300 mg; 1 placebo) who experienced neutropenia based on hematology data while no patients developed agranulocytosis during the study. Findings in weight and triglycerides were consistent with the known safety profile for quetiapine. Increases in glucose serum concentration were observed but glycated hemoglobin concentrations remained stable for all treatment groups. Increases in triglycerides and glucose, while confounded by probable non-fasting assessments, were elevated and contributed to a higher estimate of shift to meeting criteria for an aggregate of 3 metabolic syndrome risk factors among quetiapine-treated patients.

Adverse events associated with suicidality were noted for 4 quetiapine-treated patients and for no placebo-treated patients. There was only 1 suicide attempt, which was not successful, after randomization.

Although fewer quetiapine-treated patients (54% to 59%) completed the study compared to placebo (66%), all efficacy outcome variables clearly demonstrated an advantage for quetiapine. A higher discontinuation rate due to lack of efficacy in the placebo group was balanced by more patients withdrawing due to AE with quetiapine treatment. Furthermore, there were somewhat more patients discontinuing due to administrative reasons in the quetiapine group compared to placebo. The improvement in the entire range of depression symptoms assessed by the MADRS, the HAM-D and the HAM-A demonstrated that the core mood disturbance, the somatic symptoms and anxiety overlays were addressed by the treatment with the net subjective effect being an improvement in quality of life. The alleviation of the full range of depression symptoms was apparent by Day 8 (Week 1) of the study – 7 days after the beginning of treatment, when both the quetiapine 300 mg and the quetiapine 600 mg groups demonstrated separation from placebo in most efficacy assessments.

Evaluation of safety and tolerability in this study revealed a safety profile for quetiapine in patients with bipolar depression that is generally consistent with that seen in previous studies of patients with schizophrenia or mania.

9.2 Overall conclusions

- Quetiapine, at doses of either 300 mg or 600 mg once daily, was superior to placebo in treating depression in patients with either bipolar I or bipolar II disorder.

- The antidepressant effect of quetiapine treatment was observed as early as 7 days following treatment initiation and was maintained throughout the 8-week treatment course in patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine, at doses of either 300 mg or 600 mg once daily, was superior to placebo in treating anxiety symptoms in patients with bipolar disorder who were experiencing a depressive episode.

- Quetiapine, at a dose of 300 mg once daily, was superior to placebo in improving the quality of life for patients with bipolar disorder who were experiencing a depressive episode. A numerically greater improvement in quality of life was also seen with quetiapine 600 mg compared to placebo.

- Quetiapine at a dose of 300 mg or 600 mg once daily showed numerically greater reduction compared to placebo in disability in the SDS total scale score, reaching statistical significance for the quetiapine 600 mg dose. Quetiapine at a dose of 300 mg daily or 600 mg daily was statistically superior to placebo in reducing the number of unproductive days, as measured by the SDS Days Unproductive scale.

- Quetiapine, at a dose of either 300 mg or 600 mg once daily, was generally safe and well-tolerated in patients with bipolar disorder who were experiencing a depressive episode. A higher rate of discontinuation due to AEs, most of which started within the first 7 days of study treatment, was seen with the quetiapine treatment groups compared to placebo. The most common adverse events associated with quetiapine treatment were dry mouth, somnolence, sedation, dizziness and constipation.

- Treatment emergent mania and hypomania were lower in incidence in the quetiapine treatment groups compared to placebo with a significantly lower rate in the quetiapine 300 mg treatment group compared to placebo.

10. REFERENCE LIST

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11. TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

11.1 Demographic, baseline, concomitant medication and other subject specific characteristics

11.2 Efficacy and pharmacokinetic data

11.3 Safety data

11.3.1 Exposure

11.3.2 All adverse events

11.3.8 Vital Signs, ECG, physical findings and other observations

Table 11.1.1.1 Disposition of Screened Patients

	N	%
TOTAL PATIENTS SCREENED	788	
PATIENTS RANDOMIZED	509	
SCREEN FAILURES	279	
--- ELIGIBILITY CRITERIA NOT FULFILLED	181	64.9
--- ADVERSE EVENT	6	2.2
--- SUBJECT NOT WILLING TO CONTINUE STUDY	45	16.1
--- SUBJECT LOST TO FOLLOW-UP	43	15.4
--- OTHER	4	1.4

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Table 11.1.1.2 Randomized Patients by Center

CENTER	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
TOTAL	172	33.8	169	33.2	168	33.0	509	100.0
1	1	11.1	4	44.4	4	44.4	9	1.8
3	3	60.0	1	20.0	1	20.0	5	1.0
4	7	30.4	8	34.8	8	34.8	23	4.5
6	3	21.4	4	28.6	7	50.0	14	2.8
7	3	100.0	0	0	0	0	3	0.6
8	5	41.7	1	8.3	6	50.0	12	2.4
10	6	46.2	3	23.1	4	30.8	13	2.6
11	10	52.6	5	26.3	4	21.1	19	3.7
12	4	30.8	5	38.5	4	30.8	13	2.6
13	4	36.4	3	27.3	4	36.4	11	2.2
14	6	40.0	4	26.7	5	33.3	15	2.9
15	7	43.8	7	43.8	2	12.5	16	3.1
16	1	100.0	0	0	0	0	1	0.2
18	0	0	0	0	1	100.0	1	0.2
19	4	80.0	1	20.0	0	0	5	1.0
20	9	27.3	9	27.3	15	45.5	33	6.5
21	10	47.6	6	28.6	5	23.8	21	4.1

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Table 11.1.1.2 Randomized Patients by Center

CENTER	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
22	0	0	5	71.4	2	28.6	7	1.4
24	2	40.0	0	0	3	60.0	5	1.0
25	12	26.1	21	45.7	13	28.3	46	9.0
26	4	25.0	4	25.0	8	50.0	16	3.1
27	1	9.1	5	45.5	5	45.5	11	2.2
28	3	20.0	9	60.0	3	20.0	15	2.9
29	4	44.4	2	22.2	3	33.3	9	1.8
30	6	23.1	10	38.5	10	38.5	26	5.1
31	1	100.0	0	0	0	0	1	0.2
32	4	40.0	3	30.0	3	30.0	10	2.0
33	8	47.1	1	5.9	8	47.1	17	3.3
34	5	38.5	4	30.8	4	30.8	13	2.6
35	3	30.0	4	40.0	3	30.0	10	2.0
36	2	40.0	3	60.0	0	0	5	1.0
37	9	39.1	9	39.1	5	21.7	23	4.5
38	0	0	2	40.0	3	60.0	5	1.0
39	6	42.9	4	28.6	4	28.6	14	2.8
40	8	50.0	2	12.5	6	37.5	16	3.1

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Table 11.1.1.2 Randomized Patients by Center

CENTER	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
41	3	30.0	2	20.0	5	50.0	10	2.0
42	4	25.0	8	50.0	4	25.0	16	3.1
43	1	50.0	1	50.0	0	0	2	0.4
44	2	40.0	2	40.0	1	20.0	5	1.0
45	0	0	1	100.0	0	0	1	0.2
46	1	8.3	6	50.0	5	41.7	12	2.4

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Table 11.1.1.3 Randomized Patients by Center and Bipolar Diagnosis

CENTER	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TOTAL	113	33.4	112	33.1	113	33.4	59	34.5	57	33.3	55	32.2	338	100.0	171	100.0
1	1	14.3	4	57.1	2	28.6	0	0	0	0	2	100.0	7	2.1	2	1.2
3	2	50.0	1	25.0	1	25.0	1	100.0	0	0	0	0	4	1.2	1	0.6
4	4	30.8	4	30.8	5	38.5	3	30.0	4	40.0	3	30.0	13	3.8	10	5.8
6	2	18.2	4	36.4	5	45.5	1	33.3	0	0	2	66.7	11	3.3	3	1.8
7	2	100.0	0	0	0	0	1	100.0	0	0	0	0	2	0.6	1	0.6
8	3	37.5	1	12.5	4	50.0	2	50.0	0	0	2	50.0	8	2.4	4	2.3
10	2	50.0	1	25.0	1	25.0	4	44.4	2	22.2	3	33.3	4	1.2	9	5.3
11	3	60.0	1	20.0	1	20.0	7	50.0	4	28.6	3	21.4	5	1.5	14	8.2
12	4	44.4	2	22.2	3	33.3	0	0	3	75.0	1	25.0	9	2.7	4	2.3
13	2	28.6	3	42.9	2	28.6	2	50.0	0	0	2	50.0	7	2.1	4	2.3
14	3	33.3	3	33.3	3	33.3	3	50.0	1	16.7	2	33.3	9	2.7	6	3.5
15	7	43.8	7	43.8	2	12.5	0	0	0	0	0	0	16	4.7	0	0
16	1	100.0	0	0	0	0	0	0	0	0	0	0	1	0.3	0	0
18	0	0	0	0	1	100.0	0	0	0	0	0	0	1	0.3	0	0
19	2	100.0	0	0	0	0	2	66.7	1	33.3	0	0	2	0.6	3	1.8
20	5	26.3	7	36.8	7	36.8	4	28.6	2	14.3	8	57.1	19	5.6	14	8.2
21	9	47.4	6	31.6	4	21.1	1	50.0	0	0	1	50.0	19	5.6	2	1.2

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Table 11.1.1.3 Randomized Patients by Center and Bipolar Diagnosis

CENTER	TREATMENT																	
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
22	0	0	3	60.0	2	40.0	0	0	2	100.0	0	0	5	1.5	2	1.2
24	2	40.0	0	0	3	60.0	0	0	0	0	0	0	5	1.5	0	0
25	4	20.0	9	45.0	7	35.0	8	30.8	12	46.2	6	23.1	20	5.9	26	15.2
26	1	14.3	2	28.6	4	57.1	3	33.3	2	22.2	4	44.4	7	2.1	9	5.3
27	1	10.0	5	50.0	4	40.0	0	0	0	0	1	100.0	10	3.0	1	0.6
28	3	21.4	9	64.3	2	14.3	0	0	0	0	1	100.0	14	4.1	1	0.6
29	3	42.9	1	14.3	3	42.9	1	50.0	1	50.0	0	0	7	2.1	2	1.2
30	4	25.0	6	37.5	6	37.5	2	20.0	4	40.0	4	40.0	16	4.7	10	5.8
31	0	0	0	0	0	0	1	100.0	0	0	0	0	0	0	1	0.6
32	4	40.0	3	30.0	3	30.0	0	0	0	0	0	0	10	3.0	0	0
33	8	47.1	1	5.9	8	47.1	0	0	0	0	0	0	17	5.0	0	0
34	2	22.2	3	33.3	4	44.4	3	75.0	1	25.0	0	0	9	2.7	4	2.3
35	1	16.7	2	33.3	3	50.0	2	50.0	2	50.0	0	0	6	1.8	4	2.3
36	1	100.0	0	0	0	0	1	25.0	3	75.0	0	0	1	0.3	4	2.3
37	5	55.6	2	22.2	2	22.2	4	28.6	7	50.0	3	21.4	9	2.7	14	8.2
38	0	0	1	50.0	1	50.0	0	0	1	33.3	2	66.7	2	0.6	3	1.8
39	5	41.7	4	33.3	3	25.0	1	50.0	0	0	1	50.0	12	3.6	2	1.2
40	7	46.7	2	13.3	6	40.0	1	100.0	0	0	0	0	15	4.4	1	0.6

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Table 11.1.1.3 Randomized Patients by Center and Bipolar Diagnosis

CENTER	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
41	3	37.5	2	25.0	3	37.5	0	0	0	0	2	100.0	8	2.4	2	1.2
42	3	25.0	7	58.3	2	16.7	1	25.0	1	25.0	2	50.0	12	3.6	4	2.3
43	1	100.0	0	0	0	0	0	0	1	100.0	0	0	1	0.3	1	0.6
44	2	40.0	2	40.0	1	20.0	0	0	0	0	0	0	5	1.5	0	0
45	0	0	1	100.0	0	0	0	0	0	0	0	0	1	0.3	0	0
46	1	11.1	3	33.3	5	55.6	0	0	3	100.0	0	0	9	2.7	3	1.8

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Table 11.1.2.1 Patient Population Summary

POPULATION	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
RANDOMIZED	172	100.0	169	100.0	168	100.0	509	100.0
--- RANDOMIZED NO DOSE	1	0.6	1	0.6	1	0.6	3	0.6
--- SAFETY	171	99.4	168	99.4	167	99.4	506	99.4
--- INTENT-TO-TREAT	155	90.1	151	89.3	161	95.8	467	91.7
--- PER-PROTOCOL	139	80.8	133	78.7	150	89.3	422	82.9

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Table 11.1.2.2 Patient Population Summary by Bipolar Diagnosis

POPULATION	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RANDOMIZED	113	100.0	112	100.0	113	100.0	59	100.0	57	100.0	55	100.0	338	100.0	171	100.0
--- RANDOMIZED NO DOSE	1	0.9	0	0.0	1	0.9	0	0.0	1	1.8	0	0.0	2	0.6	1	0.6
--- SAFETY	112	99.1	112	100.0	112	99.1	59	100.0	56	98.2	55	100.0	336	99.4	170	99.4
--- INTENT-TO-TREAT	104	92.0	101	90.2	110	97.3	51	86.4	50	87.7	51	92.7	315	93.2	152	88.9
--- PER-PROTOCOL	96	85.0	93	83.0	103	91.2	43	72.9	40	70.2	47	85.5	292	86.4	130	76.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM204.SAS
GENERATED: 02NOV2005 15:22:23 iceadmn3

Table 11.1.3.1 Missing Data Leading to Exclusion from The Intent-to-Treat Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=171		N=168		N=167			
	N	%	N	%	N	%	N	%
PROTOCOL VIOLATORS AND DEVIATORS *	16	9.4	17	10.1	6	3.6	39	7.7
--- NO BASELINE OR POST-BASELINE MADRS ASSESSMENT	16	9.4	17	10.1	6	3.6	39	7.7

*Patients in this category may have multiple reasons listed below.
Note: Percentage is the proportion of the safety population.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIODV200.SAS
GENERATED: 02NOV2005 15:27:30 iceadmn3

Table 11.1.3.2 Protocol Violations and Deviations Leading to Exclusion from The Per-Protocol Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=155		N=151		N=161			
	N	%	N	%	N	%	N	%
PROTOCOL VIOLATORS AND DEVIATORS *	16	10.3	18	11.9	11	6.8	45	9.6
I01: NO DOCUMENTED ABILITY TO PROVIDE INFORMED CONSENT PRIOR TO START OF STUDY	0	0.0	0	0.0	0	0.0	0	0.0
I04: DOES NOT MEET DSM_IV CRITERIA FOR BIPOLAR DISORDER I OR II	0	0.0	0	0.0	0	0.0	0	0.0
I06: HAM-D (17-ITEM) TOTAL SCORE <20 AT SCREEN OR BASELINE VISIT	0	0.0	0	0.0	3	1.9	3	0.6
I07: HAM-D ITEM 1 (DEPRESSED MOOD) SCORE <2 AT SCREEN OR BASELINE VISIT	0	0.0	0	0.0	0	0.0	0	0.0
I08: YMRS TOTAL SCORE >12 AT SCREEN OR BASELINE VISIT	0	0.0	0	0.0	0	0.0	0	0.0
E01: CYCLED INTO MANIC OR HYPOMANIC EPISODE BETWEEN VISIT 1 AND VISIT 2	0	0.0	0	0.0	0	0.0	0	0.0
E02: >8 MOOD EPISODES IN THE PAST YEAR	2	1.3	0	0.0	1	0.6	3	0.6
E03: AXIS 1 DISORDER OTHER THAN BIPOLAR DISORDER WITHIN 6 MONTHS OF SCREEN	0	0.0	0	0.0	0	0.0	0	0.0
E04: DEPRESSION EPISODE >12 MONTHS OR <4 WEEKS	0	0.0	0	0.0	0	0.0	0	0.0
E05: HISTORY OF NON-RESPONSE TO AN ADEQUATE STUDY OF >2 CLASSES OF ANTIDEPRESSANTS	0	0.0	0	0.0	0	0.0	0	0.0
E06: HISTORY OF SUBSTANCE DEPENDENCE	3	1.9	3	2.0	2	1.2	8	1.7
E07: USE OF POTENT P450 INHIBITORS AND INDUCERS PRIOR TO RANDOMIZATION	0	0.0	0	0.0	0	0.0	0	0.0

(Continued)

*Patient in this category may have multiple reasons listed below.
Note: Percentage is the proportion of the intent-to-treat population.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIODV201.SAS
GENERATED: 02NOV2005 15:27:33 iceadmn3

Table 11.1.3.2 Protocol Violations and Deviations Leading to Exclusion from The Per-Protocol Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=155		N=151		N=161			
	N	%	N	%	N	%	N	%
E08: USE OF PSYCHOACTIVE MEDS WITHIN 7-28 DAYS PRIOR TO RANDOMIZATION	0	0.0	0	0.0	0	0.0	0	0.0
E09: REQUIRE INITIATION OF PSYCHOTHERAPY DURING STUDY OR ONGOING THERAPY <3 MONTHS AT SCREEN	0	0.0	0	0.0	0	0.0	0	0.0
E26: PREVIOUS PARTICIPATION IN STUDY 5077US/0049	0	0.0	0	0.0	0	0.0	0	0.0
D01: ZOLPIDEM USE FOR INSOMNIA AFTER WEEK 3	0	0.0	0	0.0	0	0.0	0	0.0
D03: LORAZEPAM USE FOR SEVERE ANXIETY AFTER WEEK 3	0	0.0	1	0.7	1	0.6	2	0.4
D04: POTENT P450 INDUCER USE	0	0.0	1	0.7	0	0.0	1	0.2
D05: POTENT P450 INHIBITOR USE	1	0.6	1	0.7	0	0.0	2	0.4
D06: ANTIPSYCHOTIC USE DURING STUDY	0	0.0	1	0.7	0	0.0	1	0.2
D07: ANTIDEPRESSANTS, HYPNOTICS, MOOD STABILIZERS DURING STUDY	2	1.3	4	2.6	0	0.0	6	1.3
D10: SUBJECTS WHO RECEIVE LESS THAN 70% OF PRESCRIBED DOSES	2	1.3	4	2.6	0	0.0	6	1.3
D11: NO BASELINE MADRS ASSESSMENT	0	0.0	0	0.0	0	0.0	0	0.0
D12: SUBJECTS WHO RECEIVE <=8 DAYS OF STUDY THERAPY	10	6.5	12	7.9	6	3.7	28	6.0
D17: MADRS ASSESSMENT COLLECTED >4 DAYS AFTER LAST DOSE OF STUDY MEDICATION	0	0.0	5	3.3	0	0.0	5	1.1
D18: DOCUMENTED DRUG ABUSE DURING STUDY	0	0.0	0	0.0	0	0.0	0	0.0
D20: NO POST-BASELINE ASSESSMENT AFTER DATA EXCLUSIONS	0	0.0	2	1.3	0	0.0	2	0.4

*Patient in this category may have multiple reasons listed below.
Note: Percentage is the proportion of the intent-to-treat population.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIODV201.SAS
GENERATED: 02NOV2005 15:27:33 iceadmn3

Table 11.1.4.1 Withdrawals and Reason For Withdrawal

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
TOTAL NUMBER OF RANDOMIZED PATIENTS	172	100.0	169	100.0	168	100.0	509	100.0
COMPLETED PROTOCOL	101	58.7	90	53.3	110	65.5	301	59.1
WITHDRAWALS	71	41.3	79	46.7	58	34.5	208	40.9
--- ELIGIBILITY CRITERIA NOT FULFILLED	0	0.0	0	0.0	2	1.2	2	0.4
--- ADVERSE EVENT	14	8.1	19	11.2	2	1.2	35	6.9
--- LACK OF THERAPEUTIC RESPONSE	3	1.7	5	3.0	13	7.7	21	4.1
--- DEVELOPMENT STUDY SPEC DISC CRITERIA	7	4.1	6	3.6	8	4.8	21	4.1
--- SUBJECT NOT WILLING TO CONTINUE	26	15.1	30	17.8	19	11.3	75	14.7
--- SUBJECT LOST TO FOLLOW-UP	21	12.2	19	11.2	14	8.3	54	10.6
--- OTHER	0	0.0	0	0.0	0	0.0	0	0.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM205.SAS
GENERATED: 02NOV2005 15:22:25 iceadmn3

Table 11.1.4.2 Withdrawals and Reason For Withdrawal by Bipolar Diagnosis

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL-BPI		TOTAL-BPII	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TOTAL NUMBER OF RANDOMIZED PATIENTS	113	100.0	112	100.0	113	100.0	59	100.0	57	100.0	55	100.0	338	100.0	171	100.0
COMPLETED PROTOCOL	64	56.6	60	53.6	73	64.6	37	62.7	30	52.6	37	67.3	197	58.3	104	60.8
WITHDRAWALS	49	43.4	52	46.4	40	35.4	22	37.3	27	47.4	18	32.7	141	41.7	67	39.2
--- ELIGIBILITY CRITERIA NOT FULFILLED	0	0.0	0	0.0	2	1.8	0	0.0	0	0.0	0	0.0	2	0.6	0	0.0
--- ADVERSE EVENT	8	7.1	11	9.8	2	1.8	6	10.2	8	14.0	0	0.0	21	6.2	14	8.2
--- LACK OF THERAPEUTIC RESPONSE	3	2.7	4	3.6	9	8.0	0	0.0	1	1.8	4	7.3	16	4.7	5	2.9
--- DEVELOPMENT STUDY SPEC DISC CRITERIA	4	3.5	4	3.6	8	7.1	3	5.1	2	3.5	0	0.0	16	4.7	5	2.9
--- SUBJECT NOT WILLING TO CONTINUE	17	15.0	21	18.8	13	11.5	9	15.3	9	15.8	6	10.9	51	15.1	24	14.0
--- SUBJECT LOST TO FOLLOW-UP	17	15.0	12	10.7	6	5.3	4	6.8	7	12.3	8	14.5	35	10.4	19	11.1
--- OTHER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM206.SAS
GENERATED: 02NOV2005 15:22:27 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=171		N=168		N=167		N=506	
	N	%	N	%	N	%	N	%
STUDY DAY								
1	171	100.0	168	100.0	167	100.0	506	100.0
2	171	100.0	168	100.0	167	100.0	506	100.0
3	171	100.0	168	100.0	167	100.0	506	100.0
4	170	99.4	168	100.0	167	100.0	505	99.8
5	170	99.4	167	99.4	167	100.0	504	99.6
6	170	99.4	167	99.4	166	99.4	503	99.4
7	169	98.8	167	99.4	166	99.4	502	99.2
8	166	97.1	165	98.2	165	98.8	496	98.0
9	160	93.6	157	93.5	158	94.6	475	93.9
10	157	91.8	148	88.1	157	94.0	462	91.3
11	156	91.2	147	87.5	157	94.0	460	90.9
12	156	91.2	147	87.5	157	94.0	460	90.9
13	156	91.2	146	86.9	157	94.0	459	90.7
14	156	91.2	144	85.7	157	94.0	457	90.3
15	155	90.6	142	84.5	156	93.4	453	89.5

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM207.SAS
GENERATED: 02NOV2005 15:22:29 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=171		N=168		N=167		N=506	
	N	%	N	%	N	%	N	%
STUDY DAY								
16	152	88.9	139	82.7	154	92.2	445	87.9
17	149	87.1	135	80.4	152	91.0	436	86.2
18	147	86.0	133	79.2	152	91.0	432	85.4
19	146	85.4	131	78.0	152	91.0	429	84.8
20	145	84.8	130	77.4	152	91.0	427	84.4
21	143	83.6	130	77.4	152	91.0	425	84.0
22	141	82.5	129	76.8	152	91.0	422	83.4
23	140	81.9	128	76.2	148	88.6	416	82.2
24	139	81.3	127	75.6	146	87.4	412	81.4
25	136	79.5	126	75.0	146	87.4	408	80.6
26	135	78.9	126	75.0	146	87.4	407	80.4
27	135	78.9	126	75.0	146	87.4	407	80.4
28	133	77.8	124	73.8	146	87.4	403	79.6
29	133	77.8	124	73.8	143	85.6	400	79.1
30	131	76.6	122	72.6	140	83.8	393	77.7

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM207.SAS
GENERATED: 02NOV2005 15:22:29 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=171		N=168		N=167		N=506	
	N	%	N	%	N	%	N	%
STUDY DAY								
31	126	73.7	118	70.2	138	82.6	382	75.5
32	125	73.1	118	70.2	138	82.6	381	75.3
33	125	73.1	117	69.6	137	82.0	379	74.9
34	124	72.5	116	69.0	137	82.0	377	74.5
35	124	72.5	115	68.5	137	82.0	376	74.3
36	124	72.5	115	68.5	136	81.4	375	74.1
37	122	71.3	111	66.1	130	77.8	363	71.7
38	121	70.8	110	65.5	128	76.6	359	70.9
39	119	69.6	110	65.5	128	76.6	357	70.6
40	119	69.6	110	65.5	127	76.0	356	70.4
41	119	69.6	110	65.5	127	76.0	356	70.4
42	118	69.0	109	64.9	127	76.0	354	70.0
43	118	69.0	108	64.3	125	74.9	351	69.4
44	118	69.0	106	63.1	125	74.9	349	69.0
45	115	67.3	104	61.9	123	73.7	342	67.6

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM207.SAS
GENERATED: 02NOV2005 15:22:29 iceadmn3

Table 11.1.4.3 Patient Participation by Day
Safety Population

	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N=171		N=168		N=167		N=506	
	N	%	N	%	N	%	N	%
STUDY DAY								
46	115	67.3	103	61.3	122	73.1	340	67.2
47	115	67.3	102	60.7	122	73.1	339	67.0
48	115	67.3	100	59.5	120	71.9	335	66.2
49	115	67.3	99	58.9	120	71.9	334	66.0
50	115	67.3	99	58.9	119	71.3	333	65.8
51	114	66.7	99	58.9	119	71.3	332	65.6
52	113	66.1	99	58.9	117	70.1	329	65.0
53	112	65.5	99	58.9	117	70.1	328	64.8
54	111	64.9	98	58.3	117	70.1	326	64.4
55	111	64.9	97	57.7	116	69.5	324	64.0
56	107	62.6	94	56.0	113	67.7	314	62.1
57	99	57.9	82	48.8	96	57.5	277	54.7
58+	58	33.9	54	32.1	50	29.9	162	32.0

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM207.SAS
GENERATED: 02NOV2005 15:22:29 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=112		N=112		N=112		N=59		N=56		N=55		N=336		N=170	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
1	112	100.0	112	100.0	112	100.0	59	100.0	56	100.0	55	100.0	336	100.0	170	100.0
2	112	100.0	112	100.0	112	100.0	59	100.0	56	100.0	55	100.0	336	100.0	170	100.0
3	112	100.0	112	100.0	112	100.0	59	100.0	56	100.0	55	100.0	336	100.0	170	100.0
4	111	99.1	112	100.0	112	100.0	59	100.0	56	100.0	55	100.0	335	99.7	170	100.0
5	111	99.1	112	100.0	112	100.0	59	100.0	55	98.2	55	100.0	335	99.7	169	99.4
6	111	99.1	112	100.0	111	99.1	59	100.0	55	98.2	55	100.0	334	99.4	169	99.4
7	110	98.2	112	100.0	111	99.1	59	100.0	55	98.2	55	100.0	333	99.1	169	99.4
8	109	97.3	110	98.2	110	98.2	57	96.6	55	98.2	55	100.0	329	97.9	167	98.2
9	106	94.6	105	93.8	106	94.6	54	91.5	52	92.9	52	94.5	317	94.3	158	92.9
10	105	93.8	101	90.2	106	94.6	52	88.1	47	83.9	51	92.7	312	92.9	150	88.2
11	104	92.9	101	90.2	106	94.6	52	88.1	46	82.1	51	92.7	311	92.6	149	87.6
12	104	92.9	101	90.2	106	94.6	52	88.1	46	82.1	51	92.7	311	92.6	149	87.6
13	104	92.9	101	90.2	106	94.6	52	88.1	45	80.4	51	92.7	311	92.6	148	87.1
14	104	92.9	99	88.4	106	94.6	52	88.1	45	80.4	51	92.7	309	92.0	148	87.1
15	104	92.9	98	87.5	105	93.8	51	86.4	44	78.6	51	92.7	307	91.4	146	85.9

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM208.SAS
GENERATED: 02NOV2005 15:22:33 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=112		N=112		N=112		N=59		N=56		N=55		N=336		N=170	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
16	102	91.1	96	85.7	104	92.9	50	84.7	43	76.8	50	90.9	302	89.9	143	84.1
17	99	88.4	93	83.0	102	91.1	50	84.7	42	75.0	50	90.9	294	87.5	142	83.5
18	99	88.4	91	81.3	102	91.1	48	81.4	42	75.0	50	90.9	292	86.9	140	82.4
19	98	87.5	89	79.5	102	91.1	48	81.4	42	75.0	50	90.9	289	86.0	140	82.4
20	97	86.6	89	79.5	102	91.1	48	81.4	41	73.2	50	90.9	288	85.7	139	81.8
21	95	84.8	89	79.5	102	91.1	48	81.4	41	73.2	50	90.9	286	85.1	139	81.8
22	94	83.9	89	79.5	102	91.1	47	79.7	40	71.4	50	90.9	285	84.8	137	80.6
23	93	83.0	88	78.6	98	87.5	47	79.7	40	71.4	50	90.9	279	83.0	137	80.6
24	92	82.1	88	78.6	97	86.6	47	79.7	39	69.6	49	89.1	277	82.4	135	79.4
25	91	81.3	87	77.7	97	86.6	45	76.3	39	69.6	49	89.1	275	81.8	133	78.2
26	91	81.3	87	77.7	97	86.6	44	74.6	39	69.6	49	89.1	275	81.8	132	77.6
27	91	81.3	87	77.7	97	86.6	44	74.6	39	69.6	49	89.1	275	81.8	132	77.6
28	89	79.5	85	75.9	97	86.6	44	74.6	39	69.6	49	89.1	271	80.7	132	77.6
29	89	79.5	85	75.9	95	84.8	44	74.6	39	69.6	48	87.3	269	80.1	131	77.1
30	87	77.7	84	75.0	93	83.0	44	74.6	38	67.9	47	85.5	264	78.6	129	75.9

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM208.SAS
GENERATED: 02NOV2005 15:22:33 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=112		N=112		N=112		N=59		N=56		N=55		N=336		N=170	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
31	83	74.1	80	71.4	92	82.1	43	72.9	38	67.9	46	83.6	255	75.9	127	74.7
32	82	73.2	80	71.4	92	82.1	43	72.9	38	67.9	46	83.6	254	75.6	127	74.7
33	82	73.2	79	70.5	92	82.1	43	72.9	38	67.9	45	81.8	253	75.3	126	74.1
34	81	72.3	78	69.6	92	82.1	43	72.9	38	67.9	45	81.8	251	74.7	126	74.1
35	81	72.3	77	68.8	92	82.1	43	72.9	38	67.9	45	81.8	250	74.4	126	74.1
36	81	72.3	77	68.8	91	81.3	43	72.9	38	67.9	45	81.8	249	74.1	126	74.1
37	79	70.5	73	65.2	87	77.7	43	72.9	38	67.9	43	78.2	239	71.1	124	72.9
38	78	69.6	72	64.3	85	75.9	43	72.9	38	67.9	43	78.2	235	69.9	124	72.9
39	76	67.9	72	64.3	85	75.9	43	72.9	38	67.9	43	78.2	233	69.3	124	72.9
40	76	67.9	72	64.3	84	75.0	43	72.9	38	67.9	43	78.2	232	69.0	124	72.9
41	76	67.9	72	64.3	84	75.0	43	72.9	38	67.9	43	78.2	232	69.0	124	72.9
42	75	67.0	72	64.3	84	75.0	43	72.9	37	66.1	43	78.2	231	68.8	123	72.4
43	75	67.0	71	63.4	82	73.2	43	72.9	37	66.1	43	78.2	228	67.9	123	72.4
44	75	67.0	70	62.5	82	73.2	43	72.9	36	64.3	43	78.2	227	67.6	122	71.8
45	72	64.3	69	61.6	81	72.3	43	72.9	35	62.5	42	76.4	222	66.1	120	70.6

(Continued)

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM208.SAS
GENERATED: 02NOV2005 15:22:33 iceadmn3

Table 11.1.4.4 Patient Participation by Day and Bipolar Diagnosis
Safety Population

	TREATMENT															
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII		TOTAL BPI		TOTAL BPII	
	N=112		N=112		N=112		N=59		N=56		N=55		N=336		N=170	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY																
46	72	64.3	68	60.7	80	71.4	43	72.9	35	62.5	42	76.4	220	65.5	120	70.6
47	72	64.3	68	60.7	80	71.4	43	72.9	34	60.7	42	76.4	220	65.5	119	70.0
48	72	64.3	67	59.8	79	70.5	43	72.9	33	58.9	41	74.5	218	64.9	117	68.8
49	72	64.3	66	58.9	79	70.5	43	72.9	33	58.9	41	74.5	217	64.6	117	68.8
50	72	64.3	66	58.9	78	69.6	43	72.9	33	58.9	41	74.5	216	64.3	117	68.8
51	71	63.4	66	58.9	78	69.6	43	72.9	33	58.9	41	74.5	215	64.0	117	68.8
52	70	62.5	66	58.9	76	67.9	43	72.9	33	58.9	41	74.5	212	63.1	117	68.8
53	70	62.5	66	58.9	76	67.9	42	71.2	33	58.9	41	74.5	212	63.1	116	68.2
54	69	61.6	65	58.0	76	67.9	42	71.2	33	58.9	41	74.5	210	62.5	116	68.2
55	69	61.6	64	57.1	76	67.9	42	71.2	33	58.9	40	72.7	209	62.2	115	67.6
56	66	58.9	64	57.1	75	67.0	41	69.5	30	53.6	38	69.1	205	61.0	109	64.1
57	62	55.4	58	51.8	65	58.0	37	62.7	24	42.9	31	56.4	185	55.1	92	54.1
58+	42	37.5	38	33.9	35	31.3	16	27.1	16	28.6	15	27.3	115	34.2	47	27.6

Note: Days calculated as date of withdrawal minus date of first study dose plus one.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM208.SAS
GENERATED: 02NOV2005 15:22:33 iceadmn3

Table 11.1.4.5 Withdrawal Analysis (CMH)
Safety Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
EVENT	STRATA													
STUDY COMPLETION	BIPOLAR I	64	112	57.1	60	112	53.6	73	112	65.2	.	.	.	.
	BIPOLAR II	37	59	62.7	30	56	53.6	37	55	67.3	.	.	.	.
	ALL	101	171	59.1	90	168	53.6	110	167	65.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.194	0.90	0.76	1.06
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.022	0.81	0.68	0.97

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM209.SAS
GENERATED: 06NOV2005 23:20:16 iceadmn3

Table 11.1.5.1.1 Age, Weight, and BMI at Study Entry by Sex - Descriptive Statistics
Safety Population

		TREATMENT									TOTAL		
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO					
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
AGE (YEARS)	N	75	96	171	73	95	168	67	100	167	215	291	506
	MEAN	36.09	37.78	37.04	38.66	37.71	38.12	38.79	36.92	37.67	37.80	37.46	37.61
	SD	10.56	10.53	10.55	11.36	11.69	11.52	10.04	12.61	11.65	10.71	11.62	11.23
	MEDIAN	35.0	37.0	37.0	39.0	38.0	39.0	39.0	35.0	37.0	38.0	37.0	37.0
	MIN	18	19	18	19	18	18	19	18	18	18	18	18
	MAX	61	64	64	61	64	64	63	60	63	63	64	64
WEIGHT (KG)	N	75	96	171	73	94	167	67	100	167	215	290	505
	MEAN	91.93	83.64	87.27	90.25	83.36	86.37	91.87	77.49	83.26	91.34	81.43	85.65
	SD	19.76	22.30	21.56	20.76	24.82	23.32	19.73	20.94	21.59	20.02	22.80	22.19
	MEDIAN	90.0	83.5	86.0	88.0	79.5	83.0	90.0	74.0	82.0	89.0	78.0	84.0
	MIN	59.0	36.0	36.0	55.0	36.0	36.0	54.0	44.0	44.0	54.0	36.0	36.0
	MAX	148.0	159.0	159.0	172.0	169.0	172.0	154.0	155.0	155.0	172.0	169.0	172.0
BMI (KG/M^2)	N	75	96	171	73	94	167	67	100	167	215	290	505
	MEAN	29.07	31.11	30.22	29.35	31.15	30.37	28.58	28.85	28.74	29.01	30.35	29.78
	SD	5.64	8.15	7.21	6.77	9.10	8.19	5.77	7.61	6.92	6.06	8.34	7.48
	MEDIAN	28.1	30.6	28.8	28.1	29.8	28.6	28.1	28.0	28.1	28.1	29.0	28.4
	MIN	19.0	16.7	16.7	18.0	16.7	16.7	19.1	18.0	18.0	18.0	16.7	16.7
	MAX	46.3	58.4	58.4	56.1	64.4	64.4	47.0	53.6	53.6	56.1	64.4	64.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM210.SAS
GENERATED: 02NOV2005 15:22:36 iceadmn3

Table 11.1.5.1.2 Age, Weight, and BMI at Study Entry by Sex - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT									TOTAL		
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO					
		MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
AGE (YEARS)	N	69	86	155	68	83	151	64	97	161	201	266	467
	MEAN	36.30	37.86	37.17	38.26	38.12	38.19	38.66	37.00	37.66	37.72	37.63	37.67
	SD	10.63	10.45	10.53	10.54	11.45	11.01	10.08	12.75	11.75	10.42	11.61	11.10
	MEDIAN	35.0	37.0	37.0	39.0	39.0	39.0	39.5	35.0	37.0	39.0	37.0	38.0
	MIN	18	19	18	19	18	18	19	18	18	18	18	18
	MAX	61	64	64	58	64	64	63	60	63	63	64	64
WEIGHT (KG)	N	69	86	155	68	82	150	64	97	161	201	265	466
	MEAN	91.38	83.41	86.95	90.62	85.22	87.67	91.70	76.69	82.66	91.22	81.51	85.70
	SD	19.85	23.01	21.96	21.46	25.22	23.67	19.85	20.66	21.57	20.31	23.13	22.46
	MEDIAN	89.0	80.0	86.0	88.0	80.0	83.5	90.0	74.0	82.0	89.0	77.0	84.0
	MIN	59.0	36.0	36.0	55.0	36.0	36.0	54.0	44.0	44.0	54.0	36.0	36.0
	MAX	148.0	159.0	159.0	172.0	169.0	172.0	154.0	155.0	155.0	172.0	169.0	172.0
BMI (KG/M^2)	N	69	86	155	68	82	150	64	97	161	201	265	466
	MEAN	28.87	30.92	30.00	29.48	31.81	30.75	28.59	28.53	28.55	28.99	30.32	29.74
	SD	5.61	8.19	7.21	6.99	9.27	8.36	5.87	7.47	6.86	6.17	8.38	7.53
	MEDIAN	28.1	30.2	28.4	28.3	30.5	29.2	28.1	27.3	28.0	28.1	28.8	28.4
	MIN	19.0	16.7	16.7	18.0	16.7	16.7	19.1	18.0	18.0	18.0	16.7	16.7
	MAX	46.3	58.4	58.4	56.1	64.4	64.4	47.0	53.6	53.6	56.1	64.4	64.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM211.SAS
GENERATED: 02NOV2005 15:22:38 iceadmn3

Table 11.1.5.1.3 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT									
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
Bipolar I	AGE (YEARS)	N	50	62	112	48	64	112	46	66	112	144	192	336
		MEAN	35.26	37.66	36.59	37.71	37.44	37.55	39.17	37.98	38.47	37.33	37.70	37.54
		SD	10.11	11.10	10.69	11.53	11.56	11.49	10.36	12.50	11.63	10.73	11.69	11.27
		MEDIAN	34.0	37.0	36.0	39.0	38.0	38.5	39.5	38.0	39.0	37.0	37.5	37.0
		MIN	18	19	18	19	18	18	24	19	19	18	18	18
		MAX	61	64	64	60	59	60	63	60	63	63	64	64
	WEIGHT (KG)	N	50	62	112	48	63	111	46	66	112	144	191	335
		MEAN	91.64	83.23	86.98	90.08	85.22	87.32	91.37	77.59	83.25	91.03	81.94	85.85
		SD	18.99	22.49	21.33	20.72	25.43	23.53	20.76	22.41	22.70	20.02	23.58	22.54
		MEDIAN	90.0	81.5	86.0	88.5	81.0	84.0	89.0	74.0	82.0	89.0	79.0	84.0
		MIN	59.0	36.0	36.0	55.0	36.0	36.0	54.0	44.0	44.0	54.0	36.0	36.0
		MAX	136.0	149.0	149.0	168.0	169.0	169.0	154.0	155.0	155.0	168.0	169.0	169.0
	BMI (KG/M^2)	N	50	62	112	48	63	111	46	66	112	144	191	335
		MEAN	28.97	31.27	30.24	29.11	32.22	30.87	28.51	28.61	28.57	28.87	30.66	29.89
		SD	4.92	8.25	7.03	7.41	9.66	8.86	5.74	7.94	7.09	6.06	8.73	7.74
		MEDIAN	28.2	30.2	28.9	27.9	30.9	29.3	28.1	26.9	27.6	28.1	29.0	28.4
		MIN	19.0	16.7	16.7	18.0	16.7	16.7	19.1	18.0	18.0	18.0	16.7	16.7
		MAX	38.9	51.1	51.1	56.1	64.4	64.4	47.0	53.6	53.6	56.1	64.4	64.4

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM213.SAS
GENERATED: 02NOV2005 15:22:40 iceadmn3

Table 11.1.5.1.3 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
Bipolar II	AGE (YEARS)	N	25	34	59	25	31	56	21	34	55	71	99	170
		MEAN	37.76	38.00	37.90	40.48	38.26	39.25	37.95	34.85	36.04	38.77	37.00	37.74
		SD	11.46	9.55	10.31	11.04	12.12	11.60	9.49	12.77	11.63	10.69	11.53	11.19
		MEDIAN	39.0	36.5	38.0	41.0	39.0	39.5	37.0	31.0	36.0	39.0	36.0	37.0
		MIN	19	19	19	20	19	19	19	18	18	19	18	18
		MAX	59	55	59	61	64	64	54	58	58	61	64	64
	WEIGHT (KG)	N	25	34	59	25	31	56	21	34	55	71	99	170
		MEAN	92.52	84.38	87.83	90.56	79.58	84.48	92.95	77.29	83.27	91.96	80.44	85.25
		SD	21.61	22.26	22.17	21.28	23.46	22.98	17.70	18.05	19.34	20.15	21.31	21.54
		MEDIAN	90.0	85.5	87.0	87.0	76.0	81.0	93.0	75.0	84.0	89.0	77.0	84.0
		MIN	61.0	53.0	53.0	66.0	42.0	42.0	61.0	52.0	52.0	61.0	42.0	42.0
		MAX	148.0	159.0	159.0	172.0	148.0	172.0	129.0	119.0	129.0	172.0	159.0	172.0
	BMI (KG/M^2)	N	25	34	59	25	31	56	21	34	55	71	99	170
		MEAN	29.27	30.84	30.17	29.82	28.99	29.36	28.74	29.31	29.09	29.31	29.73	29.55
		SD	6.98	8.08	7.61	5.42	7.55	6.64	5.98	7.03	6.60	6.10	7.53	6.95
		MEDIAN	27.2	30.8	28.4	28.4	27.7	28.2	28.4	29.4	28.7	28.1	28.9	28.4
		MIN	19.7	18.7	18.7	22.6	18.2	18.2	20.4	19.2	19.2	19.7	18.2	18.2
		MAX	46.3	58.4	58.4	45.7	46.7	46.7	43.0	45.3	45.3	46.3	58.4	58.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM213.SAS
GENERATED: 02NOV2005 15:22:40 iceadmn3

Table 11.1.5.1.4 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
Bipolar I	AGE (YEARS)	N	49	55	104	45	56	101	46	64	110	140	175	315
		MEAN	35.16	37.78	36.55	37.13	38.32	37.79	39.17	37.95	38.46	37.11	38.02	37.62
		SD	10.19	10.88	10.59	10.85	11.75	11.32	10.36	12.69	11.74	10.52	11.78	11.23
		MEDIAN	34.0	37.0	36.0	39.0	39.5	39.0	39.5	37.0	38.5	37.0	38.0	38.0
		MIN	18	19	18	19	18	18	24	19	19	18	18	18
		MAX	61	64	64	57	59	59	63	60	63	63	64	64
	WEIGHT (KG)	N	49	55	104	45	55	100	46	64	110	140	174	314
		MEAN	91.12	83.40	87.04	90.44	87.02	88.56	91.37	77.03	83.03	90.99	82.20	86.12
		SD	18.83	23.20	21.50	21.34	25.94	23.92	20.76	22.53	22.84	20.16	24.09	22.81
		MEDIAN	89.0	80.0	85.5	89.0	82.0	87.5	89.0	74.0	81.5	89.0	78.5	84.0
		MIN	59.0	36.0	36.0	55.0	36.0	36.0	54.0	44.0	44.0	54.0	36.0	36.0
		MAX	136.0	149.0	149.0	168.0	169.0	169.0	154.0	155.0	155.0	168.0	169.0	169.0
	BMI (KG/M^2)	N	49	55	104	45	55	100	46	64	110	140	174	314
		MEAN	28.78	31.25	30.09	29.27	32.88	31.25	28.51	28.38	28.44	28.85	30.71	29.88
		SD	4.78	8.25	6.92	7.63	9.83	9.04	5.74	7.96	7.08	6.09	8.83	7.77
		MEDIAN	28.1	30.1	28.8	28.4	31.3	29.8	28.1	26.7	27.2	28.1	28.9	28.4
		MIN	19.0	16.7	16.7	18.0	16.7	16.7	19.1	18.0	18.0	18.0	16.7	16.7
		MAX	38.9	51.1	51.1	56.1	64.4	64.4	47.0	53.6	53.6	56.1	64.4	64.4

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM214.SAS
GENERATED: 02NOV2005 15:22:43 iceadmn3

Table 11.1.5.1.4 Age, Weight, and BMI at Study Entry by Sex and Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT											
			QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO			TOTAL		
			MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL
Bipolar II	AGE (YEARS)	N	20	31	51	23	27	50	18	33	51	61	91	152
		MEAN	39.10	38.00	38.43	40.48	37.70	38.98	37.33	35.15	35.92	39.10	36.88	37.77
		SD	11.43	9.81	10.38	9.74	11.01	10.43	9.46	12.84	11.71	10.16	11.29	10.87
		MEDIAN	39.0	37.0	38.0	41.0	39.0	39.5	38.5	32.0	36.0	39.0	36.0	38.0
		MIN	19	19	19	24	21	21	19	18	18	19	18	18
		MAX	59	55	59	58	64	64	50	58	58	59	64	64
	WEIGHT (KG)	N	20	31	51	23	27	50	18	33	51	61	91	152
		MEAN	92.00	83.42	86.78	90.96	81.56	85.88	92.56	76.03	81.86	91.77	80.19	84.84
		SD	22.66	23.06	23.07	22.16	23.75	23.28	17.82	16.74	18.73	20.81	21.22	21.75
		MEDIAN	88.5	80.0	86.0	87.0	77.0	81.0	94.0	74.0	82.0	88.0	77.0	83.0
		MIN	61.0	53.0	53.0	66.0	48.0	48.0	61.0	52.0	52.0	61.0	48.0	48.0
		MAX	148.0	159.0	159.0	172.0	148.0	172.0	129.0	110.0	129.0	172.0	159.0	172.0
	BMI (KG/M^2)	N	20	31	51	23	27	50	18	33	51	61	91	152
		MEAN	29.08	30.32	29.83	29.90	29.63	29.75	28.79	28.82	28.81	29.30	29.57	29.46
		SD	7.41	8.19	7.84	5.65	7.72	6.78	6.35	6.53	6.41	6.39	7.42	7.01
		MEDIAN	26.8	30.8	28.3	28.1	28.2	28.2	27.8	28.9	28.7	27.8	28.6	28.3
		MIN	19.7	18.7	18.7	22.6	19.2	19.2	20.4	19.2	19.2	19.7	18.7	18.7
		MAX	46.3	58.4	58.4	45.7	46.7	46.7	43.0	43.0	43.0	46.3	58.4	58.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM214.SAS
GENERATED: 02NOV2005 15:22:43 iceadmn3

Table 11.1.5.2.1 Sex, Race, Age and BMI Groups
Safety Population

		TREATMENT						TOTAL	
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
		N	%	N	%	N	%	N	%
SEX	TOTAL	171	100.0	168	100.0	167	100.0	506	100.0
	MALE	75	43.9	73	43.5	67	40.1	215	42.5
	FEMALE	96	56.1	95	56.5	100	59.9	291	57.5
RACE	TOTAL	171	100.0	168	100.0	167	100.0	506	100.0
	CAUCASIAN	118	69.0	127	75.6	144	86.2	389	76.9
	BLACK	28	16.4	25	14.9	11	6.6	64	12.6
	ORIENTAL	3	1.8	1	0.6	1	0.6	5	1.0
	OTHER	22	12.9	15	8.9	11	6.6	48	9.5
AGE (YEARS)	TOTAL	171	100.0	168	100.0	167	100.0	506	100.0
	18-39	102	59.6	89	53.0	93	55.7	284	56.1
	40-65	69	40.4	79	47.0	74	44.3	222	43.9
BMI (KG/M^2)	TOTAL	171	100.0	167	100.0	167	100.0	505	100.0
	0 - <18.5	2	1.2	6	3.6	3	1.8	11	2.2
	18.5 - <25	41	24.0	33	19.8	49	29.3	123	24.4
	25 - <30	50	29.2	55	32.9	54	32.3	159	31.5
	30 - <40	61	35.7	56	33.5	47	28.1	164	32.5
	>=40	17	9.9	17	10.2	14	8.4	48	9.5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM216.SAS
GENERATED: 02NOV2005 15:22:45 iceadmn3

Table 11.1.5.2.2 Sex, Race, Age and BMI Groups
Intent-to-Treat Population

		TREATMENT						TOTAL	
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
		N	%	N	%	N	%	N	%
SEX	TOTAL	155	100.0	151	100.0	161	100.0	467	100.0
	MALE	69	44.5	68	45.0	64	39.8	201	43.0
	FEMALE	86	55.5	83	55.0	97	60.2	266	57.0
RACE	TOTAL	155	100.0	151	100.0	161	100.0	467	100.0
	CAUCASIAN	107	69.0	115	76.2	138	85.7	360	77.1
	BLACK	25	16.1	21	13.9	11	6.8	57	12.2
	ORIENTAL	3	1.9	0	0	1	0.6	4	0.9
	OTHER	20	12.9	15	9.9	11	6.8	46	9.9
AGE (YEARS)	TOTAL	155	100.0	151	100.0	161	100.0	467	100.0
	18-39	92	59.4	78	51.7	88	54.7	258	55.2
	40-65	63	40.6	73	48.3	73	45.3	209	44.8
BMI (KG/M^2)	TOTAL	155	100.0	150	100.0	161	100.0	466	100.0
	0 - <18.5	2	1.3	5	3.3	3	1.9	10	2.1
	18.5 - <25	38	24.5	29	19.3	48	29.8	115	24.7
	25 - <30	47	30.3	46	30.7	53	32.9	146	31.3
	30 - <40	53	34.2	54	36.0	44	27.3	151	32.4
	>=40	15	9.7	16	10.7	13	8.1	44	9.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM217.SAS
GENERATED: 02NOV2005 15:22:47 iceadmn3

Table 11.1.5.2.3 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
Bipolar I	SEX	TOTAL	112	100.0	112	100.0	112	100.0	336	100.0
		MALE	50	44.6	48	42.9	46	41.1	144	42.9
		FEMALE	62	55.4	64	57.1	66	58.9	192	57.1
	RACE	TOTAL	112	100.0	112	100.0	112	100.0	336	100.0
		CAUCASIAN	79	70.5	83	74.1	96	85.7	258	76.8
		BLACK	17	15.2	17	15.2	8	7.1	42	12.5
		ORIENTAL	3	2.7	1	0.9	1	0.9	5	1.5
		OTHER	13	11.6	11	9.8	7	6.3	31	9.2
	AGE (YEARS)	TOTAL	112	100.0	112	100.0	112	100.0	336	100.0
		18-39	67	59.8	61	54.5	59	52.7	187	55.7
		40-65	45	40.2	51	45.5	53	47.3	149	44.3
	BMI (KG/M^2)	TOTAL	112	100.0	111	100.0	112	100.0	335	100.0
		0 - <18.5	2	1.8	5	4.5	3	2.7	10	3.0
		18.5 - <25	24	21.4	20	18.0	30	26.8	74	22.1
		25 - <30	35	31.3	34	30.6	41	36.6	110	32.8
		30 - <40	39	34.8	40	36.0	28	25.0	107	31.9
		>=40	12	10.7	12	10.8	10	8.9	34	10.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM219.SAS
GENERATED: 02NOV2005 15:22:49 iceadmn3

Table 11.1.5.2.3 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Safety Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
Bipolar II	SEX	TOTAL	59	100.0	56	100.0	55	100.0	170	100.0
		MALE	25	42.4	25	44.6	21	38.2	71	41.8
		FEMALE	34	57.6	31	55.4	34	61.8	99	58.2
	RACE	TOTAL	59	100.0	56	100.0	55	100.0	170	100.0
		CAUCASIAN	39	66.1	44	78.6	48	87.3	131	77.1
		BLACK	11	18.6	8	14.3	3	5.5	22	12.9
		OTHER	9	15.3	4	7.1	4	7.3	17	10.0
	AGE (YEARS)	TOTAL	59	100.0	56	100.0	55	100.0	170	100.0
		18-39	35	59.3	28	50.0	34	61.8	97	57.1
		40-65	24	40.7	28	50.0	21	38.2	73	42.9
	BMI (KG/M^2)	TOTAL	59	100.0	56	100.0	55	100.0	170	100.0
		0 - <18.5	0	0.0	1	1.8	0	0	1	0.6
		18.5 - <25	17	28.8	13	23.2	19	34.5	49	28.8
		25 - <30	15	25.4	21	37.5	13	23.6	49	28.8
		30 - <40	22	37.3	16	28.6	19	34.5	57	33.5
		>=40	5	8.5	5	8.9	4	7.3	14	8.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM219.SAS
GENERATED: 02NOV2005 15:22:49 iceadmn3

Table 11.1.5.2.4 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT						TOTAL	
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO			
			N	%	N	%	N	%	N	%
Bipolar I	SEX	TOTAL	104	100.0	101	100.0	110	100.0	315	100.0
		MALE	49	47.1	45	44.6	46	41.8	140	44.4
		FEMALE	55	52.9	56	55.4	64	58.2	175	55.6
	RACE	TOTAL	104	100.0	101	100.0	110	100.0	315	100.0
		CAUCASIAN	72	69.2	75	74.3	94	85.5	241	76.5
		BLACK	16	15.4	15	14.9	8	7.3	39	12.4
		ORIENTAL	3	2.9	0	0	1	0.9	4	1.3
		OTHER	13	12.5	11	10.9	7	6.4	31	9.8
	AGE (YEARS)	TOTAL	104	100.0	101	100.0	110	100.0	315	100.0
		18-39	63	60.6	53	52.5	57	51.8	173	54.9
		40-65	41	39.4	48	47.5	53	48.2	142	45.1
	BMI (KG/M^2)	TOTAL	104	100.0	100	100.0	110	100.0	314	100.0
		0 - <18.5	2	1.9	5	5.0	3	2.7	10	3.2
		18.5 - <25	21	20.2	17	17.0	30	27.3	68	21.7
		25 - <30	35	33.7	29	29.0	41	37.3	105	33.4
		30 - <40	35	33.7	38	38.0	26	23.6	99	31.5
		>=40	11	10.6	11	11.0	10	9.1	32	10.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM220.SAS
GENERATED: 02NOV2005 15:22:52 iceadmn3

Table 11.1.5.2.4 Sex, Race, Age and BMI Groups by Bipolar Diagnosis
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT							
			QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
			N	%	N	%	N	%	N	%
Bipolar II	SEX	TOTAL	51	100.0	50	100.0	51	100.0	152	100.0
		MALE	20	39.2	23	46.0	18	35.3	61	40.1
		FEMALE	31	60.8	27	54.0	33	64.7	91	59.9
	RACE	TOTAL	51	100.0	50	100.0	51	100.0	152	100.0
		CAUCASIAN	35	68.6	40	80.0	44	86.3	119	78.3
		BLACK	9	17.6	6	12.0	3	5.9	18	11.8
		OTHER	7	13.7	4	8.0	4	7.8	15	9.9
	AGE (YEARS)	TOTAL	51	100.0	50	100.0	51	100.0	152	100.0
		18-39	29	56.9	25	50.0	31	60.8	85	55.9
		40-65	22	43.1	25	50.0	20	39.2	67	44.1
	BMI (KG/M^2)	TOTAL	51	100.0	50	100.0	51	100.0	152	100.0
		0 - <18.5	0	0.0	0	0	0	0	0	0.0
		18.5 - <25	17	33.3	12	24.0	18	35.3	47	30.9
		25 - <30	12	23.5	17	34.0	12	23.5	41	27.0
		30 - <40	18	35.3	16	32.0	18	35.3	52	34.2
		>=40	4	7.8	5	10.0	3	5.9	12	7.9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM220.SAS
GENERATED: 02NOV2005 15:22:52 iceadmn3

Table 11.1.6.1 DSM-IV Diagnosis by Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
SAFETY	TOTAL	171	100.0	168	100.0	167	100.0	506	100.0
	DSM-IV DIAGNOSIS								
	Bipolar I Disorder, Most Recent Episode Depressed, Unspecified	1	0.6	5	3.0	0	0	6	1.2
	Bipolar I Disorder, Most Recent Episode Depressed, Moderate	61	35.7	63	37.5	68	40.7	192	37.9
	Bipolar I Disorder, Most Recent Episode Depressed, Severe without Psychotic Features	45	26.3	41	24.4	41	24.6	127	25.1
	Bipolar I Disorder, Most Recent Episode Depressed, Severe with Psychotic Features	5	2.9	3	1.8	3	1.8	11	2.2
	Bipolar II Disorder	59	34.5	56	33.3	55	32.9	170	33.6
INTENT-TO-TREAT	TOTAL	155	100.0	151	100.0	161	100.0	467	100.0
	DSM-IV DIAGNOSIS								
	Bipolar I Disorder, Most Recent Episode Depressed, Unspecified	1	0.6	5	3.3	0	0	6	1.3

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM222.SAS
GENERATED: 02NOV2005 15:22:54 iceadmn3

Table 11.1.6.1 DSM-IV Diagnosis by Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
INTENT-TO-TREAT	DSM-IV DIAGNOSIS								
	Bipolar I Disorder, Most Recent Episode Depressed, Moderate	54	34.8	56	37.1	67	41.6	177	37.9
	Bipolar I Disorder, Most Recent Episode Depressed, Severe without Psychotic Features	44	28.4	38	25.2	40	24.8	122	26.1
	Bipolar I Disorder, Most Recent Episode Depressed, Severe with Psychotic Features	5	3.2	2	1.3	3	1.9	10	2.1
	Bipolar II Disorder	51	32.9	50	33.1	51	31.7	152	32.5
PER-PROTOCOL	TOTAL	139	100.0	133	100.0	150	100.0	422	100.0
	DSM-IV DIAGNOSIS								
	Bipolar I Disorder, Most Recent Episode Depressed, Unspecified	1	0.7	4	3.0	0	0	5	1.2
	Bipolar I Disorder, Most Recent Episode Depressed, Moderate	49	35.3	55	41.4	63	42.0	167	39.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM222.SAS
GENERATED: 02NOV2005 15:22:54 iceadmn3

Table 11.1.6.1 DSM-IV Diagnosis by Population

		TREATMENT							
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
		N	%	N	%	N	%	N	%
PER-PROTOCOL	DSM-IV DIAGNOSIS								
	Bipolar I Disorder, Most Recent Episode Depressed, Severe without Psychotic Features	41	29.5	32	24.1	37	24.7	110	26.1
	Bipolar I Disorder, Most Recent Episode Depressed, Severe with Psychotic Features	5	3.6	2	1.5	3	2.0	10	2.4
	Bipolar II Disorder	43	30.9	40	30.1	47	31.3	130	30.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DEM222.SAS
GENERATED: 02NOV2005 15:22:54 iceadmn3

Table 11.1.6.2 Psychiatric History - Descriptive Statistics
Safety Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST DEPRESSED EPISODE	N	167	168	167	502
	Mean	18.1	19.1	17.8	18.3
	Std	10.3	10.3	10.7	10.4
	Min	2	2	1	1
	Max	46	47	47	47
NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	141	135	133	409
	Mean	17.6	18.9	18.8	18.4
	Std	19.2	20.9	24.2	21.4
	Min	2	1	1	1
	Max	100	108	99	108
NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	171	168	167	506
	Mean	1.7	1.9	1.9	1.8
	Std	0.9	1.1	1.0	1.0
	Min	1	1	1	1
	Max	8	6	6	8
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	167	168	165	500
	Mean	15.3	15.7	15.2	15.4
	Std	10.1	9.8	9.9	9.9

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY202.SAS
GENERATED: 02NOV2005 15:25:04 iceadmn3

Table 11.1.6.2 Psychiatric History - Descriptive Statistics
Safety Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	Min	2	1	1	1
	Max	46	51	45	51
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	147	147	142	436
	Mean	14.2	13.6	14.7	14.2
	Std	28.6	18.9	19.3	22.7
	Min	1	1	1	1
	Max	272	108	99	272
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	171	168	167	506
	Mean	1.1	1.2	1.2	1.2
	Std	1.1	1.1	1.2	1.1
	Min	0	0	0	0
	Max	6	4	6	6

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY202.SAS
GENERATED: 02NOV2005 15:25:04 iceadmn3

Table 11.1.6.3 Psychiatric History - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST DEPRESSED EPISODE	N	151	151	161	463
	Mean	18.0	19.5	17.6	18.4
	Std	10.3	10.3	10.6	10.4
	Min	2	2	1	1
	Max	46	47	47	47
NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	131	121	128	380
	Mean	18.2	18.8	18.9	18.7
	Std	19.7	21.1	24.5	21.8
	Min	2	1	1	1
	Max	100	108	99	108
NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	155	151	161	467
	Mean	1.7	1.9	1.9	1.8
	Std	0.9	1.1	1.0	1.0
	Min	1	1	1	1
	Max	8	6	6	8
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	151	151	160	462
	Mean	15.4	15.9	15.2	15.5
	Std	10.0	9.4	9.9	9.8

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY200.SAS
GENERATED: 02NOV2005 15:24:59 iceadmn3

Table 11.1.6.3 Psychiatric History - Descriptive Statistics
Intent-to-Treat Population

		TREATMENT			
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	Min	2	1	1	1
	Max	46	39	45	46
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	136	132	137	405
	Mean	15.0	13.5	15.0	14.5
	Std	29.6	18.9	19.6	23.2
	Min	1	1	1	1
	Max	272	108	99	272
NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	155	151	161	467
	Mean	1.1	1.2	1.3	1.2
	Std	1.1	1.1	1.2	1.1
	Min	0	0	0	0
	Max	5	4	6	6

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY200.SAS
GENERATED: 02NOV2005 15:24:59 iceadmn3

Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR I	YEARS SINCE FIRST DEPRESSED EPISODE	N	103	101	110	314
		Mean	17.2	19.3	18.2	18.2
		Std	10.0	10.6	10.7	10.5
		Min	2	2	1	1
		Max	46	45	47	47
	NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	88	82	89	259
		Mean	16.6	17.9	18.6	17.7
		Std	16.4	19.2	23.6	19.9
		Min	2	1	1	1
		Max	66	108	95	108
	NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	104	101	110	315
		Mean	1.7	1.9	1.9	1.8
		Std	0.8	1.0	1.1	0.9
		Min	1	1	1	1
		Max	4	5	6	6
	YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	103	101	109	313
		Mean	15.0	15.7	16.1	15.6
		Std	9.7	9.8	10.2	9.9

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY201.SAS
GENERATED: 02NOV2005 15:25:01 iceadmn3

Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR I	YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	Min	2	1	2	1
		Max	46	39	45	46
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	91	91	93	275
		Mean	11.3	12.5	14.1	12.7
		Std	15.7	18.5	16.9	17.0
		Min	1	1	1	1
		Max	100	108	90	108
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	104	101	110	315
		Mean	1.2	1.2	1.4	1.3
		Std	1.1	1.1	1.3	1.2
		Min	0	0	0	0
		Max	5	4	6	6
BIPOLAR II	YEARS SINCE FIRST DEPRESSED EPISODE	N	48	50	51	149
		Mean	19.6	20.0	16.5	18.7
		Std	10.8	9.7	10.4	10.4
		Min	4	2	3	2
		Max	45	47	44	47

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY201.SAS
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Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR II	NUMBER OF PRIOR DEPRESSED EPISODES OVER LIFETIME	N	43	39	39	121
		Mean	21.5	20.8	19.7	20.7
		Std	25.2	24.8	27.0	25.5
		Min	2	1	2	1
		Max	100	90	99	100
	NUMBER OF PRIOR DEPRESSED EPISODES OVER THE PAST YEAR	N	51	50	51	152
		Mean	1.7	1.8	1.9	1.8
		Std	1.2	1.3	1.0	1.2
		Min	1	1	1	1
		Max	8	6	5	8
	YEARS SINCE FIRST MANIC OR HYPOMANIC EPISODE	N	48	50	51	149
		Mean	16.1	16.4	13.4	15.3
		Std	10.7	8.8	9.2	9.6
		Min	3	2	1	1
		Max	45	38	42	45
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	N	45	41	44	130
		Mean	22.4	15.5	17.0	18.4
		Std	45.9	19.8	24.4	32.4

(Continued)

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY201.SAS
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Table 11.1.6.4 Psychiatric History by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

			TREATMENT			
			QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO	TOTAL
BIPOLAR II	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER LIFETIME	Min	1	1	1	1
		Max	272	88	99	272
	NUMBER OF PRIOR MANIC OR HYPOMANIC EPISODES OVER THE PAST YEAR	N	51	50	51	152
		Mean	1.0	1.1	1.0	1.0
		Std	1.1	1.0	1.0	1.0
		Min	0	0	0	0
		Max	4	3	3	4

Years since first episode = consent year - year of first episode + one year.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HISPY201.SAS
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Table 11.1.6.5 Manic or Depressive Episodes Over the Past Year Summary
Intent-to-Treat Population

NUMBER MIXED/DEPRESSED EPISODES	TREATMENT							
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		TOTAL	
	N	%	N	%	N	%	N	%
<4	111	71.6	105	69.5	108	67.1	324	69.4
>=4	44	28.4	46	30.5	53	32.9	143	30.6
TOTAL	155	100.0	151	100.0	161	100.0	467	100.0

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		126	73.7	130	77.4	131	78.4
ALIMENTARY TRACT AND METABOLISM	TOTAL	51	29.8	55	32.7	49	29.3
	Ascorbic acid	5	2.9	4	2.4	2	1.2
	Atropine sulfate	1	0.6	0	0	0	0
	Bismuth subsalicylate	0	0	2	1.2	2	1.2
	Calcium	2	1.2	1	0.6	3	1.8
	Calcium carbonate	5	2.9	4	2.4	4	2.4
	Cimetidine	0	0	0	0	1	0.6
	Colecalciferol	0	0	0	0	1	0.6
	Dexamfetamine sulfate	1	0.6	1	0.6	0	0
	Dicycloverine	0	0	1	0.6	0	0
	Dihydroxyaluminum sodium carbonate	0	0	2	1.2	1	0.6
	Docusate sodium	0	0	2	1.2	0	0
	Ergocalciferol	8	4.7	6	3.6	3	1.8
	Esomeprazole	4	2.3	1	0.6	5	3.0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Famotidine	0	0	5	3.0	2	1.2
	Glibenclamide	0	0	0	0	1	0.6
	Glipizide	0	0	1	0.6	1	0.6
	Herbal nos	0	0	1	0.6	0	0
	Insulin human	1	0.6	0	0	2	1.2
	Lactobacillus acidophilus	1	0.6	0	0	0	0
	Lansoprazole	2	1.2	3	1.8	2	1.2
	Loperamide hydrochloride	0	0	0	0	1	0.6
	Magnesium aspartate	1	0.6	0	0	0	0
	Magnesium hydroxide	2	1.2	1	0.6	1	0.6
	Metformin	0	0	2	1.2	0	0
	Metformin hydrochloride	1	0.6	0	0	1	0.6
	Metoclopramide hydrochloride	1	0.6	0	0	0	0
	Omeprazole	0	0	4	2.4	3	1.8
	Pantoprazole	3	1.8	1	0.6	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Pioglitazone	1	0.6	1	0.6	0	0
	Psyllium hydrophilic mucilloid	1	0.6	1	0.6	0	0
	Pyridoxine hydrochloride	0	0	1	0.6	1	0.6
	Rabeprazole sodium	0	0	2	1.2	1	0.6
	Ranitidine	0	0	1	0.6	0	0
	Ranitidine hydrochloride	1	0.6	1	0.6	3	1.8
	Rosiglitazone maleate	1	0.6	0	0	1	0.6
	Tocopherol	3	1.8	1	0.6	1	0.6
	Vitamin b	1	0.6	0	0	3	1.8
	Vitamins	1	0.6	1	0.6	0	0
	Vitamins nos	17	9.9	21	12.5	18	10.8
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	9	5.3	7	4.2	11	6.6
	Amoxicillin	0	0	1	0.6	1	0.6
	Amoxicillin trihydrate	0	0	0	0	1	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Azithromycin	1	0.6	0	0	0	0
	Benzylpenicillin sodium	2	1.2	0	0	0	0
	Bicillin	0	0	0	0	1	0.6
	Cefalexin	0	0	0	0	1	0.6
	Cefalexin monohydrate	2	1.2	0	0	0	0
	Cefprozil	0	0	0	0	1	0.6
	Ceftriaxone sodium	0	0	0	0	1	0.6
	Ciprofloxacin hydrochloride	3	1.8	1	0.6	0	0
	Clarithromycin	0	0	2	1.2	0	0
	Doxycycline	2	1.2	1	0.6	0	0
	Levofloxacin	0	0	2	1.2	2	1.2
	Minocycline	0	0	1	0.6	1	0.6
	Tetracycline	0	0	0	0	2	1.2
	Valaciclovir hydrochloride	0	0	0	0	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	0.6	1	0.6	0	0
	Colostrum	1	0.6	0	0	0	0
	Hydroxycarbamide	0	0	1	0.6	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	0	0	2	1.2	3	1.8
	Cyanocobalamin-tannin complex	0	0	1	0.6	0	0
	Folic acid	0	0	1	0.6	0	0
	Iron	0	0	0	0	2	1.2
	Warfarin sodium	0	0	0	0	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	22	12.9	16	9.5	22	13.2
	Amlodipine	0	0	3	1.8	1	0.6
	Amlodipine besilate	0	0	1	0.6	0	0
	Atenolol	1	0.6	1	0.6	5	3.0
	Atorvastatin	5	2.9	3	1.8	4	2.4
	Chlortalidone	1	0.6	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Doxazosin mesilate	0	0	1	0.6	0	0
	Enalapril	0	0	0	0	1	0.6
	Fenofibrate	1	0.6	1	0.6	1	0.6
	Fish oil	3	1.8	1	0.6	1	0.6
	Furosemide	0	0	1	0.6	0	0
	Hydrochlorothiazide	6	3.5	3	1.8	1	0.6
	Isradipine	1	0.6	0	0	0	0
	Lisinopril	1	0.6	3	1.8	2	1.2
	Losartan potassium	1	0.6	0	0	0	0
	Metoprolol	0	0	2	1.2	0	0
	Metoprolol succinate	0	0	0	0	1	0.6
	Nifedipine	1	0.6	0	0	0	0
	Nisoldipine	0	0	0	0	1	0.6
	Olmesartan medoxomil	0	0	1	0.6	1	0.6
	Omega-3 triglycerides	2	1.2	0	0	1	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Preparation h	0	0	1	0.6	0	0
	Propranolol	1	0.6	0	0	0	0
	Propranolol hydrochloride	0	0	0	0	1	0.6
	Ramipril	0	0	0	0	1	0.6
	Rosuvastatin	0	0	0	0	1	0.6
	Simvastatin	0	0	1	0.6	1	0.6
	Spironolactone	0	0	1	0.6	0	0
	Timolol	0	0	1	0.6	0	0
	Ubidecarenone	0	0	0	0	1	0.6
	Valsartan	0	0	1	0.6	0	0
	Verapamil hydrochloride	1	0.6	0	0	0	0
DERMATOLOGICALS	TOTAL	0	0	2	1.2	2	1.2
	Calcipotriol	0	0	1	0.6	0	0
	Hydrocortisone	0	0	0	0	1	0.6
	Linoleic acid	0	0	0	0	1	0.6
	Nystatin	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	9	5.3	19	11.3	24	14.4
	Cimicifuga racemosa root	0	0	1	0.6	1	0.6
	Clindamycin hydrochloride	0	0	1	0.6	0	0
	Clotrimazole	1	0.6	0	0	0	0
	Estradiol	0	0	1	0.6	0	0
	Estrogens conjugated	1	0.6	1	0.6	1	0.6
	Ethinylestradiol	2	1.2	3	1.8	8	4.8
	Hormonal contraceptives for systemic use	0	0	1	0.6	0	0
	Levonorgestrel	1	0.6	1	0.6	0	0
	Medroxyprogesterone acetate	3	1.8	8	4.8	5	3.0
	Norelgestromin	0	0	1	0.6	1	0.6
	Norethisterone acetate	0	0	1	0.6	0	0
	Norgestimate	0	0	2	1.2	1	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Oral contraceptive nos	0	0	1	0.6	0	0
	Phenazopyridine	1	0.6	0	0	0	0
	Progesterone	0	0	0	0	1	0.6
	Serenoa repens	0	0	0	0	1	0.6
	Sildenafil citrate	0	0	0	0	1	0.6
	Testosterone	0	0	0	0	2	1.2
	Tolterodine l-tartrate	0	0	0	0	2	1.2
MUSCULO-SKELETAL SYSTEM	TOTAL	42	24.6	40	23.8	48	28.7
	Acetylsalicylic acid	0	0	0	0	1	0.6
	Alendronate sodium	0	0	0	0	1	0.6
	Allopurinol	0	0	1	0.6	0	0
	Baclofen	1	0.6	0	0	0	0
	Carisoprodol	0	0	1	0.6	1	0.6
	Celecoxib	1	0.6	2	1.2	1	0.6
	Chondroitin sulfate	0	0	2	1.2	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
GENERATED: 02NOV2005 15:26:06 iceadmn3

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Colchicine	0	0	1	0.6	0	0
	Cyclobenzaprine hydrochloride	3	1.8	1	0.6	1	0.6
	Diclofenac	1	0.6	0	0	0	0
	Etoricoxib	0	0	0	0	1	0.6
	Glucosamine	0	0	1	0.6	2	1.2
	Glucosamine hydrochloride	0	0	0	0	1	0.6
	Ibuprofen	29	17.0	26	15.5	33	19.8
	Ketoprofen	0	0	1	0.6	0	0
	Meloxicam	0	0	0	0	1	0.6
	Metaxalone	1	0.6	0	0	0	0
	Naproxen	3	1.8	1	0.6	2	1.2
	Naproxen sodium	5	2.9	7	4.2	10	6.0
	Piroxicam	0	0	0	0	2	1.2
	Pseudoephedrine hydrochloride	1	0.6	0	0	0	0
	Risedronate sodium	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
GENERATED: 02NOV2005 15:26:06 iceadmn3

Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Rofecoxib	1	0.6	0	0	0	0
	Valdecoxib	2	1.2	0	0	0	0
NERVOUS SYSTEM	TOTAL	75	43.9	94	56.0	82	49.1
	Acetylsalicylic acid	20	11.7	20	11.9	19	11.4
	Alprazolam	6	3.5	5	3.0	8	4.8
	Amitriptyline	0	0	0	0	1	0.6
	Amitriptyline hydrochloride	1	0.6	1	0.6	0	0
	Antidepressants	0	0	1	0.6	1	0.6
	Antipsychotics	1	0.6	0	0	1	0.6
	Anxiolytics	0	0	0	0	1	0.6
	Benzatropine mesilate	0	0	0	0	1	0.6
	Benzodiazepine derivatives	0	0	1	0.6	0	0
	Bupropion	0	0	0	0	1	0.6
	Bupropion hydrochloride	5	2.9	9	5.4	8	4.8

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Buspirone	0	0	1	0.6	0	0
	Buspirone hydrochloride	0	0	1	0.6	0	0
	Butalbital	0	0	1	0.6	0	0
	Caffeine	0	0	2	1.2	1	0.6
	Carbamazepine	1	0.6	1	0.6	0	0
	Citalopram hydrobromide	0	0	3	1.8	1	0.6
	Clomipramine hydrochloride	0	0	1	0.6	0	0
	Clonazepam	2	1.2	4	2.4	1	0.6
	Clorazepate dipotassium	0	0	0	0	1	0.6
	Codeine phosphate	0	0	2	1.2	1	0.6
	Cyclobenzaprine	0	0	1	0.6	0	0
	Dextropropoxyphene	1	0.6	0	0	0	0
	Dextropropoxyphene hydrochloride	0	0	1	0.6	0	0
	Diazepam	0	0	1	0.6	3	1.8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Diclofenac sodium	1	0.6	0	0	1	0.6
	Diphenhydramine	4	2.3	6	3.6	5	3.0
	Doxepin hydrochloride	1	0.6	0	0	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.6
	Escitalopram oxalate	2	1.2	2	1.2	5	3.0
	Ethanol	5	2.9	3	1.8	0	0
	Fluoxetine	1	0.6	0	0	0	0
	Fluoxetine hydrochloride	2	1.2	8	4.8	3	1.8
	Fluvoxamine maleate	1	0.6	0	0	0	0
	Gabapentin	0	0	1	0.6	1	0.6
	Ginkgo biloba	0	0	0	0	2	1.2
	Hydroxyzine hydrochloride	0	0	1	0.6	1	0.6
	Lamotrigine	1	0.6	6	3.6	3	1.8
	Lithium	2	1.2	6	3.6	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS200.SAS
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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Lithium carbonate	1	0.6	1	0.6	2	1.2
	Lorazepam	2	1.2	5	3.0	3	1.8
	Mepyramine maleate	1	0.6	2	1.2	1	0.6
	Methylphenidate hydrochloride	1	0.6	0	0	0	0
	Methylsulfonylmeth-ane	0	0	1	0.6	0	0
	Mirtazapine	2	1.2	1	0.6	0	0
	Modafinil	0	0	1	0.6	0	0
	Morphine hydrochloride	0	0	1	0.6	0	0
	Nefazodone hydrochloride	0	0	1	0.6	0	0
	Nortriptyline	0	0	1	0.6	0	0
	Nortriptyline hydrochloride	0	0	1	0.6	0	0
	Olanzapine	2	1.2	2	1.2	6	3.6
	Oxcarbazepine	1	0.6	2	1.2	0	0
	Oxycodone	1	0.6	0	0	1	0.6

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Paracetamol	30	17.5	25	14.9	17	10.2
	Paroxetine hydrochloride	1	0.6	4	2.4	2	1.2
	Perphenazine	0	0	1	0.6	0	0
	Phenobarbital sodium	0	0	1	0.6	0	0
	Quetiapine fumarate	2	1.2	0	0	1	0.6
	Risperidone	1	0.6	3	1.8	3	1.8
	Rizatriptan benzoate	0	0	1	0.6	0	0
	Salicylamide	1	0.6	0	0	0	0
	Sertraline hydrochloride	6	3.5	6	3.6	3	1.8
	Sumatriptan	0	0	0	0	2	1.2
	Temazepam	0	0	0	0	2	1.2
	Thioridazine hydrochloride	0	0	1	0.6	0	0
	Tomoxetine hydrochloride	1	0.6	0	0	1	0.6
	Topiramate	2	1.2	3	1.8	0	0

(Continued)

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Tramadol	0	0	1	0.6	0	0
	Tramadol hydrochloride	0	0	2	1.2	0	0
	Trazodone	5	2.9	4	2.4	5	3.0
	Trifluoperazine hydrochloride	0	0	0	0	1	0.6
	Valeriana officinalis root	1	0.6	0	0	0	0
	Valproate semisodium	7	4.1	9	5.4	7	4.2
	Venlafaxine	3	1.8	0	0	5	3.0
	Venlafaxine hydrochloride	0	0	4	2.4	4	2.4
	Ziprasidone hydrochloride	3	1.8	1	0.6	0	0
	Zolpidem tartrate	2	1.2	7	4.2	0	0
RESPIRATORY SYSTEM	TOTAL	32	18.7	30	17.9	25	15.0
	Allergy medication	1	0.6	0	0	0	0
	Antihistamines	1	0.6	0	0	0	0
	Camphor	1	0.6	0	0	0	0

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Cetirizine hydrochloride	1	0.6	2	1.2	2	1.2
	Chlorphenamine maleate	0	0	0	0	2	1.2
	Cough and cold preparations	0	0	0	0	1	0.6
	Cromoglicate sodium	0	0	1	0.6	0	0
	Desloratadine	0	0	1	0.6	1	0.6
	Dextromethorphan hydrobromide	0	0	0	0	1	0.6
	Dimenhydrinate	0	0	1	0.6	0	0
	Diphenhydramine hydrochloride	4	2.3	4	2.4	2	1.2
	Epinephrine	0	0	2	1.2	1	0.6
	Fexofenadine hydrochloride	0	0	1	0.6	2	1.2
	Flunisolide	0	0	0	0	1	0.6
	Fluticasone propionate	6	3.5	5	3.0	5	3.0
	Guaifenesin	2	1.2	1	0.6	0	0

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Hydrocodone	0	0	1	0.6	1	0.6
	Ipratropium bromide	0	0	1	0.6	0	0
	Loratadine	4	2.3	3	1.8	3	1.8
	Meclozine hydrochloride	0	0	1	0.6	0	0
	Mometasone furoate	0	0	1	0.6	1	0.6
	Montelukast sodium	3	1.8	3	1.8	0	0
	Paracetamol	2	1.2	0	0	0	0
	Phenylephrine hydrochloride	0	0	1	0.6	0	0
	Phenyltoloxamine citrate	1	0.6	0	0	0	0
	Promethazine	0	0	1	0.6	0	0
	Promethazine hydrochloride	1	0.6	0	0	0	0
	Pseudoephedrine	0	0	1	0.6	0	0
	Pseudoephedrine hydrochloride	4	2.3	2	1.2	3	1.8
	Pseudoephedrine sulfate	0	0	1	0.6	0	0

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Pseudoephedrine, combinations	1	0.6	0	0	0	0
	Salbutamol	7	4.1	9	5.4	5	3.0
	Salmeterol xinafoate	1	0.6	0	0	0	0
	Sulfogaiacol	1	0.6	0	0	0	0
	Theophylline	0	0	1	0.6	0	0
	Triamcinolone acetonide	0	0	0	0	1	0.6
SENSORY ORGANS	TOTAL	2	1.2	1	0.6	0	0
	Latanoprost	1	0.6	0	0	0	0
	Olopatadine hydrochloride	1	0.6	0	0	0	0
	Travoprost	0	0	1	0.6	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	8	4.7	7	4.2	10	6.0
	Betamethasone dipropionate	1	0.6	0	0	0	0
	Cortisone	0	0	0	0	1	0.6
	Desmopressin	0	0	0	0	1	0.6

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	Hydrocortisone	0	0	0	0	1	0.6
	Levothyroxine sodium	4	2.3	6	3.6	7	4.2
	Melatonin	2	1.2	1	0.6	2	1.2
	Methylprednisolone	1	0.6	0	0	0	0
VARIOUS	TOTAL	9	5.3	7	4.2	5	3.0
	All other therapeutic products	2	1.2	1	0.6	0	0
	Allergens nos	0	0	1	0.6	0	0
	Allium sativum	0	0	3	1.8	0	0
	Citric acid monohydrate	0	0	0	0	1	0.6
	Creatine	1	0.6	0	0	0	0
	Ginseng nos	1	0.6	0	0	0	0
	Herbal nos	1	0.6	0	0	1	0.6
	Herbal preparation	1	0.6	0	0	0	0
	Hypericum perforatum	1	0.6	1	0.6	0	0

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Table 11.1.7.1 Prior Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	Linum usitatissimum seed oil	1	0.6	0	0	0	0
	Other nutrients	0	0	2	1.2	2	1.2
	Piper methysticum rhizome	2	1.2	0	0	0	0
	Uncaria tomentosa	0	0	0	0	1	0.6

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		112	72.3	118	78.1	126	78.3
ALIMENTARY TRACT AND METABOLISM	TOTAL	45	29.0	51	33.8	46	28.6
	Ascorbic acid	5	3.2	4	2.6	1	0.6
	Atropine sulfate	1	0.6	0	0	0	0
	Bismuth subsalicylate	0	0	2	1.3	2	1.2
	Calcium	2	1.3	1	0.7	3	1.9
	Calcium carbonate	5	3.2	4	2.6	4	2.5
	Cimetidine	0	0	0	0	1	0.6
	Colecalciferol	0	0	0	0	1	0.6
	Dexamfetamine sulfate	1	0.6	1	0.7	0	0
	Dihydroxyaluminum sodium carbonate	0	0	2	1.3	1	0.6
	Docusate sodium	0	0	2	1.3	0	0
	Ergocalciferol	7	4.5	6	4.0	3	1.9
	Esomeprazole	3	1.9	1	0.7	4	2.5
	Famotidine	0	0	4	2.6	2	1.2

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Glibenclamide	0	0	0	0	1	0.6
	Glipizide	0	0	1	0.7	1	0.6
	Herbal nos	0	0	1	0.7	0	0
	Insulin human	1	0.6	0	0	2	1.2
	Lactobacillus acidophilus	1	0.6	0	0	0	0
	Lansoprazole	1	0.6	3	2.0	2	1.2
	Loperamide hydrochloride	0	0	0	0	1	0.6
	Magnesium aspartate	1	0.6	0	0	0	0
	Magnesium hydroxide	2	1.3	1	0.7	1	0.6
	Metformin	0	0	2	1.3	0	0
	Metformin hydrochloride	1	0.6	0	0	1	0.6
	Metoclopramide hydrochloride	1	0.6	0	0	0	0
	Omeprazole	0	0	3	2.0	3	1.9
	Pantoprazole	3	1.9	1	0.7	0	0
	Pioglitazone	0	0	1	0.7	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Psyllium hydrophilic mucilloid	0	0	1	0.7	0	0
	Pyridoxine hydrochloride	0	0	1	0.7	1	0.6
	Rabeprazole sodium	0	0	2	1.3	1	0.6
	Ranitidine	0	0	1	0.7	0	0
	Ranitidine hydrochloride	1	0.6	1	0.7	2	1.2
	Rosiglitazone maleate	1	0.6	0	0	1	0.6
	Tocopherol	3	1.9	1	0.7	1	0.6
	Vitamin b	1	0.6	0	0	3	1.9
	Vitamins	1	0.6	1	0.7	0	0
	Vitamins nos	16	10.3	20	13.2	18	11.2
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	9	5.8	6	4.0	11	6.8
	Amoxicillin	0	0	1	0.7	1	0.6
	Amoxicillin trihydrate	0	0	0	0	1	0.6
	Azithromycin	1	0.6	0	0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Benzylpenicillin sodium	2	1.3	0	0	0	0
	Bicillin	0	0	0	0	1	0.6
	Cefalexin	0	0	0	0	1	0.6
	Cefalexin monohydrate	2	1.3	0	0	0	0
	Cefprozil	0	0	0	0	1	0.6
	Ceftriaxone sodium	0	0	0	0	1	0.6
	Ciprofloxacin hydrochloride	3	1.9	1	0.7	0	0
	Clarithromycin	0	0	2	1.3	0	0
	Doxycycline	2	1.3	0	0	0	0
	Levofloxacin	0	0	2	1.3	2	1.2
	Minocycline	0	0	1	0.7	1	0.6
	Tetracycline	0	0	0	0	2	1.2
	Valaciclovir hydrochloride	0	0	0	0	1	0.6
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	0.6	1	0.7	0	0
	Colostrum	1	0.6	0	0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	Hydroxycarbamide	0	0	1	0.7	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	0	0	2	1.3	3	1.9
	Cyanocobalamin-tannin complex	0	0	1	0.7	0	0
	Folic acid	0	0	1	0.7	0	0
	Iron	0	0	0	0	2	1.2
	Warfarin sodium	0	0	0	0	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	19	12.3	14	9.3	20	12.4
	Amlodipine	0	0	2	1.3	1	0.6
	Amlodipine besilate	0	0	1	0.7	0	0
	Atenolol	1	0.6	1	0.7	3	1.9
	Atorvastatin	4	2.6	3	2.0	4	2.5
	Chlortalidone	1	0.6	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	0.7	0	0
	Doxazosin mesilate	0	0	1	0.7	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Enalapril	0	0	0	0	1	0.6
	Fenofibrate	0	0	1	0.7	1	0.6
	Fish oil	3	1.9	1	0.7	1	0.6
	Furosemide	0	0	1	0.7	0	0
	Hydrochlorothiazide	5	3.2	3	2.0	1	0.6
	Isradipine	1	0.6	0	0	0	0
	Lisinopril	0	0	2	1.3	2	1.2
	Losartan potassium	1	0.6	0	0	0	0
	Metoprolol	0	0	1	0.7	0	0
	Metoprolol succinate	0	0	0	0	1	0.6
	Nifedipine	1	0.6	0	0	0	0
	Nisoldipine	0	0	0	0	1	0.6
	Olmesartan medoxomil	0	0	1	0.7	1	0.6
	Omega-3 triglycerides	2	1.3	0	0	1	0.6
	Preparation h	0	0	1	0.7	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Propranolol	1	0.6	0	0	0	0
	Propranolol hydrochloride	0	0	0	0	1	0.6
	Ramipril	0	0	0	0	1	0.6
	Rosuvastatin	0	0	0	0	1	0.6
	Simvastatin	0	0	0	0	1	0.6
	Spironolactone	0	0	1	0.7	0	0
	Timolol	0	0	1	0.7	0	0
	Ubidecarenone	0	0	0	0	1	0.6
	Valsartan	0	0	1	0.7	0	0
DERMATOLOGICALS	TOTAL	0	0	2	1.3	2	1.2
	Calcipotriol	0	0	1	0.7	0	0
	Hydrocortisone	0	0	0	0	1	0.6
	Linoleic acid	0	0	0	0	1	0.6
	Nystatin	0	0	1	0.7	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	8	5.2	18	11.9	24	14.9
	Cimicifuga racemosa root	0	0	1	0.7	1	0.6

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Clindamycin hydrochloride	0	0	1	0.7	0	0
	Clotrimazole	1	0.6	0	0	0	0
	Estradiol	0	0	1	0.7	0	0
	Estrogens conjugated	1	0.6	1	0.7	1	0.6
	Ethinylestradiol	2	1.3	3	2.0	8	5.0
	Hormonal contraceptives for systemic use	0	0	1	0.7	0	0
	Levonorgestrel	0	0	1	0.7	0	0
	Medroxyprogesterone acetate	3	1.9	7	4.6	5	3.1
	Norelgestromin	0	0	1	0.7	1	0.6
	Norethisterone acetate	0	0	1	0.7	0	0
	Norgestimate	0	0	2	1.3	1	0.6
	Oral contraceptive nos	0	0	1	0.7	0	0
	Phenazopyridine	1	0.6	0	0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Progesterone	0	0	0	0	1	0.6
	Serenoa repens	0	0	0	0	1	0.6
	Sildenafil citrate	0	0	0	0	1	0.6
	Testosterone	0	0	0	0	2	1.2
	Tolterodine l-tartrate	0	0	0	0	2	1.2
MUSCULO-SKELETAL SYSTEM	TOTAL	38	24.5	39	25.8	46	28.6
	Alendronate sodium	0	0	0	0	1	0.6
	Allopurinol	0	0	1	0.7	0	0
	Baclofen	1	0.6	0	0	0	0
	Carisoprodol	0	0	1	0.7	1	0.6
	Celecoxib	1	0.6	2	1.3	1	0.6
	Chondroitin sulfate	0	0	1	0.7	0	0
	Colchicine	0	0	1	0.7	0	0
	Cyclobenzaprine hydrochloride	3	1.9	1	0.7	1	0.6
	Etoricoxib	0	0	0	0	1	0.6
	Glucosamine	0	0	1	0.7	2	1.2

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Glucosamine hydrochloride	0	0	0	0	1	0.6
	Ibuprofen	25	16.1	26	17.2	31	19.3
	Ketoprofen	0	0	1	0.7	0	0
	Meloxicam	0	0	0	0	1	0.6
	Metaxalone	1	0.6	0	0	0	0
	Naproxen	3	1.9	1	0.7	2	1.2
	Naproxen sodium	4	2.6	7	4.6	10	6.2
	Piroxicam	0	0	0	0	2	1.2
	Pseudoephedrine hydrochloride	1	0.6	0	0	0	0
	Risedronate sodium	0	0	1	0.7	0	0
	Rofecoxib	1	0.6	0	0	0	0
	Valdecoxib	2	1.3	0	0	0	0
NERVOUS SYSTEM	TOTAL	68	43.9	86	57.0	81	50.3
	Acetylsalicylic acid	18	11.6	19	12.6	19	11.8
	Alprazolam	6	3.9	3	2.0	8	5.0

(Continued)

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Amitriptyline	0	0	0	0	1	0.6
	Amitriptyline hydrochloride	1	0.6	1	0.7	0	0
	Antidepressants	0	0	1	0.7	1	0.6
	Antipsychotics	1	0.6	0	0	1	0.6
	Anxiolytics	0	0	0	0	1	0.6
	Benzodiazepine derivatives	0	0	1	0.7	0	0
	Bupropion	0	0	0	0	1	0.6
	Bupropion hydrochloride	5	3.2	9	6.0	8	5.0
	Buspirone	0	0	1	0.7	0	0
	Buspirone hydrochloride	0	0	1	0.7	0	0
	Butalbital	0	0	1	0.7	0	0
	Caffeine	0	0	1	0.7	1	0.6
	Carbamazepine	1	0.6	1	0.7	0	0
	Citalopram hydrobromide	0	0	3	2.0	1	0.6

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Clomipramine hydrochloride	0	0	1	0.7	0	0
	Clonazepam	2	1.3	3	2.0	1	0.6
	Clorazepate dipotassium	0	0	0	0	1	0.6
	Codeine phosphate	0	0	2	1.3	1	0.6
	Cyclobenzaprine	0	0	1	0.7	0	0
	Dextropropoxyphene	1	0.6	0	0	0	0
	Dextropropoxyphene hydrochloride	0	0	1	0.7	0	0
	Diazepam	0	0	1	0.7	3	1.9
	Diclofenac sodium	1	0.6	0	0	1	0.6
	Diphenhydramine	3	1.9	6	4.0	5	3.1
	Doxepin hydrochloride	1	0.6	0	0	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.6
	Escitalopram oxalate	2	1.3	2	1.3	5	3.1
	Ethanol	5	3.2	3	2.0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Fluoxetine	1	0.6	0	0	0	0
	Fluoxetine hydrochloride	2	1.3	8	5.3	3	1.9
	Gabapentin	0	0	1	0.7	1	0.6
	Ginkgo biloba	0	0	0	0	2	1.2
	Hydroxyzine hydrochloride	0	0	1	0.7	1	0.6
	Lamotrigine	1	0.6	6	4.0	3	1.9
	Lithium	2	1.3	6	4.0	1	0.6
	Lithium carbonate	0	0	1	0.7	2	1.2
	Lorazepam	2	1.3	5	3.3	3	1.9
	Mepyramine maleate	1	0.6	1	0.7	1	0.6
	Methylsulfonylmeth-ane	0	0	1	0.7	0	0
	Mirtazapine	2	1.3	1	0.7	0	0
	Modafinil	0	0	1	0.7	0	0
	Morphine hydrochloride	0	0	1	0.7	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Nefazodone hydrochloride	0	0	1	0.7	0	0
	Nortriptyline	0	0	1	0.7	0	0
	Nortriptyline hydrochloride	0	0	1	0.7	0	0
	Olanzapine	2	1.3	2	1.3	5	3.1
	Oxcarbazepine	1	0.6	2	1.3	0	0
	Oxycodone	1	0.6	0	0	1	0.6
	Paracetamol	27	17.4	23	15.2	17	10.6
	Paroxetine hydrochloride	1	0.6	4	2.6	2	1.2
	Perphenazine	0	0	1	0.7	0	0
	Phenobarbital sodium	0	0	1	0.7	0	0
	Quetiapine fumarate	2	1.3	0	0	1	0.6
	Risperidone	1	0.6	3	2.0	3	1.9
	Rizatriptan benzoate	0	0	1	0.7	0	0
	Salicylamide	1	0.6	0	0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Sertraline hydrochloride	6	3.9	6	4.0	3	1.9
	Sumatriptan	0	0	0	0	2	1.2
	Temazepam	0	0	0	0	2	1.2
	Thioridazine hydrochloride	0	0	1	0.7	0	0
	Tomoxetine hydrochloride	1	0.6	0	0	1	0.6
	Topiramate	2	1.3	3	2.0	0	0
	Tramadol	0	0	1	0.7	0	0
	Tramadol hydrochloride	0	0	2	1.3	0	0
	Trazodone	4	2.6	4	2.6	5	3.1
	Valeriana officinalis root	1	0.6	0	0	0	0
	Valproate semisodium	6	3.9	9	6.0	6	3.7
	Venlafaxine	3	1.9	0	0	5	3.1
	Venlafaxine hydrochloride	0	0	4	2.6	4	2.5

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Ziprasidone hydrochloride	1	0.6	1	0.7	0	0
	Zolpidem tartrate	2	1.3	6	4.0	0	0
RESPIRATORY SYSTEM	TOTAL	28	18.1	28	18.5	24	14.9
	Allergy medication	1	0.6	0	0	0	0
	Antihistamines	1	0.6	0	0	0	0
	Camphor	1	0.6	0	0	0	0
	Cetirizine hydrochloride	1	0.6	2	1.3	2	1.2
	Chlorphenamine maleate	0	0	0	0	2	1.2
	Cough and cold preparations	0	0	0	0	1	0.6
	Cromoglicate sodium	0	0	1	0.7	0	0
	Desloratadine	0	0	1	0.7	1	0.6
	Dextromethorphan hydrobromide	0	0	0	0	1	0.6
	Dimenhydrinate	0	0	1	0.7	0	0
	Diphenhydramine hydrochloride	4	2.6	3	2.0	2	1.2

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Epinephrine	0	0	2	1.3	1	0.6
	Fexofenadine hydrochloride	0	0	1	0.7	2	1.2
	Flunisolide	0	0	0	0	1	0.6
	Fluticasone propionate	6	3.9	5	3.3	5	3.1
	Guaifenesin	2	1.3	1	0.7	0	0
	Hydrocodone	0	0	1	0.7	1	0.6
	Ipratropium bromide	0	0	1	0.7	0	0
	Loratadine	4	2.6	3	2.0	3	1.9
	Meclozine hydrochloride	0	0	1	0.7	0	0
	Mometasone furoate	0	0	1	0.7	1	0.6
	Montelukast sodium	3	1.9	3	2.0	0	0
	Paracetamol	1	0.6	0	0	0	0
	Phenylephrine hydrochloride	0	0	1	0.7	0	0
	Phenyltoloxamine citrate	1	0.6	0	0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Promethazine	0	0	1	0.7	0	0
	Promethazine hydrochloride	1	0.6	0	0	0	0
	Pseudoephedrine	0	0	1	0.7	0	0
	Pseudoephedrine hydrochloride	3	1.9	2	1.3	3	1.9
	Pseudoephedrine sulfate	0	0	1	0.7	0	0
	Pseudoephedrine, combinations	1	0.6	0	0	0	0
	Salbutamol	5	3.2	8	5.3	4	2.5
	Salmeterol xinafoate	1	0.6	0	0	0	0
	Sulfogaiacol	1	0.6	0	0	0	0
	Theophylline	0	0	1	0.7	0	0
	Triamcinolone acetonide	0	0	0	0	1	0.6
SENSORY ORGANS	TOTAL	2	1.3	1	0.7	0	0
	Latanoprost	1	0.6	0	0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SENSORY ORGANS	Olopatadine hydrochloride	1	0.6	0	0	0	0
	Travoprost	0	0	1	0.7	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	7	4.5	7	4.6	10	6.2
	Betamethasone dipropionate	1	0.6	0	0	0	0
	Cortisone	0	0	0	0	1	0.6
	Desmopressin	0	0	0	0	1	0.6
	Hydrocortisone	0	0	0	0	1	0.6
	Levothyroxine sodium	4	2.6	6	4.0	7	4.3
	Melatonin	1	0.6	1	0.7	2	1.2
	Methylprednisolone	1	0.6	0	0	0	0
VARIOUS	TOTAL	9	5.8	7	4.6	5	3.1
	All other therapeutic products	2	1.3	1	0.7	0	0
	Allergens nos	0	0	1	0.7	0	0
	Allium sativum	0	0	3	2.0	0	0

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Table 11.1.7.2 Prior Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	Citric acid monohydrate	0	0	0	0	1	0.6
	Creatine	1	0.6	0	0	0	0
	Ginseng nos	1	0.6	0	0	0	0
	Herbal nos	1	0.6	0	0	1	0.6
	Herbal preparation	1	0.6	0	0	0	0
	Hypericum perforatum	1	0.6	1	0.7	0	0
	Linum usitatissimum seed oil	1	0.6	0	0	0	0
	Other nutrients	0	0	2	1.3	2	1.2
	Piper methysticum rhizome	2	1.3	0	0	0	0
	Uncaria tomentosa	0	0	0	0	1	0.6

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		86	76.8	86	76.8	92	82.1	40	67.8	44	78.6	39	70.9
ALIMENTARY TRACT AND METABOLISM	TOTAL	38	33.9	37	33.0	33	29.5	13	22.0	18	32.1	16	29.1
	Ascorbic acid	5	4.5	3	2.7	0	0	0	0	1	1.8	2	3.6
	Atropine sulfate	0	0	0	0	0	0	1	1.7	0	0	0	0
	Bismuth subsalicylate	0	0	2	1.8	1	0.9	0	0	0	0	1	1.8
	Calcium	2	1.8	1	0.9	1	0.9	0	0	0	0	2	3.6
	Calcium carbonate	3	2.7	3	2.7	2	1.8	2	3.4	1	1.8	2	3.6
	Cimetidine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Colecalciferol	0	0	0	0	1	0.9	0	0	0	0	0	0
	Dexamfetamine sulfate	0	0	1	0.9	0	0	1	1.7	0	0	0	0
	Dicycloverine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Dihydroxyaluminum sodium carbonate	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	Docusate sodium	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	Ergocalciferol	6	5.4	3	2.7	1	0.9	2	3.4	3	5.4	2	3.6

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Esomeprazole	3	2.7	1	0.9	4	3.6	1	1.7	0	0	1	1.8
	Famotidine	0	0	5	4.5	2	1.8	0	0	0	0	0	0
	Glibenclamide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glipizide	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	Herbal nos	0	0	1	0.9	0	0	0	0	0	0	0	0
	Insulin human	1	0.9	0	0	2	1.8	0	0	0	0	0	0
	Lactobacillus acidophilus	1	0.9	0	0	0	0	0	0	0	0	0	0
	Lansoprazole	2	1.8	1	0.9	1	0.9	0	0	2	3.6	1	1.8
	Loperamide hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Magnesium aspartate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Magnesium hydroxide	2	1.8	1	0.9	1	0.9	0	0	0	0	0	0
	Metformin	0	0	2	1.8	0	0	0	0	0	0	0	0
	Metformin hydrochloride	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	Metoclopramide hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS202.SAS
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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Omeprazole	0	0	4	3.6	2	1.8	0	0	0	0	1	1.8
	Pantoprazole	1	0.9	0	0	0	0	2	3.4	1	1.8	0	0
	Pioglitazone	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Psyllium hydrophilic mucilloid	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Pyridoxine hydrochloride	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	Rabeprazole sodium	0	0	1	0.9	0	0	0	0	1	1.8	1	1.8
	Ranitidine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Ranitidine hydrochloride	0	0	1	0.9	3	2.7	1	1.7	0	0	0	0
	Rosiglitazone maleate	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Tocopherol	2	1.8	1	0.9	0	0	1	1.7	0	0	1	1.8
	Vitamin b	1	0.9	0	0	1	0.9	0	0	0	0	2	3.6
	Vitamins	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Vitamins nos	12	10.7	14	12.5	13	11.6	5	8.5	7	12.5	5	9.1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS202.SAS
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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	6	5.4	5	4.5	6	5.4	3	5.1	2	3.6	5	9.1
	Amoxicillin	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Amoxicillin trihydrate	0	0	0	0	0	0	0	0	0	0	1	1.8
	Azithromycin	1	0.9	0	0	0	0	0	0	0	0	0	0
	Benzylpenicillin sodium	2	1.8	0	0	0	0	0	0	0	0	0	0
	Bicillin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Cefalexin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Cefalexin monohydrate	2	1.8	0	0	0	0	0	0	0	0	0	0
	Cefprozil	0	0	0	0	0	0	0	0	0	0	1	1.8
	Ceftriaxone sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
	Ciprofloxacin hydrochloride	0	0	1	0.9	0	0	3	5.1	0	0	0	0
	Clarithromycin	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	Doxycycline	2	1.8	1	0.9	0	0	0	0	0	0	0	0
	Levofloxacin	0	0	1	0.9	1	0.9	0	0	1	1.8	1	1.8

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Minocycline	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	Tetracycline	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Valaciclovir hydrochloride	0	0	0	0	0	0	0	0	0	0	1	1.8
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Colostrum	1	0.9	0	0	0	0	0	0	0	0	0	0
	Hydroxycarbamide	0	0	1	0.9	0	0	0	0	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	0	0	2	1.8	2	1.8	0	0	0	0	1	1.8
	Cyanocobalamin-tannin complex	0	0	1	0.9	0	0	0	0	0	0	0	0
	Folic acid	0	0	1	0.9	0	0	0	0	0	0	0	0
	Iron	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Warfarin sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	14	12.5	10	8.9	17	15.2	8	13.6	6	10.7	5	9.1
	Amlodipine	0	0	1	0.9	1	0.9	0	0	2	3.6	0	0
	Amlodipine besilate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Atenolol	1	0.9	1	0.9	3	2.7	0	0	0	0	2	3.6

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Atorvastatin	2	1.8	2	1.8	3	2.7	3	5.1	1	1.8	1	1.8
	Chlortalidone	0	0	0	0	0	0	1	1.7	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	0.9	0	0	0	0	0	0	0	0
	Doxazosin mesilate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Enalapril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fenofibrate	1	0.9	0	0	1	0.9	0	0	1	1.8	0	0
	Fish oil	3	2.7	1	0.9	0	0	0	0	0	0	1	1.8
	Furosemide	0	0	1	0.9	0	0	0	0	0	0	0	0
	Hydrochlorothiazide	6	5.4	2	1.8	1	0.9	0	0	1	1.8	0	0
	Isradipine	1	0.9	0	0	0	0	0	0	0	0	0	0
	Lisinopril	1	0.9	2	1.8	1	0.9	0	0	1	1.8	1	1.8
	Losartan potassium	0	0	0	0	0	0	1	1.7	0	0	0	0
	Metoprolol	0	0	2	1.8	0	0	0	0	0	0	0	0
	Metoprolol succinate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Nifedipine	0	0	0	0	0	0	1	1.7	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Nisoldipine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Olmesartan medoxomil	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	Omega-3 triglycerides	1	0.9	0	0	1	0.9	1	1.7	0	0	0	0
	Preparation h	0	0	0	0	0	0	0	0	1	1.8	0	0
	Propranolol	1	0.9	0	0	0	0	0	0	0	0	0	0
	Propranolol hydrochloride	0	0	0	0	0	0	0	0	0	0	1	1.8
	Ramipril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Rosuvastatin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Simvastatin	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Spironolactone	0	0	0	0	0	0	0	0	1	1.8	0	0
	Timolol	0	0	1	0.9	0	0	0	0	0	0	0	0
	Ubidecarenone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Valsartan	0	0	0	0	0	0	0	0	1	1.8	0	0
	Verapamil hydrochloride	0	0	0	0	0	0	1	1.7	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	TOTAL	0	0	2	1.8	1	0.9	0	0	0	0	1	1.8
	Calcipotriol	0	0	1	0.9	0	0	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	0	0	0	0	0	0	1	1.8
	Linoleic acid	0	0	0	0	1	0.9	0	0	0	0	0	0
	Nystatin	0	0	1	0.9	0	0	0	0	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	8	7.1	15	13.4	16	14.3	1	1.7	4	7.1	8	14.5
	Cimicifuga racemosa root	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Clindamycin hydrochloride	0	0	0	0	0	0	0	0	1	1.8	0	0
	Clotrimazole	1	0.9	0	0	0	0	0	0	0	0	0	0
	Estradiol	0	0	0	0	0	0	0	0	1	1.8	0	0
	Estrogens conjugated	1	0.9	1	0.9	0	0	0	0	0	0	1	1.8
	Ethinylestradiol	2	1.8	3	2.7	5	4.5	0	0	0	0	3	5.5
	Hormonal contraceptives for systemic use	0	0	1	0.9	0	0	0	0	0	0	0	0
	Levonorgestrel	0	0	0	0	0	0	1	1.7	1	1.8	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Medroxyprogesterone acetate	3	2.7	6	5.4	4	3.6	0	0	2	3.6	1	1.8
	Norelgestromin	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Norethisterone acetate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Norgestimate	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0
	Oral contraceptive nos	0	0	1	0.9	0	0	0	0	0	0	0	0
	Phenazopyridine	1	0.9	0	0	0	0	0	0	0	0	0	0
	Progesterone	0	0	0	0	0	0	0	0	0	0	1	1.8
	Serenoa repens	0	0	0	0	1	0.9	0	0	0	0	0	0
	Sildenafil citrate	0	0	0	0	0	0	0	0	0	0	1	1.8
	Testosterone	0	0	0	0	2	1.8	0	0	0	0	0	0
	Tolterodine l-tartrate	0	0	0	0	1	0.9	0	0	0	0	1	1.8
MUSCULO-SKELETAL SYSTEM	TOTAL	27	24.1	31	27.7	33	29.5	15	25.4	9	16.1	15	27.3
	Acetylsalicylic acid	0	0	0	0	0	0	0	0	0	0	1	1.8
	Alendronate sodium	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Allopurinol	0	0	0	0	0	0	0	0	1	1.8	0	0
	Baclofen	0	0	0	0	0	0	1	1.7	0	0	0	0
	Carisoprodol	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Celecoxib	0	0	2	1.8	0	0	1	1.7	0	0	1	1.8
	Chondroitin sulfate	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	Colchicine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Cyclobenzaprine hydrochloride	2	1.8	1	0.9	1	0.9	1	1.7	0	0	0	0
	Diclofenac	0	0	0	0	0	0	1	1.7	0	0	0	0
	Etoricoxib	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glucosamine	0	0	1	0.9	1	0.9	0	0	0	0	1	1.8
	Glucosamine hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Ibuprofen	20	17.9	22	19.6	24	21.4	9	15.3	4	7.1	9	16.4
	Ketoprofen	0	0	0	0	0	0	0	0	1	1.8	0	0
	Meloxicam	0	0	0	0	0	0	0	0	0	0	1	1.8
	Metaxalone	1	0.9	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Naproxen	1	0.9	1	0.9	1	0.9	2	3.4	0	0	1	1.8
	Naproxen sodium	2	1.8	6	5.4	5	4.5	3	5.1	1	1.8	5	9.1
	Piroxicam	0	0	0	0	2	1.8	0	0	0	0	0	0
	Pseudoephedrine hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Risedronate sodium	0	0	0	0	0	0	0	0	1	1.8	0	0
	Rofecoxib	0	0	0	0	0	0	1	1.7	0	0	0	0
	Valdecoxib	1	0.9	0	0	0	0	1	1.7	0	0	0	0
NERVOUS SYSTEM	TOTAL	49	43.8	65	58.0	60	53.6	26	44.1	29	51.8	22	40.0
	Acetylsalicylic acid	11	9.8	15	13.4	14	12.5	9	15.3	5	8.9	5	9.1
	Alprazolam	2	1.8	2	1.8	5	4.5	4	6.8	3	5.4	3	5.5
	Amitriptyline	0	0	0	0	1	0.9	0	0	0	0	0	0
	Amitriptyline hydrochloride	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Antidepressants	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Antipsychotics	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Anxiolytics	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Benzatropine mesilate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Benzodiazepine derivatives	0	0	1	0.9	0	0	0	0	0	0	0	0
	Bupropion	0	0	0	0	1	0.9	0	0	0	0	0	0
	Bupropion hydrochloride	5	4.5	6	5.4	5	4.5	0	0	3	5.4	3	5.5
	Buspirone	0	0	1	0.9	0	0	0	0	0	0	0	0
	Buspirone hydrochloride	0	0	0	0	0	0	0	0	1	1.8	0	0
	Butalbital	0	0	0	0	0	0	0	0	1	1.8	0	0
	Caffeine	0	0	0	0	1	0.9	0	0	2	3.6	0	0
	Carbamazepine	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Citalopram hydrobromide	0	0	1	0.9	1	0.9	0	0	2	3.6	0	0
	Clomipramine hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0
	Clonazepam	2	1.8	3	2.7	1	0.9	0	0	1	1.8	0	0
	Clorazepate dipotassium	0	0	0	0	0	0	0	0	0	0	1	1.8

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Codeine phosphate	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	Cyclobenzaprine	0	0	1	0.9	0	0	0	0	0	0	0	0
	Dextropropoxyphene	0	0	0	0	0	0	1	1.7	0	0	0	0
	Dextropropoxyphene hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0
	Diazepam	0	0	1	0.9	2	1.8	0	0	0	0	1	1.8
	Diclofenac sodium	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Diphenhydramine	3	2.7	3	2.7	3	2.7	1	1.7	3	5.4	2	3.6
	Doxepin hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Escitalopram oxalate	1	0.9	1	0.9	4	3.6	1	1.7	1	1.8	1	1.8
	Ethanol	5	4.5	3	2.7	0	0	0	0	0	0	0	0
	Fluoxetine	1	0.9	0	0	0	0	0	0	0	0	0	0
	Fluoxetine hydrochloride	1	0.9	7	6.3	2	1.8	1	1.7	1	1.8	1	1.8
	Fluvoxamine maleate	0	0	0	0	0	0	1	1.7	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Gabapentin	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Ginkgo biloba	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Hydroxyzine hydrochloride	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Lamotrigine	1	0.9	4	3.6	2	1.8	0	0	2	3.6	1	1.8
	Lithium	1	0.9	4	3.6	1	0.9	1	1.7	2	3.6	0	0
	Lithium carbonate	0	0	1	0.9	2	1.8	1	1.7	0	0	0	0
	Lorazepam	1	0.9	4	3.6	3	2.7	1	1.7	1	1.8	0	0
	Mepyramine maleate	1	0.9	2	1.8	1	0.9	0	0	0	0	0	0
	Methylphenidate hydrochloride	0	0	0	0	0	0	1	1.7	0	0	0	0
	Methylsulfonylmeth-ane	0	0	1	0.9	0	0	0	0	0	0	0	0
	Mirtazapine	1	0.9	1	0.9	0	0	1	1.7	0	0	0	0
	Modafinil	0	0	0	0	0	0	0	0	1	1.8	0	0
	Morphine hydrochloride	0	0	0	0	0	0	0	0	1	1.8	0	0
	Nefazodone hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Nortriptyline	0	0	0	0	0	0	0	0	1	1.8	0	0
	Nortriptyline hydrochloride	0	0	0	0	0	0	0	0	1	1.8	0	0
	Olanzapine	0	0	2	1.8	4	3.6	2	3.4	0	0	2	3.6
	Oxcarbazepine	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	Oxycodone	0	0	0	0	0	0	1	1.7	0	0	1	1.8
	Paracetamol	18	16.1	17	15.2	11	9.8	12	20.3	8	14.3	6	10.9
	Paroxetine hydrochloride	1	0.9	1	0.9	1	0.9	0	0	3	5.4	1	1.8
	Perphenazine	0	0	1	0.9	0	0	0	0	0	0	0	0
	Phenobarbital sodium	0	0	0	0	0	0	0	0	1	1.8	0	0
	Quetiapine fumarate	2	1.8	0	0	1	0.9	0	0	0	0	0	0
	Risperidone	1	0.9	3	2.7	1	0.9	0	0	0	0	2	3.6
	Rizatriptan benzoate	0	0	0	0	0	0	0	0	1	1.8	0	0
	Salicylamide	1	0.9	0	0	0	0	0	0	0	0	0	0
	Sertraline hydrochloride	4	3.6	3	2.7	2	1.8	2	3.4	3	5.4	1	1.8

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Sumatriptan	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Temazepam	0	0	0	0	2	1.8	0	0	0	0	0	0
	Thioridazine hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0
	Tomoxetine hydrochloride	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Topiramate	1	0.9	2	1.8	0	0	1	1.7	1	1.8	0	0
	Tramadol	0	0	1	0.9	0	0	0	0	0	0	0	0
	Tramadol hydrochloride	0	0	2	1.8	0	0	0	0	0	0	0	0
	Trazodone	3	2.7	4	3.6	5	4.5	2	3.4	0	0	0	0
	Trifluoperazine hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Valeriana officinalis root	1	0.9	0	0	0	0	0	0	0	0	0	0
	Valproate semisodium	5	4.5	9	8.0	7	6.3	2	3.4	0	0	0	0
	Venlafaxine	2	1.8	0	0	5	4.5	1	1.7	0	0	0	0
	Venlafaxine hydrochloride	0	0	2	1.8	3	2.7	0	0	2	3.6	1	1.8

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Ziprasidone hydrochloride	2	1.8	0	0	0	0	1	1.7	1	1.8	0	0
	Zolpidem tartrate	2	1.8	7	6.3	0	0	0	0	0	0	0	0
RESPIRATORY SYSTEM	TOTAL	18	16.1	25	22.3	16	14.3	14	23.7	5	8.9	9	16.4
	Allergy medication	1	0.9	0	0	0	0	0	0	0	0	0	0
	Antihistamines	1	0.9	0	0	0	0	0	0	0	0	0	0
	Camphor	1	0.9	0	0	0	0	0	0	0	0	0	0
	Cetirizine hydrochloride	0	0	2	1.8	1	0.9	1	1.7	0	0	1	1.8
	Chlorphenamine maleate	0	0	0	0	0	0	0	0	0	0	2	3.6
	Cough and cold preparations	0	0	0	0	0	0	0	0	0	0	1	1.8
	Cromoglicate sodium	0	0	1	0.9	0	0	0	0	0	0	0	0
	Desloratadine	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Dextromethorphan hydrobromide	0	0	0	0	0	0	0	0	0	0	1	1.8
	Dimenhydrinate	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Diphenhydramine hydrochloride	2	1.8	3	2.7	1	0.9	2	3.4	1	1.8	1	1.8
	Epinephrine	0	0	2	1.8	0	0	0	0	0	0	1	1.8
	Fexofenadine hydrochloride	0	0	0	0	2	1.8	0	0	1	1.8	0	0
	Flunisolide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fluticasone propionate	2	1.8	5	4.5	3	2.7	4	6.8	0	0	2	3.6
	Guaifenesin	1	0.9	1	0.9	0	0	1	1.7	0	0	0	0
	Hydrocodone	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Ipratropium bromide	0	0	1	0.9	0	0	0	0	0	0	0	0
	Loratadine	3	2.7	3	2.7	3	2.7	1	1.7	0	0	0	0
	Meclozine hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0
	Mometasone furoate	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Montelukast sodium	2	1.8	3	2.7	0	0	1	1.7	0	0	0	0
	Paracetamol	1	0.9	0	0	0	0	1	1.7	0	0	0	0
	Phenylephrine hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Phenyltoloxamine citrate	0	0	0	0	0	0	1	1.7	0	0	0	0
	Promethazine	0	0	1	0.9	0	0	0	0	0	0	0	0
	Promethazine hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Pseudoephedrine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Pseudoephedrine hydrochloride	2	1.8	2	1.8	1	0.9	2	3.4	0	0	2	3.6
	Pseudoephedrine sulfate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Pseudoephedrine, combinations	0	0	0	0	0	0	1	1.7	0	0	0	0
	Salbutamol	6	5.4	8	7.1	3	2.7	1	1.7	1	1.8	2	3.6
	Salmeterol xinafoate	0	0	0	0	0	0	1	1.7	0	0	0	0
	Sulfogaiacol	1	0.9	0	0	0	0	0	0	0	0	0	0
	Theophylline	0	0	1	0.9	0	0	0	0	0	0	0	0
	Triamcinolone acetonide	0	0	0	0	1	0.9	0	0	0	0	0	0
SENSORY ORGANS	TOTAL	1	0.9	1	0.9	0	0	1	1.7	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SENSORY ORGANS	Latanoprost	0	0	0	0	0	0	1	1.7	0	0	0	0
	Olopatadine hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Travoprost	0	0	1	0.9	0	0	0	0	0	0	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	7	6.3	4	3.6	8	7.1	1	1.7	3	5.4	2	3.6
	Betamethasone dipropionate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Cortisone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Desmopressin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Levothyroxine sodium	4	3.6	4	3.6	5	4.5	0	0	2	3.6	2	3.6
	Melatonin	2	1.8	0	0	2	1.8	0	0	1	1.8	0	0
	Methylprednisolone	0	0	0	0	0	0	1	1.7	0	0	0	0
VARIOUS	TOTAL	7	6.3	6	5.4	3	2.7	2	3.4	1	1.8	2	3.6
	All other therapeutic products	2	1.8	1	0.9	0	0	0	0	0	0	0	0
	Allergens nos	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.3 Prior Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	Allium sativum	0	0	2	1.8	0	0	0	0	1	1.8	0	0
	Citric acid monohydrate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Creatine	1	0.9	0	0	0	0	0	0	0	0	0	0
	Ginseng nos	0	0	0	0	0	0	1	1.7	0	0	0	0
	Herbal nos	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Herbal preparation	1	0.9	0	0	0	0	0	0	0	0	0	0
	Hypericum perforatum	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Linum usitatissimum seed oil	1	0.9	0	0	0	0	0	0	0	0	0	0
	Other nutrients	0	0	1	0.9	1	0.9	0	0	1	1.8	1	1.8
	Piper methysticum rhizome	1	0.9	0	0	0	0	1	1.7	0	0	0	0
	Uncaria tomentosa	0	0	0	0	0	0	0	0	0	0	1	1.8

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY PRIOR MEDICATION		80	76.9	79	78.2	90	81.8	32	62.7	39	78.0	36	70.6
ALIMENTARY TRACT AND METABOLISM	TOTAL	33	31.7	35	34.7	32	29.1	12	23.5	16	32.0	14	27.5
	Ascorbic acid	5	4.8	3	3.0	0	0	0	0	1	2.0	1	2.0
	Atropine sulfate	0	0	0	0	0	0	1	2.0	0	0	0	0
	Bismuth subsalicylate	0	0	2	2.0	1	0.9	0	0	0	0	1	2.0
	Calcium	2	1.9	1	1.0	1	0.9	0	0	0	0	2	3.9
	Calcium carbonate	3	2.9	3	3.0	2	1.8	2	3.9	1	2.0	2	3.9
	Cimetidine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Colecalciferol	0	0	0	0	1	0.9	0	0	0	0	0	0
	Dexamfetamine sulfate	0	0	1	1.0	0	0	1	2.0	0	0	0	0
	Dihydroxyaluminum sodium carbonate	0	0	2	2.0	1	0.9	0	0	0	0	0	0
	Docusate sodium	0	0	1	1.0	0	0	0	0	1	2.0	0	0
	Ergocalciferol	5	4.8	3	3.0	1	0.9	2	3.9	3	6.0	2	3.9
	Esomeprazole	3	2.9	1	1.0	4	3.6	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Famotidine	0	0	4	4.0	2	1.8	0	0	0	0	0	0
	Glibenclamide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glipizide	0	0	1	1.0	0	0	0	0	0	0	1	2.0
	Herbal nos	0	0	1	1.0	0	0	0	0	0	0	0	0
	Insulin human	1	1.0	0	0	2	1.8	0	0	0	0	0	0
	Lactobacillus acidophilus	1	1.0	0	0	0	0	0	0	0	0	0	0
	Lansoprazole	1	1.0	1	1.0	1	0.9	0	0	2	4.0	1	2.0
	Loperamide hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Magnesium aspartate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Magnesium hydroxide	2	1.9	1	1.0	1	0.9	0	0	0	0	0	0
	Metformin	0	0	2	2.0	0	0	0	0	0	0	0	0
	Metformin hydrochloride	0	0	0	0	1	0.9	1	2.0	0	0	0	0
	Metoclopramide hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Omeprazole	0	0	3	3.0	2	1.8	0	0	0	0	1	2.0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Pantoprazole	1	1.0	0	0	0	0	2	3.9	1	2.0	0	0
	Pioglitazone	0	0	0	0	0	0	0	0	1	2.0	0	0
	Psyllium hydrophilic mucilloid	0	0	0	0	0	0	0	0	1	2.0	0	0
	Pyridoxine hydrochloride	0	0	0	0	0	0	0	0	1	2.0	1	2.0
	Rabeprazole sodium	0	0	1	1.0	0	0	0	0	1	2.0	1	2.0
	Ranitidine	0	0	0	0	0	0	0	0	1	2.0	0	0
	Ranitidine hydrochloride	0	0	1	1.0	2	1.8	1	2.0	0	0	0	0
	Rosiglitazone maleate	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Tocopherol	2	1.9	1	1.0	0	0	1	2.0	0	0	1	2.0
	Vitamin b	1	1.0	0	0	1	0.9	0	0	0	0	2	3.9
	Vitamins	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Vitamins nos	11	10.6	14	13.9	13	11.8	5	9.8	6	12.0	5	9.8
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	6	5.8	4	4.0	6	5.5	3	5.9	2	4.0	5	9.8
	Amoxicillin	0	0	1	1.0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Amoxicillin trihydrate	0	0	0	0	0	0	0	0	0	0	1	2.0
	Azithromycin	1	1.0	0	0	0	0	0	0	0	0	0	0
	Benzylpenicillin sodium	2	1.9	0	0	0	0	0	0	0	0	0	0
	Bicillin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Cefalexin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Cefalexin monohydrate	2	1.9	0	0	0	0	0	0	0	0	0	0
	Cefprozil	0	0	0	0	0	0	0	0	0	0	1	2.0
	Ceftriaxone sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
	Ciprofloxacin hydrochloride	0	0	1	1.0	0	0	3	5.9	0	0	0	0
	Clarithromycin	0	0	1	1.0	0	0	0	0	1	2.0	0	0
	Doxycycline	2	1.9	0	0	0	0	0	0	0	0	0	0
	Levofloxacin	0	0	1	1.0	1	0.9	0	0	1	2.0	1	2.0
	Minocycline	0	0	1	1.0	0	0	0	0	0	0	1	2.0
	Tetracycline	0	0	0	0	1	0.9	0	0	0	0	1	2.0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Valaciclovir hydrochloride	0	0	0	0	0	0	0	0	0	0	1	2.0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	1.0	1	1.0	0	0	0	0	0	0	0	0
	Colostrum	1	1.0	0	0	0	0	0	0	0	0	0	0
	Hydroxycarbamide	0	0	1	1.0	0	0	0	0	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	0	0	2	2.0	2	1.8	0	0	0	0	1	2.0
	Cyanocobalamin-tannin complex	0	0	1	1.0	0	0	0	0	0	0	0	0
	Folic acid	0	0	1	1.0	0	0	0	0	0	0	0	0
	Iron	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Warfarin sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	13	12.5	9	8.9	16	14.5	6	11.8	5	10.0	4	7.8
	Amlodipine	0	0	1	1.0	1	0.9	0	0	1	2.0	0	0
	Amlodipine besilate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Atenolol	1	1.0	1	1.0	2	1.8	0	0	0	0	1	2.0
	Atorvastatin	2	1.9	2	2.0	3	2.7	2	3.9	1	2.0	1	2.0
	Chlortalidone	0	0	0	0	0	0	1	2.0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Cholesterol- and triglyceride reducers	0	0	1	1.0	0	0	0	0	0	0	0	0
	Doxazosin mesilate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Enalapril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fenofibrate	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Fish oil	3	2.9	1	1.0	0	0	0	0	0	0	1	2.0
	Furosemide	0	0	1	1.0	0	0	0	0	0	0	0	0
	Hydrochlorothiazide	5	4.8	2	2.0	1	0.9	0	0	1	2.0	0	0
	Isradipine	1	1.0	0	0	0	0	0	0	0	0	0	0
	Lisinopril	0	0	1	1.0	1	0.9	0	0	1	2.0	1	2.0
	Losartan potassium	0	0	0	0	0	0	1	2.0	0	0	0	0
	Metoprolol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Metoprolol succinate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Nifedipine	0	0	0	0	0	0	1	2.0	0	0	0	0
	Nisoldipine	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Olmesartan medoxomil	0	0	1	1.0	0	0	0	0	0	0	1	2.0
	Omega-3 triglycerides	1	1.0	0	0	1	0.9	1	2.0	0	0	0	0
	Preparation h	0	0	0	0	0	0	0	0	1	2.0	0	0
	Propranolol	1	1.0	0	0	0	0	0	0	0	0	0	0
	Propranolol hydrochloride	0	0	0	0	0	0	0	0	0	0	1	2.0
	Ramipril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Rosuvastatin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Simvastatin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Spironolactone	0	0	0	0	0	0	0	0	1	2.0	0	0
	Timolol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Ubidecarenone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Valsartan	0	0	0	0	0	0	0	0	1	2.0	0	0
DERMATOLOGICALS	TOTAL	0	0	2	2.0	1	0.9	0	0	0	0	1	2.0
	Calcipotriol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	0	0	0	0	0	0	1	2.0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	Linoleic acid	0	0	0	0	1	0.9	0	0	0	0	0	0
	Nystatin	0	0	1	1.0	0	0	0	0	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	8	7.7	14	13.9	16	14.5	0	0	4	8.0	8	15.7
	Cimicifuga racemosa root	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Clindamycin hydrochloride	0	0	0	0	0	0	0	0	1	2.0	0	0
	Clotrimazole	1	1.0	0	0	0	0	0	0	0	0	0	0
	Estradiol	0	0	0	0	0	0	0	0	1	2.0	0	0
	Estrogens conjugated	1	1.0	1	1.0	0	0	0	0	0	0	1	2.0
	Ethinylestradiol	2	1.9	3	3.0	5	4.5	0	0	0	0	3	5.9
	Hormonal contraceptives for systemic use	0	0	1	1.0	0	0	0	0	0	0	0	0
	Levonorgestrel	0	0	0	0	0	0	0	0	1	2.0	0	0
	Medroxyprogesterone acetate	3	2.9	5	5.0	4	3.6	0	0	2	4.0	1	2.0
	Norelgestromin	0	0	1	1.0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Norethisterone acetate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Norgestimate	0	0	1	1.0	1	0.9	0	0	1	2.0	0	0
	Oral contraceptive nos	0	0	1	1.0	0	0	0	0	0	0	0	0
	Phenazopyridine	1	1.0	0	0	0	0	0	0	0	0	0	0
	Progesterone	0	0	0	0	0	0	0	0	0	0	1	2.0
	Serenoa repens	0	0	0	0	1	0.9	0	0	0	0	0	0
	Sildenafil citrate	0	0	0	0	0	0	0	0	0	0	1	2.0
	Testosterone	0	0	0	0	2	1.8	0	0	0	0	0	0
	Tolterodine l-tartrate	0	0	0	0	1	0.9	0	0	0	0	1	2.0
MUSCULO-SKELETAL SYSTEM	TOTAL	25	24.0	31	30.7	32	29.1	13	25.5	8	16.0	14	27.5
	Alendronate sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
	Allopurinol	0	0	0	0	0	0	0	0	1	2.0	0	0
	Baclofen	0	0	0	0	0	0	1	2.0	0	0	0	0
	Carisoprodol	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Celecoxib	0	0	2	2.0	0	0	1	2.0	0	0	1	2.0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Chondroitin sulfate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Colchicine	0	0	0	0	0	0	0	0	1	2.0	0	0
	Cyclobenzaprine hydrochloride	2	1.9	1	1.0	1	0.9	1	2.0	0	0	0	0
	Etoricoxib	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glucosamine	0	0	1	1.0	1	0.9	0	0	0	0	1	2.0
	Glucosamine hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Ibuprofen	18	17.3	22	21.8	23	20.9	7	13.7	4	8.0	8	15.7
	Ketoprofen	0	0	0	0	0	0	0	0	1	2.0	0	0
	Meloxicam	0	0	0	0	0	0	0	0	0	0	1	2.0
	Metaxalone	1	1.0	0	0	0	0	0	0	0	0	0	0
	Naproxen	1	1.0	1	1.0	1	0.9	2	3.9	0	0	1	2.0
	Naproxen sodium	2	1.9	6	5.9	5	4.5	2	3.9	1	2.0	5	9.8
	Piroxicam	0	0	0	0	2	1.8	0	0	0	0	0	0
	Pseudoephedrine hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Risedronate sodium	0	0	0	0	0	0	0	0	1	2.0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Rofecoxib	0	0	0	0	0	0	1	2.0	0	0	0	0
	Valdecoxib	1	1.0	0	0	0	0	1	2.0	0	0	0	0
NERVOUS SYSTEM	TOTAL	47	45.2	60	59.4	59	53.6	21	41.2	26	52.0	22	43.1
	Acetylsalicylic acid	11	10.6	14	13.9	14	12.7	7	13.7	5	10.0	5	9.8
	Alprazolam	2	1.9	2	2.0	5	4.5	4	7.8	1	2.0	3	5.9
	Amitriptyline	0	0	0	0	1	0.9	0	0	0	0	0	0
	Amitriptyline hydrochloride	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Antidepressants	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Antipsychotics	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Anxiolytics	0	0	0	0	1	0.9	0	0	0	0	0	0
	Benzodiazepine derivatives	0	0	1	1.0	0	0	0	0	0	0	0	0
	Bupropion	0	0	0	0	1	0.9	0	0	0	0	0	0
	Bupropion hydrochloride	5	4.8	6	5.9	5	4.5	0	0	3	6.0	3	5.9
	Buspirone	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Buspirone hydrochloride	0	0	0	0	0	0	0	0	1	2.0	0	0
	Butalbital	0	0	0	0	0	0	0	0	1	2.0	0	0
	Caffeine	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Carbamazepine	1	1.0	1	1.0	0	0	0	0	0	0	0	0
	Citalopram hydrobromide	0	0	1	1.0	1	0.9	0	0	2	4.0	0	0
	Clomipramine hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Clonazepam	2	1.9	2	2.0	1	0.9	0	0	1	2.0	0	0
	Clorazepate dipotassium	0	0	0	0	0	0	0	0	0	0	1	2.0
	Codeine phosphate	0	0	2	2.0	1	0.9	0	0	0	0	0	0
	Cyclobenzaprine	0	0	1	1.0	0	0	0	0	0	0	0	0
	Dextropropoxyphene	0	0	0	0	0	0	1	2.0	0	0	0	0
	Dextropropoxyphene hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Diazepam	0	0	1	1.0	2	1.8	0	0	0	0	1	2.0
	Diclofenac sodium	1	1.0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Diphenhydramine	3	2.9	3	3.0	3	2.7	0	0	3	6.0	2	3.9
	Doxepin hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Escitalopram oxalate	1	1.0	1	1.0	4	3.6	1	2.0	1	2.0	1	2.0
	Ethanol	5	4.8	3	3.0	0	0	0	0	0	0	0	0
	Fluoxetine	1	1.0	0	0	0	0	0	0	0	0	0	0
	Fluoxetine hydrochloride	1	1.0	7	6.9	2	1.8	1	2.0	1	2.0	1	2.0
	Gabapentin	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Ginkgo biloba	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Hydroxyzine hydrochloride	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Lamotrigine	1	1.0	4	4.0	2	1.8	0	0	2	4.0	1	2.0
	Lithium	1	1.0	4	4.0	1	0.9	1	2.0	2	4.0	0	0
	Lithium carbonate	0	0	1	1.0	2	1.8	0	0	0	0	0	0
	Lorazepam	1	1.0	4	4.0	3	2.7	1	2.0	1	2.0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Mepyramine maleate	1	1.0	1	1.0	1	0.9	0	0	0	0	0	0
	Methylsulfonylmethane	0	0	1	1.0	0	0	0	0	0	0	0	0
	Mirtazapine	1	1.0	1	1.0	0	0	1	2.0	0	0	0	0
	Modafinil	0	0	0	0	0	0	0	0	1	2.0	0	0
	Morphine hydrochloride	0	0	0	0	0	0	0	0	1	2.0	0	0
	Nefazodone hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Nortriptyline	0	0	0	0	0	0	0	0	1	2.0	0	0
	Nortriptyline hydrochloride	0	0	0	0	0	0	0	0	1	2.0	0	0
	Olanzapine	0	0	2	2.0	3	2.7	2	3.9	0	0	2	3.9
	Oxcarbazepine	1	1.0	1	1.0	0	0	0	0	1	2.0	0	0
	Oxycodone	0	0	0	0	0	0	1	2.0	0	0	1	2.0
	Paracetamol	17	16.3	15	14.9	11	10.0	10	19.6	8	16.0	6	11.8
	Paroxetine hydrochloride	1	1.0	1	1.0	1	0.9	0	0	3	6.0	1	2.0
	Perphenazine	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Phenobarbital sodium	0	0	0	0	0	0	0	0	1	2.0	0	0
	Quetiapine fumarate	2	1.9	0	0	1	0.9	0	0	0	0	0	0
	Risperidone	1	1.0	3	3.0	1	0.9	0	0	0	0	2	3.9
	Rizatriptan benzoate	0	0	0	0	0	0	0	0	1	2.0	0	0
	Salicylamide	1	1.0	0	0	0	0	0	0	0	0	0	0
	Sertraline hydrochloride	4	3.8	3	3.0	2	1.8	2	3.9	3	6.0	1	2.0
	Sumatriptan	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Temazepam	0	0	0	0	2	1.8	0	0	0	0	0	0
	Thioridazine hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Tomoxetine hydrochloride	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Topiramate	1	1.0	2	2.0	0	0	1	2.0	1	2.0	0	0
	Tramadol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Tramadol hydrochloride	0	0	2	2.0	0	0	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS203.SAS
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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Trazodone	2	1.9	4	4.0	5	4.5	2	3.9	0	0	0	0
	Valeriana officinalis root	1	1.0	0	0	0	0	0	0	0	0	0	0
	Valproate semisodium	4	3.8	9	8.9	6	5.5	2	3.9	0	0	0	0
	Venlafaxine	2	1.9	0	0	5	4.5	1	2.0	0	0	0	0
	Venlafaxine hydrochloride	0	0	2	2.0	3	2.7	0	0	2	4.0	1	2.0
	Ziprasidone hydrochloride	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Zolpidem tartrate	2	1.9	6	5.9	0	0	0	0	0	0	0	0
RESPIRATORY SYSTEM	TOTAL	16	15.4	23	22.8	15	13.6	12	23.5	5	10.0	9	17.6
	Allergy medication	1	1.0	0	0	0	0	0	0	0	0	0	0
	Antihistamines	1	1.0	0	0	0	0	0	0	0	0	0	0
	Camphor	1	1.0	0	0	0	0	0	0	0	0	0	0
	Cetirizine hydrochloride	0	0	2	2.0	1	0.9	1	2.0	0	0	1	2.0
	Chlorphenamine maleate	0	0	0	0	0	0	0	0	0	0	2	3.9

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS203.SAS
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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Cough and cold preparations	0	0	0	0	0	0	0	0	0	0	1	2.0
	Cromoglicate sodium	0	0	1	1.0	0	0	0	0	0	0	0	0
	Desloratadine	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Dextromethorphan hydrobromide	0	0	0	0	0	0	0	0	0	0	1	2.0
	Dimenhydrinate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Diphenhydramine hydrochloride	2	1.9	2	2.0	1	0.9	2	3.9	1	2.0	1	2.0
	Epinephrine	0	0	2	2.0	0	0	0	0	0	0	1	2.0
	Fexofenadine hydrochloride	0	0	0	0	2	1.8	0	0	1	2.0	0	0
	Flunisolide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fluticasone propionate	2	1.9	5	5.0	3	2.7	4	7.8	0	0	2	3.9
	Guaifenesin	1	1.0	1	1.0	0	0	1	2.0	0	0	0	0
	Hydrocodone	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Ipratropium bromide	0	0	1	1.0	0	0	0	0	0	0	0	0
	Loratadine	3	2.9	3	3.0	3	2.7	1	2.0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS203.SAS
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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Meclozine hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Mometasone furoate	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Montelukast sodium	2	1.9	3	3.0	0	0	1	2.0	0	0	0	0
	Paracetamol	1	1.0	0	0	0	0	0	0	0	0	0	0
	Phenylephrine hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Phenyltoloxamine citrate	0	0	0	0	0	0	1	2.0	0	0	0	0
	Promethazine	0	0	1	1.0	0	0	0	0	0	0	0	0
	Promethazine hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Pseudoephedrine	0	0	0	0	0	0	0	0	1	2.0	0	0
	Pseudoephedrine hydrochloride	2	1.9	2	2.0	1	0.9	1	2.0	0	0	2	3.9
	Pseudoephedrine sulfate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Pseudoephedrine, combinations	0	0	0	0	0	0	1	2.0	0	0	0	0
	Salbutamol	4	3.8	7	6.9	2	1.8	1	2.0	1	2.0	2	3.9

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Salmeterol xinafoate	0	0	0	0	0	0	1	2.0	0	0	0	0
	Sulfogaiacol	1	1.0	0	0	0	0	0	0	0	0	0	0
	Theophylline	0	0	1	1.0	0	0	0	0	0	0	0	0
	Triamcinolone acetonide	0	0	0	0	1	0.9	0	0	0	0	0	0
SENSORY ORGANS	TOTAL	1	1.0	1	1.0	0	0	1	2.0	0	0	0	0
	Latanoprost	0	0	0	0	0	0	1	2.0	0	0	0	0
	Olopatadine hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Travoprost	0	0	1	1.0	0	0	0	0	0	0	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	6	5.8	4	4.0	8	7.3	1	2.0	3	6.0	2	3.9
	Betamethasone dipropionate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Cortisone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Desmopressin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Levothyroxine sodium	4	3.8	4	4.0	5	4.5	0	0	2	4.0	2	3.9

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS203.SAS
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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	Melatonin	1	1.0	0	0	2	1.8	0	0	1	2.0	0	0
	Methylprednisolone	0	0	0	0	0	0	1	2.0	0	0	0	0
VARIOUS	TOTAL	7	6.7	6	5.9	3	2.7	2	3.9	1	2.0	2	3.9
	All other therapeutic products	2	1.9	1	1.0	0	0	0	0	0	0	0	0
	Allergens nos	0	0	1	1.0	0	0	0	0	0	0	0	0
	Allium sativum	0	0	2	2.0	0	0	0	0	1	2.0	0	0
	Citric acid monohydrate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Creatine	1	1.0	0	0	0	0	0	0	0	0	0	0
	Ginseng nos	0	0	0	0	0	0	1	2.0	0	0	0	0
	Herbal nos	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Herbal preparation	1	1.0	0	0	0	0	0	0	0	0	0	0
	Hypericum perforatum	1	1.0	1	1.0	0	0	0	0	0	0	0	0
	Linum usitatissimum seed oil	1	1.0	0	0	0	0	0	0	0	0	0	0
	Other nutrients	0	0	1	1.0	1	0.9	0	0	1	2.0	1	2.0

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Table 11.1.7.4 Prior Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	Piper methysticum rhizome	1	1.0	0	0	0	0	1	2.0	0	0	0	0
	Uncaria tomentosa	0	0	0	0	0	0	0	0	0	0	1	2.0

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Table 11.1.7.5 Prior Medications of Interest Per Patient
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIDEPRESSANT	0	146	85.4	130	77.4	136	81.4
	1	18	10.5	23	13.7	24	14.4
	2	6	3.5	9	5.4	5	3.0
	3 OR MORE	1	0.6	6	3.6	2	1.2
ANXIOLYTICS/HYPNOTICS	0	156	91.2	145	86.3	148	88.6
	1	13	7.6	18	10.7	16	9.6
	2	1	0.6	4	2.4	1	0.6
	3 OR MORE	1	0.6	1	0.6	2	1.2
MOOD STABILIZERS	0	158	92.4	143	85.1	153	91.6
	1	9	5.3	17	10.1	13	7.8
	2	2	1.2	4	2.4	0	0.0
	3 OR MORE	2	1.2	4	2.4	1	0.6
ANTIPSYCHOTIC	0	163	95.3	162	96.4	156	93.4
	1	6	3.5	5	3.0	9	5.4
	2	2	1.2	1	0.6	0	0.0
	3 OR MORE	0	0.0	0	0.0	2	1.2
COMBINATION OF ABOVE	0	164	95.9	164	97.6	162	97.0

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Table 11.1.7.5 Prior Medications of Interest Per Patient
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
COMBINATION OF ABOVE	ANTIDEPRESSANT & ANTIPSYCHOTIC	7	4.1	4	2.4	5	3.0

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY CONCOMITANT MEDICATION		132	77.2	126	75.0	140	83.8
ALIMENTARY TRACT AND METABOLISM	TOTAL	56	32.7	60	35.7	54	32.3
	Ascorbic acid	4	2.3	4	2.4	2	1.2
	Atropine sulfate	1	0.6	0	0	0	0
	Bismuth subsalicylate	0	0	2	1.2	3	1.8
	Calcium	2	1.2	1	0.6	2	1.2
	Calcium carbonate	7	4.1	8	4.8	7	4.2
	Charcoal, activated	0	0	1	0.6	0	0
	Cimetidine	0	0	1	0.6	2	1.2
	Colecalciferol	0	0	0	0	1	0.6
	Dicycloverine	0	0	1	0.6	0	0
	Dihydroxyaluminum sodium carbonate	3	1.8	4	2.4	1	0.6
	Docusate sodium	1	0.6	2	1.2	0	0
	Ergocalciferol	8	4.7	6	3.6	4	2.4
	Esomeprazole	4	2.3	2	1.2	5	3.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Famotidine	1	0.6	6	3.6	2	1.2
	Glibenclamide	0	0	0	0	1	0.6
	Glipizide	0	0	1	0.6	1	0.6
	Insulin human	1	0.6	0	0	2	1.2
	Lansoprazole	3	1.8	3	1.8	2	1.2
	Loperamide hydrochloride	2	1.2	0	0	2	1.2
	Magnesium	0	0	1	0.6	0	0
	Magnesium aspartate	1	0.6	0	0	0	0
	Magnesium hydroxide	0	0	3	1.8	1	0.6
	Metformin	0	0	2	1.2	0	0
	Metformin hydrochloride	1	0.6	0	0	1	0.6
	Metoclopramide hydrochloride	1	0.6	0	0	0	0
	Omeprazole	2	1.2	7	4.2	3	1.8
	Pantoprazole	3	1.8	1	0.6	0	0
	Pioglitazone	1	0.6	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Polycarbophil calcium	1	0.6	1	0.6	0	0
	Psyllium hydrophilic mucilloid	1	0.6	1	0.6	0	0
	Pyridoxine hydrochloride	0	0	2	1.2	1	0.6
	Rabeprazole sodium	0	0	3	1.8	1	0.6
	Ranitidine	0	0	1	0.6	0	0
	Ranitidine hydrochloride	2	1.2	3	1.8	3	1.8
	Rosiglitazone maleate	1	0.6	0	0	1	0.6
	Senna alexandrina fruit	0	0	1	0.6	0	0
	Simeticone	0	0	0	0	1	0.6
	Tegaserod	1	0.6	0	0	0	0
	Tocopherol	2	1.2	1	0.6	2	1.2
	Vitamin b	1	0.6	0	0	3	1.8
	Vitamin b-complex	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Vitamins	1	0.6	1	0.6	0	0
	Vitamins nos	18	10.5	22	13.1	17	10.2
	Yellow phenolphthalein	0	0	0	0	1	0.6
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	16	9.4	19	11.3	16	9.6
	Amoxicillin	2	1.2	4	2.4	6	3.6
	Antibiotics	0	0	0	0	1	0.6
	Azithromycin	4	2.3	3	1.8	1	0.6
	Benzylpenicillin sodium	1	0.6	0	0	2	1.2
	Bicillin	0	0	0	0	1	0.6
	Cefadroxil	1	0.6	0	0	0	0
	Cefalexin	1	0.6	0	0	1	0.6
	Cefalexin monohydrate	1	0.6	0	0	0	0
	Cefditoren pivoxil	0	0	0	0	1	0.6
	Ceftriaxone sodium	0	0	1	0.6	1	0.6
	Cefuroxime	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Ciprofloxacin hydrochloride	3	1.8	1	0.6	1	0.6
	Clarithromycin	1	0.6	4	2.4	0	0
	Clindamycin	0	0	0	0	1	0.6
	Doxycycline	1	0.6	2	1.2	0	0
	Doxycycline hyclate	0	0	1	0.6	0	0
	Fluconazole	0	0	1	0.6	0	0
	Gatifloxacin	0	0	0	0	1	0.6
	Indinavir sulfate	0	0	1	0.6	0	0
	Levofloxacin	0	0	1	0.6	1	0.6
	Minocycline	0	0	1	0.6	1	0.6
	Moxifloxacin hydrochloride	1	0.6	0	0	0	0
	Nitrofurantoin	0	0	0	0	1	0.6
	Sulfamethoxazole	0	0	2	1.2	1	0.6
	Sultamicillin tosilate	0	0	1	0.6	0	0
	Valaciclovir hydrochloride	0	0	0	0	1	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Zidovudine	0	0	1	0.6	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	0.6	1	0.6	0	0
	Colostrum	1	0.6	0	0	0	0
	Hydroxycarbamide	0	0	1	0.6	0	0
ANTIPARASITIC PRODUCTS,INSECTICIDES AND REPELLENTS	TOTAL	1	0.6	0	0	0	0
	Quinine sulfate	1	0.6	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.6	4	2.4	3	1.8
	Clopidogrel sulfate	0	0	1	0.6	0	0
	Cyanocobalamin-tannin complex	0	0	1	0.6	0	0
	Ferrous sulfate	0	0	1	0.6	0	0
	Folic acid	0	0	1	0.6	0	0
	Iron	1	0.6	0	0	2	1.2
	Warfarin sodium	0	0	0	0	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	28	16.4	25	14.9	24	14.4
	Amlodipine	0	0	4	2.4	1	0.6

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Amlodipine besilate	0	0	1	0.6	0	0
	Atenolol	1	0.6	3	1.8	5	3.0
	Atorvastatin	5	2.9	3	1.8	4	2.4
	Benazepril hydrochloride	1	0.6	0	0	1	0.6
	Chlortalidone	1	0.6	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	0.6	0	0
	Doxazosin mesilate	0	0	1	0.6	0	0
	Enalapril	0	0	0	0	1	0.6
	Enalapril maleate	0	0	0	0	1	0.6
	Fenofibrate	1	0.6	1	0.6	1	0.6
	Fish oil	3	1.8	1	0.6	1	0.6
	Furosemide	0	0	1	0.6	0	0
	Glyceryl trinitrate	1	0.6	0	0	0	0
	Hydrochlorothiazide	10	5.8	7	4.2	2	1.2
	Isradipine	1	0.6	1	0.6	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Lisinopril	2	1.2	3	1.8	3	1.8
	Losartan potassium	1	0.6	0	0	0	0
	Lovastatin	1	0.6	0	0	0	0
	Metoprolol	0	0	2	1.2	0	0
	Metoprolol succinate	0	0	1	0.6	1	0.6
	Metoprolol tartrate	0	0	1	0.6	0	0
	Nifedipine	1	0.6	1	0.6	0	0
	Nisoldipine	0	0	0	0	1	0.6
	Olea europaea leaf extract	0	0	1	0.6	0	0
	Olmesartan medoxomil	1	0.6	1	0.6	1	0.6
	Omega-3 triglycerides	1	0.6	0	0	1	0.6
	Preparation h	0	0	1	0.6	0	0
	Propranolol hydrochloride	1	0.6	0	0	1	0.6
	Ramipril	0	0	0	0	1	0.6

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Rosuvastatin	0	0	0	0	1	0.6
	Simvastatin	0	0	1	0.6	1	0.6
	Spironolactone	0	0	1	0.6	0	0
	Timolol	0	0	1	0.6	0	0
	Ubidecarenone	0	0	0	0	1	0.6
	Valsartan	1	0.6	1	0.6	0	0
	Verapamil	0	0	0	0	1	0.6
	Verapamil hydrochloride	1	0.6	0	0	0	0
DERMATOLOGICALS	TOTAL	0	0	2	1.2	5	3.0
	Calcipotriol	0	0	1	0.6	0	0
	Docosanol	0	0	0	0	1	0.6
	Hydrocortisone	0	0	0	0	1	0.6
	Ketoconazole	0	0	0	0	1	0.6
	Linoleic acid	0	0	0	0	1	0.6
	Mupirocin	0	0	0	0	1	0.6
	Neomycin sulfate	0	0	0	0	1	0.6

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	Nystatin	0	0	1	0.6	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	13	7.6	18	10.7	24	14.4
	Cimicifuga racemosa root	0	0	1	0.6	0	0
	Clotrimazole	1	0.6	0	0	0	0
	Estradiol	0	0	1	0.6	0	0
	Estrogens conjugated	1	0.6	1	0.6	1	0.6
	Ethinylestradiol	2	1.2	2	1.2	10	6.0
	Etonogestrel	1	0.6	0	0	0	0
	Hormonal contraceptives for systemic use	0	0	1	0.6	0	0
	Levonorgestrel	1	0.6	1	0.6	0	0
	Medroxyprogesterone acetate	3	1.8	8	4.8	6	3.6
	Norelgestromin	0	0	1	0.6	1	0.6
	Norethisterone	1	0.6	0	0	0	0
	Norethisterone acetate	0	0	1	0.6	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Norgestimate	0	0	1	0.6	1	0.6
	Oral contraceptive nos	0	0	1	0.6	0	0
	Progesterone	0	0	0	0	1	0.6
	Sildenafil citrate	0	0	0	0	1	0.6
	Tadalafil	1	0.6	0	0	0	0
	Testosterone	0	0	0	0	2	1.2
	Tolterodine l-tartrate	0	0	0	0	2	1.2
	Vardenafil hydrochloride	2	1.2	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	52	30.4	55	32.7	71	42.5
	Acetylsalicylic acid	0	0	0	0	1	0.6
	Alendronate sodium	0	0	0	0	1	0.6
	Allopurinol	0	0	1	0.6	1	0.6
	Baclofen	1	0.6	0	0	0	0
	Carisoprodol	0	0	1	0.6	1	0.6
	Celecoxib	2	1.2	1	0.6	0	0

(Continued)

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Chondroitin sulfate	0	0	1	0.6	0	0
	Colchicine	0	0	1	0.6	0	0
	Cyclobenzaprine hydrochloride	1	0.6	2	1.2	1	0.6
	Diclofenac	1	0.6	0	0	0	0
	Diclofenac sodium	0	0	1	0.6	0	0
	Etodolac	0	0	1	0.6	1	0.6
	Etoricoxib	0	0	0	0	1	0.6
	Glucosamine	0	0	3	1.8	2	1.2
	Glucosamine hydrochloride	0	0	0	0	1	0.6
	Glucosamine sulfate	1	0.6	0	0	0	0
	Ibuprofen	41	24.0	38	22.6	51	30.5
	Indometacin	0	0	0	0	1	0.6
	Ketoprofen	0	0	1	0.6	0	0
	Ketorolac tromethamine	1	0.6	2	1.2	0	0
	Meloxicam	0	0	1	0.6	1	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Metaxalone	0	0	0	0	1	0.6
	Nabumetone	1	0.6	1	0.6	0	0
	Naproxen	2	1.2	4	2.4	3	1.8
	Naproxen sodium	8	4.7	10	6.0	13	7.8
	Orphenadrine citrate	0	0	1	0.6	0	0
	Piroxicam	0	0	0	0	2	1.2
	Pseudoephedrine hydrochloride	0	0	1	0.6	2	1.2
	Risedronate sodium	0	0	2	1.2	0	0
	Rofecoxib	0	0	1	0.6	0	0
	Valdecoxib	2	1.2	0	0	0	0
NERVOUS SYSTEM	TOTAL	56	32.7	61	36.3	67	40.1
	Acetylsalicylic acid	21	12.3	22	13.1	31	18.6
	Alprazolam	0	0	1	0.6	0	0
	Analgesics	0	0	0	0	2	1.2
	Benzatropine mesilate	4	2.3	3	1.8	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Benzocaine	0	0	0	0	1	0.6
	Bupivacaine	1	0.6	1	0.6	0	0
	Caffeine	0	0	1	0.6	0	0
	Chlorphenamine maleate	0	0	0	0	1	0.6
	Clonazepam	1	0.6	0	0	0	0
	Codeine phosphate	1	0.6	0	0	0	0
	Cyclobenzaprine	0	0	1	0.6	0	0
	Diazepam	0	0	0	0	1	0.6
	Diclofenac sodium	1	0.6	1	0.6	1	0.6
	Diphenhydramine	3	1.8	1	0.6	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.6
	Epinephrine	1	0.6	0	0	1	0.6
	Ethanol	1	0.6	6	3.6	1	0.6
	Lidocaine	0	0	1	0.6	1	0.6
	Lorazepam	2	1.2	6	3.6	5	3.0
	Mepyramine maleate	1	0.6	1	0.6	2	1.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Methylsulfonylmethane	0	0	1	0.6	0	0
	Morphine hydrochloride	0	0	1	0.6	1	0.6
	Oxcarbazepine	0	0	1	0.6	0	0
	Oxycodone	1	0.6	0	0	0	0
	Paracetamol	34	19.9	29	17.3	32	19.2
	Procaine hydrochloride	1	0.6	0	0	0	0
	Risperidone	0	0	1	0.6	0	0
	Rizatriptan benzoate	0	0	1	0.6	0	0
	Sumatriptan	0	0	0	0	2	1.2
	Zolpidem tartrate	2	1.2	3	1.8	5	3.0
RESPIRATORY SYSTEM	TOTAL	43	25.1	44	26.2	40	24.0
	Allergy medication	2	1.2	0	0	0	0
	Beclometasone dipropionate	0	0	1	0.6	0	0
	Benzonatate	0	0	1	0.6	0	0

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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Camphor	1	0.6	1	0.6	0	0
	Cetirizine hydrochloride	1	0.6	3	1.8	3	1.8
	Chlorphenamine maleate	0	0	0	0	2	1.2
	Codeine phosphate	0	0	1	0.6	1	0.6
	Cough and cold preparations	0	0	0	0	2	1.2
	Cromoglicate sodium	0	0	1	0.6	0	0
	Desloratadine	0	0	1	0.6	2	1.2
	Dexbrompheniramine maleate	0	0	1	0.6	0	0
	Dimenhydrinate	1	0.6	0	0	0	0
	Diphenhydramine hydrochloride	5	2.9	1	0.6	9	5.4
	Epinephrine	0	0	2	1.2	1	0.6
	Fexofenadine hydrochloride	1	0.6	2	1.2	2	1.2
	Flunisolide	0	0	0	0	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Fluticasone propionate	6	3.5	7	4.2	8	4.8
	Guaifenesin	7	4.1	3	1.8	2	1.2
	Hydrocodone	0	0	1	0.6	1	0.6
	Ipratropium bromide	0	0	1	0.6	0	0
	Loratadine	4	2.3	6	3.6	7	4.2
	Meclozine hydrochloride	0	0	1	0.6	0	0
	Mometasone furoate	0	0	2	1.2	1	0.6
	Montelukast sodium	3	1.8	3	1.8	0	0
	Other cold combination preparations	1	0.6	0	0	0	0
	Oxymetazoline hydrochloride	0	0	2	1.2	0	0
	Paracetamol	4	2.3	2	1.2	3	1.8
	Phenylephrine hydrochloride	1	0.6	2	1.2	0	0
	Promethazine	0	0	1	0.6	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Promethazine hydrochloride	2	1.2	2	1.2	0	0
	Pseudoephedrine	0	0	1	0.6	0	0
	Pseudoephedrine hydrochloride	8	4.7	6	3.6	5	3.0
	Pseudoephedrine sulfate	0	0	2	1.2	2	1.2
	Pseudoephedrine, combinations	1	0.6	0	0	0	0
	Salbutamol	8	4.7	9	5.4	5	3.0
	Salmeterol xinafoate	1	0.6	0	0	0	0
	Terpin hydrate	0	0	2	1.2	0	0
	Theophylline	0	0	1	0.6	0	0
	Triamcinolone acetonide	0	0	1	0.6	1	0.6
SENSORY ORGANS	TOTAL	2	1.2	2	1.2	0	0
	Latanoprost	1	0.6	0	0	0	0
	Olopatadine hydrochloride	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SENSORY ORGANS	Travoprost	0	0	1	0.6	0	0
	Xantofyl	0	0	1	0.6	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	8	4.7	9	5.4	8	4.8
	Betamethasone dipropionate	1	0.6	0	0	0	0
	Cortisone	0	0	1	0.6	0	0
	Desmopressin	0	0	0	0	1	0.6
	Dexamethasone	0	0	1	0.6	0	0
	Hydrocortisone	0	0	0	0	1	0.6
	Levothyroxine sodium	5	2.9	6	3.6	7	4.2
	Liothyronine sodium	1	0.6	0	0	0	0
	Melatonin	0	0	1	0.6	0	0
	Methylprednisolone	0	0	0	0	1	0.6
	Prednisone	2	1.2	1	0.6	0	0
VARIOUS	TOTAL	3	1.8	8	4.8	2	1.2
	All other therapeutic products	1	0.6	1	0.6	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.6 Concomitant Medication Summary
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	Allergens nos	0	0	1	0.6	0	0
	Allium sativum	0	0	3	1.8	0	0
	Herbal nos	1	0.6	0	0	0	0
	Herbal preparation	0	0	2	1.2	0	0
	Linum usitatissimum seed oil	1	0.6	1	0.6	0	0
	Other nutrients	0	0	1	0.6	2	1.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS204.SAS
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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY COMCOMITANT MEDICATION		119	76.8	118	78.1	135	83.9
ALIMENTARY TRACT AND METABOLISM	TOTAL	50	32.3	56	37.1	51	31.7
	Ascorbic acid	4	2.6	4	2.6	1	0.6
	Atropine sulfate	1	0.6	0	0	0	0
	Bismuth subsalicylate	0	0	2	1.3	3	1.9
	Calcium	2	1.3	1	0.7	2	1.2
	Calcium carbonate	6	3.9	8	5.3	7	4.3
	Charcoal, activated	0	0	1	0.7	0	0
	Cimetidine	0	0	1	0.7	2	1.2
	Colecalciferol	0	0	0	0	1	0.6
	Dihydroxyaluminum sodium carbonate	3	1.9	4	2.6	1	0.6
	Docusate sodium	1	0.6	2	1.3	0	0
	Ergocalciferol	7	4.5	6	4.0	4	2.5
	Esomeprazole	3	1.9	2	1.3	4	2.5
	Famotidine	0	0	5	3.3	2	1.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS205.SAS
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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Glibenclamide	0	0	0	0	1	0.6
	Glipizide	0	0	1	0.7	1	0.6
	Insulin human	1	0.6	0	0	2	1.2
	Lansoprazole	2	1.3	3	2.0	2	1.2
	Loperamide hydrochloride	2	1.3	0	0	2	1.2
	Magnesium	0	0	1	0.7	0	0
	Magnesium aspartate	1	0.6	0	0	0	0
	Magnesium hydroxide	0	0	3	2.0	1	0.6
	Metformin	0	0	2	1.3	0	0
	Metformin hydrochloride	1	0.6	0	0	1	0.6
	Metoclopramide hydrochloride	1	0.6	0	0	0	0
	Omeprazole	1	0.6	6	4.0	3	1.9
	Pantoprazole	3	1.9	1	0.7	0	0
	Pioglitazone	0	0	1	0.7	0	0
	Polycarbophil calcium	1	0.6	1	0.7	0	0

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Psyllium hydrophilic mucilloid	0	0	1	0.7	0	0
	Pyridoxine hydrochloride	0	0	2	1.3	1	0.6
	Rabeprazole sodium	0	0	3	2.0	1	0.6
	Ranitidine	0	0	1	0.7	0	0
	Ranitidine hydrochloride	2	1.3	3	2.0	2	1.2
	Rosiglitazone maleate	1	0.6	0	0	1	0.6
	Senna alexandrina fruit	0	0	1	0.7	0	0
	Simeticone	0	0	0	0	1	0.6
	Tegaserod	1	0.6	0	0	0	0
	Tocopherol	2	1.3	1	0.7	2	1.2
	Vitamin b	1	0.6	0	0	3	1.9
	Vitamin b-complex	0	0	1	0.7	0	0
	Vitamins	1	0.6	1	0.7	0	0
	Vitamins nos	17	11.0	21	13.9	17	10.6

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Yellow phenolphthalein	0	0	0	0	1	0.6
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	16	10.3	17	11.3	16	9.9
	Amoxicillin	2	1.3	4	2.6	6	3.7
	Antibiotics	0	0	0	0	1	0.6
	Azithromycin	4	2.6	3	2.0	1	0.6
	Benzylpenicillin sodium	1	0.6	0	0	2	1.2
	Bicillin	0	0	0	0	1	0.6
	Cefadroxil	1	0.6	0	0	0	0
	Cefalexin	1	0.6	0	0	1	0.6
	Cefalexin monohydrate	1	0.6	0	0	0	0
	Cefditoren pivoxil	0	0	0	0	1	0.6
	Ceftriaxone sodium	0	0	1	0.7	1	0.6
	Ciprofloxacin hydrochloride	3	1.9	1	0.7	1	0.6
	Clarithromycin	1	0.6	4	2.6	0	0
	Clindamycin	0	0	0	0	1	0.6

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Doxycycline	1	0.6	1	0.7	0	0
	Doxycycline hyclate	0	0	1	0.7	0	0
	Fluconazole	0	0	1	0.7	0	0
	Gatifloxacin	0	0	0	0	1	0.6
	Indinavir sulfate	0	0	1	0.7	0	0
	Levofloxacin	0	0	1	0.7	1	0.6
	Minocycline	0	0	1	0.7	1	0.6
	Moxifloxacin hydrochloride	1	0.6	0	0	0	0
	Nitrofurantoin	0	0	0	0	1	0.6
	Sulfamethoxazole	0	0	2	1.3	1	0.6
	Sultamicillin tosilate	0	0	1	0.7	0	0
	Valaciclovir hydrochloride	0	0	0	0	1	0.6
	Zidovudine	0	0	1	0.7	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	0.6	1	0.7	0	0
	Colostrum	1	0.6	0	0	0	0

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	Hydroxycarbamide	0	0	1	0.7	0	0
ANTIPARASITIC PRODUCTS,INSECTICIDES AND REPELLENTS	TOTAL	1	0.6	0	0	0	0
	Quinine sulfate	1	0.6	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.6	3	2.0	3	1.9
	Cyanocobalamin-tannin complex	0	0	1	0.7	0	0
	Ferrous sulfate	0	0	1	0.7	0	0
	Folic acid	0	0	1	0.7	0	0
	Iron	1	0.6	0	0	2	1.2
	Warfarin sodium	0	0	0	0	1	0.6
CARDIOVASCULAR SYSTEM	TOTAL	25	16.1	23	15.2	22	13.7
	Amlodipine	0	0	3	2.0	1	0.6
	Amlodipine besilate	0	0	1	0.7	0	0
	Atenolol	1	0.6	2	1.3	3	1.9
	Atorvastatin	4	2.6	3	2.0	4	2.5

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Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Benazepril hydrochloride	1	0.6	0	0	1	0.6
	Chlortalidone	1	0.6	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	0.7	0	0
	Doxazosin mesilate	0	0	1	0.7	0	0
	Enalapril	0	0	0	0	1	0.6
	Enalapril maleate	0	0	0	0	1	0.6
	Fenofibrate	0	0	1	0.7	1	0.6
	Fish oil	3	1.9	1	0.7	1	0.6
	Furosemide	0	0	1	0.7	0	0
	Glyceryl trinitrate	1	0.6	0	0	0	0
	Hydrochlorothiazide	9	5.8	7	4.6	2	1.2
	Isradipine	1	0.6	1	0.7	0	0
	Lisinopril	1	0.6	2	1.3	3	1.9
	Losartan potassium	1	0.6	0	0	0	0
	Lovastatin	1	0.6	0	0	0	0

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Table 11.1.7.7 Concomitant Medication Summary
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		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Metoprolol	0	0	1	0.7	0	0
	Metoprolol succinate	0	0	1	0.7	1	0.6
	Metoprolol tartrate	0	0	1	0.7	0	0
	Nifedipine	1	0.6	1	0.7	0	0
	Nisoldipine	0	0	0	0	1	0.6
	Olea europaea leaf extract	0	0	1	0.7	0	0
	Olmesartan medoxomil	1	0.6	1	0.7	1	0.6
	Omega-3 triglycerides	1	0.6	0	0	1	0.6
	Preparation h	0	0	1	0.7	0	0
	Propranolol hydrochloride	1	0.6	0	0	1	0.6
	Ramipril	0	0	0	0	1	0.6
	Rosuvastatin	0	0	0	0	1	0.6
	Simvastatin	0	0	0	0	1	0.6
	Spironolactone	0	0	1	0.7	0	0

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Timolol	0	0	1	0.7	0	0
	Ubidecarenone	0	0	0	0	1	0.6
	Valsartan	1	0.6	1	0.7	0	0
	Verapamil	0	0	0	0	1	0.6
DERMATOLOGICALS	TOTAL	0	0	2	1.3	5	3.1
	Calcipotriol	0	0	1	0.7	0	0
	Docosanol	0	0	0	0	1	0.6
	Hydrocortisone	0	0	0	0	1	0.6
	Ketoconazole	0	0	0	0	1	0.6
	Linoleic acid	0	0	0	0	1	0.6
	Mupirocin	0	0	0	0	1	0.6
	Neomycin sulfate	0	0	0	0	1	0.6
	Nystatin	0	0	1	0.7	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	12	7.7	17	11.3	24	14.9
	Cimicifuga racemosa root	0	0	1	0.7	0	0
	Clotrimazole	1	0.6	0	0	0	0

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		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Estradiol	0	0	1	0.7	0	0
	Estrogens conjugated	1	0.6	1	0.7	1	0.6
	Ethinylestradiol	2	1.3	2	1.3	10	6.2
	Etonogestrel	1	0.6	0	0	0	0
	Hormonal contraceptives for systemic use	0	0	1	0.7	0	0
	Levonorgestrel	0	0	1	0.7	0	0
	Medroxyprogesterone acetate	3	1.9	7	4.6	6	3.7
	Norelgestromin	0	0	1	0.7	1	0.6
	Norethisterone	1	0.6	0	0	0	0
	Norethisterone acetate	0	0	1	0.7	0	0
	Norgestimate	0	0	1	0.7	1	0.6
	Oral contraceptive nos	0	0	1	0.7	0	0
	Progesterone	0	0	0	0	1	0.6
	Sildenafil citrate	0	0	0	0	1	0.6

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MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Tadalafil	1	0.6	0	0	0	0
	Testosterone	0	0	0	0	2	1.2
	Tolterodine l-tartrate	0	0	0	0	2	1.2
	Vardenafil hydrochloride	2	1.3	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	48	31.0	54	35.8	69	42.9
	Alendronate sodium	0	0	0	0	1	0.6
	Allopurinol	0	0	1	0.7	1	0.6
	Baclofen	1	0.6	0	0	0	0
	Carisoprodol	0	0	1	0.7	1	0.6
	Celecoxib	2	1.3	1	0.7	0	0
	Colchicine	0	0	1	0.7	0	0
	Cyclobenzaprine hydrochloride	1	0.6	2	1.3	1	0.6
	Diclofenac sodium	0	0	1	0.7	0	0
	Etodolac	0	0	1	0.7	1	0.6
	Etoricoxib	0	0	0	0	1	0.6

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MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Glucosamine	0	0	3	2.0	2	1.2
	Glucosamine hydrochloride	0	0	0	0	1	0.6
	Glucosamine sulfate	1	0.6	0	0	0	0
	Ibuprofen	37	23.9	38	25.2	49	30.4
	Indometacin	0	0	0	0	1	0.6
	Ketoprofen	0	0	1	0.7	0	0
	Ketorolac tromethamine	1	0.6	2	1.3	0	0
	Meloxicam	0	0	1	0.7	1	0.6
	Metaxalone	0	0	0	0	1	0.6
	Nabumetone	1	0.6	1	0.7	0	0
	Naproxen	2	1.3	4	2.6	3	1.9
	Naproxen sodium	7	4.5	10	6.6	13	8.1
	Orphenadrine citrate	0	0	1	0.7	0	0
	Piroxicam	0	0	0	0	2	1.2
	Pseudoephedrine hydrochloride	0	0	1	0.7	2	1.2

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MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Risedronate sodium	0	0	2	1.3	0	0
	Rofecoxib	0	0	1	0.7	0	0
	Valdecoxib	2	1.3	0	0	0	0
NERVOUS SYSTEM	TOTAL	52	33.5	59	39.1	66	41.0
	Acetylsalicylic acid	19	12.3	21	13.9	31	19.3
	Alprazolam	0	0	1	0.7	0	0
	Analgesics	0	0	0	0	2	1.2
	Benzatropine mesilate	4	2.6	3	2.0	0	0
	Benzocaine	0	0	0	0	1	0.6
	Bupivacaine	1	0.6	1	0.7	0	0
	Caffeine	0	0	1	0.7	0	0
	Chlorphenamine maleate	0	0	0	0	1	0.6
	Clonazepam	1	0.6	0	0	0	0
	Codeine phosphate	1	0.6	0	0	0	0
	Cyclobenzaprine	0	0	1	0.7	0	0

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MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Diazepam	0	0	0	0	1	0.6
	Diclofenac sodium	1	0.6	1	0.7	1	0.6
	Diphenhydramine	3	1.9	1	0.7	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.6
	Epinephrine	1	0.6	0	0	1	0.6
	Ethanol	1	0.6	6	4.0	1	0.6
	Lidocaine	0	0	1	0.7	1	0.6
	Lorazepam	2	1.3	6	4.0	5	3.1
	Mepyramine maleate	1	0.6	1	0.7	2	1.2
	Methylsulfonylmethane	0	0	1	0.7	0	0
	Morphine hydrochloride	0	0	1	0.7	1	0.6
	Oxcarbazepine	0	0	1	0.7	0	0
	Oxycodone	1	0.6	0	0	0	0
	Paracetamol	31	20.0	28	18.5	32	19.9
	Procaine hydrochloride	1	0.6	0	0	0	0

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		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Risperidone	0	0	1	0.7	0	0
	Rizatriptan benzoate	0	0	1	0.7	0	0
	Sumatriptan	0	0	0	0	2	1.2
	Zolpidem tartrate	2	1.3	3	2.0	4	2.5
RESPIRATORY SYSTEM	TOTAL	39	25.2	43	28.5	39	24.2
	Allergy medication	2	1.3	0	0	0	0
	Beclometasone dipropionate	0	0	1	0.7	0	0
	Benzonatate	0	0	1	0.7	0	0
	Camphor	1	0.6	1	0.7	0	0
	Cetirizine hydrochloride	1	0.6	3	2.0	3	1.9
	Chlorphenamine maleate	0	0	0	0	2	1.2
	Codeine phosphate	0	0	1	0.7	1	0.6
	Cough and cold preparations	0	0	0	0	2	1.2
	Cromoglicate sodium	0	0	1	0.7	0	0

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		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Desloratadine	0	0	1	0.7	2	1.2
	Dexbrompheniramine maleate	0	0	1	0.7	0	0
	Dimenhydrinate	1	0.6	0	0	0	0
	Diphenhydramine hydrochloride	5	3.2	1	0.7	9	5.6
	Epinephrine	0	0	2	1.3	1	0.6
	Fexofenadine hydrochloride	1	0.6	2	1.3	2	1.2
	Flunisolide	0	0	0	0	1	0.6
	Fluticasone propionate	6	3.9	7	4.6	8	5.0
	Guaifenesin	7	4.5	3	2.0	2	1.2
	Hydrocodone	0	0	1	0.7	1	0.6
	Ipratropium bromide	0	0	1	0.7	0	0
	Loratadine	4	2.6	6	4.0	7	4.3
	Meclozine hydrochloride	0	0	1	0.7	0	0
	Mometasone furoate	0	0	2	1.3	1	0.6

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		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Montelukast sodium	3	1.9	3	2.0	0	0
	Other cold combination preparations	1	0.6	0	0	0	0
	Oxymetazoline hydrochloride	0	0	2	1.3	0	0
	Paracetamol	3	1.9	2	1.3	3	1.9
	Phenylephrine hydrochloride	1	0.6	2	1.3	0	0
	Promethazine	0	0	1	0.7	0	0
	Promethazine hydrochloride	2	1.3	2	1.3	0	0
	Pseudoephedrine	0	0	1	0.7	0	0
	Pseudoephedrine hydrochloride	7	4.5	6	4.0	5	3.1
	Pseudoephedrine sulfate	0	0	2	1.3	2	1.2
	Pseudoephedrine, combinations	1	0.6	0	0	0	0
	Salbutamol	6	3.9	8	5.3	4	2.5

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Salmeterol xinafoate	1	0.6	0	0	0	0
	Terpin hydrate	0	0	2	1.3	0	0
	Theophylline	0	0	1	0.7	0	0
	Triamcinolone acetonide	0	0	1	0.7	1	0.6
SENSORY ORGANS	TOTAL	2	1.3	2	1.3	0	0
	Latanoprost	1	0.6	0	0	0	0
	Olopatadine hydrochloride	1	0.6	0	0	0	0
	Travoprost	0	0	1	0.7	0	0
	Xantofyl	0	0	1	0.7	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	8	5.2	9	6.0	8	5.0
	Betamethasone dipropionate	1	0.6	0	0	0	0
	Cortisone	0	0	1	0.7	0	0
	Desmopressin	0	0	0	0	1	0.6
	Dexamethasone	0	0	1	0.7	0	0
	Hydrocortisone	0	0	0	0	1	0.6

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Table 11.1.7.7 Concomitant Medication Summary
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	Levothyroxine sodium	5	3.2	6	4.0	7	4.3
	Liothyronine sodium	1	0.6	0	0	0	0
	Melatonin	0	0	1	0.7	0	0
	Methylprednisolone	0	0	0	0	1	0.6
	Prednisone	2	1.3	1	0.7	0	0
VARIOUS	TOTAL	3	1.9	8	5.3	2	1.2
	All other therapeutic products	1	0.6	1	0.7	0	0
	Allergens nos	0	0	1	0.7	0	0
	Allium sativum	0	0	3	2.0	0	0
	Herbal nos	1	0.6	0	0	0	0
	Herbal preparation	0	0	2	1.3	0	0
	Linum usitatissimum seed oil	1	0.6	1	0.7	0	0
	Other nutrients	0	0	1	0.7	2	1.2

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY CONCOMITANT MEDICATION		85	75.9	86	76.8	96	85.7	47	79.7	40	71.4	44	80.0
ALIMENTARY TRACT AND METABOLISM	TOTAL	40	35.7	39	34.8	35	31.2	16	27.1	21	37.5	19	34.5
	Ascorbic acid	4	3.6	3	2.7	0	0	0	0	1	1.8	2	3.6
	Atropine sulfate	0	0	0	0	0	0	1	1.7	0	0	0	0
	Bismuth subsalicylate	0	0	1	0.9	1	0.9	0	0	1	1.8	2	3.6
	Calcium	2	1.8	1	0.9	0	0	0	0	0	0	2	3.6
	Calcium carbonate	3	2.7	6	5.4	4	3.6	4	6.8	2	3.6	3	5.5
	Charcoal, activated	0	0	0	0	0	0	0	0	1	1.8	0	0
	Cimetidine	0	0	1	0.9	2	1.8	0	0	0	0	0	0
	Colecalciferol	0	0	0	0	1	0.9	0	0	0	0	0	0
	Dicycloverine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Dihydroxyaluminum sodium carbonate	3	2.7	3	2.7	1	0.9	0	0	1	1.8	0	0
	Docusate sodium	0	0	1	0.9	0	0	1	1.7	1	1.8	0	0
	Ergocalciferol	7	6.3	3	2.7	2	1.8	1	1.7	3	5.4	2	3.6
	Esomeprazole	3	2.7	2	1.8	4	3.6	1	1.7	0	0	1	1.8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS206.SAS
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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Famotidine	0	0	6	5.4	2	1.8	1	1.7	0	0	0	0
	Glibenclamide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glipizide	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	Insulin human	1	0.9	0	0	2	1.8	0	0	0	0	0	0
	Lansoprazole	3	2.7	1	0.9	1	0.9	0	0	2	3.6	1	1.8
	Loperamide hydrochloride	1	0.9	0	0	1	0.9	1	1.7	0	0	1	1.8
	Magnesium	0	0	1	0.9	0	0	0	0	0	0	0	0
	Magnesium aspartate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Magnesium hydroxide	0	0	2	1.8	1	0.9	0	0	1	1.8	0	0
	Metformin	0	0	2	1.8	0	0	0	0	0	0	0	0
	Metformin hydrochloride	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	Metoclopramide hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Omeprazole	1	0.9	7	6.3	2	1.8	1	1.7	0	0	1	1.8
	Pantoprazole	1	0.9	1	0.9	0	0	2	3.4	0	0	0	0
	Pioglitazone	1	0.9	0	0	0	0	0	0	1	1.8	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Polycarbophil calcium	0	0	1	0.9	0	0	1	1.7	0	0	0	0
	Psyllium hydrophilic mucilloid	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Pyridoxine hydrochloride	0	0	1	0.9	0	0	0	0	1	1.8	1	1.8
	Rabeprazole sodium	0	0	2	1.8	0	0	0	0	1	1.8	1	1.8
	Ranitidine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Ranitidine hydrochloride	1	0.9	2	1.8	3	2.7	1	1.7	1	1.8	0	0
	Rosiglitazone maleate	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Senna alexandrina fruit	0	0	1	0.9	0	0	0	0	0	0	0	0
	Simeticone	0	0	0	0	0	0	0	0	0	0	1	1.8
	Tegaserod	0	0	0	0	0	0	1	1.7	0	0	0	0
	Tocopherol	1	0.9	1	0.9	0	0	1	1.7	0	0	2	3.6
	Vitamin b	1	0.9	0	0	1	0.9	0	0	0	0	2	3.6
	Vitamin b-complex	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI N=112		Q600-BPI N=112		P-BPI N=112		Q300-BPII N=59		Q600-BPII N=56		P-BPII N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Vitamins	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Vitamins nos	12	10.7	14	12.5	12	10.7	6	10.2	8	14.3	5	9.1
	Yellow phenolphthalein	0	0	0	0	1	0.9	0	0	0	0	0	0
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	11	9.8	13	11.6	11	9.8	5	8.5	6	10.7	5	9.1
	Amoxicillin	2	1.8	2	1.8	4	3.6	0	0	2	3.6	2	3.6
	Antibiotics	0	0	0	0	0	0	0	0	0	0	1	1.8
	Azithromycin	2	1.8	2	1.8	1	0.9	2	3.4	1	1.8	0	0
	Benzylpenicillin sodium	1	0.9	0	0	2	1.8	0	0	0	0	0	0
	Bicillin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Cefadroxil	1	0.9	0	0	0	0	0	0	0	0	0	0
	Cefalexin	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Cefalexin monohydrate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Cefditoren pivoxil	0	0	0	0	1	0.9	0	0	0	0	0	0
	Ceftriaxone sodium	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Cefuroxime	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Ciprofloxacin hydrochloride	1	0.9	1	0.9	1	0.9	2	3.4	0	0	0	0
	Clarithromycin	1	0.9	2	1.8	0	0	0	0	2	3.6	0	0
	Clindamycin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Doxycycline	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	Doxycycline hyclate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Fluconazole	0	0	0	0	0	0	0	0	1	1.8	0	0
	Gatifloxacin	0	0	0	0	0	0	0	0	0	0	1	1.8
	Indinavir sulfate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Levofloxacin	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Minocycline	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	Moxifloxacin hydrochloride	0	0	0	0	0	0	1	1.7	0	0	0	0
	Nitrofurantoin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Sulfamethoxazole	0	0	1	0.9	1	0.9	0	0	1	1.8	0	0
	Sultamicillin tosilate	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Valaciclovir hydrochloride	0	0	0	0	0	0	0	0	0	0	1	1.8
	Zidovudine	0	0	1	0.9	0	0	0	0	0	0	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Colostrum	1	0.9	0	0	0	0	0	0	0	0	0	0
	Hydroxycarbamide	0	0	1	0.9	0	0	0	0	0	0	0	0
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	TOTAL	1	0.9	0	0	0	0	0	0	0	0	0	0
	Quinine sulfate	1	0.9	0	0	0	0	0	0	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	0.9	4	3.6	2	1.8	0	0	0	0	1	1.8
	Clopidogrel sulfate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Cyanocobalamin-tannin complex	0	0	1	0.9	0	0	0	0	0	0	0	0
	Ferrous sulfate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Folic acid	0	0	1	0.9	0	0	0	0	0	0	0	0
	Iron	1	0.9	0	0	1	0.9	0	0	0	0	1	1.8
	Warfarin sodium	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	TOTAL	16	14.3	15	13.4	19	17.0	12	20.3	10	17.9	5	9.1
	Amlodipine	0	0	2	1.8	1	0.9	0	0	2	3.6	0	0
	Amlodipine besilate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Atenolol	1	0.9	2	1.8	3	2.7	0	0	1	1.8	2	3.6
	Atorvastatin	2	1.8	2	1.8	3	2.7	3	5.1	1	1.8	1	1.8
	Benazepril hydrochloride	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	Chlortalidone	0	0	0	0	0	0	1	1.7	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	0.9	0	0	0	0	0	0	0	0
	Doxazosin mesilate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Enalapril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Enalapril maleate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fenofibrate	1	0.9	0	0	1	0.9	0	0	1	1.8	0	0
	Fish oil	3	2.7	1	0.9	0	0	0	0	0	0	1	1.8
	Furosemide	0	0	1	0.9	0	0	0	0	0	0	0	0
	Glyceryl trinitrate	1	0.9	0	0	0	0	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Hydrochlorothiazide	7	6.3	3	2.7	2	1.8	3	5.1	4	7.1	0	0
	Isradipine	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Lisinopril	1	0.9	2	1.8	2	1.8	1	1.7	1	1.8	1	1.8
	Losartan potassium	0	0	0	0	0	0	1	1.7	0	0	0	0
	Lovastatin	1	0.9	0	0	0	0	0	0	0	0	0	0
	Metoprolol	0	0	2	1.8	0	0	0	0	0	0	0	0
	Metoprolol succinate	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Metoprolol tartrate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Nifedipine	0	0	0	0	0	0	1	1.7	1	1.8	0	0
	Nisoldipine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Olea europaea leaf extract	0	0	1	0.9	0	0	0	0	0	0	0	0
	Olmesartan medoxomil	1	0.9	1	0.9	0	0	0	0	0	0	1	1.8
	Omega-3 triglycerides	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	Preparation h	0	0	0	0	0	0	0	0	1	1.8	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Propranolol hydrochloride	0	0	0	0	0	0	1	1.7	0	0	1	1.8
	Ramipril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Rosuvastatin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Simvastatin	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Spironolactone	0	0	0	0	0	0	0	0	1	1.8	0	0
	Timolol	0	0	1	0.9	0	0	0	0	0	0	0	0
	Ubidecarenone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Valsartan	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Verapamil	0	0	0	0	1	0.9	0	0	0	0	0	0
	Verapamil hydrochloride	0	0	0	0	0	0	1	1.7	0	0	0	0
DERMATOLOGICALS	TOTAL	0	0	2	1.8	3	2.7	0	0	0	0	2	3.6
	Calcipotriol	0	0	1	0.9	0	0	0	0	0	0	0	0
	Docosanol	0	0	0	0	1	0.9	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	0	0	0	0	0	0	1	1.8
	Ketoconazole	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DERMATOLOGICALS	Linoleic acid	0	0	0	0	1	0.9	0	0	0	0	0	0
	Mupirocin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Neomycin sulfate	0	0	0	0	0	0	0	0	0	0	1	1.8
	Nystatin	0	0	1	0.9	0	0	0	0	0	0	0	0
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	9	8.0	14	12.5	16	14.3	4	6.8	4	7.1	8	14.5
	Cimicifuga racemosa root	0	0	0	0	0	0	0	0	1	1.8	0	0
	Clotrimazole	1	0.9	0	0	0	0	0	0	0	0	0	0
	Estradiol	0	0	0	0	0	0	0	0	1	1.8	0	0
	Estrogens conjugated	1	0.9	1	0.9	0	0	0	0	0	0	1	1.8
	Ethinylestradiol	2	1.8	2	1.8	6	5.4	0	0	0	0	4	7.3
	Etonogestrel	0	0	0	0	0	0	1	1.7	0	0	0	0
	Hormonal contraceptives for systemic use	0	0	1	0.9	0	0	0	0	0	0	0	0
	Levonorgestrel	0	0	0	0	0	0	1	1.7	1	1.8	0	0
	Medroxyprogesterone acetate	3	2.7	6	5.4	5	4.5	0	0	2	3.6	1	1.8

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI N=112		Q600-BPI N=112		P-BPI N=112		Q300-BPII N=59		Q600-BPII N=56		P-BPII N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Norelgestromin	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Norethisterone	1	0.9	0	0	0	0	0	0	0	0	0	0
	Norethisterone acetate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Norgestimate	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Oral contraceptive nos	0	0	1	0.9	0	0	0	0	0	0	0	0
	Progesterone	0	0	0	0	0	0	0	0	0	0	1	1.8
	Sildenafil citrate	0	0	0	0	0	0	0	0	0	0	1	1.8
	Tadalafil	0	0	0	0	0	0	1	1.7	0	0	0	0
	Testosterone	0	0	0	0	2	1.8	0	0	0	0	0	0
	Tolterodine l-tartrate	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Vardenafil hydrochloride	1	0.9	0	0	0	0	1	1.7	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	31	27.7	40	35.7	48	42.9	21	35.6	15	26.8	23	41.8
	Acetylsalicylic acid	0	0	0	0	0	0	0	0	0	0	1	1.8
	Alendronate sodium	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Allopurinol	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	Baclofen	0	0	0	0	0	0	1	1.7	0	0	0	0
	Carisoprodol	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Celecoxib	1	0.9	1	0.9	0	0	1	1.7	0	0	0	0
	Chondroitin sulfate	0	0	0	0	0	0	0	0	1	1.8	0	0
	Colchicine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Cyclobenzaprine hydrochloride	0	0	2	1.8	1	0.9	1	1.7	0	0	0	0
	Diclofenac	0	0	0	0	0	0	1	1.7	0	0	0	0
	Diclofenac sodium	0	0	1	0.9	0	0	0	0	0	0	0	0
	Etodolac	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Etoricoxib	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glucosamine	0	0	3	2.7	1	0.9	0	0	0	0	1	1.8
	Glucosamine hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glucosamine sulfate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Ibuprofen	27	24.1	30	26.8	33	29.5	14	23.7	8	14.3	18	32.7

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Indometacin	0	0	0	0	0	0	0	0	0	0	1	1.8
	Ketoprofen	0	0	0	0	0	0	0	0	1	1.8	0	0
	Ketorolac tromethamine	0	0	1	0.9	0	0	1	1.7	1	1.8	0	0
	Meloxicam	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	Metaxalone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Nabumetone	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Naproxen	0	0	2	1.8	2	1.8	2	3.4	2	3.6	1	1.8
	Naproxen sodium	4	3.6	9	8.0	9	8.0	4	6.8	1	1.8	4	7.3
	Orphenadrine citrate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Piroxicam	0	0	0	0	2	1.8	0	0	0	0	0	0
	Pseudoephedrine hydrochloride	0	0	1	0.9	1	0.9	0	0	0	0	1	1.8
	Risedronate sodium	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	Rofecoxib	0	0	0	0	0	0	0	0	1	1.8	0	0
	Valdecoxib	1	0.9	0	0	0	0	1	1.7	0	0	0	0
NERVOUS SYSTEM	TOTAL	35	31.2	42	37.5	49	43.8	21	35.6	19	33.9	18	32.7

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Acetylsalicylic acid	12	10.7	15	13.4	23	20.5	9	15.3	7	12.5	8	14.5
	Alprazolam	0	0	1	0.9	0	0	0	0	0	0	0	0
	Analgesics	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Benzatropine mesilate	4	3.6	3	2.7	0	0	0	0	0	0	0	0
	Benzocaine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Bupivacaine	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Caffeine	0	0	1	0.9	0	0	0	0	0	0	0	0
	Chlorphenamine maleate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Clonazepam	1	0.9	0	0	0	0	0	0	0	0	0	0
	Codeine phosphate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Cyclobenzaprine	0	0	1	0.9	0	0	0	0	0	0	0	0
	Diazepam	0	0	0	0	1	0.9	0	0	0	0	0	0
	Diclofenac sodium	1	0.9	1	0.9	1	0.9	0	0	0	0	0	0
	Diphenhydramine	1	0.9	0	0	0	0	2	3.4	1	1.8	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Eletriptan hydrobromide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Epinephrine	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	Ethanol	1	0.9	4	3.6	0	0	0	0	2	3.6	1	1.8
	Lidocaine	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	Lorazepam	0	0	4	3.6	4	3.6	2	3.4	2	3.6	1	1.8
	Mepyramine maleate	1	0.9	1	0.9	1	0.9	0	0	0	0	1	1.8
	Methylsulfonylmethane	0	0	1	0.9	0	0	0	0	0	0	0	0
	Morphine hydrochloride	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	Oxcarbazepine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Oxycodone	0	0	0	0	0	0	1	1.7	0	0	0	0
	Paracetamol	21	18.8	21	18.8	22	19.6	13	22.0	8	14.3	10	18.2
	Procaine hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Risperidone	0	0	0	0	0	0	0	0	1	1.8	0	0
	Rizatriptan benzoate	0	0	0	0	0	0	0	0	1	1.8	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Sumatriptan	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Zolpidem tartrate	2	1.8	2	1.8	5	4.5	0	0	1	1.8	0	0
RESPIRATORY SYSTEM	TOTAL	25	22.3	33	29.5	26	23.2	18	30.5	11	19.6	14	25.5
	Allergy medication	1	0.9	0	0	0	0	1	1.7	0	0	0	0
	Beclometasone dipropionate	0	0	0	0	0	0	0	0	1	1.8	0	0
	Benzonatate	0	0	1	0.9	0	0	0	0	0	0	0	0
	Camphor	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	Cetirizine hydrochloride	0	0	3	2.7	1	0.9	1	1.7	0	0	2	3.6
	Chlorphenamine maleate	0	0	0	0	0	0	0	0	0	0	2	3.6
	Codeine phosphate	0	0	0	0	1	0.9	0	0	1	1.8	0	0
	Cough and cold preparations	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	Cromoglicate sodium	0	0	1	0.9	0	0	0	0	0	0	0	0
	Desloratadine	0	0	0	0	2	1.8	0	0	1	1.8	0	0
	Dexbrompheniramine maleate	0	0	1	0.9	0	0	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Dimenhydrinate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Diphenhydramine hydrochloride	3	2.7	1	0.9	5	4.5	2	3.4	0	0	4	7.3
	Epinephrine	0	0	2	1.8	0	0	0	0	0	0	1	1.8
	Fexofenadine hydrochloride	0	0	1	0.9	2	1.8	1	1.7	1	1.8	0	0
	Flunisolide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fluticasone propionate	2	1.8	7	6.3	5	4.5	4	6.8	0	0	3	5.5
	Guaifenesin	4	3.6	3	2.7	1	0.9	3	5.1	0	0	1	1.8
	Hydrocodone	0	0	0	0	0	0	0	0	1	1.8	1	1.8
	Ipratropium bromide	0	0	1	0.9	0	0	0	0	0	0	0	0
	Loratadine	2	1.8	6	5.4	3	2.7	2	3.4	0	0	4	7.3
	Meclozine hydrochloride	0	0	1	0.9	0	0	0	0	0	0	0	0
	Mometasone furoate	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	Montelukast sodium	2	1.8	3	2.7	0	0	1	1.7	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Other cold combination preparations	1	0.9	0	0	0	0	0	0	0	0	0	0
	Oxymetazoline hydrochloride	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	Paracetamol	2	1.8	0	0	2	1.8	2	3.4	2	3.6	1	1.8
	Phenylephrine hydrochloride	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	Promethazine	0	0	1	0.9	0	0	0	0	0	0	0	0
	Promethazine hydrochloride	1	0.9	2	1.8	0	0	1	1.7	0	0	0	0
	Pseudoephedrine	0	0	0	0	0	0	0	0	1	1.8	0	0
	Pseudoephedrine hydrochloride	6	5.4	6	5.4	3	2.7	2	3.4	0	0	2	3.6
	Pseudoephedrine sulfate	0	0	2	1.8	1	0.9	0	0	0	0	1	1.8
	Pseudoephedrine, combinations	0	0	0	0	0	0	1	1.7	0	0	0	0
	Salbutamol	6	5.4	8	7.1	3	2.7	2	3.4	1	1.8	2	3.6
	Salmeterol xinafoate	0	0	0	0	0	0	1	1.7	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Terpin hydrate	0	0	2	1.8	0	0	0	0	0	0	0	0
	Theophylline	0	0	1	0.9	0	0	0	0	0	0	0	0
	Triamcinolone acetonide	0	0	0	0	1	0.9	0	0	1	1.8	0	0
SENSORY ORGANS	TOTAL	1	0.9	2	1.8	0	0	1	1.7	0	0	0	0
	Latanoprost	0	0	0	0	0	0	1	1.7	0	0	0	0
	Olopatadine hydrochloride	1	0.9	0	0	0	0	0	0	0	0	0	0
	Travoprost	0	0	1	0.9	0	0	0	0	0	0	0	0
	Xantofyl	0	0	1	0.9	0	0	0	0	0	0	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	6	5.4	5	4.5	5	4.5	2	3.4	4	7.1	3	5.5
	Betamethasone dipropionate	1	0.9	0	0	0	0	0	0	0	0	0	0
	Cortisone	0	0	0	0	0	0	0	0	1	1.8	0	0
	Desmopressin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Dexamethasone	0	0	1	0.9	0	0	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.8 Concomitant Medication Summary by Bipolar Diagnosis
Safety Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	Levothyroxine sodium	5	4.5	4	3.6	5	4.5	0	0	2	3.6	2	3.6
	Liothyronine sodium	1	0.9	0	0	0	0	0	0	0	0	0	0
	Melatonin	0	0	0	0	0	0	0	0	1	1.8	0	0
	Methylprednisolone	0	0	0	0	0	0	0	0	0	0	1	1.8
	Prednisone	0	0	1	0.9	0	0	2	3.4	0	0	0	0
VARIOUS	TOTAL	2	1.8	7	6.3	1	0.9	1	1.7	1	1.8	1	1.8
	All other therapeutic products	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Allergens nos	0	0	1	0.9	0	0	0	0	0	0	0	0
	Allium sativum	0	0	2	1.8	0	0	0	0	1	1.8	0	0
	Herbal nos	0	0	0	0	0	0	1	1.7	0	0	0	0
	Herbal preparation	0	0	2	1.8	0	0	0	0	0	0	0	0
	Linum usitatissimum seed oil	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	Other nutrients	0	0	0	0	1	0.9	0	0	1	1.8	1	1.8

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY CONCOMITANT MEDICATION		79	76.0	81	80.2	94	85.5	40	78.4	37	74.0	41	80.4
ALIMENTARY TRACT AND METABOLISM	TOTAL	35	33.7	37	36.6	34	30.9	15	29.4	19	38.0	17	33.3
	Ascorbic acid	4	3.8	3	3.0	0	0	0	0	1	2.0	1	2.0
	Atropine sulfate	0	0	0	0	0	0	1	2.0	0	0	0	0
	Bismuth subsalicylate	0	0	1	1.0	1	0.9	0	0	1	2.0	2	3.9
	Calcium	2	1.9	1	1.0	0	0	0	0	0	0	2	3.9
	Calcium carbonate	3	2.9	6	5.9	4	3.6	3	5.9	2	4.0	3	5.9
	Charcoal, activated	0	0	0	0	0	0	0	0	1	2.0	0	0
	Cimetidine	0	0	1	1.0	2	1.8	0	0	0	0	0	0
	Colecalciferol	0	0	0	0	1	0.9	0	0	0	0	0	0
	Dihydroxyaluminum sodium carbonate	3	2.9	3	3.0	1	0.9	0	0	1	2.0	0	0
	Docusate sodium	0	0	1	1.0	0	0	1	2.0	1	2.0	0	0
	Ergocalciferol	6	5.8	3	3.0	2	1.8	1	2.0	3	6.0	2	3.9
	Esomeprazole	3	2.9	2	2.0	4	3.6	0	0	0	0	0	0
	Famotidine	0	0	5	5.0	2	1.8	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS207.SAS
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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Glibenclamide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glipizide	0	0	1	1.0	0	0	0	0	0	0	1	2.0
	Insulin human	1	1.0	0	0	2	1.8	0	0	0	0	0	0
	Lansoprazole	2	1.9	1	1.0	1	0.9	0	0	2	4.0	1	2.0
	Loperamide hydrochloride	1	1.0	0	0	1	0.9	1	2.0	0	0	1	2.0
	Magnesium	0	0	1	1.0	0	0	0	0	0	0	0	0
	Magnesium aspartate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Magnesium hydroxide	0	0	2	2.0	1	0.9	0	0	1	2.0	0	0
	Metformin	0	0	2	2.0	0	0	0	0	0	0	0	0
	Metformin hydrochloride	0	0	0	0	1	0.9	1	2.0	0	0	0	0
	Metoclopramide hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Omeprazole	1	1.0	6	5.9	2	1.8	0	0	0	0	1	2.0
	Pantoprazole	1	1.0	1	1.0	0	0	2	3.9	0	0	0	0
	Pioglitazone	0	0	0	0	0	0	0	0	1	2.0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS207.SAS
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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Polycarbophil calcium	0	0	1	1.0	0	0	1	2.0	0	0	0	0
	Psyllium hydrophilic mucilloid	0	0	0	0	0	0	0	0	1	2.0	0	0
	Pyridoxine hydrochloride	0	0	1	1.0	0	0	0	0	1	2.0	1	2.0
	Rabeprazole sodium	0	0	2	2.0	0	0	0	0	1	2.0	1	2.0
	Ranitidine	0	0	0	0	0	0	0	0	1	2.0	0	0
	Ranitidine hydrochloride	1	1.0	2	2.0	2	1.8	1	2.0	1	2.0	0	0
	Rosiglitazone maleate	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Senna alexandrina fruit	0	0	1	1.0	0	0	0	0	0	0	0	0
	Simeticone	0	0	0	0	0	0	0	0	0	0	1	2.0
	Tegaserod	0	0	0	0	0	0	1	2.0	0	0	0	0
	Tocopherol	1	1.0	1	1.0	0	0	1	2.0	0	0	2	3.9
	Vitamin b	1	1.0	0	0	1	0.9	0	0	0	0	2	3.9
	Vitamin b-complex	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ALIMENTARY TRACT AND METABOLISM	Vitamins	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Vitamins nos	11	10.6	14	13.9	12	10.9	6	11.8	7	14.0	5	9.8
	Yellow phenolphthalein	0	0	0	0	1	0.9	0	0	0	0	0	0
ANTIINFECTIVES FOR SYSTEMIC USE	TOTAL	11	10.6	11	10.9	11	10.0	5	9.8	6	12.0	5	9.8
	Amoxicillin	2	1.9	2	2.0	4	3.6	0	0	2	4.0	2	3.9
	Antibiotics	0	0	0	0	0	0	0	0	0	0	1	2.0
	Azithromycin	2	1.9	2	2.0	1	0.9	2	3.9	1	2.0	0	0
	Benzylpenicillin sodium	1	1.0	0	0	2	1.8	0	0	0	0	0	0
	Bicillin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Cefadroxil	1	1.0	0	0	0	0	0	0	0	0	0	0
	Cefalexin	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Cefalexin monohydrate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Cefditoren pivoxil	0	0	0	0	1	0.9	0	0	0	0	0	0
	Ceftriaxone sodium	0	0	1	1.0	1	0.9	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Ciprofloxacin hydrochloride	1	1.0	1	1.0	1	0.9	2	3.9	0	0	0	0
	Clarithromycin	1	1.0	2	2.0	0	0	0	0	2	4.0	0	0
	Clindamycin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Doxycycline	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Doxycycline hyclate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Fluconazole	0	0	0	0	0	0	0	0	1	2.0	0	0
	Gatifloxacin	0	0	0	0	0	0	0	0	0	0	1	2.0
	Indinavir sulfate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Levofloxacin	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Minocycline	0	0	1	1.0	0	0	0	0	0	0	1	2.0
	Moxifloxacin hydrochloride	0	0	0	0	0	0	1	2.0	0	0	0	0
	Nitrofurantoin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Sulfamethoxazole	0	0	1	1.0	1	0.9	0	0	1	2.0	0	0
	Sultamicillin tosilate	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANTIINFECTIVES FOR SYSTEMIC USE	Valaciclovir hydrochloride	0	0	0	0	0	0	0	0	0	0	1	2.0
	Zidovudine	0	0	1	1.0	0	0	0	0	0	0	0	0
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	TOTAL	1	1.0	1	1.0	0	0	0	0	0	0	0	0
	Colostrum	1	1.0	0	0	0	0	0	0	0	0	0	0
	Hydroxycarbamide	0	0	1	1.0	0	0	0	0	0	0	0	0
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	TOTAL	1	1.0	0	0	0	0	0	0	0	0	0	0
	Quinine sulfate	1	1.0	0	0	0	0	0	0	0	0	0	0
BLOOD AND BLOOD FORMING ORGANS	TOTAL	1	1.0	3	3.0	2	1.8	0	0	0	0	1	2.0
	Cyanocobalamin-tannin complex	0	0	1	1.0	0	0	0	0	0	0	0	0
	Ferrous sulfate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Folic acid	0	0	1	1.0	0	0	0	0	0	0	0	0
	Iron	1	1.0	0	0	1	0.9	0	0	0	0	1	2.0
	Warfarin sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
CARDIOVASCULAR SYSTEM	TOTAL	15	14.4	14	13.9	18	16.4	10	19.6	9	18.0	4	7.8
	Amlodipine	0	0	2	2.0	1	0.9	0	0	1	2.0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Amlodipine besilate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Atenolol	1	1.0	1	1.0	2	1.8	0	0	1	2.0	1	2.0
	Atorvastatin	2	1.9	2	2.0	3	2.7	2	3.9	1	2.0	1	2.0
	Benazepril hydrochloride	1	1.0	0	0	1	0.9	0	0	0	0	0	0
	Chlortalidone	0	0	0	0	0	0	1	2.0	0	0	0	0
	Cholesterol- and triglyceride reducers	0	0	1	1.0	0	0	0	0	0	0	0	0
	Doxazosin mesilate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Enalapril	0	0	0	0	1	0.9	0	0	0	0	0	0
	Enalapril maleate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fenofibrate	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Fish oil	3	2.9	1	1.0	0	0	0	0	0	0	1	2.0
	Furosemide	0	0	1	1.0	0	0	0	0	0	0	0	0
	Glyceryl trinitrate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Hydrochlorothiazide	6	5.8	3	3.0	2	1.8	3	5.9	4	8.0	0	0
	Isradipine	1	1.0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Lisinopril	0	0	1	1.0	2	1.8	1	2.0	1	2.0	1	2.0
	Losartan potassium	0	0	0	0	0	0	1	2.0	0	0	0	0
	Lovastatin	1	1.0	0	0	0	0	0	0	0	0	0	0
	Metoprolol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Metoprolol succinate	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Metoprolol tartrate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Nifedipine	0	0	0	0	0	0	1	2.0	1	2.0	0	0
	Nisoldipine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Olea europaea leaf extract	0	0	1	1.0	0	0	0	0	0	0	0	0
	Olmesartan medoxomil	1	1.0	1	1.0	0	0	0	0	0	0	1	2.0
	Omega-3 triglycerides	0	0	0	0	1	0.9	1	2.0	0	0	0	0
	Preparation h	0	0	0	0	0	0	0	0	1	2.0	0	0
	Propranolol hydrochloride	0	0	0	0	0	0	1	2.0	0	0	1	2.0
	Ramipril	0	0	0	0	1	0.9	0	0	0	0	0	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MEDS207.SAS
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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
CARDIOVASCULAR SYSTEM	Rosuvastatin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Simvastatin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Spironolactone	0	0	0	0	0	0	0	0	1	2.0	0	0
	Timolol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Ubidecarenone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Valsartan	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Verapamil	0	0	0	0	1	0.9	0	0	0	0	0	0
DERMATOLOGICALS	TOTAL	0	0	2	2.0	3	2.7	0	0	0	0	2	3.9
	Calcipotriol	0	0	1	1.0	0	0	0	0	0	0	0	0
	Docosanol	0	0	0	0	1	0.9	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	0	0	0	0	0	0	1	2.0
	Ketoconazole	0	0	0	0	1	0.9	0	0	0	0	0	0
	Linoleic acid	0	0	0	0	1	0.9	0	0	0	0	0	0
	Mupirocin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Neomycin sulfate	0	0	0	0	0	0	0	0	0	0	1	2.0
	Nystatin	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	TOTAL	9	8.7	13	12.9	16	14.5	3	5.9	4	8.0	8	15.7
	Cimicifuga racemosa root	0	0	0	0	0	0	0	0	1	2.0	0	0
	Clotrimazole	1	1.0	0	0	0	0	0	0	0	0	0	0
	Estradiol	0	0	0	0	0	0	0	0	1	2.0	0	0
	Estrogens conjugated	1	1.0	1	1.0	0	0	0	0	0	0	1	2.0
	Ethinylestradiol	2	1.9	2	2.0	6	5.5	0	0	0	0	4	7.8
	Etonogestrel	0	0	0	0	0	0	1	2.0	0	0	0	0
	Hormonal contraceptives for systemic use	0	0	1	1.0	0	0	0	0	0	0	0	0
	Levonorgestrel	0	0	0	0	0	0	0	0	1	2.0	0	0
	Medroxyprogesterone acetate	3	2.9	5	5.0	5	4.5	0	0	2	4.0	1	2.0
	Norelgestromin	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Norethisterone	1	1.0	0	0	0	0	0	0	0	0	0	0
	Norethisterone acetate	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENITO URINARY SYSTEM AND SEX HORMONES	Norgestimate	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Oral contraceptive nos	0	0	1	1.0	0	0	0	0	0	0	0	0
	Progesterone	0	0	0	0	0	0	0	0	0	0	1	2.0
	Sildenafil citrate	0	0	0	0	0	0	0	0	0	0	1	2.0
	Tadalafil	0	0	0	0	0	0	1	2.0	0	0	0	0
	Testosterone	0	0	0	0	2	1.8	0	0	0	0	0	0
	Tolterodine l-tartrate	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Vardenafil hydrochloride	1	1.0	0	0	0	0	1	2.0	0	0	0	0
MUSCULO-SKELETAL SYSTEM	TOTAL	29	27.9	40	39.6	47	42.7	19	37.3	14	28.0	22	43.1
	Alendronate sodium	0	0	0	0	1	0.9	0	0	0	0	0	0
	Allopurinol	0	0	0	0	0	0	0	0	1	2.0	1	2.0
	Baclofen	0	0	0	0	0	0	1	2.0	0	0	0	0
	Carisoprodol	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Celecoxib	1	1.0	1	1.0	0	0	1	2.0	0	0	0	0
	Colchicine	0	0	0	0	0	0	0	0	1	2.0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Cyclobenzaprine hydrochloride	0	0	2	2.0	1	0.9	1	2.0	0	0	0	0
	Diclofenac sodium	0	0	1	1.0	0	0	0	0	0	0	0	0
	Etodolac	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Etoricoxib	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glucosamine	0	0	3	3.0	1	0.9	0	0	0	0	1	2.0
	Glucosamine hydrochloride	0	0	0	0	1	0.9	0	0	0	0	0	0
	Glucosamine sulfate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Ibuprofen	25	24.0	30	29.7	32	29.1	12	23.5	8	16.0	17	33.3
	Indometacin	0	0	0	0	0	0	0	0	0	0	1	2.0
	Ketoprofen	0	0	0	0	0	0	0	0	1	2.0	0	0
	Ketorolac tromethamine	0	0	1	1.0	0	0	1	2.0	1	2.0	0	0
	Meloxicam	0	0	1	1.0	0	0	0	0	0	0	1	2.0
	Metaxalone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Nabumetone	1	1.0	0	0	0	0	0	0	1	2.0	0	0
	Naproxen	0	0	2	2.0	2	1.8	2	3.9	2	4.0	1	2.0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULO-SKELETAL SYSTEM	Naproxen sodium	4	3.8	9	8.9	9	8.2	3	5.9	1	2.0	4	7.8
	Orphenadrine citrate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Piroxicam	0	0	0	0	2	1.8	0	0	0	0	0	0
	Pseudoephedrine hydrochloride	0	0	1	1.0	1	0.9	0	0	0	0	1	2.0
	Risedronate sodium	0	0	1	1.0	0	0	0	0	1	2.0	0	0
	Rofecoxib	0	0	0	0	0	0	0	0	1	2.0	0	0
	Valdecoxib	1	1.0	0	0	0	0	1	2.0	0	0	0	0
NERVOUS SYSTEM	TOTAL	34	32.7	40	39.6	48	43.6	18	35.3	19	38.0	18	35.3
	Acetylsalicylic acid	12	11.5	14	13.9	23	20.9	7	13.7	7	14.0	8	15.7
	Alprazolam	0	0	1	1.0	0	0	0	0	0	0	0	0
	Analgesics	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Benzatropine mesilate	4	3.8	3	3.0	0	0	0	0	0	0	0	0
	Benzocaine	0	0	0	0	1	0.9	0	0	0	0	0	0
	Bupivacaine	1	1.0	0	0	0	0	0	0	1	2.0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Caffeine	0	0	1	1.0	0	0	0	0	0	0	0	0
	Chlorphenamine maleate	0	0	0	0	1	0.9	0	0	0	0	0	0
	Clonazepam	1	1.0	0	0	0	0	0	0	0	0	0	0
	Codeine phosphate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Cyclobenzaprine	0	0	1	1.0	0	0	0	0	0	0	0	0
	Diazepam	0	0	0	0	1	0.9	0	0	0	0	0	0
	Diclofenac sodium	1	1.0	1	1.0	1	0.9	0	0	0	0	0	0
	Diphenhydramine	1	1.0	0	0	0	0	2	3.9	1	2.0	0	0
	Eletriptan hydrobromide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Epinephrine	0	0	0	0	1	0.9	1	2.0	0	0	0	0
	Ethanol	1	1.0	4	4.0	0	0	0	0	2	4.0	1	2.0
	Lidocaine	0	0	0	0	0	0	0	0	1	2.0	1	2.0
	Lorazepam	0	0	4	4.0	4	3.6	2	3.9	2	4.0	1	2.0
	Mepyramine maleate	1	1.0	1	1.0	1	0.9	0	0	0	0	1	2.0
	Methylsulfonylmeth-ane	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM	Morphine hydrochloride	0	0	1	1.0	1	0.9	0	0	0	0	0	0
	Oxcarbazepine	0	0	0	0	0	0	0	0	1	2.0	0	0
	Oxycodone	0	0	0	0	0	0	1	2.0	0	0	0	0
	Paracetamol	20	19.2	20	19.8	22	20.0	11	21.6	8	16.0	10	19.6
	Procaine hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Risperidone	0	0	0	0	0	0	0	0	1	2.0	0	0
	Rizatriptan benzoate	0	0	0	0	0	0	0	0	1	2.0	0	0
	Sumatriptan	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Zolpidem tartrate	2	1.9	2	2.0	4	3.6	0	0	1	2.0	0	0
RESPIRATORY SYSTEM	TOTAL	23	22.1	32	31.7	25	22.7	16	31.4	11	22.0	14	27.5
	Allergy medication	1	1.0	0	0	0	0	1	2.0	0	0	0	0
	Beclometasone dipropionate	0	0	0	0	0	0	0	0	1	2.0	0	0
	Benzonatate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Camphor	1	1.0	0	0	0	0	0	0	1	2.0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Cetirizine hydrochloride	0	0	3	3.0	1	0.9	1	2.0	0	0	2	3.9
	Chlorphenamine maleate	0	0	0	0	0	0	0	0	0	0	2	3.9
	Codeine phosphate	0	0	0	0	1	0.9	0	0	1	2.0	0	0
	Cough and cold preparations	0	0	0	0	1	0.9	0	0	0	0	1	2.0
	Cromoglicate sodium	0	0	1	1.0	0	0	0	0	0	0	0	0
	Desloratadine	0	0	0	0	2	1.8	0	0	1	2.0	0	0
	Dexbrompheniramine maleate	0	0	1	1.0	0	0	0	0	0	0	0	0
	Dimenhydrinate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Diphenhydramine hydrochloride	3	2.9	1	1.0	5	4.5	2	3.9	0	0	4	7.8
	Epinephrine	0	0	2	2.0	0	0	0	0	0	0	1	2.0
	Fexofenadine hydrochloride	0	0	1	1.0	2	1.8	1	2.0	1	2.0	0	0
	Flunisolide	0	0	0	0	1	0.9	0	0	0	0	0	0
	Fluticasone propionate	2	1.9	7	6.9	5	4.5	4	7.8	0	0	3	5.9

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Guaifenesin	4	3.8	3	3.0	1	0.9	3	5.9	0	0	1	2.0
	Hydrocodone	0	0	0	0	0	0	0	0	1	2.0	1	2.0
	Ipratropium bromide	0	0	1	1.0	0	0	0	0	0	0	0	0
	Loratadine	2	1.9	6	5.9	3	2.7	2	3.9	0	0	4	7.8
	Meclozine hydrochloride	0	0	1	1.0	0	0	0	0	0	0	0	0
	Mometasone furoate	0	0	2	2.0	1	0.9	0	0	0	0	0	0
	Montelukast sodium	2	1.9	3	3.0	0	0	1	2.0	0	0	0	0
	Other cold combination preparations	1	1.0	0	0	0	0	0	0	0	0	0	0
	Oxymetazoline hydrochloride	0	0	1	1.0	0	0	0	0	1	2.0	0	0
	Paracetamol	2	1.9	0	0	2	1.8	1	2.0	2	4.0	1	2.0
	Phenylephrine hydrochloride	1	1.0	1	1.0	0	0	0	0	1	2.0	0	0
	Promethazine	0	0	1	1.0	0	0	0	0	0	0	0	0
	Promethazine hydrochloride	1	1.0	2	2.0	0	0	1	2.0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY SYSTEM	Pseudoephedrine	0	0	0	0	0	0	0	0	1	2.0	0	0
	Pseudoephedrine hydrochloride	6	5.8	6	5.9	3	2.7	1	2.0	0	0	2	3.9
	Pseudoephedrine sulfate	0	0	2	2.0	1	0.9	0	0	0	0	1	2.0
	Pseudoephedrine, combinations	0	0	0	0	0	0	1	2.0	0	0	0	0
	Salbutamol	4	3.8	7	6.9	2	1.8	2	3.9	1	2.0	2	3.9
	Salmeterol xinafoate	0	0	0	0	0	0	1	2.0	0	0	0	0
	Terpin hydrate	0	0	2	2.0	0	0	0	0	0	0	0	0
	Theophylline	0	0	1	1.0	0	0	0	0	0	0	0	0
	Triamcinolone acetonide	0	0	0	0	1	0.9	0	0	1	2.0	0	0
SENSORY ORGANS	TOTAL	1	1.0	2	2.0	0	0	1	2.0	0	0	0	0
	Latanoprost	0	0	0	0	0	0	1	2.0	0	0	0	0
	Olopatadine hydrochloride	1	1.0	0	0	0	0	0	0	0	0	0	0
	Travoprost	0	0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SENSORY ORGANS	Xantofyl	0	0	1	1.0	0	0	0	0	0	0	0	0
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	TOTAL	6	5.8	5	5.0	5	4.5	2	3.9	4	8.0	3	5.9
	Betamethasone dipropionate	1	1.0	0	0	0	0	0	0	0	0	0	0
	Cortisone	0	0	0	0	0	0	0	0	1	2.0	0	0
	Desmopressin	0	0	0	0	1	0.9	0	0	0	0	0	0
	Dexamethasone	0	0	1	1.0	0	0	0	0	0	0	0	0
	Hydrocortisone	0	0	0	0	1	0.9	0	0	0	0	0	0
	Levothyroxine sodium	5	4.8	4	4.0	5	4.5	0	0	2	4.0	2	3.9
	Liothyronine sodium	1	1.0	0	0	0	0	0	0	0	0	0	0
	Melatonin	0	0	0	0	0	0	0	0	1	2.0	0	0
	Methylprednisolone	0	0	0	0	0	0	0	0	0	0	1	2.0
	Prednisone	0	0	1	1.0	0	0	2	3.9	0	0	0	0
VARIOUS	TOTAL	2	1.9	7	6.9	1	0.9	1	2.0	1	2.0	1	2.0
	All other therapeutic products	1	1.0	1	1.0	0	0	0	0	0	0	0	0

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Table 11.1.7.9 Concomitant Medication Summary by Bipolar Diagnosis
Intent-to-Treat Population

MEDICATION CLASSIFICATION	MEDICATION GENERIC TERM	TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=104		N=101		N=110		N=51		N=50		N=51	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
VARIOUS	Allergens nos	0	0	1	1.0	0	0	0	0	0	0	0	0
	Allium sativum	0	0	2	2.0	0	0	0	0	1	2.0	0	0
	Herbal nos	0	0	0	0	0	0	1	2.0	0	0	0	0
	Herbal preparation	0	0	2	2.0	0	0	0	0	0	0	0	0
	Linum usitatissimum seed oil	1	1.0	1	1.0	0	0	0	0	0	0	0	0
	Other nutrients	0	0	0	0	1	0.9	0	0	1	2.0	1	2.0

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Table 11.1.7.10 Anticholinergic Medications During the Randomized Treatment Phase
Safety Population

Treatment Interval(Weeks since randomization)	TREATMENT								
	QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
	N=171			N=168			N=167		
	N*	n**	%	N*	n**	%	N*	n**	%
WEEK 1	171	3	1.8	168	1	0.6	167	2	1.2
WEEK 2	153	6	3.9	150	2	1.3	158	1	0.6
WEEK 3	139	5	3.6	130	2	1.5	152	2	1.3
WEEK 4	130	5	3.8	122	2	1.6	143	4	2.8
WEEK 5	124	4	3.2	115	2	1.7	137	2	1.5
WEEK 6	115	6	5.2	106	2	1.9	127	2	1.6
WEEK 7	111	8	7.2	99	2	2.0	121	2	1.7
WEEK 8	106	6	5.7	94	2	2.1	114	2	1.8

* Number of patients in the study at the start of the treatment interval.
** Number of patients receiving at least one dose of medication during the treatment interval.
Percentages are calculated as n**/N* x 100.

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Table 11.2.1.1.1 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	155	31.1	5.68	31.0	17	46	151	29.9	5.61	30.0	14	46	161	29.6	5.44	30.0	17	44
	DAY 8	153	21.3	8.15	21.0	0	39	147	20.9	7.92	21.0	1	40	161	23.6	8.62	25.0	3	45
	DAY 15	155	18.0	8.93	18.0	0	45	148	17.8	8.60	17.5	1	39	161	21.1	9.06	21.0	0	45
	DAY 22	155	16.1	9.66	15.0	0	45	150	16.2	9.00	15.0	0	37	161	19.9	9.75	20.0	0	48
	DAY 29	155	15.6	9.39	14.0	0	45	150	15.4	9.45	15.0	0	43	161	19.1	10.28	19.0	0	48
	DAY 36	155	14.5	9.82	13.0	0	45	150	15.1	9.71	15.0	0	42	161	18.8	10.23	18.0	0	48
	DAY 43	155	14.0	10.25	12.0	0	45	151	14.3	9.81	13.0	0	44	161	18.5	10.91	18.0	0	48
	DAY 50	155	13.9	10.43	13.0	0	45	151	14.3	9.77	13.0	0	44	161	18.1	10.94	17.0	0	48
	DAY 57	155	13.7	10.80	11.0	0	45	151	14.0	10.34	12.0	0	44	161	18.0	11.22	17.0	0	48
CHG FROM BASELINE	DAY 8	153	-9.8	7.45	-8.0	-34	4	147	-9.0	7.53	-8.0	-31	6	161	-5.9	7.76	-4.0	-38	13
	DAY 15	155	-13.1	9.14	-13.0	-36	7	148	-12.0	8.83	-11.0	-38	6	161	-8.4	8.64	-7.0	-37	11
	DAY 22	155	-15.0	9.90	-15.0	-41	11	150	-13.7	8.97	-12.0	-39	6	161	-9.6	9.65	-8.0	-37	12
	DAY 29	155	-15.5	9.73	-16.0	-42	10	150	-14.4	9.55	-13.0	-37	9	161	-10.4	10.37	-9.0	-37	16
	DAY 36	155	-16.6	10.33	-17.0	-43	6	150	-14.7	9.57	-13.0	-37	6	161	-10.8	10.88	-10.0	-37	10
	DAY 43	155	-17.0	10.71	-17.0	-45	4	151	-15.5	9.73	-14.0	-37	14	161	-11.1	11.22	-11.0	-37	10
	DAY 50	155	-17.2	10.86	-17.0	-46	4	151	-15.5	9.74	-15.0	-37	14	161	-11.5	11.13	-11.0	-37	11

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS202.SAS
GENERATED: 17NOV2005 13:50:48 iceadmn3

Table 11.2.1.1.1 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT															
		QUETIAPINE 300 MG					QUETIAPINE 600 MG					PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	155	-17.4	11.22	-19.0	-45	9	151	-15.9	10.04	-16.0	-37	14	161	-11.6	11.36	-11.0	-37	10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS202.SAS
GENERATED: 17NOV2005 13:50:48 iceadmn3

Table 11.2.1.1.2 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	155	31.1	5.68	31.0	17	46	151	29.9	5.61	30.0	14	46	161	29.6	5.44	30.0	17	44
	DAY 8	153	21.3	8.15	21.0	0	39	147	20.9	7.92	21.0	1	40	161	23.6	8.62	25.0	3	45
	DAY 15	133	17.4	8.95	17.0	0	45	126	17.1	8.22	17.0	1	39	146	20.6	8.95	21.0	0	43
	DAY 22	123	14.3	8.74	13.0	0	44	119	14.7	8.55	13.0	0	37	136	19.0	9.39	19.0	0	48
	DAY 29	117	14.1	8.34	13.0	0	34	109	13.5	8.86	13.0	0	43	133	17.8	9.46	18.0	0	40
	DAY 36	111	12.1	8.70	11.0	0	33	104	13.1	9.08	12.5	0	42	124	16.5	9.11	15.0	0	40
	DAY 43	98	11.0	9.04	9.0	0	38	97	11.5	8.40	11.0	0	36	114	15.6	9.47	15.0	0	37
	DAY 50	102	11.0	9.04	9.0	0	32	89	11.3	8.39	10.0	0	33	112	15.4	9.49	15.5	0	40
	DAY 57	97	10.8	9.75	7.0	0	35	86	10.9	9.53	8.0	0	35	103	15.4	9.60	14.0	0	41
CHG FROM BASELINE	DAY 8	153	-9.8	7.45	-8.0	-34	4	147	-9.0	7.53	-8.0	-31	6	161	-5.9	7.76	-4.0	-38	13
	DAY 15	133	-13.9	9.13	-14.0	-36	7	126	-12.4	8.63	-11.0	-38	5	146	-8.9	8.65	-8.0	-37	11
	DAY 22	123	-16.7	9.63	-17.0	-41	11	119	-14.9	8.73	-14.0	-39	4	136	-10.4	9.42	-10.0	-36	12
	DAY 29	117	-16.8	9.20	-17.0	-42	10	109	-16.0	9.55	-15.0	-37	9	133	-11.4	9.93	-10.0	-36	16
	DAY 36	111	-18.6	9.54	-18.0	-43	6	104	-16.2	9.16	-15.0	-36	1	124	-12.8	10.43	-13.5	-36	8
	DAY 43	98	-19.7	10.05	-20.0	-45	1	97	-17.6	8.66	-17.0	-35	-1	114	-13.6	10.57	-14.0	-36	8
	DAY 50	102	-19.9	10.09	-21.0	-46	-1	89	-17.7	8.70	-18.0	-35	5	112	-13.9	10.42	-13.5	-36	11

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS200.SAS
GENERATED: 17NOV2005 13:50:43 iceadmn3

Table 11.2.1.1.2 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	97	-20.2	10.75	-21.0	-45	9	86	-18.3	9.29	-17.5	-36	1	103	-13.8	10.59	-16.0	-36	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS200.SAS
GENERATED: 17NOV2005 13:50:43 iceadmn3

Table 11.2.1.1.3 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	139	31.2	5.68	31.0	17	46	133	29.6	5.47	30.0	14	46	150	29.7	5.35	30.0	17	42
	DAY 8	137	21.3	8.17	21.0	0	39	131	20.5	7.59	21.0	3	40	150	23.6	8.42	25.0	3	42
	DAY 15	139	17.8	8.96	17.0	0	45	132	17.0	7.91	17.0	1	39	150	20.9	9.06	21.0	0	43
	DAY 22	139	15.6	9.69	14.0	0	45	133	15.3	8.23	14.0	0	36	150	19.8	9.82	20.0	0	48
	DAY 29	139	15.2	9.32	14.0	0	45	133	14.4	8.75	14.0	0	43	150	18.9	10.19	19.5	0	48
	DAY 36	139	14.0	9.68	13.0	0	45	133	14.0	8.96	14.0	0	42	150	18.4	10.17	18.0	0	48
	DAY 43	139	13.5	10.17	12.0	0	45	133	13.2	8.99	12.0	0	44	150	18.1	10.81	17.0	0	48
	DAY 50	139	13.3	10.21	12.0	0	45	133	13.1	9.02	12.0	0	44	150	17.5	10.70	17.0	0	48
	DAY 57	139	13.0	10.69	10.0	0	45	133	12.5	9.34	11.0	0	44	150	17.5	11.07	16.0	0	48
CHG FROM BASELINE	DAY 8	137	-9.9	7.52	-9.0	-34	4	131	-9.1	7.21	-9.0	-31	5	150	-6.0	7.75	-4.5	-38	13
	DAY 15	139	-13.4	9.28	-14.0	-36	7	132	-12.5	8.44	-11.0	-38	5	150	-8.7	8.80	-8.0	-38	11
	DAY 22	139	-15.6	9.95	-15.0	-41	11	133	-14.3	8.57	-13.0	-39	4	150	-9.9	9.85	-9.0	-38	12
	DAY 29	139	-16.1	9.70	-16.0	-42	10	133	-15.2	9.26	-14.0	-37	9	150	-10.7	10.37	-10.0	-38	16
	DAY 36	139	-17.2	10.10	-17.0	-43	6	133	-15.6	9.22	-14.0	-37	1	150	-11.3	10.92	-10.0	-38	10
	DAY 43	139	-17.7	10.60	-18.0	-45	4	133	-16.4	9.30	-15.0	-37	14	150	-11.6	11.23	-12.0	-38	10
	DAY 50	139	-17.9	10.73	-18.0	-46	4	133	-16.4	9.37	-16.0	-37	14	150	-12.2	11.00	-11.0	-38	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS203.SAS
GENERATED: 17NOV2005 13:50:50 iceadmn3

Table 11.2.1.1.3 MADRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	139	-18.2	11.18	-20.0	-45	9	133	-17.1	9.52	-17.0	-37	14	150	-12.2	11.24	-13.5	-38	10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS203.SAS
GENERATED: 17NOV2005 13:50:50 iceadmn3

Table 11.2.1.1.4 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	139	31.2	5.68	31.0	17	46	133	29.6	5.47	30.0	14	46	150	29.7	5.35	30.0	17	42
	DAY 8	137	21.3	8.17	21.0	0	39	131	20.5	7.59	21.0	3	40	150	23.6	8.42	25.0	3	42
	DAY 15	128	17.5	9.07	17.0	0	45	122	16.9	7.95	17.0	1	39	140	20.8	8.99	21.0	0	43
	DAY 22	118	14.2	8.84	13.0	0	44	112	14.3	8.14	13.0	0	36	128	19.1	9.64	20.0	0	48
	DAY 29	111	14.0	8.41	13.0	0	34	105	13.3	8.81	12.0	0	43	125	17.7	9.44	18.0	0	40
	DAY 36	105	12.2	8.84	11.0	0	33	100	12.8	8.95	12.0	0	42	114	16.2	9.18	15.0	0	40
	DAY 43	92	11.1	9.22	9.0	0	38	91	11.3	8.16	10.0	0	36	106	15.4	9.52	14.0	0	37
	DAY 50	97	11.0	8.97	9.0	0	32	84	10.9	8.26	9.0	0	33	103	15.0	9.30	15.0	0	40
	DAY 57	91	10.8	9.85	7.0	0	35	79	10.2	8.72	8.0	0	35	95	15.0	9.60	13.0	0	41
CHG FROM BASELINE	DAY 8	137	-9.9	7.52	-9.0	-34	4	131	-9.1	7.21	-9.0	-31	5	150	-6.0	7.75	-4.5	-38	13
	DAY 15	128	-13.9	9.26	-14.0	-36	7	122	-12.6	8.53	-11.0	-38	5	140	-8.8	8.47	-8.0	-32	11
	DAY 22	118	-16.9	9.67	-17.0	-41	11	112	-15.0	8.68	-14.5	-39	4	128	-10.4	9.60	-10.0	-36	12
	DAY 29	111	-17.0	9.20	-17.0	-42	10	105	-16.1	9.60	-15.0	-37	9	125	-11.7	9.80	-11.0	-36	16
	DAY 36	105	-18.7	9.42	-18.0	-43	6	100	-16.4	9.14	-15.0	-36	1	114	-13.2	10.40	-15.0	-36	8
	DAY 43	92	-19.6	10.05	-20.0	-45	1	91	-17.8	8.61	-17.0	-35	-1	106	-13.9	10.57	-14.0	-36	8
	DAY 50	97	-19.9	10.07	-21.0	-46	-1	84	-18.0	8.71	-18.0	-35	5	103	-14.5	10.21	-15.0	-36	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS201.SAS
GENERATED: 17NOV2005 13:50:45 iceadmn3

Table 11.2.1.1.4 MADRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Per-Protocol Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	91	-20.3	10.90	-22.0	-45	9	79	-18.9	8.99	-19.0	-36	1	95	-14.4	10.48	-17.0	-36	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS201.SAS
GENERATED: 17NOV2005 13:50:45 iceadmn3

Table 11.2.1.2.1 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	31.1	5.72	-9.8	7.45	-9.42	0.752	-10.91	-7.93	.
	Q600MG	147	29.8	5.61	-9.0	7.53	-9.14	0.769	-10.66	-7.61	.
	P	161	29.6	5.44	-5.9	7.76	-6.10	0.751	-7.59	-4.61	.
	Q300MG VS P	.	.	.	.	.	-3.32	0.796	-4.88	-1.75	<.001
	Q600MG VS P	.	.	.	.	.	-3.03	0.803	-4.61	-1.46	<.001
DAY 15	Q300MG	155	31.1	5.68	-13.1	9.14	-12.90	0.844	-14.57	-11.22	.
	Q600MG	148	29.8	5.62	-12.0	8.83	-12.59	0.864	-14.31	-10.88	.
	P	161	29.6	5.44	-8.4	8.64	-9.07	0.845	-10.75	-7.40	.
	Q300MG VS P	.	.	.	.	.	-3.83	0.915	-5.62	-2.03	<.001
	Q600MG VS P	.	.	.	.	.	-3.52	0.925	-5.34	-1.70	<.001
DAY 22	Q300MG	155	31.1	5.68	-15.0	9.90	-14.66	0.898	-16.44	-12.87	.
	Q600MG	150	29.8	5.61	-13.7	8.97	-14.09	0.918	-15.91	-12.26	.
	P	161	29.6	5.44	-9.6	9.65	-10.19	0.899	-11.97	-8.40	.
	Q300MG VS P	.	.	.	.	.	-4.47	0.995	-6.42	-2.52	<.001
	Q600MG VS P	.	.	.	.	.	-3.90	1.001	-5.87	-1.93	<.001
DAY 29	Q300MG	155	31.1	5.68	-15.5	9.73	-15.19	0.919	-17.01	-13.36	.
	Q600MG	150	29.8	5.61	-14.4	9.55	-14.85	0.939	-16.71	-12.99	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS223.SAS
GENERATED: 17NOV2005 13:32:00 iceadmn3

Table 11.2.1.2.1 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	29.6	5.44	-10.4	10.37	-11.07	0.919	-12.89	-9.24	.
	Q300MG VS P	.	.	.	.	.	-4.12	1.033	-6.15	-2.09	<.001
	Q600MG VS P	.	.	.	.	.	-3.78	1.040	-5.82	-1.74	<.001
DAY 36	Q300MG	155	31.1	5.68	-16.6	10.33	-16.02	0.914	-17.83	-14.21	.
	Q600MG	150	29.8	5.61	-14.7	9.57	-15.08	0.935	-16.93	-13.23	.
	P	161	29.6	5.44	-10.8	10.88	-11.14	0.913	-12.95	-9.34	.
	Q300MG VS P	.	.	.	.	.	-4.87	1.075	-6.99	-2.76	<.001
	Q600MG VS P	.	.	.	.	.	-3.93	1.082	-6.06	-1.81	<.001
DAY 43	Q300MG	155	31.1	5.68	-17.0	10.71	-16.50	0.952	-18.39	-14.62	.
	Q600MG	151	29.9	5.61	-15.5	9.73	-15.80	0.972	-17.73	-13.88	.
	P	161	29.6	5.44	-11.1	11.22	-11.36	0.951	-13.24	-9.47	.
	Q300MG VS P	.	.	.	.	.	-5.15	1.120	-7.35	-2.95	<.001
	Q600MG VS P	.	.	.	.	.	-4.45	1.125	-6.66	-2.24	<.001
DAY 50	Q300MG	155	31.1	5.68	-17.2	10.86	-16.67	0.987	-18.63	-14.71	.
	Q600MG	151	29.9	5.61	-15.5	9.74	-15.69	1.008	-17.69	-13.69	.
	P	161	29.6	5.44	-11.5	11.13	-11.86	0.988	-13.82	-9.90	.
	Q300MG VS P	.	.	.	.	.	-4.81	1.116	-7.00	-2.62	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS223.SAS
GENERATED: 17NOV2005 13:32:00 iceadmn3

Table 11.2.1.2.1 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-3.83	1.122	-6.04	-1.63	<.001
DAY 57	Q300MG	155	31.1	5.68	-17.4	11.22	-16.94	0.992	-18.91	-14.98	.
	Q600MG	151	29.9	5.61	-15.9	10.04	-16.00	1.012	-18.00	-13.99	.
	P	161	29.6	5.44	-11.6	11.36	-11.93	0.990	-13.89	-9.96	.
	Q300MG VS P	.	.	.	.	.	-5.02	1.166	-7.31	-2.72	<.001
	Q600MG VS P	.	.	.	.	.	-4.07	1.172	-6.37	-1.77	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS223.SAS
GENERATED: 17NOV2005 13:32:00 iceadmn3

Table 11.2.1.2.2 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	31.1	5.72	-9.8	7.45	-9.42	0.752	-10.91	-7.93	.
	Q600MG	147	29.8	5.61	-9.0	7.53	-9.14	0.769	-10.66	-7.61	.
	P	161	29.6	5.44	-5.9	7.76	-6.10	0.751	-7.59	-4.61	.
	Q300MG VS P	.	.	.	.	.	-3.32	0.796	-4.88	-1.75	<.001
	Q600MG VS P	.	.	.	.	.	-3.03	0.803	-4.61	-1.46	<.001
DAY 15	Q300MG	133	31.3	5.82	-13.9	9.13	-13.51	0.900	-15.30	-11.72	.
	Q600MG	126	29.5	5.49	-12.4	8.63	-13.16	0.924	-14.99	-11.33	.
	P	146	29.5	5.37	-8.9	8.65	-9.62	0.889	-11.38	-7.85	.
	Q300MG VS P	.	.	.	.	.	-3.90	0.959	-5.78	-2.01	<.001
	Q600MG VS P	.	.	.	.	.	-3.54	0.960	-5.43	-1.66	<.001
DAY 22	Q300MG	123	31.0	5.65	-16.7	9.63	-15.96	0.958	-17.86	-14.06	.
	Q600MG	119	29.5	5.85	-14.9	8.73	-15.38	0.978	-17.32	-13.44	.
	P	136	29.4	5.25	-10.4	9.42	-11.05	0.933	-12.90	-9.19	.
	Q300MG VS P	.	.	.	.	.	-4.91	1.042	-6.96	-2.86	<.001
	Q600MG VS P	.	.	.	.	.	-4.33	1.046	-6.39	-2.28	<.001
DAY 29	Q300MG	117	30.9	5.79	-16.8	9.20	-16.31	0.958	-18.21	-14.41	.
	Q600MG	109	29.5	5.78	-16.0	9.55	-16.53	0.992	-18.50	-14.57	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS229.SAS
GENERATED: 17NOV2005 13:32:15 iceadmn3

Table 11.2.1.2.2 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	133	29.2	5.32	-11.4	9.93	-12.31	0.923	-14.14	-10.47	.
	Q300MG VS P	.	.	.	.	.	-4.00	1.090	-6.14	-1.86	<.001
	Q600MG VS P	.	.	.	.	.	-4.22	1.100	-6.39	-2.06	<.001
DAY 36	Q300MG	111	30.7	5.66	-18.6	9.54	-17.81	0.945	-19.68	-15.94	.
	Q600MG	104	29.3	5.41	-16.2	9.16	-16.73	0.973	-18.65	-14.80	.
	P	124	29.3	5.50	-12.8	10.43	-13.18	0.906	-14.98	-11.38	.
	Q300MG VS P	.	.	.	.	.	-4.63	1.152	-6.90	-2.37	<.001
	Q600MG VS P	.	.	.	.	.	-3.55	1.162	-5.83	-1.26	0.002
DAY 43	Q300MG	98	30.7	5.84	-19.7	10.05	-18.67	0.969	-20.59	-16.75	.
	Q600MG	97	29.1	5.46	-17.6	8.66	-17.88	0.977	-19.81	-15.95	.
	P	114	29.1	5.16	-13.6	10.57	-13.72	0.911	-15.53	-11.91	.
	Q300MG VS P	.	.	.	.	.	-4.95	1.233	-7.38	-2.52	<.001
	Q600MG VS P	.	.	.	.	.	-4.16	1.227	-6.57	-1.74	<.001
DAY 50	Q300MG	102	30.8	5.78	-19.9	10.09	-18.89	0.993	-20.86	-16.92	.
	Q600MG	89	29.0	5.42	-17.7	8.70	-18.19	1.048	-20.27	-16.12	.
	P	112	29.3	5.25	-13.9	10.42	-14.22	0.964	-16.14	-12.31	.
	Q300MG VS P	.	.	.	.	.	-4.66	1.215	-7.05	-2.27	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS229.SAS
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Table 11.2.1.2.2 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-3.97	1.249	-6.43	-1.51	0.002
DAY 57	Q300MG	97	31.0	5.80	-20.2	10.75	-19.24	1.033	-21.29	-17.19	.
	Q600MG	86	29.1	5.54	-18.3	9.29	-18.70	1.095	-20.87	-16.54	.
	P	103	29.2	5.23	-13.8	10.59	-14.18	1.016	-16.20	-12.17	.
	Q300MG VS P	.	.	.	.	.	-5.06	1.354	-7.72	-2.39	<.001
	Q600MG VS P	.	.	.	.	.	-4.52	1.383	-7.24	-1.80	0.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS229.SAS
GENERATED: 17NOV2005 13:32:15 iceadmn3

Table 11.2.1.2.3 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	137	31.2	5.72	-9.9	7.52	-9.29	0.789	-10.85	-7.72	.
	Q600MG	131	29.6	5.48	-9.1	7.21	-9.15	0.806	-10.75	-7.55	.
	P	150	29.7	5.35	-6.0	7.75	-6.11	0.778	-7.66	-4.57	.
	Q300MG VS P	.	.	.	.	.	-3.17	0.813	-4.77	-1.57	<.001
	Q600MG VS P	.	.	.	.	.	-3.03	0.819	-4.64	-1.42	<.001
DAY 15	Q300MG	139	31.2	5.68	-13.4	9.28	-13.11	0.878	-14.85	-11.37	.
	Q600MG	132	29.6	5.49	-12.5	8.44	-13.19	0.899	-14.97	-11.41	.
	P	150	29.7	5.35	-8.7	8.80	-9.43	0.867	-11.15	-7.71	.
	Q300MG VS P	.	.	.	.	.	-3.68	0.941	-5.53	-1.83	<.001
	Q600MG VS P	.	.	.	.	.	-3.76	0.950	-5.63	-1.89	<.001
DAY 22	Q300MG	139	31.2	5.68	-15.6	9.95	-15.12	0.952	-17.01	-13.23	.
	Q600MG	133	29.6	5.47	-14.3	8.57	-14.96	0.972	-16.89	-13.03	.
	P	150	29.7	5.35	-9.9	9.85	-10.53	0.940	-12.40	-8.67	.
	Q300MG VS P	.	.	.	.	.	-4.59	1.017	-6.59	-2.59	<.001
	Q600MG VS P	.	.	.	.	.	-4.43	1.024	-6.44	-2.42	<.001
DAY 29	Q300MG	139	31.2	5.68	-16.1	9.70	-15.64	0.968	-17.56	-13.72	.
	Q600MG	133	29.6	5.47	-15.2	9.26	-15.87	0.989	-17.83	-13.91	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS225.SAS
GENERATED: 17NOV2005 13:32:03 iceadmn3

Table 11.2.1.2.3 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	150	29.7	5.35	-10.7	10.37	-11.52	0.956	-13.42	-9.62	.
	Q300MG VS P	.	.	.	.	.	-4.11	1.045	-6.17	-2.06	<.001
	Q600MG VS P	.	.	.	.	.	-4.35	1.051	-6.41	-2.28	<.001
DAY 36	Q300MG	139	31.2	5.68	-17.2	10.10	-16.48	0.964	-18.39	-14.57	.
	Q600MG	133	29.6	5.47	-15.6	9.22	-16.14	0.986	-18.09	-14.19	.
	P	150	29.7	5.35	-11.3	10.92	-11.80	0.948	-13.68	-9.92	.
	Q300MG VS P	.	.	.	.	.	-4.69	1.087	-6.82	-2.55	<.001
	Q600MG VS P	.	.	.	.	.	-4.34	1.094	-6.50	-2.19	<.001
DAY 43	Q300MG	139	31.2	5.68	-17.7	10.60	-17.06	0.996	-19.03	-15.08	.
	Q600MG	133	29.6	5.47	-16.4	9.30	-16.89	1.019	-18.90	-14.87	.
	P	150	29.7	5.35	-11.6	11.23	-11.94	0.979	-13.88	-10.00	.
	Q300MG VS P	.	.	.	.	.	-5.12	1.138	-7.35	-2.88	<.001
	Q600MG VS P	.	.	.	.	.	-4.95	1.145	-7.20	-2.70	<.001
DAY 50	Q300MG	139	31.2	5.68	-17.9	10.73	-17.19	1.025	-19.22	-15.16	.
	Q600MG	133	29.6	5.47	-16.4	9.37	-16.80	1.047	-18.88	-14.72	.
	P	150	29.7	5.35	-12.2	11.00	-12.59	1.010	-14.60	-10.58	.
	Q300MG VS P	.	.	.	.	.	-4.60	1.124	-6.81	-2.39	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS225.SAS
GENERATED: 17NOV2005 13:32:03 iceadmn3

Table 11.2.1.2.3 MADRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-4.21	1.132	-6.43	-1.98	<.001
DAY 57	Q300MG	139	31.2	5.68	-18.2	11.18	-17.59	1.037	-19.65	-15.53	.
	Q600MG	133	29.6	5.47	-17.1	9.52	-17.50	1.060	-19.60	-15.39	.
	P	150	29.7	5.35	-12.2	11.24	-12.65	1.020	-14.67	-10.62	.
	Q300MG VS P	.	.	.	.	.	-4.94	1.176	-7.26	-2.63	<.001
	Q600MG VS P	.	.	.	.	.	-4.85	1.183	-7.18	-2.52	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS225.SAS
GENERATED: 17NOV2005 13:32:03 iceadmn3

Table 11.2.1.2.4 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	137	31.2	5.72	-9.9	7.52	-9.29	0.789	-10.85	-7.72	.
	Q600MG	131	29.6	5.48	-9.1	7.21	-9.15	0.806	-10.75	-7.55	.
	P	150	29.7	5.35	-6.0	7.75	-6.11	0.778	-7.66	-4.57	.
	Q300MG VS P	.	.	.	.	.	-3.17	0.813	-4.77	-1.57	<.001
	Q600MG VS P	.	.	.	.	.	-3.03	0.819	-4.64	-1.42	<.001
DAY 15	Q300MG	128	31.4	5.78	-13.9	9.26	-13.56	0.900	-15.35	-11.78	.
	Q600MG	122	29.4	5.54	-12.6	8.53	-13.29	0.920	-15.11	-11.46	.
	P	140	29.6	5.28	-8.8	8.47	-9.57	0.887	-11.33	-7.80	.
	Q300MG VS P	.	.	.	.	.	-4.00	0.982	-5.93	-2.07	<.001
	Q600MG VS P	.	.	.	.	.	-3.72	0.980	-5.65	-1.80	<.001
DAY 22	Q300MG	118	31.1	5.61	-16.9	9.67	-16.09	0.986	-18.05	-14.13	.
	Q600MG	112	29.2	5.74	-15.0	8.68	-15.71	1.009	-17.71	-13.71	.
	P	128	29.5	5.25	-10.4	9.60	-11.08	0.962	-13.00	-9.17	.
	Q300MG VS P	.	.	.	.	.	-5.01	1.072	-7.12	-2.90	<.001
	Q600MG VS P	.	.	.	.	.	-4.63	1.080	-6.75	-2.50	<.001
DAY 29	Q300MG	111	31.0	5.77	-17.0	9.20	-16.51	0.976	-18.45	-14.58	.
	Q600MG	105	29.4	5.85	-16.1	9.60	-16.68	1.003	-18.67	-14.69	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS230.SAS
GENERATED: 17NOV2005 13:32:18 iceadmn3

Table 11.2.1.2.4 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	125	29.3	5.32	-11.7	9.80	-12.59	0.941	-14.46	-10.72	.
	Q300MG VS P	.	.	.	.	.	-3.92	1.121	-6.13	-1.72	<.001
	Q600MG VS P	.	.	.	.	.	-4.09	1.126	-6.30	-1.87	<.001
DAY 36	Q300MG	105	30.8	5.62	-18.7	9.42	-17.88	0.983	-19.83	-15.94	.
	Q600MG	100	29.2	5.46	-16.4	9.14	-17.00	1.000	-18.98	-15.02	.
	P	114	29.4	5.46	-13.2	10.40	-13.66	0.949	-15.54	-11.78	.
	Q300MG VS P	.	.	.	.	.	-4.22	1.193	-6.57	-1.87	<.001
	Q600MG VS P	.	.	.	.	.	-3.34	1.195	-5.69	-0.99	0.006
DAY 43	Q300MG	92	30.7	5.83	-19.6	10.05	-18.67	1.008	-20.66	-16.67	.
	Q600MG	91	29.0	5.52	-17.8	8.61	-18.16	1.011	-20.16	-16.15	.
	P	106	29.2	5.15	-13.9	10.57	-14.04	0.949	-15.92	-12.15	.
	Q300MG VS P	.	.	.	.	.	-4.63	1.275	-7.14	-2.12	<.001
	Q600MG VS P	.	.	.	.	.	-4.12	1.269	-6.62	-1.62	0.001
DAY 50	Q300MG	97	30.9	5.74	-19.9	10.07	-18.97	1.014	-20.98	-16.96	.
	Q600MG	84	28.9	5.47	-18.0	8.71	-18.65	1.067	-20.76	-16.54	.
	P	103	29.5	5.26	-14.5	10.21	-14.68	0.993	-16.65	-12.71	.
	Q300MG VS P	.	.	.	.	.	-4.29	1.231	-6.71	-1.86	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS230.SAS
GENERATED: 17NOV2005 13:32:18 iceadmn3

Table 11.2.1.2.4 MADRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Per-Protocol Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	LOWER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-3.97	1.267	-6.46	-1.47	0.002
DAY 57	Q300MG	91	31.1	5.77	-20.3	10.90	-19.38	1.070	-21.50	-17.26	.
	Q600MG	79	29.1	5.56	-18.9	8.99	-19.59	1.138	-21.84	-17.34	.
	P	95	29.4	5.22	-14.4	10.48	-14.83	1.055	-16.92	-12.73	.
	Q300MG VS P	.	.	.	.	.	-4.55	1.373	-7.26	-1.85	0.001
	Q600MG VS P	.	.	.	.	.	-4.77	1.410	-7.55	-1.99	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS230.SAS
GENERATED: 17NOV2005 13:32:18 iceadmn3

Table 11.2.1.2.5 MADRS Total Score Change from Baseline (MMRM)
Repeated Measure: Visit (Week)
Intent-to-Treat Population

	LS Means			Quetiapine 300 mg vs Placebo			Quetiapine 600 mg vs Placebo		
	Placebo	300 mg	600 mg	Estimate	SE	P-value	Estimate	SE	P-Value
DAY 8	-6.1	-9.2	-9.0	-3.1	0.95	<.001	-2.9	0.96	0.003
DAY 15	-8.9	-12.9	-12.6	-4.0	0.97	<.001	-3.7	0.98	<.001
DAY 22	-10.4	-15.4	-14.9	-5.0	1.00	<.001	-4.5	1.00	<.001
DAY 29	-11.4	-16.0	-16.0	-4.6	1.01	<.001	-4.6	1.03	<.001
DAY 36	-12.0	-17.6	-16.5	-5.5	1.04	<.001	-4.5	1.05	<.001
DAY 43	-12.8	-18.6	-18.0	-5.8	1.07	<.001	-5.2	1.08	<.001
DAY 50	-13.3	-18.6	-18.0	-5.3	1.09	<.001	-4.7	1.11	<.001
DAY 57	-13.5	-19.1	-18.4	-5.6	1.12	<.001	-4.9	1.15	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/STAT/MADRS253.SAS
GENERATED: 17NOV2005 13:33:07 iceadmn3

Table 11.2.1.2.6 MADRS Total Score Effect Sizes (MMRM)
Repeated Measure: Visit (Week)
Intent-to-Treat Population

	Quetiapine 300 mg vs Placebo			Quetiapine 600 mg vs Placebo		
	Estimate	Std Dev	Effect Size	Estimate	Std Dev	Effect Size
DAY 8	-3.13	10.34	0.30	-2.87	10.34	0.28
DAY 15	-3.98	9.88	0.40	-3.66	9.88	0.37
DAY 22	-5.00	9.70	0.52	-4.51	9.70	0.47
DAY 29	-4.58	9.60	0.48	-4.60	9.60	0.48
DAY 36	-5.53	9.48	0.58	-4.46	9.48	0.47
DAY 43	-5.81	9.27	0.63	-5.23	9.27	0.56
DAY 50	-5.35	9.31	0.57	-4.69	9.31	0.50
DAY 57	-5.62	9.23	0.61	-4.95	9.23	0.54

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/STAT/MADRS254.SAS
GENERATED: 17NOV2005 13:34:26 iceadmn3

FIGURE 11.2.1.3.1 MADRS TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

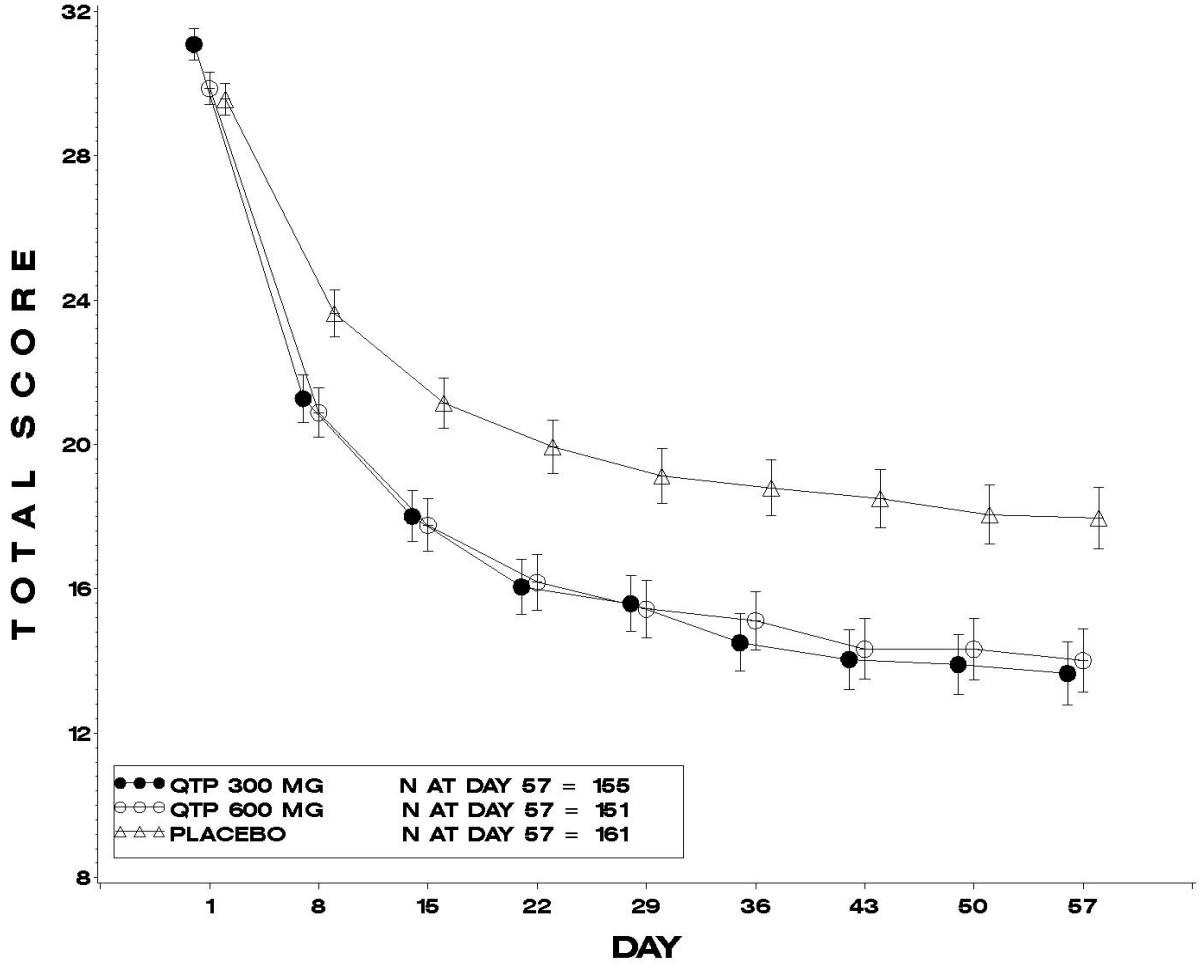

FIGURE 11.2.1.3.2 MADRS TOTAL SCORE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

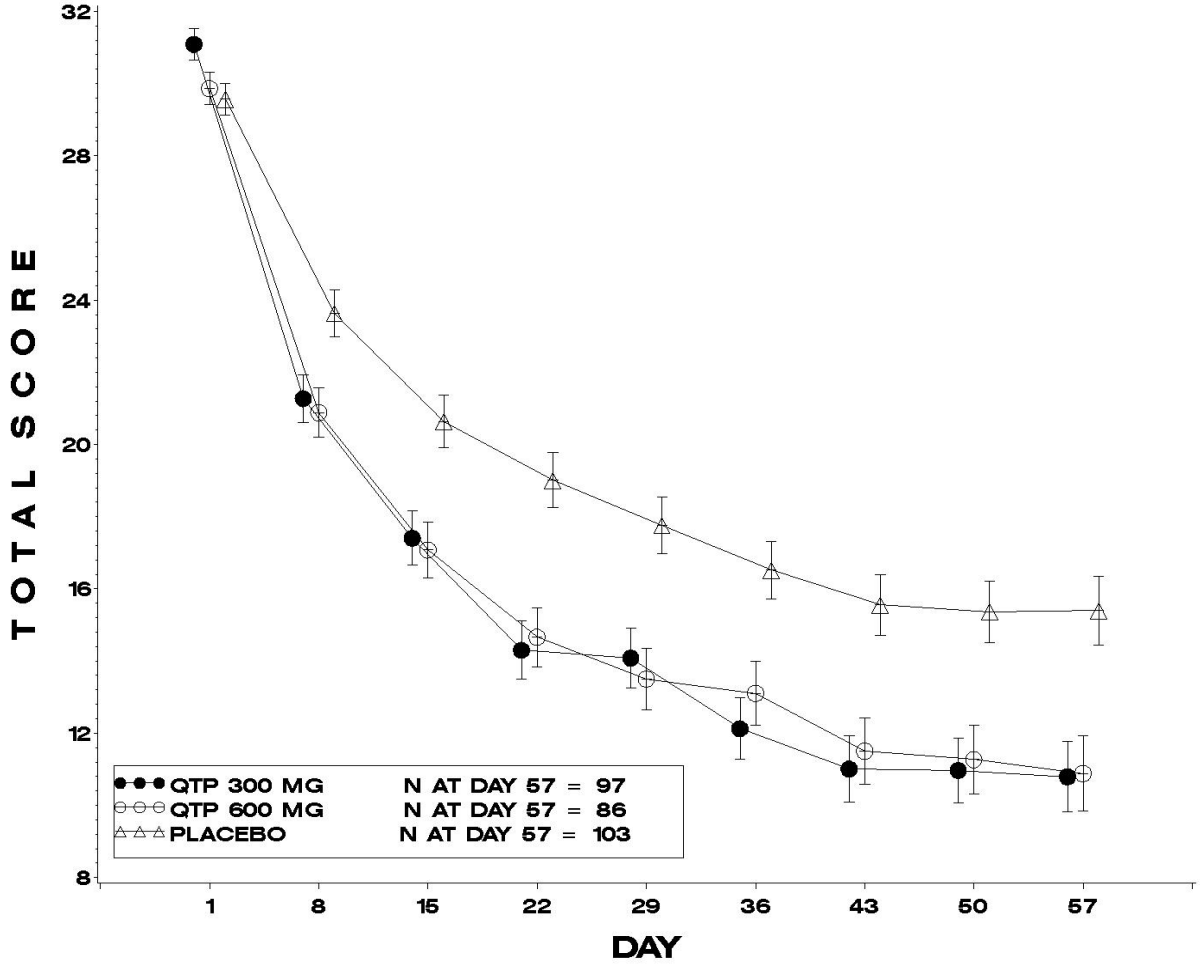

FIGURE 11.2.1.3.3 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

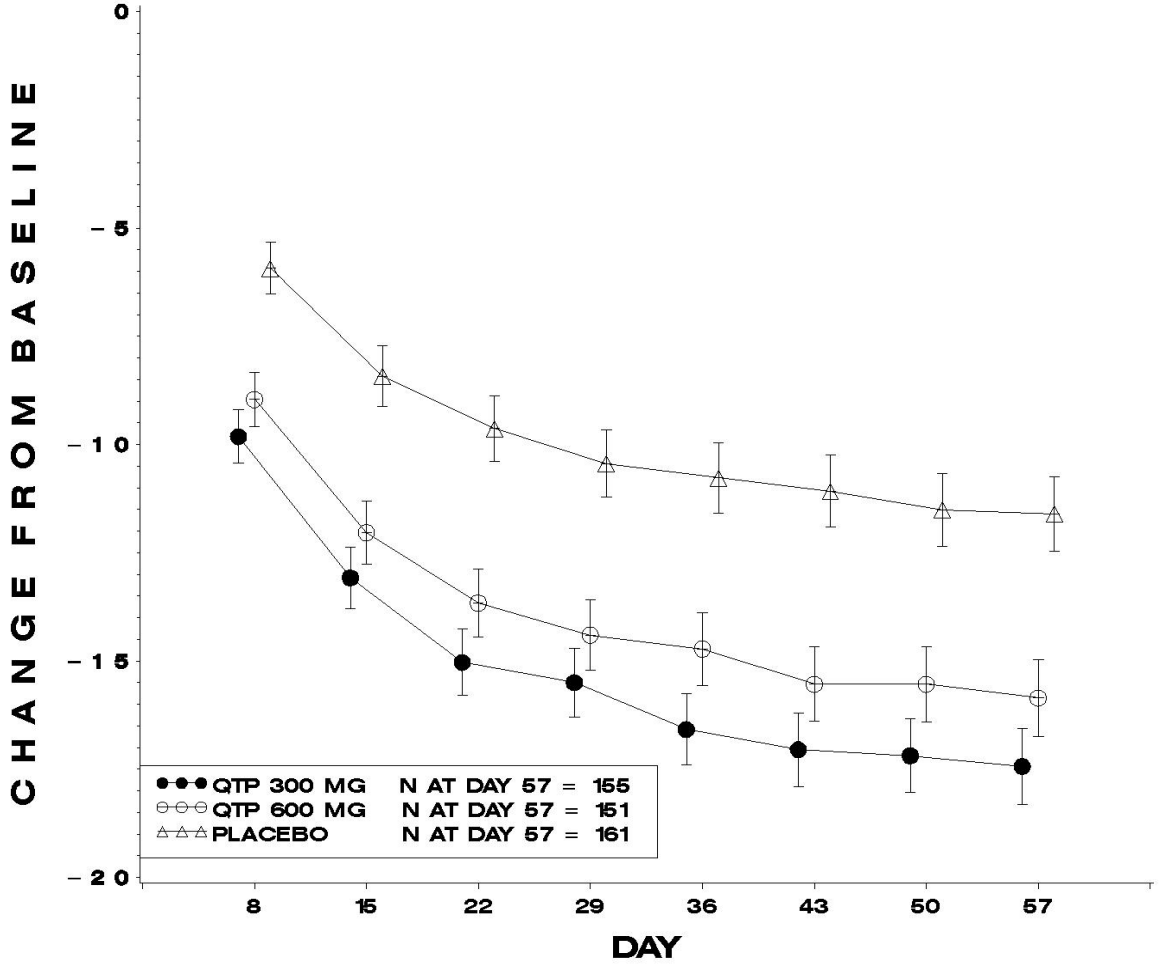

FIGURE 11.2.1.3.4 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

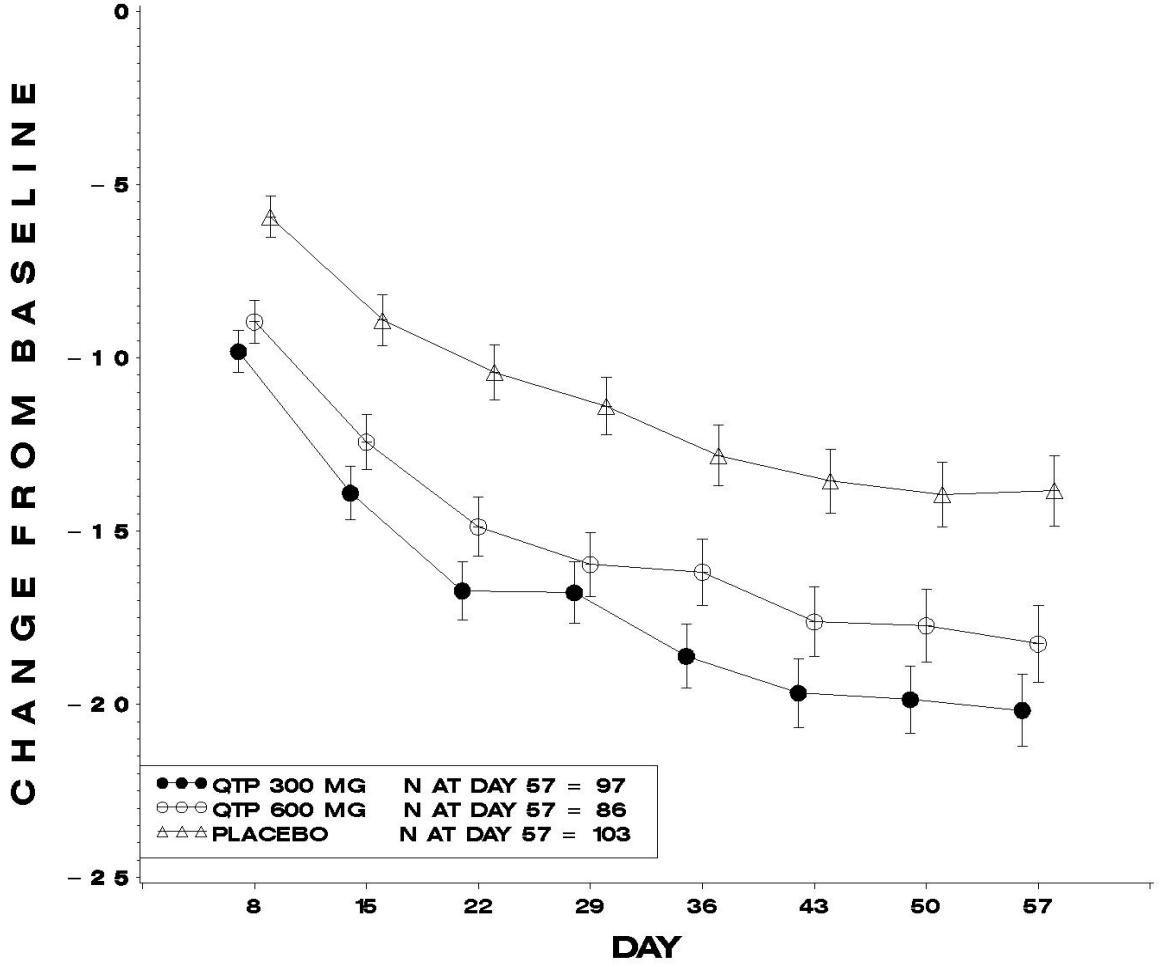

FIGURE 11.2.1.3.5 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

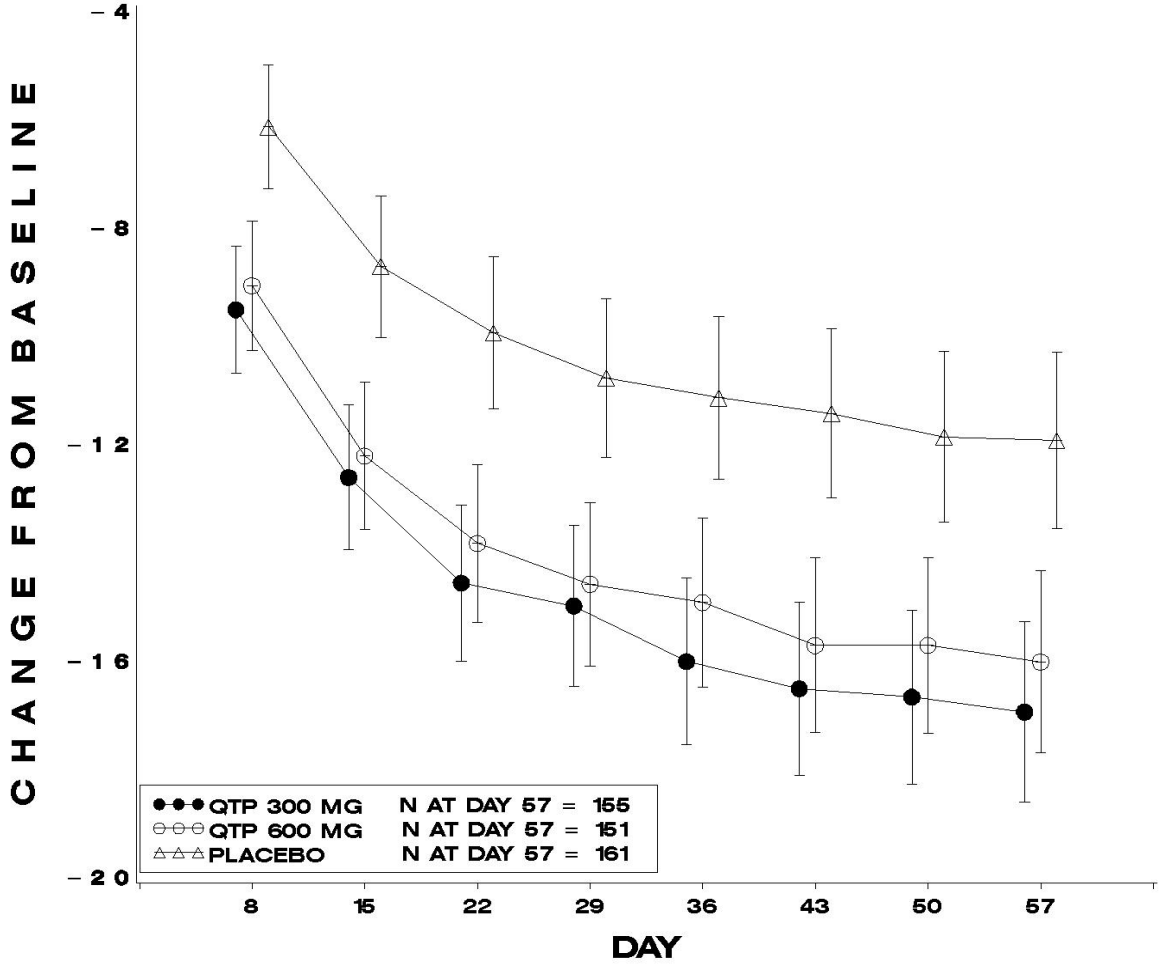

FIGURE 11.2.1.3.6 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(OBSERVED CASES - INTENT TO TREAT)

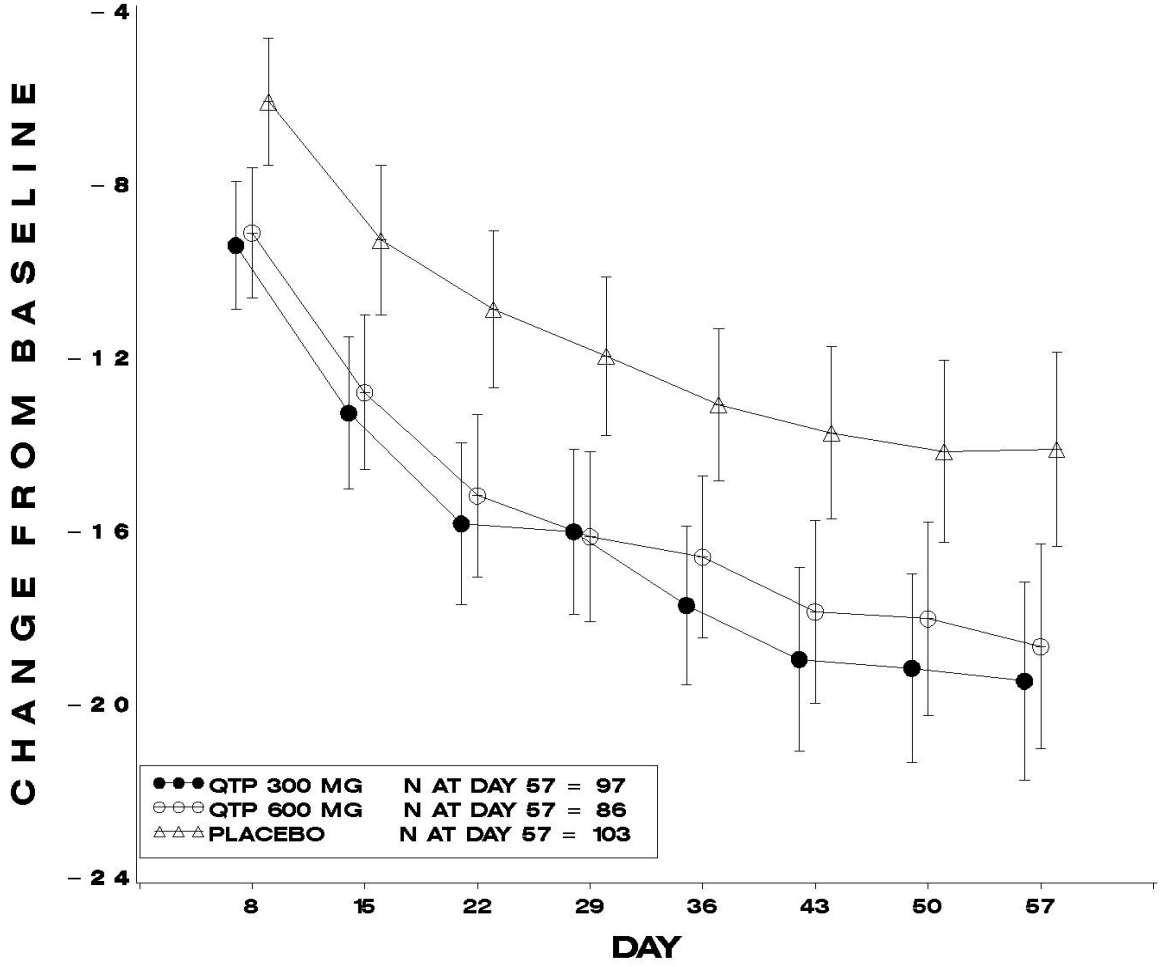

Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	104	32.2	5.08	32.0	20	43	101	30.0	5.94	30.0	14	46	110	30.6	5.00	30.0	19	44
	DAY 8	102	22.4	8.02	24.0	0	39	98	20.9	8.04	21.0	4	40	110	24.2	8.56	25.0	3	45
	DAY 15	104	19.3	9.42	19.0	0	45	99	17.5	8.47	16.0	1	39	110	21.9	9.17	22.0	0	45
	DAY 22	104	17.1	10.56	15.0	0	45	101	16.0	8.56	15.0	0	37	110	20.6	10.28	20.5	0	48
	DAY 29	104	17.0	9.58	15.5	0	45	101	15.4	9.34	14.0	0	43	110	19.7	10.59	20.0	0	48
	DAY 36	104	15.5	10.29	14.0	0	45	101	14.9	9.63	14.0	0	42	110	19.3	10.80	18.0	0	48
	DAY 43	104	15.1	10.60	14.0	0	45	101	14.1	9.72	13.0	0	44	110	18.8	11.60	17.5	0	48
	DAY 50	104	14.9	10.88	13.0	0	45	101	14.4	9.72	13.0	0	44	110	18.3	11.75	18.0	0	48
	DAY 57	104	14.5	11.17	13.0	0	45	101	14.0	10.25	12.0	0	44	110	18.5	12.00	18.5	0	48
CHG FROM BASELINE	DAY 8	102	-9.8	7.39	-8.0	-34	4	98	-9.1	7.17	-9.0	-26	5	110	-6.5	8.16	-5.0	-38	9
	DAY 15	104	-12.8	9.40	-12.0	-36	7	99	-12.4	8.38	-11.0	-32	5	110	-8.7	8.98	-8.0	-37	7
	DAY 22	104	-15.1	10.27	-15.5	-37	11	101	-14.0	8.34	-13.0	-35	5	110	-10.0	10.21	-8.0	-37	12
	DAY 29	104	-15.2	9.60	-14.5	-36	10	101	-14.6	9.34	-13.0	-37	9	110	-10.9	10.68	-10.0	-37	10
	DAY 36	104	-16.7	10.06	-16.5	-39	4	101	-15.1	9.27	-14.0	-37	5	110	-11.3	11.45	-10.0	-37	10
	DAY 43	104	-17.1	10.73	-19.0	-39	4	101	-15.9	9.46	-14.0	-37	14	110	-11.9	11.84	-12.5	-37	10
	DAY 50	104	-17.2	10.89	-19.0	-39	4	101	-15.6	9.46	-15.0	-37	14	110	-12.4	11.77	-11.0	-37	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS206.SAS
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Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	104	-17.6	11.01	-20.0	-37	4	101	-16.0	9.68	-15.0	-37	14	110	-12.1	11.95	-12.0	-37	10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS206.SAS
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Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	51	28.9	6.23	29.0	17	46	50	29.6	4.91	29.0	21	45	51	27.3	5.71	28.0	17	38
	DAY 8	51	19.0	7.99	18.0	2	32	49	20.9	7.76	22.0	1	38	51	22.5	8.72	22.0	6	42
	DAY 15	51	15.3	7.18	16.0	2	30	49	18.3	8.91	19.0	1	37	51	19.4	8.67	20.0	2	40
	DAY 22	51	13.9	7.12	13.0	2	26	49	16.6	9.93	17.0	0	37	51	18.4	8.37	20.0	2	40
	DAY 29	51	12.7	8.36	12.0	0	34	49	15.6	9.75	16.0	0	37	51	17.8	9.54	16.0	2	40
	DAY 36	51	12.6	8.54	11.0	1	31	49	15.6	9.94	17.0	0	37	51	17.8	8.90	17.0	3	40
	DAY 43	51	11.9	9.25	11.0	0	31	50	14.8	10.06	15.0	0	37	51	17.9	9.31	18.0	3	40
	DAY 50	51	11.8	9.17	11.0	0	30	50	14.2	9.98	13.0	0	37	51	17.6	9.02	17.0	2	40
	DAY 57	51	11.8	9.84	9.0	0	35	50	14.0	10.64	11.5	0	37	51	16.8	9.31	15.0	2	40
CHG FROM BASELINE	DAY 8	51	-9.9	7.65	-8.0	-29	3	49	-8.6	8.26	-7.0	-31	6	51	-4.8	6.75	-4.0	-18	13
	DAY 15	51	-13.6	8.67	-14.0	-34	7	49	-11.3	9.71	-11.0	-38	6	51	-7.9	7.91	-7.0	-24	11
	DAY 22	51	-15.0	9.19	-14.0	-41	1	49	-13.0	10.21	-12.0	-39	6	51	-8.9	8.36	-9.0	-27	8
	DAY 29	51	-16.2	10.06	-17.0	-42	0	49	-14.0	10.06	-13.0	-35	6	51	-9.5	9.71	-9.0	-26	16
	DAY 36	51	-16.3	10.97	-17.0	-43	6	49	-13.9	10.22	-12.0	-36	6	51	-9.5	9.53	-6.0	-26	8
	DAY 43	51	-16.9	10.79	-16.0	-45	0	50	-14.9	10.31	-13.0	-36	6	51	-9.4	9.64	-8.0	-30	8
	DAY 50	51	-17.1	10.91	-16.0	-46	0	50	-15.4	10.39	-15.5	-36	6	51	-9.7	9.47	-9.0	-27	8

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS206.SAS
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Table 11.2.1.4.1 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	51	-17.0	11.73	-17.0	-45	9	50	-15.6	10.81	-16.0	-36	6	51	-10.5	9.99	-11.0	-27	8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS206.SAS
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Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	104	32.2	5.08	32.0	20	43	101	30.0	5.94	30.0	14	46	110	30.6	5.00	30.0	19	44
	DAY 8	102	22.4	8.02	24.0	0	39	98	20.9	8.04	21.0	4	40	110	24.2	8.56	25.0	3	45
	DAY 15	87	18.5	9.70	17.0	0	45	88	17.3	8.24	17.0	1	39	100	21.4	9.14	21.0	0	43
	DAY 22	80	14.6	9.61	13.5	0	44	83	14.7	8.08	13.0	0	36	92	19.3	10.14	18.5	0	48
	DAY 29	78	14.9	8.32	14.0	0	34	76	13.8	9.09	13.5	0	43	87	18.3	9.63	19.0	0	37
	DAY 36	74	12.3	8.87	11.5	0	33	71	13.3	9.30	13.0	0	42	81	16.7	9.62	17.0	0	37
	DAY 43	63	10.9	8.85	9.0	0	38	64	11.3	8.37	11.0	0	36	76	15.3	10.10	14.5	0	36
	DAY 50	65	11.1	9.17	9.0	0	32	58	11.5	8.49	11.0	0	33	75	14.9	10.40	15.0	0	40
	DAY 57	61	10.6	9.61	7.0	0	35	57	11.0	9.47	9.0	0	35	69	15.5	10.50	14.0	0	41
CHG FROM BASELINE	DAY 8	102	-9.8	7.39	-8.0	-34	4	98	-9.1	7.17	-9.0	-26	5	110	-6.5	8.16	-5.0	-38	9
	DAY 15	87	-14.0	9.45	-15.0	-36	7	88	-12.4	8.31	-11.0	-32	5	100	-9.2	9.01	-8.0	-37	7
	DAY 22	80	-17.5	9.69	-17.5	-37	11	83	-14.7	8.32	-14.0	-35	4	92	-11.1	9.87	-11.0	-36	12
	DAY 29	78	-16.9	8.63	-16.5	-36	10	76	-15.4	9.65	-13.5	-37	9	87	-11.9	10.07	-10.0	-36	10
	DAY 36	74	-19.5	8.49	-21.0	-39	1	71	-15.7	8.97	-15.0	-35	1	81	-13.7	10.92	-15.0	-36	8
	DAY 43	63	-20.9	9.22	-22.0	-39	1	64	-17.5	8.59	-15.5	-35	-1	76	-15.0	10.89	-18.0	-36	8
	DAY 50	65	-20.8	9.39	-22.0	-39	-1	58	-17.3	8.58	-17.5	-35	5	75	-15.6	10.68	-17.0	-36	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS204.SAS
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Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	61	-21.4	9.58	-25.0	-37	2	57	-17.8	8.97	-17.0	-35	0	69	-14.8	10.90	-18.0	-36	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS204.SAS
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Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	51	28.9	6.23	29.0	17	46	50	29.6	4.91	29.0	21	45	51	27.3	5.71	28.0	17	38
	DAY 8	51	19.0	7.99	18.0	2	32	49	20.9	7.76	22.0	1	38	51	22.5	8.72	22.0	6	42
	DAY 15	46	15.4	6.98	16.0	3	30	38	16.6	8.27	17.0	1	34	46	19.0	8.37	20.5	2	39
	DAY 22	43	13.7	6.89	12.0	3	26	36	14.5	9.66	13.0	0	37	44	18.3	7.67	19.5	3	36
	DAY 29	39	12.5	8.26	12.0	0	34	33	12.8	8.38	11.0	0	30	46	16.8	9.16	15.0	2	40
	DAY 36	37	11.8	8.45	11.0	1	31	33	12.8	8.71	12.0	0	30	43	16.1	8.16	15.0	3	40
	DAY 43	35	11.1	9.51	10.0	0	31	33	11.9	8.57	10.0	0	29	38	16.1	8.15	15.5	3	37
	DAY 50	37	10.7	8.94	11.0	0	30	31	10.9	8.35	8.0	0	26	37	16.3	7.35	16.0	2	33
	DAY 57	36	11.1	10.11	8.0	0	35	29	10.7	9.80	8.0	0	35	34	15.1	7.60	14.5	2	35
CHG FROM BASELINE	DAY 8	51	-9.9	7.65	-8.0	-29	3	49	-8.6	8.26	-7.0	-31	6	51	-4.8	6.75	-4.0	-18	13
	DAY 15	46	-13.7	8.60	-13.5	-34	7	38	-12.6	9.44	-11.5	-38	5	46	-8.3	7.88	-7.0	-24	11
	DAY 22	43	-15.3	9.46	-14.0	-41	1	36	-15.4	9.71	-15.5	-39	2	44	-9.1	8.35	-8.0	-27	8
	DAY 29	39	-16.5	10.35	-17.0	-42	-1	33	-17.2	9.36	-18.0	-35	2	46	-10.4	9.70	-10.5	-26	16
	DAY 36	37	-16.9	11.30	-17.0	-43	6	33	-17.1	9.62	-18.0	-36	1	43	-11.2	9.33	-10.0	-26	6
	DAY 43	35	-17.5	11.20	-16.0	-45	-1	33	-17.8	8.92	-21.0	-34	-3	38	-10.7	9.38	-8.5	-30	7
	DAY 50	37	-18.2	11.15	-17.0	-46	-1	31	-18.5	9.01	-18.0	-32	5	37	-10.6	9.14	-11.0	-27	6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS204.SAS
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Table 11.2.1.4.2 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	36	-18.1	12.35	-19.0	-45	9	29	-19.2	9.98	-21.0	-36	1	34	-11.9	9.81	-13.5	-27	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS204.SAS
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Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	96	32.2	5.19	32.0	20	43	93	29.7	5.88	30.0	14	46	103	30.7	4.92	30.0	19	42
	DAY 8	94	22.1	8.21	22.0	0	39	91	20.7	7.79	21.0	4	40	103	24.1	8.21	25.0	3	41
	DAY 15	96	18.8	9.53	18.5	0	45	92	17.0	7.73	16.0	1	39	103	21.7	9.08	22.0	0	43
	DAY 22	96	16.4	10.61	14.5	0	45	93	15.5	7.96	15.0	0	36	103	20.5	10.30	21.0	0	48
	DAY 29	96	16.3	9.42	15.0	0	45	93	14.7	8.86	14.0	0	43	103	19.6	10.38	20.0	0	48
	DAY 36	96	14.7	10.06	13.5	0	45	93	14.2	9.10	14.0	0	42	103	18.8	10.67	18.0	0	48
	DAY 43	96	14.3	10.35	13.0	0	45	93	13.4	9.14	12.0	0	44	103	18.3	11.38	17.0	0	48
	DAY 50	96	14.1	10.65	13.0	0	45	93	13.7	9.21	12.0	0	44	103	17.5	11.34	17.0	0	48
	DAY 57	96	13.7	10.94	11.0	0	45	93	13.1	9.55	11.0	0	44	103	18.0	11.77	17.0	0	48
CHG FROM BASELINE	DAY 8	94	-10.1	7.55	-9.0	-34	4	91	-9.1	6.97	-9.0	-26	5	103	-6.6	8.04	-5.0	-38	9
	DAY 15	96	-13.3	9.52	-14.0	-36	7	92	-12.8	7.99	-11.5	-32	5	103	-9.0	9.13	-8.0	-38	7
	DAY 22	96	-15.7	10.31	-16.0	-37	11	93	-14.3	8.04	-13.0	-35	4	103	-10.1	10.42	-8.0	-38	12
	DAY 29	96	-15.9	9.42	-16.0	-36	10	93	-15.1	9.20	-14.0	-37	9	103	-11.0	10.67	-10.0	-38	10
	DAY 36	96	-17.5	9.78	-18.5	-39	4	93	-15.6	9.06	-14.0	-37	1	103	-11.8	11.48	-11.0	-38	10
	DAY 43	96	-17.9	10.48	-19.5	-39	4	93	-16.3	9.21	-15.0	-37	14	103	-12.3	11.78	-13.0	-38	10
	DAY 50	96	-18.1	10.64	-20.5	-39	4	93	-16.0	9.25	-15.0	-37	14	103	-13.1	11.48	-13.0	-38	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	96	-18.5	10.74	-20.0	-37	4	93	-16.6	9.35	-16.0	-37	14	103	-12.6	11.85	-14.0	-38	10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	43	29.0	6.17	29.0	17	46	40	29.2	4.42	29.0	21	40	47	27.6	5.68	28.0	17	38
	DAY 8	43	19.6	7.90	20.0	2	32	40	20.3	7.19	20.5	3	38	47	22.7	8.89	24.0	6	42
	DAY 15	43	15.4	7.11	16.0	3	30	40	17.2	8.40	18.0	1	34	47	19.3	8.90	20.0	2	40
	DAY 22	43	13.7	6.95	12.0	3	26	40	14.8	8.92	14.0	0	32	47	18.3	8.56	20.0	2	40
	DAY 29	43	12.5	8.63	12.0	0	34	40	13.8	8.56	13.0	0	30	47	17.4	9.69	16.0	2	40
	DAY 36	43	12.5	8.71	11.0	1	31	40	13.7	8.75	14.0	0	30	47	17.3	9.02	15.0	3	40
	DAY 43	43	11.8	9.66	10.0	0	31	40	12.6	8.71	11.5	0	30	47	17.6	9.53	18.0	3	40
	DAY 50	43	11.6	9.02	11.0	0	30	40	11.8	8.52	9.5	0	30	47	17.3	9.24	16.0	2	40
	DAY 57	43	11.5	10.09	8.0	0	35	40	10.9	8.76	8.0	0	35	47	16.2	9.33	15.0	2	40
CHG FROM BASELINE	DAY 8	43	-9.4	7.53	-7.0	-29	3	40	-8.9	7.82	-8.0	-31	3	47	-4.9	7.02	-4.0	-18	13
	DAY 15	43	-13.6	8.84	-13.0	-34	7	40	-12.0	9.49	-11.0	-38	5	47	-8.3	8.12	-7.0	-24	11
	DAY 22	43	-15.3	9.18	-14.0	-41	1	40	-14.4	9.81	-13.5	-39	2	47	-9.3	8.56	-10.0	-27	8
	DAY 29	43	-16.5	10.42	-17.0	-42	0	40	-15.4	9.50	-17.0	-35	2	47	-10.1	9.76	-10.0	-26	16
	DAY 36	43	-16.5	10.86	-17.0	-43	6	40	-15.5	9.68	-14.0	-36	1	47	-10.2	9.60	-10.0	-26	8
	DAY 43	43	-17.2	10.96	-16.0	-45	0	40	-16.6	9.62	-16.5	-36	-1	47	-9.9	9.83	-8.0	-30	8
	DAY 50	43	-17.4	11.05	-16.0	-46	0	40	-17.4	9.69	-17.5	-36	5	47	-10.2	9.66	-11.0	-27	8

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.3 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Per-Protocol Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	43	-17.5	12.20	-18.0	-45	9	40	-18.3	9.92	-18.0	-36	1	47	-11.4	9.82	-12.0	-27	8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS207.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	96	32.2	5.19	32.0	20	43	93	29.7	5.88	30.0	14	46	103	30.7	4.92	30.0	19	42
	DAY 8	94	22.1	8.21	22.0	0	39	91	20.7	7.79	21.0	4	40	103	24.1	8.21	25.0	3	41
	DAY 15	86	18.5	9.75	17.5	0	45	85	17.0	7.81	17.0	1	39	96	21.7	9.12	21.5	0	43
	DAY 22	79	14.6	9.67	13.0	0	44	78	14.6	7.81	13.0	0	36	86	19.5	10.43	19.5	0	48
	DAY 29	76	14.8	8.23	14.0	0	34	73	13.6	8.99	13.0	0	43	82	18.2	9.49	19.5	0	36
	DAY 36	72	12.4	8.95	11.5	0	33	68	13.0	9.11	12.5	0	42	74	16.4	9.68	15.5	0	37
	DAY 43	61	11.2	8.85	9.0	0	38	60	11.2	8.05	11.0	0	36	71	15.1	10.06	14.0	0	36
	DAY 50	64	11.2	9.18	9.0	0	32	55	11.2	8.32	11.0	0	33	69	14.4	10.01	14.0	0	40
	DAY 57	60	10.7	9.64	7.0	0	35	53	10.5	8.78	9.0	0	34	64	15.3	10.52	13.0	0	41
CHG FROM BASELINE	DAY 8	94	-10.1	7.55	-9.0	-34	4	91	-9.1	6.97	-9.0	-26	5	103	-6.6	8.04	-5.0	-38	9
	DAY 15	86	-14.0	9.50	-15.0	-36	7	85	-12.6	8.10	-11.0	-32	5	96	-8.9	8.71	-8.0	-32	7
	DAY 22	79	-17.5	9.75	-18.0	-37	11	78	-14.6	8.17	-13.5	-35	4	86	-11.0	10.10	-10.5	-36	12
	DAY 29	76	-17.0	8.45	-16.5	-36	10	73	-15.6	9.66	-14.0	-37	9	82	-12.1	9.90	-10.0	-36	9
	DAY 36	72	-19.5	8.54	-21.0	-39	1	68	-15.9	8.90	-15.0	-35	1	74	-13.9	10.96	-15.5	-36	8
	DAY 43	61	-20.6	9.25	-22.0	-39	1	60	-17.6	8.49	-15.5	-35	-1	71	-15.1	10.91	-18.0	-36	8
	DAY 50	64	-20.7	9.42	-22.0	-39	-1	55	-17.6	8.56	-17.0	-35	5	69	-16.1	10.31	-17.0	-36	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS205.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	60	-21.3	9.63	-24.5	-37	2	53	-18.2	8.64	-17.0	-35	0	64	-15.1	10.98	-18.0	-36	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS205.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MADRS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	43	29.0	6.17	29.0	17	46	40	29.2	4.42	29.0	21	40	47	27.6	5.68	28.0	17	38
	DAY 8	43	19.6	7.90	20.0	2	32	40	20.3	7.19	20.5	3	38	47	22.7	8.89	24.0	6	42
	DAY 15	42	15.3	7.14	16.0	3	30	37	16.6	8.38	17.0	1	34	44	19.0	8.53	20.5	2	39
	DAY 22	39	13.4	6.90	12.0	3	26	34	13.6	8.94	12.5	0	32	42	18.4	7.84	20.0	3	36
	DAY 29	35	12.2	8.65	12.0	0	34	32	12.7	8.50	11.0	0	30	43	16.6	9.34	14.0	2	40
	DAY 36	33	11.7	8.69	11.0	1	31	32	12.5	8.72	11.0	0	30	40	15.8	8.29	15.0	3	40
	DAY 43	31	10.9	10.04	8.0	0	31	31	11.5	8.51	10.0	0	29	35	15.9	8.43	14.0	3	37
	DAY 50	33	10.4	8.65	11.0	0	30	29	10.4	8.25	8.0	0	26	34	16.2	7.67	15.5	2	33
	DAY 57	31	10.9	10.40	8.0	0	35	26	9.4	8.72	7.5	0	35	31	14.5	7.49	14.0	2	35
CHG FROM BASELINE	DAY 8	43	-9.4	7.53	-7.0	-29	3	40	-8.9	7.82	-8.0	-31	3	47	-4.9	7.02	-4.0	-18	13
	DAY 15	42	-13.8	8.86	-13.5	-34	7	37	-12.6	9.57	-11.0	-38	5	44	-8.5	7.98	-7.0	-24	11
	DAY 22	39	-15.7	9.52	-15.0	-41	1	34	-15.8	9.82	-16.0	-39	2	42	-9.2	8.48	-8.0	-27	8
	DAY 29	35	-16.8	10.78	-17.0	-42	-1	32	-17.2	9.51	-18.5	-35	2	43	-11.0	9.68	-11.0	-26	16
	DAY 36	33	-17.0	11.06	-17.0	-43	6	32	-17.3	9.71	-18.5	-36	1	40	-11.9	9.24	-11.0	-26	6
	DAY 43	31	-17.6	11.38	-16.0	-45	-1	31	-18.1	8.96	-21.0	-34	-3	35	-11.3	9.50	-11.0	-30	7
	DAY 50	33	-18.5	11.23	-17.0	-46	-1	29	-18.9	9.10	-21.0	-32	5	34	-11.2	9.30	-11.0	-27	6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS205.SAS
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Table 11.2.1.4.4 MADRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Per-Protocol Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG					QUETIAPINE 600 MG					PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 57	31	-18.4	12.96	-19.0	-45	9	26	-20.3	9.69	-22.5	-36	1	31	-13.0	9.34	-15.0	-27	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS205.SAS
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FIGURE 11.2.1.5.1 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE) FOR BIPOLAR I DIAGNOSIS

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

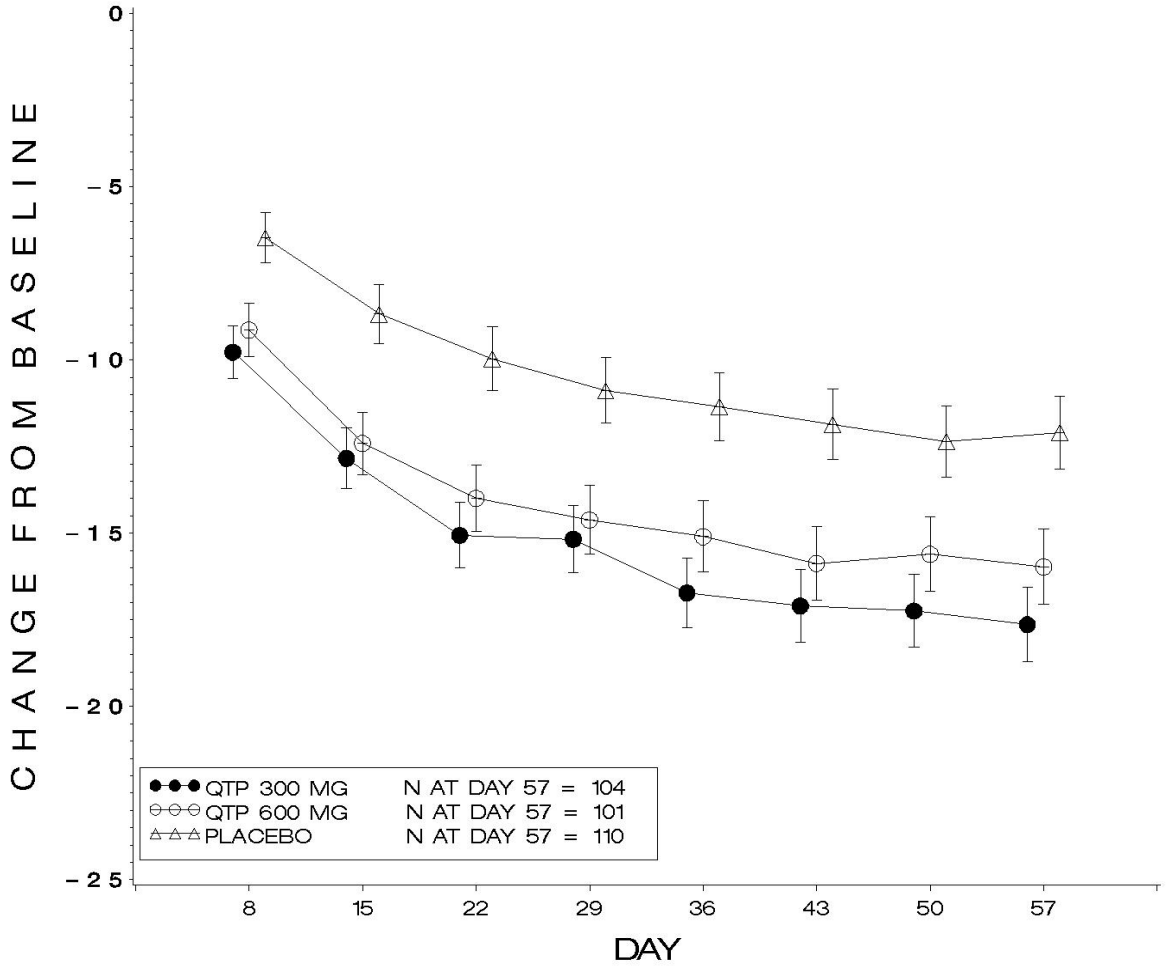

FIGURE 11.2.1.5.2 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE) FOR BIPOLAR II DIAGNOSIS

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

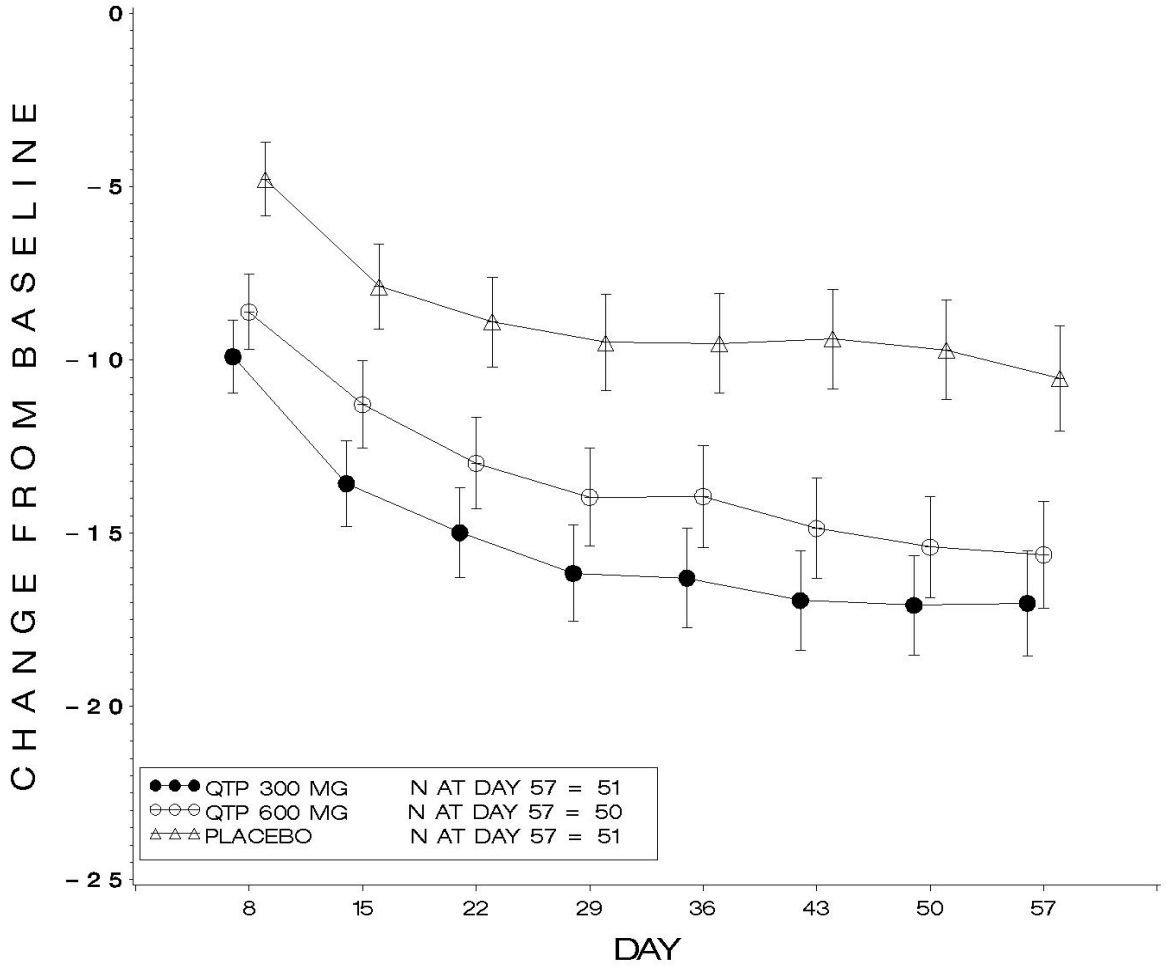

FIGURE 11.2.1.5.3 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE) FOR BIPOLAR I DIAGNOSIS

(OBSERVED CASES - INTENT TO TREAT)

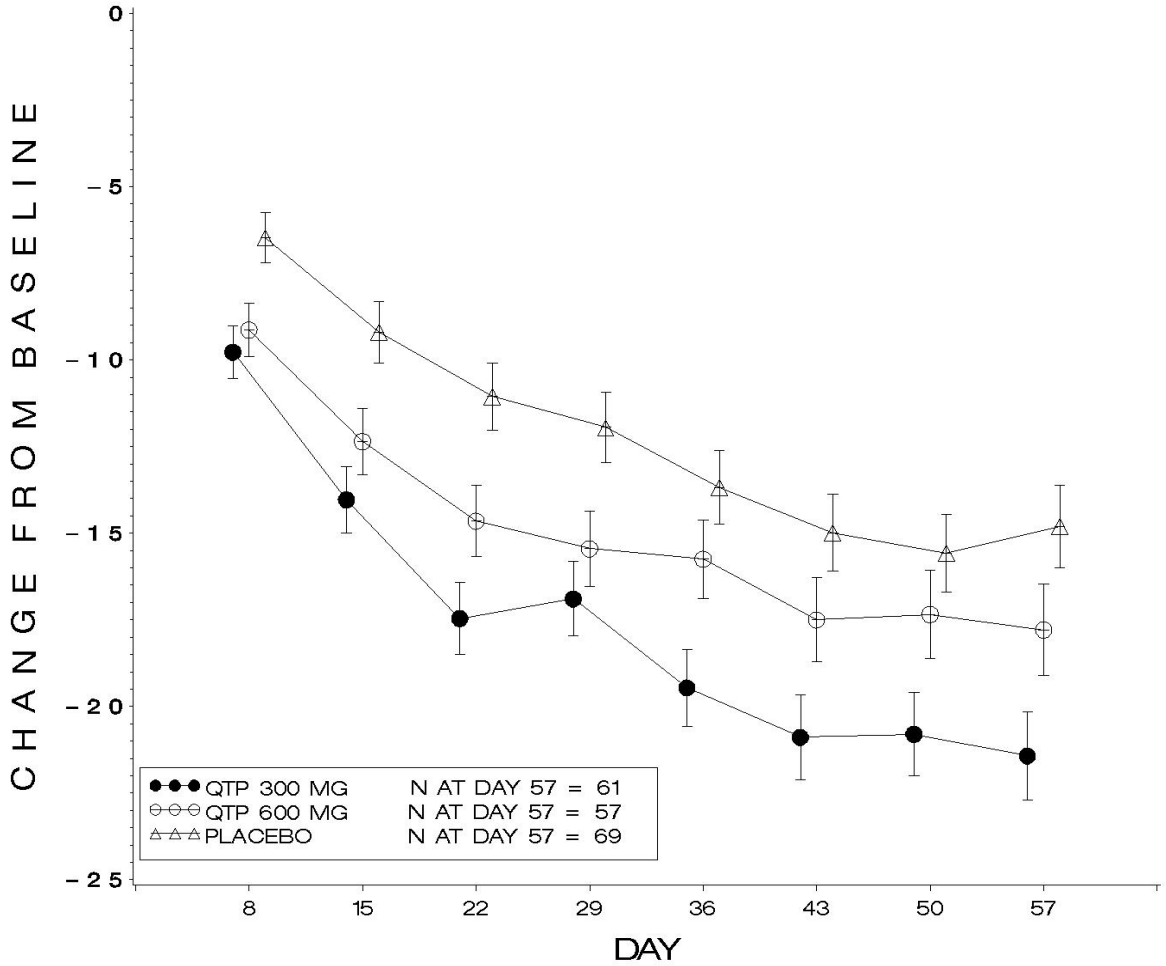

FIGURE 11.2.1.5.4 MADRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE) FOR BIPOLAR II DIAGNOSIS

(OBSERVED CASES - INTENT TO TREAT)

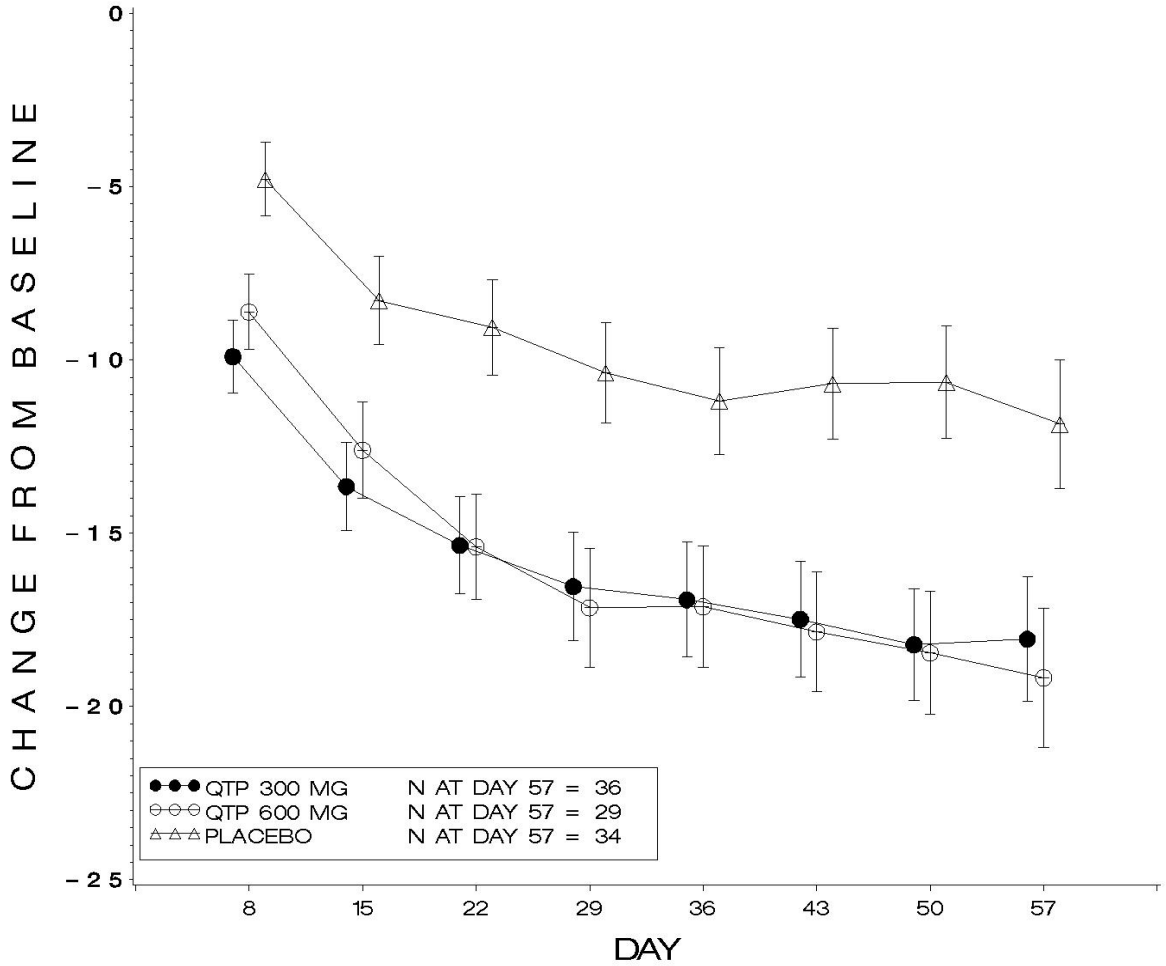

Table 11.2.1.6 MADRS Total Score and Change from Baseline by Race - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

RACE			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CAUCASIAN	MADRS TOTAL SCORE	WINDOWED VISIT																		
		DAY 1	107	31.2	5.61	31.0	17	46	115	30.3	5.82	30.0	14	46	138	29.4	5.46	30.0	17	44
		DAY 8	106	21.3	7.98	21.0	2	39	111	20.8	7.67	21.0	1	40	138	23.5	8.76	25.0	3	45
		DAY 15	107	17.5	8.92	17.0	0	45	112	17.4	8.12	17.0	1	37	138	21.1	9.32	22.0	0	45
		DAY 22	107	15.4	9.93	13.0	0	45	114	15.9	8.97	14.5	0	37	138	20.0	10.09	20.0	0	48
		DAY 29	107	15.5	9.71	14.0	0	45	114	15.0	9.28	14.5	0	39	138	19.3	10.57	19.0	0	48
		DAY 36	107	14.7	9.84	13.0	0	45	114	14.6	9.64	14.0	0	42	138	18.9	10.40	18.0	0	48
		DAY 43	107	14.6	10.64	13.0	0	45	115	13.9	9.92	13.0	0	44	138	18.7	11.16	18.0	0	48
		DAY 50	107	13.6	10.85	12.0	0	45	115	13.9	10.06	12.0	0	44	138	18.4	11.08	17.0	0	48
		DAY 57	107	13.4	10.92	11.0	0	45	115	13.5	10.40	11.0	0	44	138	18.3	11.37	17.0	0	48
	CHG FROM BASELINE	DAY 8	106	-9.9	7.21	-9.0	-34	3	111	-9.4	7.24	-9.0	-31	5	138	-5.9	7.83	-5.0	-38	13
		DAY 15	107	-13.7	9.20	-14.0	-36	7	112	-12.8	8.57	-12.0	-38	5	138	-8.3	8.89	-7.0	-37	11
		DAY 22	107	-15.9	10.19	-16.0	-41	4	114	-14.4	8.98	-13.0	-39	4	138	-9.4	9.90	-8.5	-37	12
		DAY 29	107	-15.8	9.99	-16.0	-42	4	114	-15.3	9.42	-14.0	-37	2	138	-10.1	10.58	-9.0	-37	16
		DAY 36	107	-16.6	10.36	-17.0	-43	4	114	-15.7	9.32	-14.5	-37	1	138	-10.5	10.99	-10.0	-37	10
		DAY 43	107	-16.6	11.02	-17.0	-45	4	115	-16.3	9.74	-15.0	-37	14	138	-10.8	11.37	-10.0	-37	10
		DAY 50	107	-17.6	11.35	-17.0	-46	4	115	-16.4	9.88	-16.0	-37	14	138	-11.0	11.07	-11.0	-37	11

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS213.SAS
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Table 11.2.1.6 MADRS Total Score and Change from Baseline by Race - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

RACE			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CAUCASIAN	CHG FROM BASELINE	WINDOWED VISIT DAY 57	107	-17.8	11.59	-19.0	-45	4	115	-16.8	9.94	-17.0	-37	14	138	-11.1	11.30	-11.0	-37	10
BLACK	MADRS TOTAL SCORE	DAY 1	25	29.6	6.05	30.0	18	40	21	27.8	4.58	27.0	20	36	11	29.6	4.13	30.0	24	38
		DAY 8	25	20.1	9.51	21.0	0	36	21	20.0	7.58	20.0	3	37	11	23.5	8.91	25.0	9	34
		DAY 15	25	18.7	9.54	19.0	0	34	21	19.6	9.94	20.0	1	39	11	19.5	7.95	19.0	6	30
		DAY 22	25	17.9	9.96	16.0	0	36	21	16.6	8.93	16.0	1	37	11	17.6	8.50	17.0	3	30
		DAY 29	25	16.7	9.80	16.0	0	34	21	16.5	10.37	16.0	0	43	11	16.5	10.06	16.0	1	32
		DAY 36	25	12.8	10.82	10.0	0	31	21	16.5	9.14	16.0	2	37	11	17.2	9.84	16.0	0	32
		DAY 43	25	11.9	9.56	10.0	0	28	21	15.6	7.97	15.0	2	37	11	16.2	9.48	16.0	2	32
		DAY 50	25	13.6	10.62	10.0	0	32	21	16.0	7.93	15.0	2	37	11	15.1	11.02	16.0	0	33
		DAY 57	25	13.4	10.83	11.0	0	35	21	16.5	10.02	15.0	0	37	11	16.7	11.07	16.0	0	35
	CHG FROM BASELINE	DAY 8	25	-9.4	8.37	-7.0	-33	4	21	-7.8	7.45	-6.0	-26	6	11	-6.2	8.39	-4.0	-22	1
		DAY 15	25	-10.9	9.52	-9.0	-33	7	21	-8.2	8.93	-8.0	-28	6	11	-10.1	7.83	-8.0	-26	-2
		DAY 22	25	-11.7	10.00	-12.0	-33	11	21	-11.2	9.11	-12.0	-26	6	11	-12.0	9.48	-8.0	-29	0
		DAY 29	25	-12.9	10.41	-12.0	-33	10	21	-11.3	9.95	-11.0	-29	9	11	-13.1	10.51	-10.0	-31	3
		DAY 36	25	-16.8	11.90	-15.0	-36	6	21	-11.3	9.51	-11.0	-26	6	11	-12.5	10.60	-10.0	-32	3
		DAY 43	25	-17.6	10.19	-18.0	-33	4	21	-12.2	8.18	-14.0	-27	6	11	-13.5	9.77	-14.0	-30	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS213.SAS
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Table 11.2.1.6 MADRS Total Score and Change from Baseline by Race - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

RACE			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
BLACK	CHG FROM BASELINE	WINDOWED VISIT																		
		DAY 50	25	-15.9	10.73	-16.0	-33	4	21	-11.9	8.57	-14.0	-27	6	11	-14.5	11.69	-18.0	-32	4
		DAY 57	25	-16.2	10.92	-16.0	-33	4	21	-11.3	9.31	-13.0	-27	6	11	-12.9	11.06	-14.0	-32	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS213.SAS
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Table 11.2.1.7 MADRS Total Score and Change from Baseline by Age Group - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

AGE GROUP			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
18-39	MADRS TOTAL SCORE	WINDOWED VISIT																		
		DAY 1	92	31.7	5.85	32.0	17	46	78	29.4	5.56	30.0	14	44	88	29.6	5.57	30.0	18	44
		DAY 8	90	20.4	7.94	20.0	2	36	77	20.3	8.00	20.0	1	37	88	22.6	8.54	23.0	3	45
		DAY 15	92	17.5	9.02	17.0	0	45	77	16.7	8.50	16.0	1	37	88	20.5	8.74	21.0	4	45
		DAY 22	92	15.5	9.77	13.5	0	45	78	15.2	9.11	13.0	0	37	88	19.4	9.72	18.5	0	48
		DAY 29	92	14.9	9.37	13.5	0	45	78	14.3	9.53	14.0	0	37	88	18.3	10.14	18.0	0	48
		DAY 36	92	13.4	9.70	12.0	0	45	78	14.1	9.62	14.0	0	37	88	18.7	9.81	17.5	0	48
		DAY 43	92	13.1	10.23	11.0	0	45	78	13.4	9.64	12.5	0	37	88	17.5	10.82	17.0	0	48
		DAY 50	92	13.4	10.55	12.5	0	45	78	13.1	10.01	11.0	0	37	88	17.3	10.82	16.5	0	48
		DAY 57	92	13.0	10.69	11.0	0	45	78	12.8	9.82	9.5	0	37	88	16.6	10.84	16.0	0	48
	CHG FROM BASELINE	DAY 8	90	-11.3	7.33	-10.0	-34	3	77	-9.0	8.13	-8.0	-31	6	88	-7.0	8.15	-5.5	-38	13
		DAY 15	92	-14.2	9.59	-14.0	-36	7	77	-12.6	9.33	-11.0	-38	6	88	-9.1	8.81	-8.0	-37	11
		DAY 22	92	-16.2	10.00	-16.0	-41	11	78	-14.2	9.45	-13.5	-39	6	88	-10.2	10.11	-10.0	-37	12
		DAY 29	92	-16.8	10.01	-17.0	-42	10	78	-15.1	10.35	-14.0	-37	6	88	-11.3	10.60	-10.5	-37	10
		DAY 36	92	-18.3	10.53	-19.0	-43	6	78	-15.2	10.46	-15.0	-37	6	88	-10.9	10.66	-10.0	-37	10
		DAY 43	92	-18.6	10.74	-19.0	-45	4	78	-16.0	10.30	-16.5	-37	6	88	-12.1	11.43	-12.0	-37	10
		DAY 50	92	-18.3	11.09	-19.5	-46	4	78	-16.3	10.74	-17.5	-37	6	88	-12.3	11.25	-12.0	-37	10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS214.SAS
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Table 11.2.1.7 MADRS Total Score and Change from Baseline by Age Group - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

AGE GROUP			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
18-39	CHG FROM BASELINE	WINDOWED VISIT DAY 57	92	-18.7	10.97	-19.5	-45	4	78	-16.6	10.57	-17.0	-37	6	88	-13.0	11.63	-15.0	-37	10
40-65	MADRS TOTAL SCORE	DAY 1	63	30.2	5.36	30.0	20	43	73	30.4	5.64	30.0	17	46	73	29.5	5.33	30.0	17	42
		DAY 8	63	22.5	8.36	24.0	0	39	70	21.5	7.84	22.0	3	40	73	24.9	8.58	26.0	4	42
		DAY 15	63	18.7	8.81	18.0	0	37	71	18.9	8.61	19.0	1	39	73	21.9	9.45	23.0	0	40
		DAY 22	63	16.9	9.52	16.0	0	37	72	17.3	8.81	17.5	0	37	73	20.6	9.81	21.0	0	40
		DAY 29	63	16.6	9.41	16.0	0	37	72	16.7	9.25	16.0	0	43	73	20.1	10.43	20.0	0	40
		DAY 36	63	16.1	9.85	15.0	0	37	72	16.2	9.75	16.0	0	42	73	19.0	10.79	20.0	0	40
		DAY 43	63	15.5	10.19	15.0	0	37	73	15.4	9.94	14.0	0	44	73	19.7	10.96	19.0	1	40
		DAY 50	63	14.7	10.28	13.0	0	37	73	15.6	9.41	14.0	0	44	73	19.0	11.08	18.0	0	40
		DAY 57	63	14.6	10.96	11.0	0	37	73	15.4	10.78	12.0	0	44	73	19.6	11.52	19.0	0	41
	CHG FROM BASELINE	DAY 8	63	-7.8	7.18	-6.0	-33	4	70	-8.9	6.86	-8.5	-26	2	73	-4.6	7.08	-3.0	-25	12
		DAY 15	63	-11.5	8.28	-10.0	-33	4	71	-11.5	8.27	-11.0	-32	5	73	-7.6	8.43	-6.0	-29	7
		DAY 22	63	-13.4	9.58	-13.0	-37	4	72	-13.1	8.45	-12.0	-32	4	73	-9.0	9.09	-7.0	-30	7
		DAY 29	63	-13.7	9.08	-13.0	-33	4	72	-13.6	8.60	-12.5	-31	9	73	-9.4	10.07	-9.0	-31	16
		DAY 36	63	-14.1	9.61	-13.0	-33	4	72	-14.2	8.54	-12.5	-34	1	73	-10.6	11.21	-10.0	-36	10
		DAY 43	63	-14.8	10.33	-15.0	-36	4	73	-15.0	9.12	-13.0	-34	14	73	-9.9	10.91	-8.0	-34	10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS214.SAS
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Table 11.2.1.7 MADRS Total Score and Change from Baseline by Age Group - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

AGE GROUP			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
40-65	CHG FROM BASELINE	WINDOWED VISIT																		
		DAY 50	63	-15.6	10.39	-15.0	-39	4	73	-14.8	8.57	-14.0	-32	14	73	-10.6	10.98	-10.0	-32	11
		DAY 57	63	-15.6	11.41	-16.0	-35	9	73	-15.0	9.44	-14.0	-36	14	73	-9.9	10.87	-8.0	-29	10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS214.SAS
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Table 11.2.1.8 MADRS Total Score and Change from Baseline by Sex - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

SEX			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MALE	MADRS TOTAL SCORE	WINDOWED VISIT																		
		DAY 1	69	30.6	5.42	31.0	18	43	68	29.3	5.38	30.0	14	45	64	29.7	5.41	30.0	18	42
		DAY 8	69	20.6	8.81	20.0	0	36	66	21.2	6.92	21.5	3	36	64	23.6	7.89	25.0	5	41
		DAY 15	69	17.0	9.31	17.0	0	45	66	19.3	8.12	18.0	1	39	64	21.4	8.48	21.0	6	43
		DAY 22	69	15.4	9.60	14.0	0	45	68	17.5	8.49	16.0	1	37	64	20.9	9.58	21.0	0	48
		DAY 29	69	14.7	9.39	13.0	0	45	68	17.7	8.65	17.5	0	37	64	18.3	10.64	19.5	1	48
		DAY 36	69	14.1	9.51	13.0	0	45	68	16.9	8.87	16.0	1	37	64	18.1	10.11	17.5	0	48
		DAY 43	69	13.9	10.39	12.0	0	45	68	16.2	9.82	16.0	0	44	64	18.3	10.83	17.0	0	48
		DAY 50	69	13.1	10.05	11.0	0	45	68	15.7	9.87	14.5	0	44	64	16.7	11.11	16.0	0	48
		DAY 57	69	13.3	10.70	10.0	0	45	68	15.5	10.44	14.0	0	44	64	17.1	10.95	16.0	0	48
	CHG FROM BASEL-INE	DAY 8	69	-10.0	8.08	-8.0	-33	4	66	-8.0	7.35	-7.0	-26	5	64	-6.2	6.18	-5.0	-22	7
		DAY 15	69	-13.6	9.36	-14.0	-35	4	66	-9.9	8.36	-9.5	-32	5	64	-8.3	7.99	-8.0	-28	6
		DAY 22	69	-15.2	9.32	-15.0	-33	4	68	-11.7	8.52	-12.0	-31	5	64	-8.8	9.52	-8.0	-35	12
		DAY 29	69	-15.9	9.27	-17.0	-33	4	68	-11.6	9.07	-11.0	-34	5	64	-11.4	10.56	-10.5	-34	16
		DAY 36	69	-16.5	9.46	-17.0	-36	4	68	-12.4	9.24	-11.5	-34	5	64	-11.7	10.72	-10.0	-36	10
		DAY 43	69	-16.7	10.24	-17.0	-34	4	68	-13.1	9.60	-13.0	-34	14	64	-11.5	10.82	-12.0	-36	10
		DAY 50	69	-17.4	10.21	-19.0	-37	4	68	-13.5	9.86	-13.0	-34	14	64	-13.0	11.34	-11.0	-36	10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS215.SAS
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Table 11.2.1.8 MADRS Total Score and Change from Baseline by Sex - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

SEX			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
MALE	CHG FROM BASELINE	WINDOWED VISIT																		
		DAY 57	69	-17.2	11.04	-19.0	-36	9	68	-13.8	10.10	-13.0	-34	14	64	-12.6	11.16	-13.0	-36	10
FEMALE	MADRS TOTAL SCORE	DAY 1	86	31.5	5.88	31.0	17	46	83	30.4	5.77	30.0	17	46	97	29.5	5.49	30.0	17	44
		DAY 8	84	21.9	7.57	22.0	2	39	81	20.7	8.69	21.0	1	40	97	23.7	9.11	25.0	3	45
		DAY 15	86	18.8	8.58	18.5	0	37	82	16.5	8.82	16.0	1	39	97	21.0	9.47	21.0	0	45
		DAY 22	86	16.6	9.74	16.0	2	44	82	15.0	9.29	14.0	0	37	97	19.3	9.85	19.0	0	45
		DAY 29	86	16.3	9.38	16.0	0	37	82	13.6	9.72	11.5	0	43	97	19.6	10.06	19.0	0	45
		DAY 36	86	14.8	10.10	13.5	0	37	82	13.6	10.16	11.5	0	42	97	19.3	10.34	18.0	0	45
		DAY 43	86	14.2	10.20	12.5	0	37	83	12.8	9.59	12.0	0	37	97	18.6	11.01	18.0	1	45
		DAY 50	86	14.5	10.74	13.5	0	37	83	13.2	9.60	12.0	0	37	97	19.0	10.78	18.0	0	45
		DAY 57	86	13.9	10.93	11.0	0	37	83	12.8	10.17	11.0	0	37	97	18.5	11.41	18.0	0	45
	CHG FROM BASELINE	DAY 8	84	-9.7	6.94	-8.0	-34	1	81	-9.8	7.63	-9.0	-31	6	97	-5.8	8.67	-4.0	-38	13
		DAY 15	86	-12.7	9.01	-13.0	-36	7	82	-13.8	8.86	-13.0	-38	6	97	-8.5	9.08	-7.0	-37	11
		DAY 22	86	-14.9	10.39	-14.0	-41	11	82	-15.3	9.07	-14.5	-39	6	97	-10.2	9.75	-9.0	-37	8
		DAY 29	86	-15.2	10.13	-16.0	-42	10	82	-16.7	9.36	-17.0	-37	9	97	-9.8	10.26	-8.0	-37	9
		DAY 36	86	-16.7	11.03	-16.0	-43	6	82	-16.7	9.44	-17.5	-37	6	97	-10.2	11.00	-9.0	-37	8
		DAY 43	86	-17.4	11.13	-17.0	-45	2	83	-17.5	9.42	-17.0	-37	6	97	-10.8	11.52	-8.0	-37	8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS215.SAS
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Table 11.2.1.8 MADRS Total Score and Change from Baseline by Sex - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

SEX			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
FEMALE	CHG FROM BASELINE	WINDOWED VISIT																		
		DAY 50	86	-17.0	11.41	-17.0	-46	2	83	-17.2	9.40	-18.0	-37	6	97	-10.5	10.93	-10.0	-37	11
		DAY 57	86	-17.6	11.42	-18.5	-45	2	83	-17.5	9.72	-18.0	-37	6	97	-10.9	11.50	-11.0	-37	8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS215.SAS
GENERATED: 17NOV2005 13:51:13 iceadmn3

Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	WINDOWED VISIT																		
	DAY 1	155	3.6	0.95	4.0	1	6	151	3.5	0.89	4.0	0	6	161	3.5	1.03	4.0	1	6
	DAY 8	153	2.6	1.30	3.0	0	6	147	2.6	1.20	3.0	0	5	161	2.8	1.28	3.0	0	6
	DAY 15	155	2.3	1.32	2.0	0	5	148	2.2	1.22	2.0	0	5	161	2.4	1.30	2.0	0	5
	DAY 22	155	2.0	1.40	2.0	0	6	150	2.0	1.32	2.0	0	5	161	2.2	1.40	2.0	0	5
	DAY 29	155	2.0	1.35	2.0	0	6	150	1.9	1.36	2.0	0	5	161	2.1	1.37	2.0	0	5
	DAY 36	155	1.8	1.48	2.0	0	6	150	1.9	1.34	2.0	0	5	161	2.1	1.43	2.0	0	5
	DAY 43	155	1.7	1.53	2.0	0	6	151	1.7	1.38	2.0	0	6	161	2.1	1.49	2.0	0	5
	DAY 50	155	1.7	1.51	2.0	0	6	151	1.8	1.40	2.0	0	6	161	2.0	1.51	2.0	0	5
	DAY 57	155	1.7	1.52	2.0	0	6	151	1.7	1.47	2.0	0	6	161	2.0	1.59	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	WINDOWED VISIT																		
	DAY 1	155	3.9	0.81	4.0	1	6	151	3.8	0.77	4.0	2	6	161	3.8	0.85	4.0	1	6
	DAY 8	153	2.7	1.28	3.0	0	6	147	2.8	1.15	3.0	0	6	161	3.0	1.27	3.0	0	6
	DAY 15	155	2.3	1.33	2.0	0	6	148	2.3	1.34	2.0	0	6	161	2.6	1.30	3.0	0	5
	DAY 22	155	2.0	1.39	2.0	0	6	150	2.0	1.44	2.0	0	6	161	2.5	1.46	3.0	0	6
	DAY 29	155	2.0	1.39	2.0	0	6	150	2.0	1.44	2.0	0	6	161	2.4	1.44	2.0	0	6
	DAY 36	155	1.8	1.39	2.0	0	6	150	2.0	1.48	2.0	0	6	161	2.3	1.54	2.0	0	6
	DAY 43	155	1.7	1.51	2.0	0	6	151	1.8	1.43	2.0	0	6	161	2.3	1.51	2.0	0	6
	DAY 50	155	1.7	1.56	2.0	0	6	151	1.9	1.42	2.0	0	6	161	2.2	1.57	2.0	0	6
	DAY 57	155	1.7	1.56	1.0	0	6	151	1.8	1.47	2.0	0	6	161	2.2	1.56	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
GENERATED: 17NOV2005 13:51:21 iceadmn3

Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	WINDOWED VISIT																		
	DAY 1	155	3.2	0.99	3.0	0	6	151	3.0	0.89	3.0	0	5	161	3.1	0.93	3.0	0	5
	DAY 8	153	2.4	1.21	2.0	0	5	147	2.4	1.00	2.0	0	4	161	2.7	1.15	3.0	0	5
	DAY 15	155	2.1	1.28	2.0	0	4	148	2.1	1.17	2.0	0	5	161	2.4	1.21	2.0	0	5
	DAY 22	155	1.9	1.29	2.0	0	4	150	2.0	1.18	2.0	0	4	161	2.3	1.22	2.0	0	6
	DAY 29	155	1.9	1.29	2.0	0	4	150	1.9	1.18	2.0	0	5	161	2.2	1.17	2.0	0	5
	DAY 36	155	2.0	1.31	2.0	0	4	150	1.8	1.22	2.0	0	4	161	2.2	1.27	2.0	0	5
	DAY 43	155	1.9	1.42	2.0	0	5	151	1.8	1.23	2.0	0	4	161	2.2	1.30	2.0	0	5
	DAY 50	155	1.8	1.37	2.0	0	5	151	1.7	1.25	2.0	0	4	161	2.2	1.30	2.0	0	5
	DAY 57	155	1.8	1.39	2.0	0	5	151	1.7	1.29	2.0	0	4	161	2.2	1.31	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
GENERATED: 17NOV2005 13:51:21 iceadmn3

Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	WINDOWED VISIT																		
	DAY 1	155	3.8	1.23	4.0	0	6	151	3.6	1.23	4.0	0	6	161	3.6	1.20	4.0	0	6
	DAY 8	153	1.3	1.46	1.0	0	5	147	1.2	1.45	1.0	0	5	161	2.7	1.57	3.0	0	6
	DAY 15	155	1.2	1.50	0.0	0	6	148	1.1	1.39	0.0	0	6	161	2.5	1.68	3.0	0	6
	DAY 22	155	1.3	1.49	0.0	0	6	150	1.0	1.40	0.0	0	5	161	2.4	1.76	3.0	0	6
	DAY 29	155	1.1	1.45	0.0	0	6	150	1.1	1.43	0.0	0	5	161	2.3	1.71	2.0	0	6
	DAY 36	155	1.0	1.37	0.0	0	5	150	1.0	1.42	0.0	0	5	161	2.3	1.78	2.0	0	6
	DAY 43	155	1.1	1.38	0.0	0	5	151	1.0	1.42	0.0	0	6	161	2.3	1.80	2.0	0	6
	DAY 50	155	1.1	1.37	0.0	0	5	151	1.0	1.48	0.0	0	6	161	2.3	1.83	2.0	0	6
	DAY 57	155	1.0	1.35	0.0	0	5	151	1.1	1.57	0.0	0	6	161	2.2	1.83	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	WINDOWED VISIT																		
	DAY 1	155	1.7	1.65	2.0	0	5	151	1.6	1.51	2.0	0	5	161	1.5	1.45	2.0	0	5
	DAY 8	153	1.2	1.38	0.0	0	5	147	1.1	1.32	0.0	0	5	161	1.1	1.40	0.0	0	5
	DAY 15	155	0.9	1.28	0.0	0	5	148	0.9	1.24	0.0	0	4	161	1.1	1.35	0.0	0	5
	DAY 22	155	0.8	1.30	0.0	0	6	150	0.8	1.20	0.0	0	4	161	1.0	1.37	0.0	0	6
	DAY 29	155	0.9	1.25	0.0	0	6	150	0.7	1.23	0.0	0	5	161	1.0	1.34	0.0	0	6
	DAY 36	155	0.8	1.15	0.0	0	5	150	0.7	1.17	0.0	0	5	161	0.9	1.34	0.0	0	6
	DAY 43	155	0.8	1.17	0.0	0	5	151	0.7	1.17	0.0	0	5	161	0.9	1.32	0.0	0	6
	DAY 50	155	0.7	1.17	0.0	0	5	151	0.7	1.21	0.0	0	5	161	0.9	1.33	0.0	0	6
	DAY 57	155	0.7	1.19	0.0	0	5	151	0.6	1.14	0.0	0	5	161	0.9	1.33	0.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
GENERATED: 17NOV2005 13:51:21 iceadmn3

Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	WINDOWED VISIT																		
	DAY 1	155	3.4	1.05	4.0	0	5	151	3.3	1.01	4.0	0	5	161	3.3	1.08	4.0	0	6
	DAY 8	153	2.6	1.36	3.0	0	5	147	2.5	1.32	2.0	0	5	161	2.7	1.25	3.0	0	5
	DAY 15	155	2.2	1.54	2.0	0	5	148	2.3	1.36	2.0	0	4	161	2.4	1.30	2.0	0	5
	DAY 22	155	2.0	1.54	2.0	0	5	150	2.0	1.38	2.0	0	5	161	2.3	1.30	2.0	0	5
	DAY 29	155	1.8	1.54	2.0	0	5	150	1.9	1.37	2.0	0	5	161	2.2	1.37	2.0	0	4
	DAY 36	155	1.7	1.55	2.0	0	5	150	1.8	1.37	2.0	0	5	161	2.2	1.36	2.0	0	4
	DAY 43	155	1.6	1.53	1.0	0	5	151	1.7	1.40	2.0	0	5	161	2.1	1.43	2.0	0	4
	DAY 50	155	1.7	1.59	2.0	0	5	151	1.7	1.42	2.0	0	5	161	2.1	1.41	2.0	0	4
	DAY 57	155	1.7	1.59	2.0	0	5	151	1.6	1.42	2.0	0	5	161	2.1	1.40	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	WINDOWED VISIT																		
	DAY 1	155	3.6	1.08	4.0	0	5	151	3.4	1.15	4.0	0	6	161	3.3	1.11	4.0	0	5
	DAY 8	153	2.8	1.34	3.0	0	6	147	2.6	1.31	3.0	0	5	161	2.7	1.45	3.0	0	5
	DAY 15	155	2.4	1.46	2.0	0	6	148	2.3	1.37	2.0	0	6	161	2.4	1.42	2.0	0	5
	DAY 22	155	2.2	1.43	2.0	0	6	150	2.2	1.36	2.0	0	6	161	2.1	1.49	2.0	0	5
	DAY 29	155	2.1	1.55	2.0	0	6	150	2.0	1.41	2.0	0	6	161	2.2	1.51	2.0	0	5
	DAY 36	155	1.9	1.49	2.0	0	6	150	2.0	1.43	2.0	0	6	161	2.1	1.51	2.0	0	5
	DAY 43	155	1.7	1.51	2.0	0	6	151	1.9	1.47	2.0	0	6	161	2.1	1.59	2.0	0	5
	DAY 50	155	1.7	1.54	2.0	0	6	151	1.9	1.44	2.0	0	6	161	2.1	1.59	2.0	0	5
	DAY 57	155	1.7	1.58	2.0	0	6	151	1.8	1.53	2.0	0	6	161	2.1	1.61	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
GENERATED: 17NOV2005 13:51:21 iceadmn3

Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	WINDOWED VISIT																		
	DAY 1	155	3.5	1.03	4.0	0	5	151	3.5	0.97	4.0	0	5	161	3.4	0.99	4.0	0	6
	DAY 8	153	2.7	1.36	3.0	0	6	147	2.6	1.30	3.0	0	5	161	2.8	1.30	3.0	0	6
	DAY 15	155	2.2	1.40	2.0	0	6	148	2.1	1.40	2.0	0	5	161	2.5	1.38	2.0	0	6
	DAY 22	155	1.8	1.49	2.0	0	6	150	2.0	1.42	2.0	0	5	161	2.3	1.50	2.0	0	6
	DAY 29	155	2.0	1.56	2.0	0	6	150	1.8	1.52	2.0	0	5	161	2.2	1.53	2.0	0	6
	DAY 36	155	1.6	1.61	1.0	0	6	150	1.8	1.48	2.0	0	5	161	2.1	1.47	2.0	0	6
	DAY 43	155	1.6	1.63	2.0	0	6	151	1.7	1.44	2.0	0	5	161	2.0	1.54	2.0	0	6
	DAY 50	155	1.6	1.61	1.0	0	6	151	1.7	1.45	2.0	0	5	161	1.9	1.59	2.0	0	6
	DAY 57	155	1.5	1.63	1.0	0	6	151	1.6	1.48	1.0	0	5	161	1.9	1.60	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	WINDOWED VISIT																		
	DAY 1	155	3.1	1.08	3.0	0	5	151	3.0	1.04	3.0	0	5	161	2.9	1.12	3.0	0	5
	DAY 8	153	2.2	1.30	2.0	0	5	147	2.2	1.23	2.0	0	5	161	2.3	1.25	2.0	0	5
	DAY 15	155	1.8	1.26	2.0	0	4	148	1.9	1.30	2.0	0	6	161	2.1	1.32	2.0	0	5
	DAY 22	155	1.6	1.33	2.0	0	4	150	1.7	1.32	2.0	0	5	161	2.0	1.34	2.0	0	5
	DAY 29	155	1.5	1.35	2.0	0	4	150	1.7	1.36	2.0	0	5	161	1.9	1.42	2.0	0	5
	DAY 36	155	1.5	1.36	2.0	0	4	150	1.7	1.44	2.0	0	5	161	1.8	1.39	2.0	0	5
	DAY 43	155	1.4	1.29	2.0	0	4	151	1.5	1.41	1.0	0	5	161	1.7	1.35	2.0	0	5
	DAY 50	155	1.3	1.33	1.0	0	4	151	1.5	1.42	1.0	0	5	161	1.7	1.34	2.0	0	5
	DAY 57	155	1.3	1.36	1.0	0	4	151	1.5	1.46	1.0	0	5	161	1.7	1.46	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.9.1 MADRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	WINDOWED VISIT																		
	DAY 1	155	1.2	1.08	1.0	0	4	151	1.2	1.04	1.0	0	4	161	1.1	1.08	1.0	0	4
	DAY 8	153	0.7	0.95	0.0	0	4	147	0.7	0.96	0.0	0	4	161	0.8	0.96	0.0	0	4
	DAY 15	155	0.6	0.92	0.0	0	4	148	0.6	0.97	0.0	0	4	161	0.7	0.97	0.0	0	4
	DAY 22	155	0.5	0.88	0.0	0	4	150	0.6	0.88	0.0	0	4	161	0.8	1.01	0.0	0	4
	DAY 29	155	0.5	0.88	0.0	0	4	150	0.5	0.89	0.0	0	4	161	0.7	1.00	0.0	0	4
	DAY 36	155	0.5	0.90	0.0	0	4	150	0.5	0.91	0.0	0	4	161	0.7	1.02	0.0	0	4
	DAY 43	155	0.5	0.91	0.0	0	4	151	0.5	0.97	0.0	0	4	161	0.6	0.96	0.0	0	4
	DAY 50	155	0.4	0.81	0.0	0	4	151	0.6	0.96	0.0	0	4	161	0.6	0.97	0.0	0	4
	DAY 57	155	0.4	0.91	0.0	0	6	151	0.5	0.93	0.0	0	4	161	0.6	0.93	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS217.SAS
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Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	WINDOWED VISIT																		
	DAY 1	155	3.6	0.95	4.0	1	6	151	3.5	0.89	4.0	0	6	161	3.5	1.03	4.0	1	6
	DAY 8	153	2.6	1.30	3.0	0	6	147	2.6	1.20	3.0	0	5	161	2.8	1.28	3.0	0	6
	DAY 15	134	2.2	1.33	2.0	0	5	126	2.1	1.20	2.0	0	5	146	2.3	1.31	2.0	0	5
	DAY 22	123	1.8	1.35	2.0	0	6	119	1.8	1.29	2.0	0	4	136	2.2	1.40	2.0	0	5
	DAY 29	117	1.9	1.31	2.0	0	6	109	1.7	1.33	2.0	0	5	133	2.0	1.30	2.0	0	5
	DAY 36	111	1.5	1.44	2.0	0	6	104	1.8	1.32	2.0	0	5	124	1.9	1.36	2.0	0	5
	DAY 43	98	1.4	1.43	1.0	0	5	97	1.3	1.21	1.0	0	4	114	1.9	1.36	2.0	0	5
	DAY 50	102	1.3	1.35	1.0	0	4	89	1.5	1.30	1.0	0	4	112	1.8	1.35	2.0	0	5
	DAY 57	97	1.4	1.40	1.0	0	5	86	1.4	1.43	1.0	0	5	103	1.7	1.45	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
GENERATED: 17NOV2005 13:51:16 iceadmn3

Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	WINDOWED VISIT																		
	DAY 1	155	3.9	0.81	4.0	1	6	151	3.8	0.77	4.0	2	6	161	3.8	0.85	4.0	1	6
	DAY 8	153	2.7	1.28	3.0	0	6	147	2.8	1.15	3.0	0	6	161	3.0	1.27	3.0	0	6
	DAY 15	134	2.2	1.33	2.0	0	6	126	2.2	1.32	2.0	0	5	146	2.5	1.31	3.0	0	5
	DAY 22	123	1.8	1.31	2.0	0	6	119	1.8	1.39	2.0	0	5	136	2.4	1.46	2.0	0	6
	DAY 29	117	1.8	1.35	2.0	0	6	109	1.8	1.37	2.0	0	5	133	2.2	1.35	2.0	0	5
	DAY 36	111	1.6	1.29	2.0	0	6	104	1.8	1.42	2.0	0	5	124	2.0	1.46	2.0	0	5
	DAY 43	98	1.3	1.39	1.0	0	5	97	1.5	1.28	1.0	0	5	114	2.0	1.35	2.0	0	5
	DAY 50	102	1.3	1.43	1.0	0	5	89	1.5	1.25	2.0	0	4	112	1.8	1.41	2.0	0	5
	DAY 57	97	1.3	1.44	1.0	0	5	86	1.4	1.35	1.0	0	4	103	1.9	1.39	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
GENERATED: 17NOV2005 13:51:16 iceadmn3

Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	WINDOWED VISIT																		
	DAY 1	155	3.2	0.99	3.0	0	6	151	3.0	0.89	3.0	0	5	161	3.1	0.93	3.0	0	5
	DAY 8	153	2.4	1.21	2.0	0	5	147	2.4	1.00	2.0	0	4	161	2.7	1.15	3.0	0	5
	DAY 15	134	2.1	1.26	2.0	0	4	126	2.1	1.15	2.0	0	5	146	2.4	1.22	2.0	0	5
	DAY 22	123	1.7	1.20	2.0	0	4	119	1.8	1.13	2.0	0	4	136	2.2	1.21	2.0	0	6
	DAY 29	117	1.7	1.22	2.0	0	4	109	1.7	1.11	2.0	0	5	133	2.1	1.12	2.0	0	4
	DAY 36	111	1.8	1.27	2.0	0	4	104	1.5	1.12	2.0	0	4	124	2.0	1.25	2.0	0	4
	DAY 43	98	1.6	1.39	2.0	0	5	97	1.4	1.10	2.0	0	4	114	1.9	1.31	2.0	0	5
	DAY 50	102	1.5	1.27	2.0	0	5	89	1.3	1.12	1.0	0	4	112	2.0	1.31	2.0	0	5
	DAY 57	97	1.5	1.32	2.0	0	5	86	1.4	1.21	1.0	0	4	103	2.0	1.31	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
GENERATED: 17NOV2005 13:51:16 iceadmn3

Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	WINDOWED VISIT																		
	DAY 1	155	3.8	1.23	4.0	0	6	151	3.6	1.23	4.0	0	6	161	3.6	1.20	4.0	0	6
	DAY 8	153	1.3	1.46	1.0	0	5	147	1.2	1.45	1.0	0	5	161	2.7	1.57	3.0	0	6
	DAY 15	134	1.2	1.49	0.0	0	6	126	1.1	1.36	0.0	0	6	146	2.5	1.69	3.0	0	6
	DAY 22	123	1.1	1.39	0.0	0	5	119	0.9	1.31	0.0	0	5	136	2.3	1.78	2.5	0	6
	DAY 29	117	1.0	1.42	0.0	0	6	109	1.0	1.36	0.0	0	5	133	2.2	1.68	2.0	0	6
	DAY 36	111	0.9	1.31	0.0	0	5	104	0.9	1.36	0.0	0	5	124	2.1	1.77	2.0	0	6
	DAY 43	98	0.9	1.24	0.0	0	4	97	0.8	1.25	0.0	0	5	114	2.1	1.78	2.0	0	6
	DAY 50	102	1.0	1.30	0.0	0	5	89	0.9	1.38	0.0	0	6	112	2.2	1.82	2.0	0	6
	DAY 57	97	0.9	1.25	0.0	0	4	86	1.0	1.49	0.0	0	6	103	2.0	1.79	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
GENERATED: 17NOV2005 13:51:16 iceadmn3

Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	WINDOWED VISIT																		
	DAY 1	155	1.7	1.65	2.0	0	5	151	1.6	1.51	2.0	0	5	161	1.5	1.45	2.0	0	5
	DAY 8	153	1.2	1.38	0.0	0	5	147	1.1	1.32	0.0	0	5	161	1.1	1.40	0.0	0	5
	DAY 15	134	0.9	1.29	0.0	0	5	126	0.8	1.23	0.0	0	4	146	1.0	1.33	0.0	0	5
	DAY 22	123	0.7	1.24	0.0	0	6	119	0.7	1.20	0.0	0	4	136	0.9	1.32	0.0	0	6
	DAY 29	117	0.7	1.16	0.0	0	6	109	0.6	1.17	0.0	0	5	133	0.9	1.23	0.0	0	4
	DAY 36	111	0.6	1.03	0.0	0	4	104	0.5	1.00	0.0	0	4	124	0.7	1.18	0.0	0	5
	DAY 43	98	0.5	1.05	0.0	0	4	97	0.5	0.96	0.0	0	4	114	0.7	1.13	0.0	0	4
	DAY 50	102	0.5	1.06	0.0	0	5	89	0.6	1.08	0.0	0	5	112	0.7	1.18	0.0	0	5
	DAY 57	97	0.6	1.11	0.0	0	5	86	0.5	0.94	0.0	0	3	103	0.6	1.14	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	WINDOWED VISIT																		
	DAY 1	155	3.4	1.05	4.0	0	5	151	3.3	1.01	4.0	0	5	161	3.3	1.08	4.0	0	6
	DAY 8	153	2.6	1.36	3.0	0	5	147	2.5	1.32	2.0	0	5	161	2.7	1.25	3.0	0	5
	DAY 15	134	2.2	1.55	2.0	0	5	126	2.2	1.35	2.0	0	4	146	2.3	1.31	2.0	0	5
	DAY 22	123	1.7	1.43	2.0	0	5	119	1.8	1.34	2.0	0	5	136	2.2	1.28	2.0	0	4
	DAY 29	117	1.5	1.41	2.0	0	4	109	1.7	1.30	2.0	0	4	133	2.0	1.34	2.0	0	4
	DAY 36	111	1.3	1.39	1.0	0	4	104	1.6	1.29	2.0	0	4	124	1.9	1.31	2.0	0	4
	DAY 43	98	1.1	1.31	1.0	0	4	97	1.4	1.30	2.0	0	4	114	1.8	1.37	2.0	0	4
	DAY 50	102	1.3	1.46	1.0	0	5	89	1.3	1.30	1.0	0	4	112	1.8	1.35	2.0	0	4
	DAY 57	97	1.4	1.48	1.0	0	5	86	1.1	1.24	1.0	0	4	103	1.8	1.33	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	WINDOWED VISIT																		
	DAY 1	155	3.6	1.08	4.0	0	5	151	3.4	1.15	4.0	0	6	161	3.3	1.11	4.0	0	5
	DAY 8	153	2.8	1.34	3.0	0	6	147	2.6	1.31	3.0	0	5	161	2.7	1.45	3.0	0	5
	DAY 15	134	2.3	1.42	2.0	0	5	126	2.3	1.34	2.0	0	6	146	2.3	1.39	2.0	0	5
	DAY 22	123	2.0	1.33	2.0	0	5	119	2.0	1.24	2.0	0	4	136	2.0	1.45	2.0	0	5
	DAY 29	117	1.9	1.46	2.0	0	5	109	1.8	1.28	2.0	0	5	133	2.0	1.43	2.0	0	5
	DAY 36	111	1.5	1.33	2.0	0	4	104	1.7	1.28	2.0	0	5	124	1.9	1.39	2.0	0	5
	DAY 43	98	1.4	1.32	1.5	0	4	97	1.6	1.30	2.0	0	5	114	1.7	1.43	2.0	0	5
	DAY 50	102	1.4	1.34	1.0	0	4	89	1.6	1.25	2.0	0	5	112	1.7	1.45	2.0	0	5
	DAY 57	97	1.4	1.42	1.0	0	5	86	1.4	1.38	1.0	0	5	103	1.8	1.48	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	WINDOWED VISIT																		
	DAY 1	155	3.5	1.03	4.0	0	5	151	3.5	0.97	4.0	0	5	161	3.4	0.99	4.0	0	6
	DAY 8	153	2.7	1.36	3.0	0	6	147	2.6	1.30	3.0	0	5	161	2.8	1.30	3.0	0	6
	DAY 15	134	2.1	1.36	2.0	0	6	126	2.0	1.39	2.0	0	5	146	2.5	1.38	2.0	0	6
	DAY 22	123	1.6	1.38	2.0	0	5	119	1.9	1.40	2.0	0	5	136	2.2	1.51	2.0	0	6
	DAY 29	117	1.8	1.51	2.0	0	6	109	1.6	1.49	1.0	0	5	133	2.0	1.49	2.0	0	6
	DAY 36	111	1.2	1.48	1.0	0	5	104	1.6	1.43	2.0	0	5	124	1.9	1.43	2.0	0	6
	DAY 43	98	1.3	1.52	0.5	0	5	97	1.4	1.33	1.0	0	5	114	1.7	1.39	2.0	0	5
	DAY 50	102	1.3	1.45	1.0	0	5	89	1.3	1.32	1.0	0	4	112	1.6	1.45	2.0	0	5
	DAY 57	97	1.2	1.45	0.0	0	6	86	1.3	1.42	1.0	0	5	103	1.6	1.47	2.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	WINDOWED VISIT																		
	DAY 1	155	3.1	1.08	3.0	0	5	151	3.0	1.04	3.0	0	5	161	2.9	1.12	3.0	0	5
	DAY 8	153	2.2	1.30	2.0	0	5	147	2.2	1.23	2.0	0	5	161	2.3	1.25	2.0	0	5
	DAY 15	133	1.7	1.24	2.0	0	4	126	1.8	1.29	2.0	0	6	146	2.1	1.32	2.0	0	4
	DAY 22	123	1.4	1.30	2.0	0	4	119	1.6	1.31	2.0	0	5	136	1.9	1.31	2.0	0	5
	DAY 29	117	1.3	1.32	1.0	0	4	109	1.4	1.26	1.0	0	4	133	1.8	1.37	2.0	0	4
	DAY 36	111	1.2	1.30	1.0	0	4	104	1.4	1.38	1.0	0	4	124	1.6	1.28	2.0	0	4
	DAY 43	98	1.1	1.18	1.0	0	4	97	1.2	1.23	1.0	0	4	114	1.4	1.25	1.5	0	4
	DAY 50	102	1.0	1.23	0.0	0	4	89	1.1	1.24	1.0	0	5	112	1.4	1.19	1.0	0	4
	DAY 57	97	1.0	1.29	0.0	0	4	86	1.1	1.27	1.0	0	4	103	1.4	1.37	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.9.2 MADRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	WINDOWED VISIT																		
	DAY 1	155	1.2	1.08	1.0	0	4	151	1.2	1.04	1.0	0	4	161	1.1	1.08	1.0	0	4
	DAY 8	153	0.7	0.95	0.0	0	4	147	0.7	0.96	0.0	0	4	161	0.8	0.96	0.0	0	4
	DAY 15	133	0.6	0.94	0.0	0	4	126	0.5	0.86	0.0	0	4	146	0.7	0.94	0.0	0	4
	DAY 22	123	0.4	0.77	0.0	0	3	119	0.4	0.78	0.0	0	3	136	0.7	0.98	0.0	0	4
	DAY 29	117	0.3	0.73	0.0	0	4	109	0.4	0.80	0.0	0	4	133	0.6	0.92	0.0	0	4
	DAY 36	111	0.4	0.78	0.0	0	4	104	0.4	0.80	0.0	0	4	124	0.6	0.91	0.0	0	4
	DAY 43	98	0.4	0.81	0.0	0	4	97	0.4	0.82	0.0	0	4	114	0.4	0.69	0.0	0	3
	DAY 50	102	0.3	0.62	0.0	0	3	89	0.3	0.77	0.0	0	3	112	0.4	0.78	0.0	0	4
	DAY 57	97	0.3	0.81	0.0	0	6	86	0.3	0.71	0.0	0	3	103	0.4	0.69	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS216.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	WINDOWED VISIT																		
	DAY 8	153	-1.0	1.07	-1.0	-4	1	147	-0.9	1.16	-1.0	-4	2	161	-0.7	1.22	-1.0	-5	3
	DAY 15	155	-1.4	1.37	-1.0	-4	3	148	-1.4	1.30	-1.0	-5	1	161	-1.2	1.42	-1.0	-6	1
	DAY 22	155	-1.7	1.50	-2.0	-5	3	150	-1.6	1.41	-1.0	-4	2	161	-1.3	1.54	-1.0	-6	2
	DAY 29	155	-1.7	1.49	-2.0	-5	2	150	-1.6	1.47	-2.0	-5	2	161	-1.4	1.56	-1.0	-6	2
	DAY 36	155	-1.8	1.59	-2.0	-5	2	150	-1.6	1.41	-2.0	-5	2	161	-1.4	1.64	-1.0	-6	2
	DAY 43	155	-1.9	1.62	-2.0	-6	1	151	-1.8	1.42	-2.0	-5	2	161	-1.4	1.63	-1.0	-6	2
	DAY 50	155	-2.0	1.63	-2.0	-6	1	151	-1.7	1.49	-2.0	-5	4	161	-1.5	1.63	-1.0	-6	2
	DAY 57	155	-1.9	1.67	-2.0	-5	1	151	-1.8	1.49	-2.0	-5	2	161	-1.5	1.77	-2.0	-6	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	WINDOWED VISIT																		
	DAY 8	153	-1.1	1.18	-1.0	-4	1	147	-1.0	1.15	-1.0	-4	2	161	-0.8	1.24	0.0	-6	2
	DAY 15	155	-1.6	1.36	-2.0	-5	1	148	-1.5	1.44	-1.0	-5	2	161	-1.2	1.43	-1.0	-6	1
	DAY 22	155	-1.9	1.48	-2.0	-5	1	150	-1.8	1.53	-2.0	-6	2	161	-1.3	1.57	-1.0	-6	2
	DAY 29	155	-1.9	1.45	-2.0	-5	2	150	-1.8	1.59	-2.0	-6	2	161	-1.5	1.57	-1.0	-6	1
	DAY 36	155	-2.0	1.54	-2.0	-5	2	150	-1.8	1.61	-2.0	-6	2	161	-1.5	1.70	-1.0	-6	1
	DAY 43	155	-2.2	1.58	-2.0	-6	2	151	-1.9	1.57	-2.0	-6	2	161	-1.5	1.67	-1.0	-6	2
	DAY 50	155	-2.2	1.62	-2.0	-6	2	151	-1.9	1.54	-2.0	-6	2	161	-1.6	1.67	-2.0	-6	1
	DAY 57	155	-2.2	1.64	-2.0	-5	2	151	-2.0	1.56	-2.0	-6	2	161	-1.6	1.65	-2.0	-6	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	WINDOWED VISIT																		
	DAY 8	153	-0.8	1.26	-1.0	-4	2	147	-0.6	1.04	0.0	-4	2	161	-0.5	1.13	0.0	-4	2
	DAY 15	155	-1.0	1.37	-1.0	-6	2	148	-0.9	1.28	-1.0	-4	3	161	-0.7	1.38	-1.0	-5	3
	DAY 22	155	-1.3	1.42	-1.0	-5	2	150	-1.0	1.24	-1.0	-4	2	161	-0.8	1.32	-1.0	-4	3
	DAY 29	155	-1.2	1.41	-1.0	-5	2	150	-1.1	1.25	-1.0	-4	2	161	-0.9	1.32	-1.0	-4	2
	DAY 36	155	-1.2	1.54	-1.0	-5	2	150	-1.2	1.39	-1.0	-4	2	161	-0.9	1.47	-1.0	-5	2
	DAY 43	155	-1.2	1.67	-1.0	-5	3	151	-1.2	1.37	-1.0	-4	2	161	-0.9	1.55	-1.0	-5	3
	DAY 50	155	-1.3	1.69	-1.0	-6	3	151	-1.3	1.42	-1.0	-4	2	161	-0.9	1.47	-1.0	-4	3
	DAY 57	155	-1.3	1.59	-1.0	-5	2	151	-1.3	1.36	-1.0	-4	2	161	-0.9	1.50	-1.0	-4	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	WINDOWED VISIT																		
	DAY 8	153	-2.5	1.86	-3.0	-6	4	147	-2.4	1.71	-3.0	-6	3	161	-0.9	1.56	-1.0	-6	2
	DAY 15	155	-2.6	1.85	-3.0	-6	2	148	-2.5	1.68	-3.0	-6	3	161	-1.1	1.77	-1.0	-5	4
	DAY 22	155	-2.5	1.77	-3.0	-6	1	150	-2.6	1.62	-3.0	-6	3	161	-1.2	1.76	-1.0	-5	3
	DAY 29	155	-2.7	1.78	-3.0	-6	1	150	-2.5	1.69	-3.0	-6	3	161	-1.3	1.76	-1.0	-6	4
	DAY 36	155	-2.8	1.70	-3.0	-6	1	150	-2.6	1.61	-3.0	-6	3	161	-1.3	1.87	-1.0	-6	3
	DAY 43	155	-2.7	1.68	-3.0	-6	1	151	-2.6	1.69	-3.0	-6	3	161	-1.3	1.80	-1.0	-6	4
	DAY 50	155	-2.7	1.75	-3.0	-6	1	151	-2.6	1.72	-3.0	-5	3	161	-1.3	1.80	-1.0	-6	4
	DAY 57	155	-2.8	1.72	-3.0	-6	1	151	-2.5	1.80	-3.0	-5	3	161	-1.4	1.85	-1.0	-6	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	WINDOWED VISIT																		
	DAY 8	153	-0.6	1.44	0.0	-4	3	147	-0.6	1.53	0.0	-5	3	161	-0.4	1.50	0.0	-4	5
	DAY 15	155	-0.8	1.58	0.0	-5	4	148	-0.8	1.47	0.0	-5	3	161	-0.4	1.51	0.0	-4	4
	DAY 22	155	-0.9	1.60	0.0	-4	5	150	-0.9	1.50	0.0	-5	3	161	-0.5	1.69	0.0	-4	4
	DAY 29	155	-0.9	1.73	0.0	-5	6	150	-1.0	1.54	0.0	-5	3	161	-0.5	1.74	0.0	-4	4
	DAY 36	155	-0.9	1.58	0.0	-4	2	150	-1.0	1.60	-0.5	-5	3	161	-0.6	1.75	0.0	-4	4
	DAY 43	155	-1.0	1.68	0.0	-5	4	151	-1.0	1.64	0.0	-5	4	161	-0.6	1.72	0.0	-4	4
	DAY 50	155	-1.0	1.68	0.0	-5	3	151	-1.0	1.64	0.0	-5	4	161	-0.6	1.64	0.0	-4	4
	DAY 57	155	-1.0	1.72	0.0	-5	4	151	-1.0	1.60	0.0	-5	4	161	-0.6	1.76	0.0	-4	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	WINDOWED VISIT																		
	DAY 8	153	-0.8	1.36	-1.0	-5	4	147	-0.8	1.30	-1.0	-5	2	161	-0.5	1.29	0.0	-6	3
	DAY 15	155	-1.2	1.61	-1.0	-5	4	148	-1.0	1.49	-1.0	-5	3	161	-0.9	1.34	-1.0	-6	3
	DAY 22	155	-1.5	1.66	-1.0	-5	4	150	-1.3	1.41	-1.0	-5	2	161	-1.0	1.43	-1.0	-6	3
	DAY 29	155	-1.6	1.63	-2.0	-5	2	150	-1.4	1.51	-1.0	-5	3	161	-1.1	1.55	-1.0	-6	3
	DAY 36	155	-1.8	1.72	-2.0	-5	4	150	-1.5	1.47	-1.0	-5	2	161	-1.1	1.54	-1.0	-6	3
	DAY 43	155	-1.9	1.71	-2.0	-5	4	151	-1.6	1.53	-2.0	-5	2	161	-1.2	1.61	-1.0	-6	3
	DAY 50	155	-1.7	1.75	-2.0	-5	3	151	-1.6	1.56	-2.0	-5	2	161	-1.2	1.53	-1.0	-5	3
	DAY 57	155	-1.7	1.72	-2.0	-5	4	151	-1.7	1.60	-2.0	-5	2	161	-1.2	1.52	-1.0	-6	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	WINDOWED VISIT																		
	DAY 8	153	-0.8	1.43	0.0	-4	3	147	-0.7	1.27	0.0	-4	4	161	-0.6	1.42	0.0	-5	4
	DAY 15	155	-1.2	1.62	-1.0	-5	3	148	-1.0	1.48	-1.0	-4	4	161	-1.0	1.46	-1.0	-4	3
	DAY 22	155	-1.4	1.66	-1.0	-5	2	150	-1.1	1.46	-1.0	-5	4	161	-1.2	1.59	-1.0	-5	4
	DAY 29	155	-1.5	1.76	-2.0	-5	3	150	-1.3	1.54	-1.0	-5	4	161	-1.1	1.58	-1.0	-5	4
	DAY 36	155	-1.7	1.71	-2.0	-5	2	150	-1.4	1.55	-1.0	-5	4	161	-1.2	1.67	-1.0	-5	4
	DAY 43	155	-1.9	1.77	-2.0	-5	2	151	-1.5	1.58	-1.0	-5	4	161	-1.3	1.78	-1.0	-5	4
	DAY 50	155	-1.9	1.74	-2.0	-5	2	151	-1.5	1.52	-2.0	-5	4	161	-1.3	1.73	-1.0	-5	4
	DAY 57	155	-1.9	1.77	-2.0	-5	3	151	-1.6	1.58	-2.0	-5	4	161	-1.2	1.73	-1.0	-5	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	WINDOWED VISIT																		
	DAY 8	153	-0.9	1.39	0.0	-4	2	147	-0.9	1.28	-1.0	-4	3	161	-0.7	1.22	0.0	-4	2
	DAY 15	155	-1.4	1.61	-1.0	-5	4	148	-1.4	1.38	-1.0	-4	3	161	-0.9	1.29	-1.0	-5	2
	DAY 22	155	-1.7	1.65	-2.0	-5	3	150	-1.5	1.41	-1.5	-4	3	161	-1.1	1.57	-1.0	-5	2
	DAY 29	155	-1.6	1.67	-2.0	-5	4	150	-1.7	1.53	-2.0	-5	3	161	-1.2	1.60	-1.0	-5	3
	DAY 36	155	-2.0	1.65	-2.0	-5	4	150	-1.7	1.55	-2.0	-4	3	161	-1.3	1.69	-1.0	-5	3
	DAY 43	155	-1.9	1.71	-2.0	-5	2	151	-1.8	1.53	-2.0	-5	3	161	-1.4	1.62	-1.0	-5	2
	DAY 50	155	-1.9	1.68	-2.0	-5	2	151	-1.8	1.55	-2.0	-4	3	161	-1.5	1.70	-1.0	-5	2
	DAY 57	155	-2.0	1.70	-2.0	-5	3	151	-1.9	1.56	-2.0	-4	3	161	-1.5	1.69	-1.0	-5	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	WINDOWED VISIT																		
	DAY 8	153	-0.9	1.25	-1.0	-5	2	147	-0.8	1.16	-1.0	-4	2	161	-0.5	1.26	0.0	-4	4
	DAY 15	155	-1.4	1.37	-1.0	-5	2	148	-1.0	1.44	-1.0	-5	4	161	-0.7	1.35	-1.0	-4	4
	DAY 22	155	-1.5	1.41	-1.0	-5	2	150	-1.2	1.42	-1.0	-5	2	161	-0.9	1.51	-1.0	-4	4
	DAY 29	155	-1.6	1.45	-2.0	-5	2	150	-1.3	1.51	-1.0	-5	3	161	-1.0	1.60	-1.0	-4	4
	DAY 36	155	-1.7	1.52	-2.0	-5	2	150	-1.3	1.56	-1.0	-5	2	161	-1.1	1.58	-1.0	-4	4
	DAY 43	155	-1.7	1.47	-2.0	-5	2	151	-1.4	1.54	-1.0	-5	2	161	-1.1	1.52	-1.0	-4	4
	DAY 50	155	-1.8	1.50	-2.0	-5	2	151	-1.5	1.52	-2.0	-5	2	161	-1.2	1.58	-1.0	-4	4
	DAY 57	155	-1.8	1.49	-2.0	-5	2	151	-1.5	1.55	-1.0	-5	2	161	-1.2	1.62	-1.0	-4	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.3 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	WINDOWED VISIT																		
	DAY 8	153	-0.5	0.98	0.0	-4	3	147	-0.5	0.98	0.0	-4	2	161	-0.3	0.99	0.0	-4	3
	DAY 15	155	-0.7	1.09	0.0	-4	2	148	-0.6	1.14	0.0	-4	4	161	-0.4	1.02	0.0	-4	3
	DAY 22	155	-0.7	1.12	0.0	-4	2	150	-0.6	1.05	0.0	-4	2	161	-0.3	1.06	0.0	-4	3
	DAY 29	155	-0.8	1.07	-1.0	-4	2	150	-0.6	1.03	0.0	-4	2	161	-0.4	1.13	0.0	-4	3
	DAY 36	155	-0.7	1.02	-1.0	-4	2	150	-0.7	1.04	0.0	-4	2	161	-0.4	1.26	0.0	-4	4
	DAY 43	155	-0.7	1.05	-1.0	-4	2	151	-0.6	1.12	0.0	-4	4	161	-0.5	1.14	0.0	-4	2
	DAY 50	155	-0.8	1.11	-1.0	-4	2	151	-0.6	1.13	-1.0	-4	4	161	-0.5	1.21	0.0	-4	4
	DAY 57	155	-0.8	1.17	-1.0	-4	5	151	-0.6	1.09	0.0	-4	4	161	-0.5	1.12	0.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS219.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. APPARENT SADNESS	WINDOWED VISIT																		
	DAY 8	153	-1.0	1.07	-1.0	-4	1	147	-0.9	1.16	-1.0	-4	2	161	-0.7	1.22	-1.0	-5	3
	DAY 15	134	-1.5	1.37	-2.0	-4	3	126	-1.4	1.30	-1.0	-5	1	146	-1.2	1.44	-1.0	-6	1
	DAY 22	123	-1.9	1.44	-2.0	-5	3	119	-1.7	1.42	-2.0	-4	2	136	-1.4	1.52	-1.0	-6	2
	DAY 29	117	-1.8	1.48	-2.0	-5	2	109	-1.8	1.49	-2.0	-5	2	133	-1.5	1.52	-1.0	-6	2
	DAY 36	111	-2.1	1.55	-2.0	-5	2	104	-1.8	1.41	-2.0	-4	2	124	-1.6	1.61	-2.0	-6	2
	DAY 43	98	-2.2	1.57	-2.0	-6	1	97	-2.1	1.32	-2.0	-5	0	114	-1.6	1.56	-2.0	-6	2
	DAY 50	102	-2.4	1.54	-2.0	-6	1	89	-2.0	1.50	-2.0	-4	4	112	-1.8	1.54	-2.0	-5	2
	DAY 57	97	-2.3	1.63	-2.0	-5	1	86	-2.1	1.48	-2.0	-5	1	103	-1.8	1.76	-2.0	-6	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. REPORTED SADNESS	WINDOWED VISIT																		
	DAY 8	153	-1.1	1.18	-1.0	-4	1	147	-1.0	1.15	-1.0	-4	2	161	-0.8	1.24	0.0	-6	2
	DAY 15	134	-1.7	1.35	-2.0	-5	1	126	-1.6	1.44	-2.0	-5	2	146	-1.3	1.43	-1.0	-6	1
	DAY 22	123	-2.1	1.43	-2.0	-5	1	119	-2.0	1.52	-2.0	-6	1	136	-1.5	1.52	-1.0	-6	2
	DAY 29	117	-2.0	1.43	-2.0	-5	2	109	-2.0	1.59	-2.0	-6	2	133	-1.6	1.45	-2.0	-6	1
	DAY 36	111	-2.3	1.49	-2.0	-5	1	104	-2.0	1.59	-2.0	-5	2	124	-1.8	1.62	-2.0	-6	1
	DAY 43	98	-2.5	1.54	-3.0	-6	1	97	-2.3	1.49	-2.0	-6	1	114	-1.8	1.54	-2.0	-6	2
	DAY 50	102	-2.5	1.56	-3.0	-6	1	89	-2.3	1.46	-2.0	-5	2	112	-2.0	1.49	-2.0	-5	1
	DAY 57	97	-2.6	1.62	-3.0	-5	2	86	-2.4	1.49	-2.0	-5	1	103	-1.9	1.49	-2.0	-6	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. INNER TENSION	WINDOWED VISIT																		
	DAY 8	153	-0.8	1.26	-1.0	-4	2	147	-0.6	1.04	0.0	-4	2	161	-0.5	1.13	0.0	-4	2
	DAY 15	134	-1.1	1.34	-1.0	-6	2	126	-0.9	1.28	-1.0	-4	3	146	-0.7	1.40	-1.0	-5	3
	DAY 22	123	-1.5	1.36	-1.0	-5	2	119	-1.1	1.19	-1.0	-4	2	136	-0.9	1.33	-1.0	-4	3
	DAY 29	117	-1.4	1.33	-1.0	-5	2	109	-1.2	1.21	-1.0	-4	1	133	-1.0	1.33	-1.0	-4	2
	DAY 36	111	-1.3	1.48	-1.0	-5	2	104	-1.3	1.37	-1.0	-4	2	124	-1.1	1.52	-1.0	-5	2
	DAY 43	98	-1.5	1.58	-1.0	-5	3	97	-1.4	1.31	-1.0	-4	2	114	-1.2	1.60	-1.0	-5	3
	DAY 50	102	-1.6	1.62	-2.0	-6	3	89	-1.5	1.38	-2.0	-4	2	112	-1.1	1.51	-1.0	-4	3
	DAY 57	97	-1.7	1.44	-2.0	-5	1	86	-1.5	1.25	-1.0	-4	1	103	-1.1	1.53	-1.0	-4	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. REDUCED SLEEP	WINDOWED VISIT																		
	DAY 8	153	-2.5	1.86	-3.0	-6	4	147	-2.4	1.71	-3.0	-6	3	161	-0.9	1.56	-1.0	-6	2
	DAY 15	134	-2.6	1.84	-3.0	-6	2	126	-2.5	1.62	-3.0	-6	2	146	-1.1	1.78	-1.0	-5	4
	DAY 22	123	-2.6	1.71	-3.0	-6	1	119	-2.7	1.52	-3.0	-6	2	136	-1.3	1.71	-1.0	-5	3
	DAY 29	117	-2.7	1.75	-3.0	-6	1	109	-2.6	1.58	-3.0	-6	2	133	-1.4	1.77	-1.0	-6	4
	DAY 36	111	-2.8	1.66	-3.0	-6	1	104	-2.7	1.54	-3.0	-6	1	124	-1.5	1.89	-1.0	-6	3
	DAY 43	98	-2.8	1.56	-3.0	-6	1	97	-2.7	1.61	-3.0	-6	2	114	-1.5	1.80	-2.0	-6	4
	DAY 50	102	-2.7	1.69	-3.0	-6	1	89	-2.7	1.57	-3.0	-5	2	112	-1.4	1.78	-1.0	-6	4
	DAY 57	97	-2.9	1.68	-3.0	-6	1	86	-2.6	1.70	-3.0	-5	2	103	-1.6	1.84	-1.0	-6	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
GENERATED: 17NOV2005 13:51:25 iceadmn3

Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. REDUCED APPETITE	WINDOWED VISIT																		
	DAY 8	153	-0.6	1.44	0.0	-4	3	147	-0.6	1.53	0.0	-5	3	161	-0.4	1.50	0.0	-4	5
	DAY 15	134	-0.8	1.60	0.0	-5	4	126	-0.7	1.37	0.0	-4	3	146	-0.4	1.53	0.0	-4	4
	DAY 22	123	-1.0	1.61	0.0	-4	5	119	-0.9	1.35	0.0	-4	2	136	-0.6	1.68	0.0	-4	3
	DAY 29	117	-0.9	1.74	0.0	-5	6	109	-1.0	1.42	0.0	-4	2	133	-0.6	1.68	0.0	-4	4
	DAY 36	111	-1.0	1.50	0.0	-4	2	104	-1.0	1.48	-1.0	-4	2	124	-0.8	1.68	0.0	-4	4
	DAY 43	98	-1.1	1.71	0.0	-5	4	97	-1.0	1.45	0.0	-4	2	114	-0.8	1.62	0.0	-4	3
	DAY 50	102	-1.1	1.66	0.0	-5	3	89	-0.9	1.46	0.0	-4	3	112	-0.9	1.47	0.0	-4	4
	DAY 57	97	-1.1	1.74	0.0	-5	4	86	-1.0	1.38	0.0	-4	2	103	-0.9	1.67	0.0	-4	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. CONCENTRATION DIFFICULTIES	WINDOWED VISIT																		
	DAY 8	153	-0.8	1.36	-1.0	-5	4	147	-0.8	1.30	-1.0	-5	2	161	-0.5	1.29	0.0	-6	3
	DAY 15	134	-1.3	1.65	-1.0	-5	4	126	-1.1	1.48	-1.0	-4	3	146	-0.9	1.34	-1.0	-6	2
	DAY 22	123	-1.7	1.66	-2.0	-4	4	119	-1.5	1.35	-2.0	-4	2	136	-1.1	1.43	-1.0	-6	2
	DAY 29	117	-1.9	1.60	-2.0	-5	2	109	-1.6	1.50	-2.0	-5	3	133	-1.2	1.55	-1.0	-6	2
	DAY 36	111	-2.1	1.66	-2.0	-5	4	104	-1.7	1.40	-2.0	-5	2	124	-1.3	1.51	-1.0	-6	2
	DAY 43	98	-2.3	1.66	-2.0	-5	4	97	-1.9	1.42	-2.0	-5	2	114	-1.5	1.62	-1.0	-6	2
	DAY 50	102	-2.0	1.76	-2.0	-5	3	89	-2.0	1.44	-2.0	-5	1	112	-1.5	1.50	-1.0	-5	2
	DAY 57	97	-2.0	1.74	-2.0	-5	4	86	-2.1	1.44	-2.0	-5	1	103	-1.4	1.49	-1.0	-6	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LASSITUDE	WINDOWED VISIT																		
	DAY 8	153	-0.8	1.43	0.0	-4	3	147	-0.7	1.27	0.0	-4	4	161	-0.6	1.42	0.0	-5	4
	DAY 15	134	-1.3	1.63	-1.0	-5	3	126	-1.1	1.44	-1.0	-4	3	146	-1.0	1.49	-1.0	-4	3
	DAY 22	123	-1.6	1.62	-2.0	-5	2	119	-1.3	1.41	-1.0	-5	2	136	-1.3	1.64	-1.0	-5	4
	DAY 29	117	-1.7	1.73	-2.0	-5	3	109	-1.5	1.51	-2.0	-5	2	133	-1.2	1.57	-1.0	-4	4
	DAY 36	111	-2.0	1.61	-2.0	-5	2	104	-1.7	1.47	-2.0	-5	1	124	-1.4	1.63	-1.5	-5	2
	DAY 43	98	-2.1	1.74	-2.0	-5	2	97	-1.7	1.50	-2.0	-5	1	114	-1.6	1.71	-1.0	-5	2
	DAY 50	102	-2.2	1.65	-2.0	-5	2	89	-1.7	1.43	-2.0	-5	2	112	-1.6	1.64	-1.0	-5	1
	DAY 57	97	-2.2	1.70	-2.0	-5	3	86	-1.8	1.48	-2.0	-5	1	103	-1.5	1.62	-2.0	-5	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. INABILITY TO FEEL	WINDOWED VISIT																		
	DAY 8	153	-0.9	1.39	0.0	-4	2	147	-0.9	1.28	-1.0	-4	3	161	-0.7	1.22	0.0	-4	2
	DAY 15	134	-1.5	1.62	-1.5	-5	4	126	-1.5	1.36	-1.0	-4	2	146	-0.9	1.31	-1.0	-5	2
	DAY 22	123	-1.9	1.63	-2.0	-5	3	119	-1.6	1.35	-2.0	-4	1	136	-1.2	1.62	-1.0	-5	2
	DAY 29	117	-1.7	1.68	-2.0	-5	4	109	-1.9	1.49	-2.0	-5	1	133	-1.4	1.56	-1.0	-5	3
	DAY 36	111	-2.2	1.58	-2.0	-5	4	104	-1.9	1.50	-2.0	-4	2	124	-1.5	1.68	-1.0	-5	3
	DAY 43	98	-2.2	1.70	-2.0	-5	2	97	-2.1	1.42	-2.0	-5	1	114	-1.6	1.56	-2.0	-5	2
	DAY 50	102	-2.2	1.63	-2.0	-5	2	89	-2.1	1.47	-2.0	-4	2	112	-1.7	1.69	-2.0	-5	2
	DAY 57	97	-2.3	1.66	-2.0	-5	3	86	-2.2	1.49	-2.0	-4	2	103	-1.7	1.67	-2.0	-5	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
GENERATED: 17NOV2005 13:51:25 iceadmn3

Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. PESSIMISTIC THOUGHTS	WINDOWED VISIT																		
	DAY 8	153	-0.9	1.25	-1.0	-5	2	147	-0.8	1.16	-1.0	-4	2	161	-0.5	1.26	0.0	-4	4
	DAY 15	133	-1.5	1.37	-1.0	-5	1	126	-1.1	1.46	-1.0	-5	4	146	-0.8	1.37	-1.0	-4	4
	DAY 22	123	-1.7	1.40	-2.0	-5	1	119	-1.3	1.42	-1.0	-5	2	136	-1.0	1.47	-1.0	-4	4
	DAY 29	117	-1.8	1.46	-2.0	-5	2	109	-1.5	1.53	-1.0	-5	3	133	-1.1	1.60	-1.0	-4	4
	DAY 36	111	-1.9	1.54	-2.0	-5	2	104	-1.5	1.58	-1.5	-5	2	124	-1.3	1.55	-1.0	-4	2
	DAY 43	98	-2.1	1.42	-2.0	-5	1	97	-1.7	1.37	-2.0	-5	2	114	-1.4	1.45	-1.0	-4	2
	DAY 50	102	-2.2	1.48	-2.0	-5	1	89	-1.8	1.26	-2.0	-5	1	112	-1.5	1.54	-1.0	-4	3
	DAY 57	97	-2.1	1.44	-2.0	-5	1	86	-1.9	1.36	-2.0	-5	2	103	-1.4	1.59	-2.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
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Table 11.2.1.9.4 MADRS Change from Baseline in Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. SUICIDAL THOUGHTS	WINDOWED VISIT																		
	DAY 8	153	-0.5	0.98	0.0	-4	3	147	-0.5	0.98	0.0	-4	2	161	-0.3	0.99	0.0	-4	3
	DAY 15	133	-0.7	1.11	0.0	-4	2	126	-0.6	1.12	0.0	-4	4	146	-0.4	1.00	0.0	-4	3
	DAY 22	123	-0.8	1.08	0.0	-4	1	119	-0.7	0.96	0.0	-4	2	136	-0.3	1.02	0.0	-4	3
	DAY 29	117	-0.8	1.03	-1.0	-4	1	109	-0.7	0.96	-1.0	-4	2	133	-0.4	1.09	0.0	-4	3
	DAY 36	111	-0.8	1.02	-1.0	-4	1	104	-0.7	0.99	-1.0	-4	2	124	-0.4	1.28	0.0	-4	4
	DAY 43	98	-0.8	1.09	-1.0	-4	2	97	-0.7	0.93	-1.0	-3	1	114	-0.5	1.06	0.0	-4	2
	DAY 50	102	-0.9	1.14	-1.0	-4	1	89	-0.7	1.00	-1.0	-3	2	112	-0.5	1.16	0.0	-4	4
	DAY 57	97	-0.9	1.23	-1.0	-4	5	86	-0.7	0.86	-1.0	-3	2	103	-0.5	1.02	0.0	-4	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS218.SAS
GENERATED: 17NOV2005 13:51:25 iceadmn3

Table 11.2.1.10.1 MADRS Item 1 Score (Apparent Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.6	0.95	-1.0	1.07	-0.95	0.105	-1.16	-0.74	.
	Q600MG	147	3.5	0.90	-0.9	1.16	-0.89	0.108	-1.10	-0.68	.
	P	161	3.5	1.03	-0.7	1.22	-0.74	0.105	-0.95	-0.53	.
	Q300MG VS P	.	.	.	.	.	-0.21	0.121	-0.45	0.03	0.079
	Q600MG VS P	.	.	.	.	.	-0.15	0.122	-0.39	0.09	0.212
DAY 15	Q300MG	155	3.6	0.95	-1.4	1.37	-1.36	0.121	-1.60	-1.12	.
	Q600MG	148	3.5	0.90	-1.4	1.30	-1.43	0.124	-1.68	-1.19	.
	P	161	3.5	1.03	-1.2	1.42	-1.23	0.121	-1.47	-0.99	.
	Q300MG VS P	.	.	.	.	.	-0.13	0.133	-0.39	0.13	0.335
	Q600MG VS P	.	.	.	.	.	-0.20	0.135	-0.47	0.06	0.137
DAY 22	Q300MG	155	3.6	0.95	-1.7	1.50	-1.64	0.126	-1.89	-1.39	.
	Q600MG	150	3.5	0.90	-1.6	1.41	-1.64	0.129	-1.89	-1.38	.
	P	161	3.5	1.03	-1.3	1.54	-1.36	0.126	-1.61	-1.11	.
	Q300MG VS P	.	.	.	.	.	-0.28	0.148	-0.57	0.01	0.059
	Q600MG VS P	.	.	.	.	.	-0.28	0.149	-0.57	0.02	0.065
DAY 29	Q300MG	155	3.6	0.95	-1.7	1.49	-1.67	0.125	-1.91	-1.42	.
	Q600MG	150	3.5	0.90	-1.6	1.47	-1.74	0.128	-2.00	-1.49	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS236.SAS
GENERATED: 17NOV2005 13:32:30 iceadmn3

Table 11.2.1.10.1 MADRS Item 1 Score (Apparent Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.5	1.03	-1.4	1.56	-1.52	0.125	-1.76	-1.27	.
	Q300MG VS P	.	.	.	.	.	-0.15	0.147	-0.44	0.14	0.308
	Q600MG VS P	.	.	.	.	.	-0.23	0.148	-0.52	0.06	0.127
DAY 36	Q300MG	155	3.6	0.95	-1.8	1.59	-1.78	0.127	-2.03	-1.52	.
	Q600MG	150	3.5	0.90	-1.6	1.41	-1.66	0.130	-1.92	-1.40	.
	P	161	3.5	1.03	-1.4	1.64	-1.42	0.127	-1.67	-1.17	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.155	-0.66	-0.05	0.022
	Q600MG VS P	.	.	.	.	.	-0.24	0.157	-0.55	0.07	0.128
DAY 43	Q300MG	155	3.6	0.95	-1.9	1.62	-1.87	0.134	-2.13	-1.60	.
	Q600MG	151	3.5	0.89	-1.8	1.42	-1.89	0.137	-2.16	-1.62	.
	P	161	3.5	1.03	-1.4	1.63	-1.45	0.133	-1.72	-1.19	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.159	-0.73	-0.11	0.009
	Q600MG VS P	.	.	.	.	.	-0.44	0.160	-0.76	-0.13	0.006
DAY 50	Q300MG	155	3.6	0.95	-2.0	1.63	-1.94	0.140	-2.22	-1.67	.
	Q600MG	151	3.5	0.89	-1.7	1.49	-1.79	0.143	-2.07	-1.50	.
	P	161	3.5	1.03	-1.5	1.63	-1.56	0.140	-1.84	-1.28	.
	Q300MG VS P	.	.	.	.	.	-0.38	0.159	-0.70	-0.07	0.016

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS236.SAS
GENERATED: 17NOV2005 13:32:30 iceadmn3

Table 11.2.1.10.1 MADRS Item 1 Score (Apparent Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.23	0.160	-0.54	0.09	0.157
DAY 57	Q300MG	155	3.6	0.95	-1.9	1.67	-1.91	0.132	-2.17	-1.65	.
	Q600MG	151	3.5	0.89	-1.8	1.49	-1.87	0.135	-2.14	-1.61	.
	P	161	3.5	1.03	-1.5	1.77	-1.59	0.131	-1.85	-1.33	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.168	-0.65	0.01	0.058
	Q600MG VS P	.	.	.	.	.	-0.28	0.169	-0.61	0.05	0.097

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS236.SAS
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Table 11.2.1.10.2 MADRS Item 2 Score (Reported Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.9	0.81	-1.1	1.18	-1.11	0.112	-1.33	-0.89	.
	Q600MG	147	3.8	0.77	-1.0	1.15	-1.04	0.115	-1.26	-0.81	.
	P	161	3.8	0.85	-0.8	1.24	-0.78	0.111	-1.00	-0.56	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.125	-0.58	-0.09	0.008
	Q600MG VS P	.	.	.	.	.	-0.26	0.126	-0.50	-0.01	0.043
DAY 15	Q300MG	155	3.9	0.81	-1.6	1.36	-1.61	0.123	-1.86	-1.37	.
	Q600MG	148	3.8	0.77	-1.5	1.44	-1.56	0.127	-1.82	-1.31	.
	P	161	3.8	0.85	-1.2	1.43	-1.25	0.123	-1.49	-1.00	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.142	-0.64	-0.08	0.011
	Q600MG VS P	.	.	.	.	.	-0.32	0.145	-0.60	-0.03	0.030
DAY 22	Q300MG	155	3.9	0.81	-1.9	1.48	-1.90	0.134	-2.17	-1.64	.
	Q600MG	150	3.8	0.77	-1.8	1.53	-1.85	0.138	-2.13	-1.58	.
	P	161	3.8	0.85	-1.3	1.57	-1.39	0.134	-1.66	-1.13	.
	Q300MG VS P	.	.	.	.	.	-0.51	0.155	-0.81	-0.20	0.001
	Q600MG VS P	.	.	.	.	.	-0.46	0.157	-0.77	-0.15	0.004
DAY 29	Q300MG	155	3.9	0.81	-1.9	1.45	-1.92	0.131	-2.18	-1.66	.
	Q600MG	150	3.8	0.77	-1.8	1.59	-1.88	0.134	-2.14	-1.61	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS237.SAS
GENERATED: 17NOV2005 13:32:33 iceadmn3

Table 11.2.1.10.2 MADRS Item 2 Score (Reported Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.8	0.85	-1.5	1.57	-1.52	0.130	-1.78	-1.26	.
	Q300MG VS P	.	.	.	.	.	-0.40	0.156	-0.70	-0.09	0.011
	Q600MG VS P	.	.	.	.	.	-0.36	0.158	-0.67	-0.05	0.024
DAY 36	Q300MG	155	3.9	0.81	-2.0	1.54	-2.01	0.135	-2.27	-1.74	.
	Q600MG	150	3.8	0.77	-1.8	1.61	-1.86	0.138	-2.13	-1.59	.
	P	161	3.8	0.85	-1.5	1.70	-1.54	0.134	-1.81	-1.28	.
	Q300MG VS P	.	.	.	.	.	-0.46	0.163	-0.78	-0.14	0.005
	Q600MG VS P	.	.	.	.	.	-0.31	0.165	-0.64	0.01	0.057
DAY 43	Q300MG	155	3.9	0.81	-2.2	1.58	-2.17	0.134	-2.43	-1.90	.
	Q600MG	151	3.8	0.77	-1.9	1.57	-2.01	0.137	-2.28	-1.74	.
	P	161	3.8	0.85	-1.5	1.67	-1.51	0.134	-1.77	-1.24	.
	Q300MG VS P	.	.	.	.	.	-0.66	0.164	-0.98	-0.34	<.001
	Q600MG VS P	.	.	.	.	.	-0.50	0.166	-0.82	-0.17	0.003
DAY 50	Q300MG	155	3.9	0.81	-2.2	1.62	-2.16	0.137	-2.43	-1.89	.
	Q600MG	151	3.8	0.77	-1.9	1.54	-1.98	0.140	-2.26	-1.71	.
	P	161	3.8	0.85	-1.6	1.67	-1.66	0.136	-1.93	-1.39	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.167	-0.83	-0.17	0.003

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS237.SAS
GENERATED: 17NOV2005 13:32:33 iceadmn3

Table 11.2.1.10.2 MADRS Item 2 Score (Reported Sadness) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.33	0.169	-0.66	0.00	0.052
DAY 57	Q300MG	155	3.9	0.81	-2.2	1.64	-2.21	0.131	-2.47	-1.95	.
	Q600MG	151	3.8	0.77	-2.0	1.56	-2.04	0.134	-2.31	-1.77	.
	P	161	3.8	0.85	-1.6	1.65	-1.63	0.130	-1.89	-1.37	.
	Q300MG VS P	.	.	.	.	.	-0.58	0.170	-0.91	-0.24	<.001
	Q600MG VS P	.	.	.	.	.	-0.41	0.171	-0.74	-0.07	0.018

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS237.SAS
GENERATED: 17NOV2005 13:32:33 iceadmn3

Table 11.2.1.10.3 MADRS Item 3 Score (Inner Tension) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.2	1.00	-0.8	1.26	-0.74	0.096	-0.93	-0.55	.
	Q600MG	147	3.0	0.89	-0.6	1.04	-0.63	0.099	-0.82	-0.43	.
	P	161	3.1	0.93	-0.5	1.13	-0.47	0.096	-0.66	-0.28	.
	Q300MG VS P	.	.	.	.	.	-0.27	0.115	-0.50	-0.04	0.020
	Q600MG VS P	.	.	.	.	.	-0.16	0.117	-0.38	0.07	0.183
DAY 15	Q300MG	155	3.2	0.99	-1.0	1.37	-1.06	0.115	-1.29	-0.83	.
	Q600MG	148	3.0	0.88	-0.9	1.28	-1.03	0.119	-1.27	-0.80	.
	P	161	3.1	0.93	-0.7	1.38	-0.81	0.115	-1.04	-0.58	.
	Q300MG VS P	.	.	.	.	.	-0.25	0.128	-0.50	0.00	0.051
	Q600MG VS P	.	.	.	.	.	-0.23	0.131	-0.48	0.03	0.085
DAY 22	Q300MG	155	3.2	0.99	-1.3	1.42	-1.24	0.106	-1.45	-1.03	.
	Q600MG	150	3.0	0.89	-1.0	1.24	-1.07	0.109	-1.29	-0.86	.
	P	161	3.1	0.93	-0.8	1.32	-0.82	0.105	-1.03	-0.61	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.133	-0.68	-0.16	0.002
	Q600MG VS P	.	.	.	.	.	-0.25	0.134	-0.52	0.01	0.061
DAY 29	Q300MG	155	3.2	0.99	-1.2	1.41	-1.23	0.104	-1.44	-1.03	.
	Q600MG	150	3.0	0.89	-1.1	1.25	-1.18	0.107	-1.39	-0.97	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS238.SAS
GENERATED: 17NOV2005 13:32:37 iceadmn3

Table 11.2.1.10.3 MADRS Item 3 Score (Inner Tension) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.1	0.93	-0.9	1.32	-0.96	0.103	-1.17	-0.76	.
	Q300MG VS P	.	.	.	.	.	-0.27	0.131	-0.53	-0.02	0.038
	Q600MG VS P	.	.	.	.	.	-0.21	0.132	-0.47	0.05	0.106
DAY 36	Q300MG	155	3.2	0.99	-1.2	1.54	-1.13	0.113	-1.36	-0.91	.
	Q600MG	150	3.0	0.89	-1.2	1.39	-1.25	0.116	-1.48	-1.02	.
	P	161	3.1	0.93	-0.9	1.47	-0.91	0.112	-1.14	-0.69	.
	Q300MG VS P	.	.	.	.	.	-0.22	0.140	-0.50	0.06	0.117
	Q600MG VS P	.	.	.	.	.	-0.34	0.142	-0.62	-0.06	0.017
DAY 43	Q300MG	155	3.2	0.99	-1.2	1.67	-1.18	0.118	-1.42	-0.95	.
	Q600MG	151	3.0	0.89	-1.2	1.37	-1.32	0.121	-1.56	-1.08	.
	P	161	3.1	0.93	-0.9	1.55	-0.92	0.117	-1.15	-0.69	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.146	-0.55	0.02	0.072
	Q600MG VS P	.	.	.	.	.	-0.40	0.148	-0.69	-0.11	0.007
DAY 50	Q300MG	155	3.2	0.99	-1.3	1.69	-1.30	0.120	-1.54	-1.06	.
	Q600MG	151	3.0	0.89	-1.3	1.42	-1.36	0.123	-1.61	-1.12	.
	P	161	3.1	0.93	-0.9	1.47	-0.92	0.120	-1.16	-0.68	.
	Q300MG VS P	.	.	.	.	.	-0.38	0.144	-0.66	-0.10	0.009

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS238.SAS
GENERATED: 17NOV2005 13:32:37 iceadmn3

Table 11.2.1.10.3 MADRS Item 3 Score (Inner Tension) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.44	0.146	-0.73	-0.16	0.003
DAY 57	Q300MG	155	3.2	0.99	-1.3	1.59	-1.34	0.118	-1.57	-1.10	.
	Q600MG	151	3.0	0.89	-1.3	1.36	-1.37	0.121	-1.61	-1.13	.
	P	161	3.1	0.93	-0.9	1.50	-0.95	0.117	-1.18	-0.72	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.146	-0.67	-0.10	0.008
	Q600MG VS P	.	.	.	.	.	-0.42	0.147	-0.71	-0.13	0.005

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS238.SAS
GENERATED: 17NOV2005 13:32:37 iceadmn3

Table 11.2.1.10.4 MADRS Item 4 Score (Reduced Sleep) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.8	1.24	-2.5	1.86	-2.40	0.124	-2.65	-2.16	.
	Q600MG	147	3.6	1.24	-2.4	1.71	-2.44	0.127	-2.69	-2.19	.
	P	161	3.6	1.20	-0.9	1.56	-0.98	0.122	-1.22	-0.74	.
	Q300MG VS P	.	.	.	.	.	-1.43	0.165	-1.75	-1.10	<.001
	Q600MG VS P	.	.	.	.	.	-1.46	0.167	-1.79	-1.13	<.001
DAY 15	Q300MG	155	3.8	1.23	-2.6	1.85	-2.51	0.134	-2.78	-2.25	.
	Q600MG	148	3.6	1.24	-2.5	1.68	-2.58	0.137	-2.85	-2.30	.
	P	161	3.6	1.20	-1.1	1.77	-1.13	0.133	-1.39	-0.86	.
	Q300MG VS P	.	.	.	.	.	-1.39	0.168	-1.72	-1.06	<.001
	Q600MG VS P	.	.	.	.	.	-1.45	0.171	-1.78	-1.11	<.001
DAY 22	Q300MG	155	3.8	1.23	-2.5	1.77	-2.45	0.139	-2.72	-2.17	.
	Q600MG	150	3.6	1.24	-2.6	1.62	-2.68	0.142	-2.96	-2.40	.
	P	161	3.6	1.20	-1.2	1.76	-1.25	0.138	-1.53	-0.98	.
	Q300MG VS P	.	.	.	.	.	-1.19	0.167	-1.52	-0.86	<.001
	Q600MG VS P	.	.	.	.	.	-1.43	0.169	-1.76	-1.09	<.001
DAY 29	Q300MG	155	3.8	1.23	-2.7	1.78	-2.58	0.131	-2.84	-2.32	.
	Q600MG	150	3.6	1.24	-2.5	1.69	-2.56	0.134	-2.83	-2.30	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS239.SAS
GENERATED: 17NOV2005 13:32:40 iceadmn3

Table 11.2.1.10.4 MADRS Item 4 Score (Reduced Sleep) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
VISIT	TREATMENT	N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
DAY 29	P	161	3.6	1.20	-1.3	1.76	-1.35	0.130	-1.61	-1.10	.
	Q300MG VS P	.	.	.	.	.	-1.23	0.168	-1.56	-0.90	<.001
	Q600MG VS P	.	.	.	.	.	-1.21	0.170	-1.54	-0.87	<.001
DAY 36	Q300MG	155	3.8	1.23	-2.8	1.70	-2.68	0.127	-2.93	-2.43	.
	Q600MG	150	3.6	1.24	-2.6	1.61	-2.66	0.129	-2.92	-2.40	.
	P	161	3.6	1.20	-1.3	1.87	-1.32	0.125	-1.57	-1.07	.
	Q300MG VS P	.	.	.	.	.	-1.36	0.169	-1.69	-1.03	<.001
	Q600MG VS P	.	.	.	.	.	-1.34	0.170	-1.68	-1.01	<.001
DAY 43	Q300MG	155	3.8	1.23	-2.7	1.68	-2.64	0.129	-2.89	-2.38	.
	Q600MG	151	3.6	1.23	-2.6	1.69	-2.70	0.131	-2.95	-2.44	.
	P	161	3.6	1.20	-1.3	1.80	-1.32	0.127	-1.57	-1.07	.
	Q300MG VS P	.	.	.	.	.	-1.32	0.169	-1.65	-0.99	<.001
	Q600MG VS P	.	.	.	.	.	-1.38	0.170	-1.71	-1.04	<.001
DAY 50	Q300MG	155	3.8	1.23	-2.7	1.75	-2.60	0.129	-2.86	-2.35	.
	Q600MG	151	3.6	1.23	-2.6	1.72	-2.64	0.131	-2.90	-2.38	.
	P	161	3.6	1.20	-1.3	1.80	-1.31	0.127	-1.56	-1.05	.
	Q300MG VS P	.	.	.	.	.	-1.30	0.173	-1.64	-0.96	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS239.SAS
GENERATED: 17NOV2005 13:32:40 iceadmn3

Table 11.2.1.10.4 MADRS Item 4 Score (Reduced Sleep) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-1.34	0.174	-1.68	-0.99	<.001
DAY 57	Q300MG	155	3.8	1.23	-2.8	1.72	-2.67	0.128	-2.93	-2.42	.
	Q600MG	151	3.6	1.23	-2.5	1.80	-2.54	0.130	-2.79	-2.28	.
	P	161	3.6	1.20	-1.4	1.85	-1.43	0.126	-1.68	-1.18	.
	Q300MG VS P	.	.	.	.	.	-1.24	0.176	-1.59	-0.90	<.001
	Q600MG VS P	.	.	.	.	.	-1.11	0.177	-1.46	-0.76	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS239.SAS
GENERATED: 17NOV2005 13:32:40 iceadmn3

Table 11.2.1.10.5 MADRS Item 5 Score (Reduced Appetite) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.7	1.65	-0.6	1.44	-0.51	0.106	-0.72	-0.30	.
	Q600MG	147	1.6	1.52	-0.6	1.53	-0.53	0.109	-0.75	-0.32	.
	P	161	1.5	1.45	-0.4	1.50	-0.44	0.105	-0.65	-0.23	.
	Q300MG VS P	.	.	.	.	.	-0.07	0.135	-0.34	0.19	0.598
	Q600MG VS P	.	.	.	.	.	-0.10	0.137	-0.36	0.17	0.481
DAY 15	Q300MG	155	1.7	1.65	-0.8	1.58	-0.74	0.103	-0.95	-0.54	.
	Q600MG	148	1.6	1.52	-0.8	1.47	-0.79	0.106	-1.00	-0.58	.
	P	161	1.5	1.45	-0.4	1.51	-0.50	0.102	-0.70	-0.30	.
	Q300MG VS P	.	.	.	.	.	-0.24	0.131	-0.50	0.01	0.064
	Q600MG VS P	.	.	.	.	.	-0.29	0.132	-0.55	-0.03	0.029
DAY 22	Q300MG	155	1.7	1.65	-0.9	1.60	-0.83	0.102	-1.03	-0.63	.
	Q600MG	150	1.6	1.52	-0.9	1.50	-0.89	0.104	-1.10	-0.68	.
	P	161	1.5	1.45	-0.5	1.69	-0.58	0.101	-0.78	-0.38	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.135	-0.52	0.01	0.059
	Q600MG VS P	.	.	.	.	.	-0.31	0.136	-0.58	-0.04	0.022
DAY 29	Q300MG	155	1.7	1.65	-0.9	1.73	-0.82	0.101	-1.02	-0.62	.
	Q600MG	150	1.6	1.52	-1.0	1.54	-0.97	0.103	-1.18	-0.77	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS240.SAS
GENERATED: 17NOV2005 13:32:43 iceadmn3

Table 11.2.1.10.5 MADRS Item 5 Score (Reduced Appetite) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	1.5	1.45	-0.5	1.74	-0.62	0.100	-0.82	-0.42	.
	Q300MG VS P	.	.	.	.	.	-0.20	0.137	-0.47	0.07	0.152
	Q600MG VS P	.	.	.	.	.	-0.35	0.138	-0.62	-0.08	0.011
DAY 36	Q300MG	155	1.7	1.65	-0.9	1.58	-0.84	0.096	-1.03	-0.65	.
	Q600MG	150	1.6	1.52	-1.0	1.60	-0.96	0.098	-1.16	-0.77	.
	P	161	1.5	1.45	-0.6	1.75	-0.68	0.095	-0.86	-0.49	.
	Q300MG VS P	.	.	.	.	.	-0.16	0.132	-0.42	0.10	0.220
	Q600MG VS P	.	.	.	.	.	-0.29	0.133	-0.55	-0.03	0.031
DAY 43	Q300MG	155	1.7	1.65	-1.0	1.68	-0.89	0.097	-1.08	-0.70	.
	Q600MG	151	1.6	1.51	-1.0	1.64	-0.95	0.098	-1.14	-0.76	.
	P	161	1.5	1.45	-0.6	1.72	-0.66	0.095	-0.85	-0.47	.
	Q300MG VS P	.	.	.	.	.	-0.23	0.133	-0.49	0.03	0.083
	Q600MG VS P	.	.	.	.	.	-0.29	0.134	-0.55	-0.03	0.030
DAY 50	Q300MG	155	1.7	1.65	-1.0	1.68	-0.92	0.098	-1.11	-0.72	.
	Q600MG	151	1.6	1.51	-1.0	1.64	-0.96	0.099	-1.15	-0.76	.
	P	161	1.5	1.45	-0.6	1.64	-0.70	0.097	-0.89	-0.51	.
	Q300MG VS P	.	.	.	.	.	-0.22	0.133	-0.48	0.04	0.102

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS240.SAS
GENERATED: 17NOV2005 13:32:43 iceadmn3

Table 11.2.1.10.5 MADRS Item 5 Score (Reduced Appetite) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.26	0.134	-0.52	0.01	0.056
DAY 57	Q300MG	155	1.7	1.65	-1.0	1.72	-0.93	0.098	-1.12	-0.73	.
	Q600MG	151	1.6	1.51	-1.0	1.60	-1.00	0.099	-1.19	-0.80	.
	P	161	1.5	1.45	-0.6	1.76	-0.72	0.097	-0.92	-0.53	.
	Q300MG VS P	.	.	.	.	.	-0.20	0.134	-0.47	0.06	0.127
	Q600MG VS P	.	.	.	.	.	-0.27	0.134	-0.54	-0.01	0.043

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS240.SAS
GENERATED: 17NOV2005 13:32:43 iceadmn3

Table 11.2.1.10.6 MADRS Item 6 Score (Concentration Difficulties) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.4	1.05	-0.8	1.36	-0.73	0.114	-0.96	-0.51	.
	Q600MG	147	3.3	1.01	-0.8	1.30	-0.78	0.117	-1.01	-0.55	.
	P	161	3.3	1.08	-0.5	1.29	-0.53	0.113	-0.76	-0.31	.
	Q300MG VS P	.	.	.	.	.	-0.20	0.133	-0.46	0.06	0.135
	Q600MG VS P	.	.	.	.	.	-0.24	0.135	-0.51	0.02	0.071
DAY 15	Q300MG	155	3.4	1.05	-1.2	1.61	-1.16	0.123	-1.40	-0.92	.
	Q600MG	148	3.3	1.01	-1.0	1.49	-1.03	0.126	-1.28	-0.78	.
	P	161	3.3	1.08	-0.9	1.34	-0.86	0.122	-1.10	-0.62	.
	Q300MG VS P	.	.	.	.	.	-0.30	0.149	-0.59	-0.01	0.046
	Q600MG VS P	.	.	.	.	.	-0.16	0.151	-0.46	0.13	0.276
DAY 22	Q300MG	155	3.4	1.05	-1.5	1.66	-1.40	0.128	-1.65	-1.14	.
	Q600MG	150	3.3	1.01	-1.3	1.41	-1.38	0.131	-1.64	-1.12	.
	P	161	3.3	1.08	-1.0	1.43	-1.01	0.127	-1.26	-0.76	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.149	-0.68	-0.09	0.010
	Q600MG VS P	.	.	.	.	.	-0.37	0.151	-0.66	-0.07	0.015
DAY 29	Q300MG	155	3.4	1.05	-1.6	1.63	-1.59	0.130	-1.85	-1.34	.
	Q600MG	150	3.3	1.01	-1.4	1.51	-1.45	0.133	-1.71	-1.19	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS241.SAS
GENERATED: 17NOV2005 13:32:46 iceadmn3

Table 11.2.1.10.6 MADRS Item 6 Score (Concentration Difficulties) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.3	1.08	-1.1	1.55	-1.15	0.130	-1.41	-0.89	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.154	-0.75	-0.14	0.004
	Q600MG VS P	.	.	.	.	.	-0.30	0.156	-0.61	0.01	0.054
DAY 36	Q300MG	155	3.4	1.05	-1.8	1.72	-1.72	0.129	-1.97	-1.46	.
	Q600MG	150	3.3	1.01	-1.5	1.47	-1.54	0.132	-1.80	-1.27	.
	P	161	3.3	1.08	-1.1	1.54	-1.16	0.129	-1.42	-0.91	.
	Q300MG VS P	.	.	.	.	.	-0.55	0.155	-0.86	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.37	0.156	-0.68	-0.06	0.018
DAY 43	Q300MG	155	3.4	1.05	-1.9	1.71	-1.78	0.129	-2.04	-1.53	.
	Q600MG	151	3.3	1.01	-1.6	1.53	-1.58	0.131	-1.84	-1.32	.
	P	161	3.3	1.08	-1.2	1.61	-1.18	0.128	-1.43	-0.93	.
	Q300MG VS P	.	.	.	.	.	-0.61	0.159	-0.92	-0.29	<.001
	Q600MG VS P	.	.	.	.	.	-0.41	0.161	-0.72	-0.09	0.012
DAY 50	Q300MG	155	3.4	1.05	-1.7	1.75	-1.61	0.139	-1.88	-1.33	.
	Q600MG	151	3.3	1.01	-1.6	1.56	-1.63	0.142	-1.91	-1.34	.
	P	161	3.3	1.08	-1.2	1.53	-1.19	0.138	-1.46	-0.91	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.159	-0.74	-0.11	0.008

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS241.SAS
GENERATED: 17NOV2005 13:32:46 iceadmn3

Table 11.2.1.10.6 MADRS Item 6 Score (Concentration Difficulties) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.44	0.160	-0.75	-0.13	0.006
DAY 57	Q300MG	155	3.4	1.05	-1.7	1.72	-1.62	0.135	-1.89	-1.35	.
	Q600MG	151	3.3	1.01	-1.7	1.60	-1.75	0.138	-2.02	-1.48	.
	P	161	3.3	1.08	-1.2	1.52	-1.20	0.134	-1.46	-0.93	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.159	-0.74	-0.11	0.008
	Q600MG VS P	.	.	.	.	.	-0.55	0.161	-0.87	-0.24	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS241.SAS
GENERATED: 17NOV2005 13:32:46 iceadmn3

Table 11.2.1.10.7 MADRS Item 7 Score (Lassitude) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.6	1.07	-0.8	1.43	-0.73	0.120	-0.97	-0.49	.
	Q600MG	147	3.4	1.16	-0.7	1.27	-0.78	0.123	-1.03	-0.54	.
	P	161	3.3	1.11	-0.6	1.42	-0.68	0.119	-0.92	-0.45	.
	Q300MG VS P	.	.	.	.	.	-0.05	0.140	-0.32	0.23	0.732
	Q600MG VS P	.	.	.	.	.	-0.10	0.141	-0.38	0.18	0.476
DAY 15	Q300MG	155	3.6	1.08	-1.2	1.62	-1.13	0.128	-1.39	-0.88	.
	Q600MG	148	3.4	1.16	-1.0	1.48	-1.12	0.132	-1.38	-0.86	.
	P	161	3.3	1.11	-1.0	1.46	-1.08	0.128	-1.33	-0.82	.
	Q300MG VS P	.	.	.	.	.	-0.06	0.149	-0.35	0.24	0.699
	Q600MG VS P	.	.	.	.	.	-0.05	0.151	-0.34	0.25	0.762
DAY 22	Q300MG	155	3.6	1.08	-1.4	1.66	-1.32	0.125	-1.57	-1.07	.
	Q600MG	150	3.4	1.16	-1.1	1.46	-1.22	0.128	-1.47	-0.96	.
	P	161	3.3	1.11	-1.2	1.59	-1.27	0.124	-1.52	-1.03	.
	Q300MG VS P	.	.	.	.	.	-0.05	0.155	-0.35	0.26	0.762
	Q600MG VS P	.	.	.	.	.	0.06	0.156	-0.25	0.36	0.711
DAY 29	Q300MG	155	3.6	1.08	-1.5	1.76	-1.45	0.131	-1.71	-1.19	.
	Q600MG	150	3.4	1.16	-1.3	1.54	-1.39	0.134	-1.65	-1.12	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS242.SAS
GENERATED: 17NOV2005 13:32:49 iceadmn3

Table 11.2.1.10.7 MADRS Item 7 Score (Lassitude) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.3	1.11	-1.1	1.58	-1.19	0.130	-1.45	-0.93	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.162	-0.58	0.06	0.112
	Q600MG VS P	.	.	.	.	.	-0.20	0.163	-0.52	0.13	0.231
DAY 36	Q300MG	155	3.6	1.08	-1.7	1.71	-1.64	0.131	-1.90	-1.38	.
	Q600MG	150	3.4	1.16	-1.4	1.55	-1.52	0.134	-1.78	-1.25	.
	P	161	3.3	1.11	-1.2	1.67	-1.30	0.131	-1.56	-1.04	.
	Q300MG VS P	.	.	.	.	.	-0.34	0.161	-0.66	-0.02	0.035
	Q600MG VS P	.	.	.	.	.	-0.22	0.162	-0.53	0.10	0.185
DAY 43	Q300MG	155	3.6	1.08	-1.9	1.77	-1.73	0.134	-1.99	-1.46	.
	Q600MG	151	3.4	1.15	-1.5	1.58	-1.54	0.137	-1.81	-1.27	.
	P	161	3.3	1.11	-1.3	1.78	-1.35	0.134	-1.61	-1.08	.
	Q300MG VS P	.	.	.	.	.	-0.38	0.168	-0.71	-0.05	0.024
	Q600MG VS P	.	.	.	.	.	-0.19	0.169	-0.52	0.14	0.257
DAY 50	Q300MG	155	3.6	1.08	-1.9	1.74	-1.73	0.138	-2.01	-1.46	.
	Q600MG	151	3.4	1.15	-1.5	1.52	-1.52	0.141	-1.80	-1.24	.
	P	161	3.3	1.11	-1.3	1.73	-1.34	0.138	-1.61	-1.07	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.165	-0.72	-0.07	0.018

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS242.SAS
GENERATED: 17NOV2005 13:32:49 iceadmn3

Table 11.2.1.10.7 MADRS Item 7 Score (Lassitude) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.18	0.166	-0.50	0.15	0.290
DAY 57	Q300MG	155	3.6	1.08	-1.9	1.77	-1.78	0.142	-2.06	-1.50	.
	Q600MG	151	3.4	1.15	-1.6	1.58	-1.61	0.145	-1.89	-1.32	.
	P	161	3.3	1.11	-1.2	1.73	-1.29	0.142	-1.57	-1.00	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.170	-0.83	-0.16	0.004
	Q600MG VS P	.	.	.	.	.	-0.32	0.171	-0.66	0.02	0.064

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS242.SAS
GENERATED: 17NOV2005 13:32:49 iceadmn3

Table 11.2.1.10.8 MADRS Item 8 Score (Inability to Feel) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.5	1.03	-0.9	1.39	-0.84	0.120	-1.08	-0.61	.
	Q600MG	147	3.5	0.97	-0.9	1.28	-0.87	0.123	-1.12	-0.63	.
	P	161	3.4	0.99	-0.7	1.22	-0.72	0.119	-0.95	-0.48	.
	Q300MG VS P	.	.	.	.	.	-0.13	0.133	-0.39	0.13	0.333
	Q600MG VS P	.	.	.	.	.	-0.16	0.135	-0.42	0.11	0.238
DAY 15	Q300MG	155	3.5	1.03	-1.4	1.61	-1.36	0.136	-1.63	-1.09	.
	Q600MG	148	3.5	0.97	-1.4	1.38	-1.42	0.139	-1.69	-1.14	.
	P	161	3.4	0.99	-0.9	1.29	-1.02	0.136	-1.29	-0.75	.
	Q300MG VS P	.	.	.	.	.	-0.34	0.142	-0.62	-0.06	0.017
	Q600MG VS P	.	.	.	.	.	-0.40	0.144	-0.68	-0.11	0.006
DAY 22	Q300MG	155	3.5	1.03	-1.7	1.65	-1.69	0.142	-1.97	-1.41	.
	Q600MG	150	3.5	0.97	-1.5	1.41	-1.51	0.145	-1.79	-1.22	.
	P	161	3.4	0.99	-1.1	1.57	-1.19	0.142	-1.47	-0.90	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.155	-0.81	-0.20	0.001
	Q600MG VS P	.	.	.	.	.	-0.32	0.157	-0.63	-0.01	0.041
DAY 29	Q300MG	155	3.5	1.03	-1.6	1.67	-1.56	0.149	-1.86	-1.27	.
	Q600MG	150	3.5	0.97	-1.7	1.53	-1.74	0.152	-2.04	-1.44	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS243.SAS
GENERATED: 17NOV2005 13:32:52 iceadmn3

Table 11.2.1.10.8 MADRS Item 8 Score (Inability to Feel) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.4	0.99	-1.2	1.60	-1.33	0.149	-1.63	-1.04	.
	Q300MG VS P	.	.	.	.	.	-0.23	0.161	-0.55	0.09	0.153
	Q600MG VS P	.	.	.	.	.	-0.41	0.163	-0.73	-0.09	0.013
DAY 36	Q300MG	155	3.5	1.03	-2.0	1.65	-1.92	0.143	-2.20	-1.63	.
	Q600MG	150	3.5	0.97	-1.7	1.55	-1.68	0.146	-1.97	-1.39	.
	P	161	3.4	0.99	-1.3	1.69	-1.32	0.143	-1.61	-1.04	.
	Q300MG VS P	.	.	.	.	.	-0.59	0.163	-0.92	-0.27	<.001
	Q600MG VS P	.	.	.	.	.	-0.36	0.165	-0.68	-0.03	0.031
DAY 43	Q300MG	155	3.5	1.03	-1.9	1.71	-1.84	0.144	-2.12	-1.55	.
	Q600MG	151	3.5	0.97	-1.8	1.53	-1.80	0.147	-2.09	-1.51	.
	P	161	3.4	0.99	-1.4	1.62	-1.37	0.144	-1.65	-1.08	.
	Q300MG VS P	.	.	.	.	.	-0.47	0.164	-0.79	-0.15	0.004
	Q600MG VS P	.	.	.	.	.	-0.44	0.166	-0.76	-0.11	0.009
DAY 50	Q300MG	155	3.5	1.03	-1.9	1.68	-1.87	0.150	-2.17	-1.57	.
	Q600MG	151	3.5	0.97	-1.8	1.55	-1.82	0.153	-2.12	-1.51	.
	P	161	3.4	0.99	-1.5	1.70	-1.52	0.150	-1.81	-1.22	.
	Q300MG VS P	.	.	.	.	.	-0.35	0.165	-0.68	-0.03	0.032

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS243.SAS
GENERATED: 17NOV2005 13:32:52 iceadmn3

Table 11.2.1.10.8 MADRS Item 8 Score (Inability to Feel) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.30	0.167	-0.63	0.03	0.071
DAY 57	Q300MG	155	3.5	1.03	-2.0	1.70	-1.94	0.151	-2.24	-1.64	.
	Q600MG	151	3.5	0.97	-1.9	1.56	-1.86	0.154	-2.16	-1.55	.
	P	161	3.4	0.99	-1.5	1.69	-1.50	0.151	-1.80	-1.20	.
	Q300MG VS P	.	.	.	.	.	-0.44	0.167	-0.77	-0.11	0.009
	Q600MG VS P	.	.	.	.	.	-0.35	0.169	-0.69	-0.02	0.037

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS243.SAS
GENERATED: 17NOV2005 13:32:52 iceadmn3

Table 11.2.1.10.9 MADRS Item 9 Score (Pessimistic Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.1	1.08	-0.9	1.25	-0.85	0.107	-1.06	-0.64	.
	Q600MG	147	3.0	1.03	-0.8	1.16	-0.80	0.109	-1.02	-0.58	.
	P	161	2.9	1.12	-0.5	1.26	-0.64	0.106	-0.85	-0.43	.
	Q300MG VS P	.	.	.	.	.	-0.21	0.124	-0.45	0.04	0.093
	Q600MG VS P	.	.	.	.	.	-0.16	0.125	-0.41	0.09	0.200
DAY 15	Q300MG	155	3.1	1.08	-1.4	1.37	-1.30	0.123	-1.54	-1.06	.
	Q600MG	148	2.9	1.03	-1.0	1.44	-1.08	0.126	-1.33	-0.83	.
	P	161	2.9	1.12	-0.7	1.35	-0.87	0.123	-1.12	-0.63	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.133	-0.69	-0.17	0.001
	Q600MG VS P	.	.	.	.	.	-0.21	0.134	-0.47	0.05	0.119
DAY 22	Q300MG	155	3.1	1.08	-1.5	1.41	-1.43	0.123	-1.67	-1.19	.
	Q600MG	150	2.9	1.03	-1.2	1.42	-1.24	0.126	-1.49	-0.99	.
	P	161	2.9	1.12	-0.9	1.51	-1.02	0.123	-1.26	-0.78	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.140	-0.69	-0.13	0.004
	Q600MG VS P	.	.	.	.	.	-0.22	0.141	-0.50	0.06	0.122
DAY 29	Q300MG	155	3.1	1.08	-1.6	1.45	-1.56	0.130	-1.82	-1.30	.
	Q600MG	150	2.9	1.03	-1.3	1.51	-1.36	0.133	-1.62	-1.09	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS244.SAS
GENERATED: 17NOV2005 13:32:55 iceadmn3

Table 11.2.1.10.9 MADRS Item 9 Score (Pessimistic Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	2.9	1.12	-1.0	1.60	-1.11	0.130	-1.36	-0.85	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.146	-0.74	-0.17	0.002
	Q600MG VS P	.	.	.	.	.	-0.25	0.147	-0.54	0.04	0.088
DAY 36	Q300MG	155	3.1	1.08	-1.7	1.52	-1.59	0.129	-1.85	-1.33	.
	Q600MG	150	2.9	1.03	-1.3	1.56	-1.34	0.132	-1.60	-1.08	.
	P	161	2.9	1.12	-1.1	1.58	-1.17	0.129	-1.43	-0.92	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.151	-0.71	-0.12	0.006
	Q600MG VS P	.	.	.	.	.	-0.17	0.152	-0.47	0.13	0.269
DAY 43	Q300MG	155	3.1	1.08	-1.7	1.47	-1.65	0.121	-1.89	-1.41	.
	Q600MG	151	3.0	1.04	-1.4	1.54	-1.47	0.123	-1.72	-1.23	.
	P	161	2.9	1.12	-1.1	1.52	-1.24	0.120	-1.48	-1.00	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.146	-0.70	-0.12	0.005
	Q600MG VS P	.	.	.	.	.	-0.23	0.147	-0.52	0.06	0.115
DAY 50	Q300MG	155	3.1	1.08	-1.8	1.50	-1.72	0.126	-1.97	-1.47	.
	Q600MG	151	3.0	1.04	-1.5	1.52	-1.49	0.129	-1.74	-1.23	.
	P	161	2.9	1.12	-1.2	1.58	-1.30	0.126	-1.55	-1.05	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.147	-0.72	-0.14	0.004

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS244.SAS
GENERATED: 17NOV2005 13:32:55 iceadmn3

Table 11.2.1.10.9 MADRS Item 9 Score (Pessimistic Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.19	0.148	-0.48	0.10	0.192
DAY 57	Q300MG	155	3.1	1.08	-1.8	1.49	-1.72	0.129	-1.98	-1.47	.
	Q600MG	151	3.0	1.04	-1.5	1.55	-1.48	0.131	-1.74	-1.22	.
	P	161	2.9	1.12	-1.2	1.62	-1.29	0.128	-1.54	-1.04	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.154	-0.73	-0.13	0.005
	Q600MG VS P	.	.	.	.	.	-0.19	0.155	-0.49	0.12	0.227

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS244.SAS
GENERATED: 17NOV2005 13:32:55 iceadmn3

Table 11.2.1.10.10 MADRS Item 10 Score (Suicidal Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.2	1.08	-0.5	0.98	-0.49	0.073	-0.63	-0.34	.
	Q600MG	147	1.2	1.05	-0.5	0.98	-0.47	0.075	-0.62	-0.32	.
	P	161	1.1	1.08	-0.3	0.99	-0.33	0.072	-0.47	-0.19	.
	Q300MG VS P	.	.	.	.	.	-0.16	0.091	-0.34	0.02	0.083
	Q600MG VS P	.	.	.	.	.	-0.14	0.092	-0.32	0.04	0.125
DAY 15	Q300MG	155	1.2	1.08	-0.7	1.09	-0.64	0.080	-0.80	-0.48	.
	Q600MG	148	1.2	1.04	-0.6	1.14	-0.59	0.082	-0.76	-0.43	.
	P	161	1.1	1.08	-0.4	1.02	-0.42	0.080	-0.58	-0.26	.
	Q300MG VS P	.	.	.	.	.	-0.22	0.095	-0.40	-0.03	0.023
	Q600MG VS P	.	.	.	.	.	-0.17	0.096	-0.36	0.02	0.074
DAY 22	Q300MG	155	1.2	1.08	-0.7	1.12	-0.68	0.075	-0.83	-0.54	.
	Q600MG	150	1.2	1.04	-0.6	1.05	-0.65	0.076	-0.80	-0.50	.
	P	161	1.1	1.08	-0.3	1.06	-0.40	0.074	-0.55	-0.25	.
	Q300MG VS P	.	.	.	.	.	-0.28	0.093	-0.47	-0.10	0.003
	Q600MG VS P	.	.	.	.	.	-0.25	0.094	-0.43	-0.06	0.009
DAY 29	Q300MG	155	1.2	1.08	-0.8	1.07	-0.73	0.077	-0.89	-0.58	.
	Q600MG	150	1.2	1.04	-0.6	1.03	-0.64	0.078	-0.80	-0.49	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS245.SAS
GENERATED: 17NOV2005 13:32:58 iceadmn3

Table 11.2.1.10.10 MADRS Item 10 Score (Suicidal Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	1.1	1.08	-0.4	1.13	-0.43	0.076	-0.58	-0.27	.
	Q300MG VS P	.	.	.	.	.	-0.31	0.094	-0.49	-0.13	0.001
	Q600MG VS P	.	.	.	.	.	-0.22	0.095	-0.40	-0.03	0.021
DAY 36	Q300MG	155	1.2	1.08	-0.7	1.02	-0.69	0.076	-0.84	-0.54	.
	Q600MG	150	1.2	1.04	-0.7	1.04	-0.67	0.078	-0.83	-0.52	.
	P	161	1.1	1.08	-0.4	1.26	-0.44	0.076	-0.59	-0.29	.
	Q300MG VS P	.	.	.	.	.	-0.25	0.098	-0.44	-0.06	0.011
	Q600MG VS P	.	.	.	.	.	-0.23	0.099	-0.43	-0.04	0.019
DAY 43	Q300MG	155	1.2	1.08	-0.7	1.05	-0.69	0.076	-0.84	-0.54	.
	Q600MG	151	1.2	1.04	-0.6	1.12	-0.63	0.077	-0.78	-0.48	.
	P	161	1.1	1.08	-0.5	1.14	-0.53	0.075	-0.68	-0.39	.
	Q300MG VS P	.	.	.	.	.	-0.16	0.097	-0.35	0.04	0.110
	Q600MG VS P	.	.	.	.	.	-0.10	0.098	-0.29	0.10	0.324
DAY 50	Q300MG	155	1.2	1.08	-0.8	1.11	-0.75	0.075	-0.90	-0.60	.
	Q600MG	151	1.2	1.04	-0.6	1.13	-0.61	0.077	-0.77	-0.46	.
	P	161	1.1	1.08	-0.5	1.21	-0.55	0.074	-0.70	-0.40	.
	Q300MG VS P	.	.	.	.	.	-0.20	0.097	-0.39	-0.01	0.039

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS245.SAS
GENERATED: 17NOV2005 13:32:58 iceadmn3

Table 11.2.1.10.10 MADRS Item 10 Score (Suicidal Thoughts) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.06	0.098	-0.26	0.13	0.517
DAY 57	Q300MG	155	1.2	1.08	-0.8	1.17	-0.77	0.074	-0.92	-0.63	.
	Q600MG	151	1.2	1.04	-0.6	1.09	-0.63	0.075	-0.78	-0.49	.
	P	161	1.1	1.08	-0.5	1.12	-0.54	0.073	-0.68	-0.39	.
	Q300MG VS P	.	.	.	.	.	-0.24	0.097	-0.43	-0.05	0.014
	Q600MG VS P	.	.	.	.	.	-0.10	0.097	-0.29	0.09	0.311

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS245.SAS
GENERATED: 17NOV2005 13:32:58 iceadmn3

Table 11.2.1.11 MADRS Total Score Responder Summary (Criteria Reduction from Baseline)
Last Observation Carried Forward
Intent-to-Treat Population

RESPONSE RATE	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=155		N=151		N=161	
	N	%	N	%	N	%
>=70%	71	45.8	55	36.4	39	24.2
>=60%	83	53.5	70	46.4	59	36.6
>=50%	93	60.0	88	58.3	72	44.7
>=40%	103	66.5	100	66.2	82	50.9
>=30%	112	72.3	113	74.8	93	57.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS212.SAS
GENERATED: 17NOV2005 13:51:03 iceadmn3

Table 11.2.1.12.1 MADRS Response (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 8	BIPOLAR I	19	102	18.6	21	98	21.4	16	110	14.5	.	.	.	.
	BIPOLAR II	12	51	23.5	11	49	22.4	8	51	15.7	.	.	.	.
	ALL	31	153	20.3	32	147	21.8	24	161	14.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.218	1.36	0.83	2.20
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.121	1.46	0.90	2.36
DAY 15	BIPOLAR I	40	104	38.5	38	99	38.4	24	110	21.8	.	.	.	.
	BIPOLAR II	22	51	43.1	16	49	32.7	14	51	27.5	.	.	.	.
	ALL	62	155	40.0	54	148	36.5	38	161	23.6	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.69	1.21	2.37
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.014	1.54	1.09	2.19
DAY 22	BIPOLAR I	54	104	51.9	48	101	47.5	33	110	30.0	.	.	.	.
	BIPOLAR II	27	51	52.9	23	49	46.9	14	51	27.5	.	.	.	.
	ALL	81	155	52.3	71	150	47.3	47	161	29.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.79	1.35	2.38
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.001	1.62	1.21	2.18
DAY 29	BIPOLAR I	51	104	49.0	49	101	48.5	36	110	32.7	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/STAT/MADRS226.SAS
GENERATED: 17NOV2005 13:32:05 iceadmn3

Table 11.2.1.12.1 MADRS Response (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	29	51	56.9	25	49	51.0	19	51	37.3	.	.	.	.
	ALL	80	155	51.6	74	150	49.3	55	161	34.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.51	1.16	1.96
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.007	1.44	1.10	1.89
DAY 36	BIPOLAR I	59	104	56.7	50	101	49.5	45	110	40.9	.	.	.	.
	BIPOLAR II	30	51	58.8	21	49	42.9	20	51	39.2	.	.	.	.
	ALL	89	155	57.4	71	150	47.3	65	161	40.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.003	1.42	1.13	1.79
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.215	1.17	0.91	1.51
DAY 43	BIPOLAR I	61	104	58.7	57	101	56.4	49	110	44.5	.	.	.	.
	BIPOLAR II	31	51	60.8	25	50	50.0	18	51	35.3	.	.	.	.
	ALL	92	155	59.4	82	151	54.3	67	161	41.6	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.43	1.14	1.79
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.024	1.31	1.04	1.65
DAY 50	BIPOLAR I	59	104	56.7	56	101	55.4	47	110	42.7	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/STAT/MADRS226.SAS
GENERATED: 17NOV2005 13:32:05 iceadmn3

Table 11.2.1.12.1 MADRS Response (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	31	51	60.8	28	50	56.0	18	51	35.3	.	.	.	.
	ALL	90	155	58.1	84	151	55.6	65	161	40.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.44	1.14	1.81
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.007	1.38	1.09	1.75
DAY 57	BIPOLAR I	62	104	59.6	59	101	58.4	49	110	44.5	.	.	.	.
	BIPOLAR II	31	51	60.8	29	50	58.0	23	51	45.1	.	.	.	.
	ALL	93	155	60.0	88	151	58.3	72	161	44.7	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.007	1.34	1.08	1.66
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.017	1.30	1.05	1.62

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/STAT/MADRS226.SAS
GENERATED: 17NOV2005 13:32:05 iceadmn3

Table 11.2.1.12.2 MADRS Response (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)			
		Q300MG			Q600MG			P						
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	19	102	18.6	21	98	21.4	16	110	14.5	.	.	.	.
	BIPOLAR II	12	51	23.5	11	49	22.4	8	51	15.7	.	.	.	.
	ALL	31	153	20.3	32	147	21.8	24	161	14.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.218	1.36	0.83	2.20
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.121	1.46	0.90	2.36
DAY 15	BIPOLAR I	38	87	43.7	33	88	37.5	23	100	23.0	.	.	.	.
	BIPOLAR II	20	46	43.5	15	38	39.5	13	46	28.3	.	.	.	.
	ALL	58	133	43.6	48	126	38.1	36	146	24.7	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.76	1.25	2.48
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.017	1.55	1.08	2.22
DAY 22	BIPOLAR I	50	80	62.5	43	83	51.8	31	92	33.7	.	.	.	.
	BIPOLAR II	24	43	55.8	22	36	61.1	11	44	25.0	.	.	.	.
	ALL	74	123	60.2	65	119	54.6	42	136	30.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.96	1.47	2.62
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.77	1.31	2.38
DAY 29	BIPOLAR I	43	78	55.1	40	76	52.6	31	87	35.6	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS232.SAS
GENERATED: 17NOV2005 13:32:21 iceadmn3

Table 11.2.1.12.2 MADRS Response (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	23	39	59.0	22	33	66.7	19	46	41.3	.	.	.	.
	ALL	66	117	56.4	62	109	56.9	50	133	37.6	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.003	1.50	1.15	1.97
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.002	1.53	1.16	2.00
DAY 36	BIPOLAR I	50	74	67.6	38	71	53.5	41	81	50.6	.	.	.	.
	BIPOLAR II	24	37	64.9	18	33	54.5	20	43	46.5	.	.	.	.
	ALL	74	111	66.7	56	104	53.8	61	124	49.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.007	1.35	1.08	1.69
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.491	1.09	0.85	1.41
DAY 43	BIPOLAR I	46	63	73.0	43	64	67.2	42	76	55.3	.	.	.	.
	BIPOLAR II	23	35	65.7	21	33	63.6	15	38	39.5	.	.	.	.
	ALL	69	98	70.4	64	97	66.0	57	114	50.0	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.42	1.13	1.77
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.019	1.32	1.05	1.67
DAY 50	BIPOLAR I	45	65	69.2	38	58	65.5	39	75	52.0	.	.	.	.

(Continued)

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS232.SAS
GENERATED: 17NOV2005 13:32:21 iceadmn3

Table 11.2.1.12.2 MADRS Response (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	25	37	67.6	22	31	71.0	13	37	35.1	.	.	.	.
	ALL	70	102	68.6	60	89	67.4	52	112	46.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.49	1.17	1.89
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.003	1.46	1.14	1.87
DAY 57	BIPOLAR I	45	61	73.8	39	57	68.4	37	69	53.6	.	.	.	.
	BIPOLAR II	24	36	66.7	21	29	72.4	17	34	50.0	.	.	.	.
	ALL	69	97	71.1	60	86	69.8	54	103	52.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.006	1.36	1.09	1.70
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.016	1.33	1.06	1.68

MADRS Response is a decrease from baseline MADRS total score of >=50%.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS232.SAS
GENERATED: 17NOV2005 13:32:21 iceadmn3

Table 11.2.1.12.3 MADRS Response (CMH) at Final Assessment
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)			
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
EVENT	STRATA													
>=30% REDUCTION	BIPOLAR I	74	104	71.2	78	101	77.2	63	110	57.3	.	.	.	.
	BIPOLAR II	38	51	74.5	35	50	70.0	30	51	58.8	.	.	.	.
	ALL	112	155	72.3	113	151	74.8	93	161	57.8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.007	1.25	1.06	1.47
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.001	1.30	1.10	1.52
>=40% REDUCTION	BIPOLAR I	67	104	64.4	68	101	67.3	55	110	50.0	.	.	.	.
	BIPOLAR II	36	51	70.6	32	50	64.0	27	51	52.9	.	.	.	.
	ALL	103	155	66.5	100	151	66.2	82	161	50.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.005	1.30	1.08	1.57
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.006	1.30	1.08	1.57
>=50% REDUCTION	BIPOLAR I	62	104	59.6	59	101	58.4	49	110	44.5	.	.	.	.
	BIPOLAR II	31	51	60.8	29	50	58.0	23	51	45.1	.	.	.	.
	ALL	93	155	60.0	88	151	58.3	72	161	44.7	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.007	1.34	1.08	1.66
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.017	1.30	1.05	1.62
response60	BIPOLAR I	54	104	51.9	45	101	44.6	41	110	37.3	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS227.SAS
GENERATED: 17NOV2005 13:32:09 iceadmn3

Table 11.2.1.12.3 MADRS Response (CMH) at Final Assessment
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)		
		Q300MG			Q600MG			P					
EVENT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
response60	BIPOLAR II	29	51	56.9	25	50	50.0	18	51	35.3	.	.	.	.
	ALL	83	155	53.5	70	151	46.4	59	161	36.6	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.003	1.46	1.14	1.88
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.083	1.26	0.97	1.65
response70	BIPOLAR I	45	104	43.3	35	101	34.7	29	110	26.4	.	.	.	.
	BIPOLAR II	26	51	51.0	20	50	40.0	10	51	19.6	.	.	.	.
	ALL	71	155	45.8	55	151	36.4	39	161	24.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.89	1.37	2.62
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.019	1.51	1.06	2.13

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS227.SAS
GENERATED: 17NOV2005 13:32:09 iceadmn3

Table 11.2.1.12.4 MADRS Response (CMH) at Day 57
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)			
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
EVENT	STRATA													
>=30% REDUCTION	BIPOLAR I	53	61	86.9	49	57	86.0	46	69	66.7	.	.	.	.
	BIPOLAR II	28	36	77.8	24	29	82.8	23	34	67.6	.	.	.	.
	ALL	81	97	83.5	73	86	84.9	69	103	67.0	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.007	1.25	1.06	1.47
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.005	1.27	1.08	1.49
>=40% REDUCTION	BIPOLAR I	48	61	78.7	44	57	77.2	42	69	60.9	.	.	.	.
	BIPOLAR II	26	36	72.2	22	29	75.9	21	34	61.8	.	.	.	.
	ALL	74	97	76.3	66	86	76.7	63	103	61.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.021	1.25	1.03	1.51
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.023	1.25	1.03	1.52
>=50% REDUCTION	BIPOLAR I	45	61	73.8	39	57	68.4	37	69	53.6	.	.	.	.
	BIPOLAR II	24	36	66.7	21	29	72.4	17	34	50.0	.	.	.	.
	ALL	69	97	71.1	60	86	69.8	54	103	52.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.006	1.36	1.09	1.70
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.016	1.33	1.06	1.68
response60	BIPOLAR I	40	61	65.6	31	57	54.4	32	69	46.4	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS233.SAS
GENERATED: 17NOV2005 13:32:24 iceadmn3

Table 11.2.1.12.4 MADRS Response (CMH) at Day 57
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)			
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
EVENT	STRATA													
response60	BIPOLAR II	22	36	61.1	20	29	69.0	13	34	38.2	.	.	.	.
	ALL	62	97	63.9	51	86	59.3	45	103	43.7	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.004	1.47	1.13	1.92
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.034	1.36	1.02	1.80
response70	BIPOLAR I	36	61	59.0	26	57	45.6	22	69	31.9	.	.	.	.
	BIPOLAR II	20	36	55.6	17	29	58.6	7	34	20.6	.	.	.	.
	ALL	56	97	57.7	43	86	50.0	29	103	28.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	2.07	1.45	2.95
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.002	1.78	1.22	2.59

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS233.SAS
GENERATED: 17NOV2005 13:32:24 iceadmn3

Table 11.2.1.12.5 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 8	Q300MG VS P		.	.	.	0.742
		BIPOLAR I	1.2806	0.6972	2.3523	.
		BIPOLAR II	1.5000	0.6700	3.3584	.
	Q600MG VS P		.	.	.	0.963
		BIPOLAR I	1.4732	0.8161	2.6595	.
		BIPOLAR II	1.4311	0.6291	3.2559	.
DAY 15	Q300MG VS P		.	.	.	0.832
		BIPOLAR I	1.7628	1.1476	2.7078	.
		BIPOLAR II	1.5714	0.9101	2.7134	.
	Q600MG VS P		.	.	.	0.300
		BIPOLAR I	1.7593	1.1411	2.7124	.
		BIPOLAR II	1.1895	0.6524	2.1688	.
DAY 22	Q300MG VS P		.	.	.	0.745
		BIPOLAR I	1.7308	1.2318	2.4319	.
		BIPOLAR II	1.9286	1.1514	3.2302	.
	Q600MG VS P		.	.	.	0.844
		BIPOLAR I	1.5842	1.1148	2.2512	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS228.SAS
GENERATED: 17NOV2005 13:32:12 iceadmn3

Table 11.2.1.12.5 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 22	Q600MG VS P	BIPOLAR II	1.7099	1.0001	2.9236	.
DAY 29	Q300MG VS P		.	.	.	0.815
		BIPOLAR I	1.4984	1.0752	2.0882	.
		BIPOLAR II	1.5263	0.9939	2.3439	.
	Q600MG VS P		.	.	.	0.842
		BIPOLAR I	1.4824	1.0605	2.0721	.
		BIPOLAR II	1.3695	0.8736	2.1469	.
DAY 36	Q300MG VS P		.	.	.	0.750
		BIPOLAR I	1.3868	1.0477	1.8356	.
		BIPOLAR II	1.5000	0.9938	2.2640	.
	Q600MG VS P		.	.	.	0.689
		BIPOLAR I	1.2101	0.8976	1.6314	.
		BIPOLAR II	1.0929	0.6828	1.7493	.
DAY 43	Q300MG VS P		.	.	.	0.336
		BIPOLAR I	1.3167	1.0116	1.7139	.
		BIPOLAR II	1.7222	1.1180	2.6530	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS228.SAS
GENERATED: 17NOV2005 13:32:12 iceadmn3

Table 11.2.1.12.5 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Last Observation Carried Forward
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 43	Q600MG VS P		.	.	.	0.795
		BIPOLAR I	1.2669	0.9673	1.6594	.
		BIPOLAR II	1.4167	0.8911	2.2522	.
DAY 50	Q300MG VS P		.	.	.	0.331
		BIPOLAR I	1.3277	1.0097	1.7460	.
		BIPOLAR II	1.7222	1.1180	2.6530	.
	Q600MG VS P		.	.	.	0.497
		BIPOLAR I	1.2977	0.9826	1.7138	.
		BIPOLAR II	1.5867	1.0163	2.4772	.
DAY 57	Q300MG VS P		.	.	.	0.957
		BIPOLAR I	1.3383	1.0301	1.7387	.
		BIPOLAR II	1.3478	0.9268	1.9602	.
	Q600MG VS P		.	.	.	0.936
		BIPOLAR I	1.3114	1.0055	1.7103	.
		BIPOLAR II	1.2861	0.8761	1.8879	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS228.SAS
GENERATED: 17NOV2005 13:32:12 iceadmn3

Table 11.2.1.12.6 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Observed Cases
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 8	Q300MG VS P		.	.	.	0.742
		BIPOLAR I	1.2806	0.6972	2.3523	.
		BIPOLAR II	1.5000	0.6700	3.3584	.
	Q600MG VS P		.	.	.	0.963
		BIPOLAR I	1.4732	0.8161	2.6595	.
		BIPOLAR II	1.4311	0.6291	3.2559	.
DAY 15	Q300MG VS P		.	.	.	0.602
		BIPOLAR I	1.8991	1.2344	2.9215	.
		BIPOLAR II	1.5385	0.8734	2.7100	.
	Q600MG VS P		.	.	.	0.733
		BIPOLAR I	1.6304	1.0409	2.5538	.
		BIPOLAR II	1.3968	0.7621	2.5599	.
DAY 22	Q300MG VS P		.	.	.	0.798
		BIPOLAR I	1.8548	1.3293	2.5881	.
		BIPOLAR II	2.2326	1.2541	3.9745	.
	Q600MG VS P		.	.	.	0.165
		BIPOLAR I	1.5375	1.0793	2.1903	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS234.SAS
GENERATED: 17NOV2005 13:32:27 iceadmn3

Table 11.2.1.12.6 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Observed Cases
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 22	Q600MG VS P	BIPOLAR II	2.4444	1.3765	4.3411	.
DAY 29	Q300MG VS P		.	.	.	0.879
		BIPOLAR I	1.5471	1.0944	2.1872	.
		BIPOLAR II	1.4278	0.9263	2.2007	.
	Q600MG VS P		.	.	.	0.544
		BIPOLAR I	1.4771	1.0368	2.1043	.
		BIPOLAR II	1.6140	1.0599	2.4579	.
DAY 36	Q300MG VS P		.	.	.	0.939
		BIPOLAR I	1.3349	1.0223	1.7431	.
		BIPOLAR II	1.3946	0.9360	2.0778	.
	Q600MG VS P		.	.	.	0.717
		BIPOLAR I	1.0574	0.7791	1.4350	.
		BIPOLAR II	1.1727	0.7501	1.8336	.
DAY 43	Q300MG VS P		.	.	.	0.629
		BIPOLAR I	1.3212	1.0270	1.6997	.
		BIPOLAR II	1.6648	1.0502	2.6390	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS234.SAS
GENERATED: 17NOV2005 13:32:27 iceadmn3

Table 11.2.1.12.6 MADRS Response - Homogeneity Across Diagnosis (Breslow-Day Test)
Observed Cases
Intent-to-Treat Population

VISIT	COMPARISON	STRATA	RELATIVE RISK	95% CONFIDENCE INTERVAL LOWER	95% CONFIDENCE INTERVAL UPPER	P-VALUE
DAY 43	Q600MG VS P		.	.	.	0.425
		BIPOLAR I	1.2158	0.9327	1.5847	.
		BIPOLAR II	1.6121	1.0069	2.5811	.
DAY 50	Q300MG VS P		.	.	.	0.309
		BIPOLAR I	1.3314	1.0151	1.7461	.
		BIPOLAR II	1.9231	1.1764	3.1436	.
	Q600MG VS P		.	.	.	0.136
		BIPOLAR I	1.2599	0.9460	1.6781	.
		BIPOLAR II	2.0199	1.2346	3.3047	.
DAY 57	Q300MG VS P		.	.	.	0.753
		BIPOLAR I	1.3757	1.0548	1.7942	.
		BIPOLAR II	1.3333	0.8868	2.0048	.
	Q600MG VS P		.	.	.	0.607
		BIPOLAR I	1.2760	0.9629	1.6908	.
		BIPOLAR II	1.4483	0.9667	2.1699	.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS234.SAS
GENERATED: 17NOV2005 13:32:27 iceadmn3

FIGURE 11.2.1.13 PERCENT OF PATIENTS RESPONDING (50% REDUCTION IN MADRS)

(LAST OBSERVATION CARRIED FORWARD- INTENT TO TREAT)

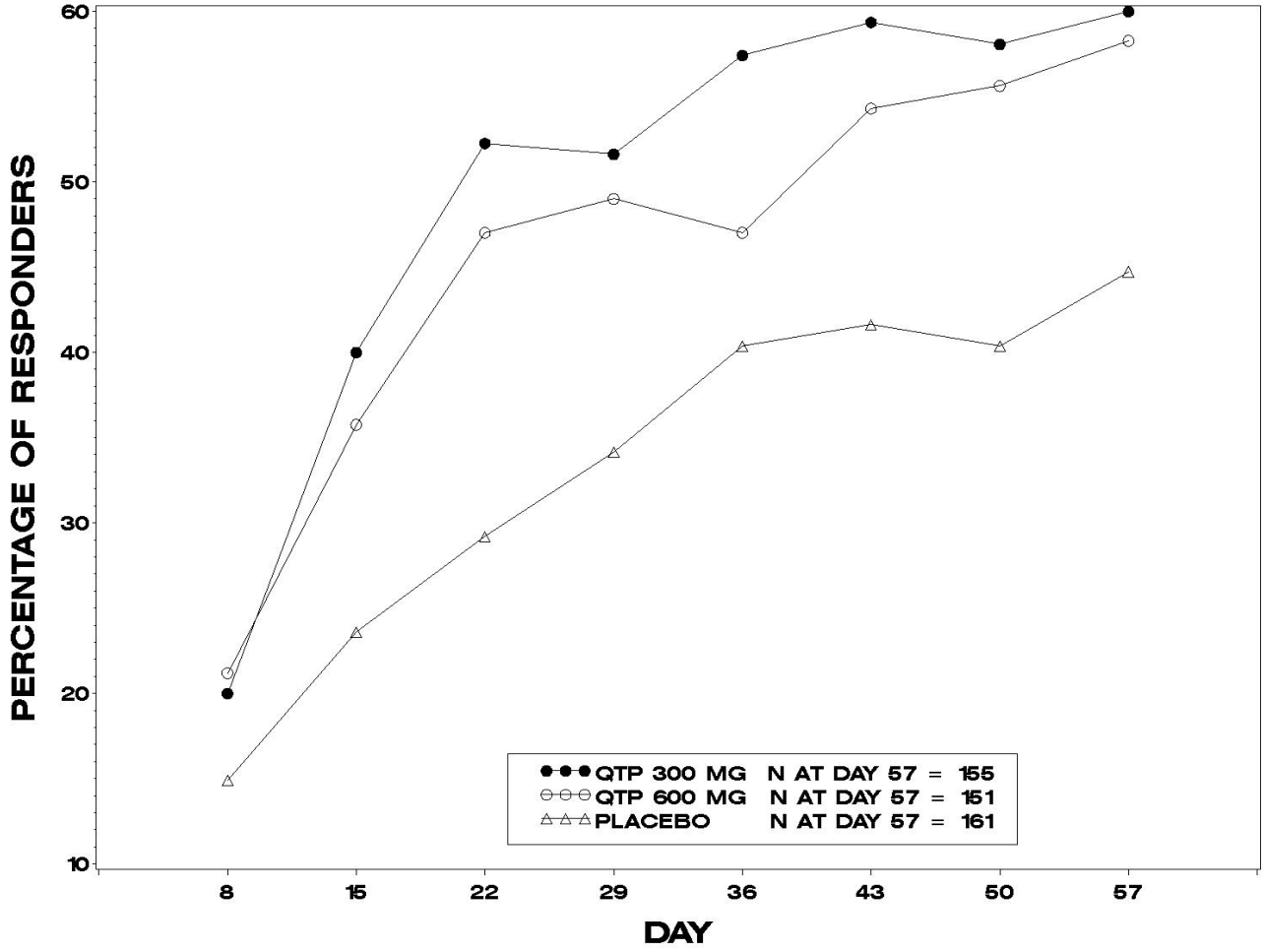

Table 11.2.1.14 MADRS Total Score Response of >=50% and Remission Rate
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		N	%	N	%	N	%
Response Rate >=50%	WINDOWED VISIT						
	DAY 8	31	20.0	32	21.2	24	14.9
	DAY 15	62	40.0	54	35.8	38	23.6
	DAY 22	81	52.3	71	47.0	47	29.2
	DAY 29	80	51.6	74	49.0	55	34.2
	DAY 36	89	57.4	71	47.0	65	40.4
	DAY 43	92	59.4	82	54.3	67	41.6
	DAY 50	90	58.1	84	55.6	65	40.4
	DAY 57	93	60.0	88	58.3	72	44.7
Remission Total Score <=8	DAY 8	12	7.7	10	6.6	8	5.0
	DAY 15	23	14.8	25	16.6	16	9.9
	DAY 22	36	23.2	34	22.5	22	13.7
	DAY 29	39	25.2	45	29.8	29	18.0
	DAY 36	48	31.0	44	29.1	29	18.0
	DAY 43	57	36.8	51	33.8	36	22.4

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS235.SAS
GENERATED: 17NOV2005 13:51:33 iceadmn3

Table 11.2.1.14 MADRS Total Score Response of >=50% and Remission Rate
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		N	%	N	%	N	%
Remission Total Score <=8	WINDOWED VISIT						
	DAY 50	59	38.1	50	33.1	36	22.4
	DAY 57	66	42.6	57	37.7	33	20.5
Remission Total Score <=10	DAY 8	19	12.3	14	9.3	12	7.5
	DAY 15	32	20.6	35	23.2	23	14.3
	DAY 22	48	31.0	48	31.8	32	19.9
	DAY 29	48	31.0	55	36.4	35	21.7
	DAY 36	59	38.1	56	37.1	34	21.1
	DAY 43	66	42.6	61	40.4	49	30.4
	DAY 50	70	45.2	60	39.7	46	28.6
	DAY 57	75	48.4	66	43.7	49	30.4
Remission Total Score <=12	DAY 8	23	14.8	24	15.9	18	11.2
	DAY 15	43	27.7	40	26.5	29	18.0
	DAY 22	64	41.3	56	37.1	36	22.4
	DAY 29	65	41.9	63	41.7	47	29.2

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS235.SAS
GENERATED: 17NOV2005 13:51:33 iceadmn3

Table 11.2.1.14 MADRS Total Score Response of >=50% and Remission Rate
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=155		N=151		N=161	
		N	%	N	%	N	%
Remission Total Score <=12	WINDOWED VISIT						
	DAY 36	73	47.1	64	42.4	44	27.3
	DAY 43	79	51.0	71	47.0	56	34.8
	DAY 50	76	49.0	73	48.3	53	32.9
	DAY 57	80	51.6	79	52.3	60	37.3

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS235.SAS
GENERATED: 17NOV2005 13:51:33 iceadmn3

Table 11.2.1.15.1 MADRS Remission Rate (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)			
		Q300MG			Q600MG			P						
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	12	102	11.8	17	98	17.3	10	110	9.1	.	.	.	.
	BIPOLAR II	11	51	21.6	7	49	14.3	8	51	15.7	.	.	.	.
	ALL	23	153	15.0	24	147	16.3	18	161	11.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.327	1.33	0.75	2.36
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.193	1.46	0.82	2.57
DAY 15	BIPOLAR I	23	104	22.1	27	99	27.3	17	110	15.5	.	.	.	.
	BIPOLAR II	20	51	39.2	13	49	26.5	12	51	23.5	.	.	.	.
	ALL	43	155	27.7	40	148	27.0	29	161	18.0	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.041	1.53	1.01	2.31
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.059	1.50	0.98	2.28
DAY 22	BIPOLAR I	39	104	37.5	38	101	37.6	23	110	20.9	.	.	.	.
	BIPOLAR II	25	51	49.0	18	49	36.7	13	51	25.5	.	.	.	.
	ALL	64	155	41.3	56	150	37.3	36	161	22.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.84	1.31	2.59
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.004	1.67	1.17	2.38
DAY 29	BIPOLAR I	39	104	37.5	42	101	41.6	30	110	27.3	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS247.SAS
GENERATED: 17NOV2005 13:33:04 iceadmn3

Table 11.2.1.15.1 MADRS Remission Rate (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 29	BIPOLAR II	26	51	51.0	21	49	42.9	17	51	33.3	.	.	.	.
	ALL	65	155	41.9	63	150	42.0	47	161	29.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.019	1.43	1.06	1.94
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.019	1.44	1.06	1.95
DAY 36	BIPOLAR I	45	104	43.3	44	101	43.6	31	110	28.2	.	.	.	.
	BIPOLAR II	28	51	54.9	20	49	40.8	13	51	25.5	.	.	.	.
	ALL	73	155	47.1	64	150	42.7	44	161	27.3	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.72	1.27	2.33
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.005	1.56	1.14	2.14
DAY 43	BIPOLAR I	47	104	45.2	49	101	48.5	39	110	35.5	.	.	.	.
	BIPOLAR II	32	51	62.7	22	50	44.0	17	51	33.3	.	.	.	.
	ALL	79	155	51.0	71	151	47.0	56	161	34.8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.004	1.46	1.12	1.90
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.028	1.35	1.03	1.77
DAY 50	BIPOLAR I	48	104	46.2	49	101	48.5	40	110	36.4	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS247.SAS
GENERATED: 17NOV2005 13:33:04 iceadmn3

Table 11.2.1.15.1 MADRS Remission Rate (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA												
DAY 50	BIPOLAR II	28	51	54.9	24	50	48.0	13	51	25.5	.	.	.	.
	ALL	76	155	49.0	73	151	48.3	53	161	32.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.004	1.49	1.13	1.96
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.005	1.47	1.12	1.94
DAY 57	BIPOLAR I	51	104	49.0	52	101	51.5	40	110	36.4	.	.	.	.
	BIPOLAR II	29	51	56.9	27	50	54.0	20	51	39.2	.	.	.	.
	ALL	80	155	51.6	79	151	52.3	60	161	37.3	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.011	1.38	1.08	1.78
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.008	1.40	1.09	1.80

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS247.SAS
GENERATED: 17NOV2005 13:33:04 iceadmn3

Table 11.2.1.15.2 MADRS Remission Rate (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	12	102	11.8	17	98	17.3	10	110	9.1	.	.	.	.
	BIPOLAR II	11	51	21.6	7	49	14.3	8	51	15.7	.	.	.	.
	ALL	23	153	15.0	24	147	16.3	18	161	11.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.327	1.33	0.75	2.36
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.193	1.46	0.82	2.57
DAY 15	BIPOLAR I	22	88	25.0	24	88	27.3	17	100	17.0	.	.	.	.
	BIPOLAR II	18	46	39.1	12	38	31.6	11	46	23.9	.	.	.	.
	ALL	40	134	29.9	36	126	28.6	28	146	19.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.043	1.54	1.01	2.34
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.067	1.50	0.97	2.30
DAY 22	BIPOLAR I	36	80	45.0	36	83	43.4	22	92	23.9	.	.	.	.
	BIPOLAR II	22	43	51.2	17	36	47.2	10	44	22.7	.	.	.	.
	ALL	58	123	47.2	53	119	44.5	32	136	23.5	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	2.00	1.40	2.86
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.89	1.32	2.72
DAY 29	BIPOLAR I	34	78	43.6	36	76	47.4	26	87	29.9	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS246.SAS
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Table 11.2.1.15.2 MADRS Remission Rate (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 29	BIPOLAR II	20	39	51.3	18	33	54.5	17	46	37.0	.	.	.	.
	ALL	54	117	46.2	54	109	49.5	43	133	32.3	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.025	1.43	1.05	1.96
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.006	1.54	1.13	2.11
DAY 36	BIPOLAR I	40	74	54.1	35	71	49.3	28	81	34.6	.	.	.	.
	BIPOLAR II	22	37	59.5	17	33	51.5	13	43	30.2	.	.	.	.
	ALL	62	111	55.9	52	104	50.0	41	124	33.1	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.69	1.25	2.28
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.010	1.51	1.10	2.07
DAY 43	BIPOLAR I	39	63	61.9	38	64	59.4	35	76	46.1	.	.	.	.
	BIPOLAR II	24	35	68.6	18	33	54.5	15	38	39.5	.	.	.	.
	ALL	63	98	64.3	56	97	57.7	50	114	43.9	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.003	1.47	1.14	1.90
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.045	1.32	1.01	1.72
DAY 50	BIPOLAR I	40	65	61.5	36	58	62.1	35	75	46.7	.	.	.	.

(Continued)

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS246.SAS
GENERATED: 17NOV2005 13:33:01 iceadmn3

Table 11.2.1.15.2 MADRS Remission Rate (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA												
DAY 50	BIPOLAR II	22	37	59.5	19	31	61.3	9	37	24.3	.	.	.	.
	ALL	62	102	60.8	55	89	61.8	44	112	39.3	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.001	1.56	1.18	2.07
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.001	1.58	1.19	2.10
DAY 57	BIPOLAR I	40	61	65.6	37	57	64.9	31	69	44.9	.	.	.	.
	BIPOLAR II	22	36	61.1	20	29	69.0	15	34	44.1	.	.	.	.
	ALL	62	97	63.9	57	86	66.3	46	103	44.7	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.006	1.43	1.10	1.86
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.003	1.48	1.14	1.93

Remission is a MADRS total score of <=12.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS246.SAS
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FIGURE 11.2.1.16 MADRS PERCENTAGE OF PATIENTS WITH REMISSION

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

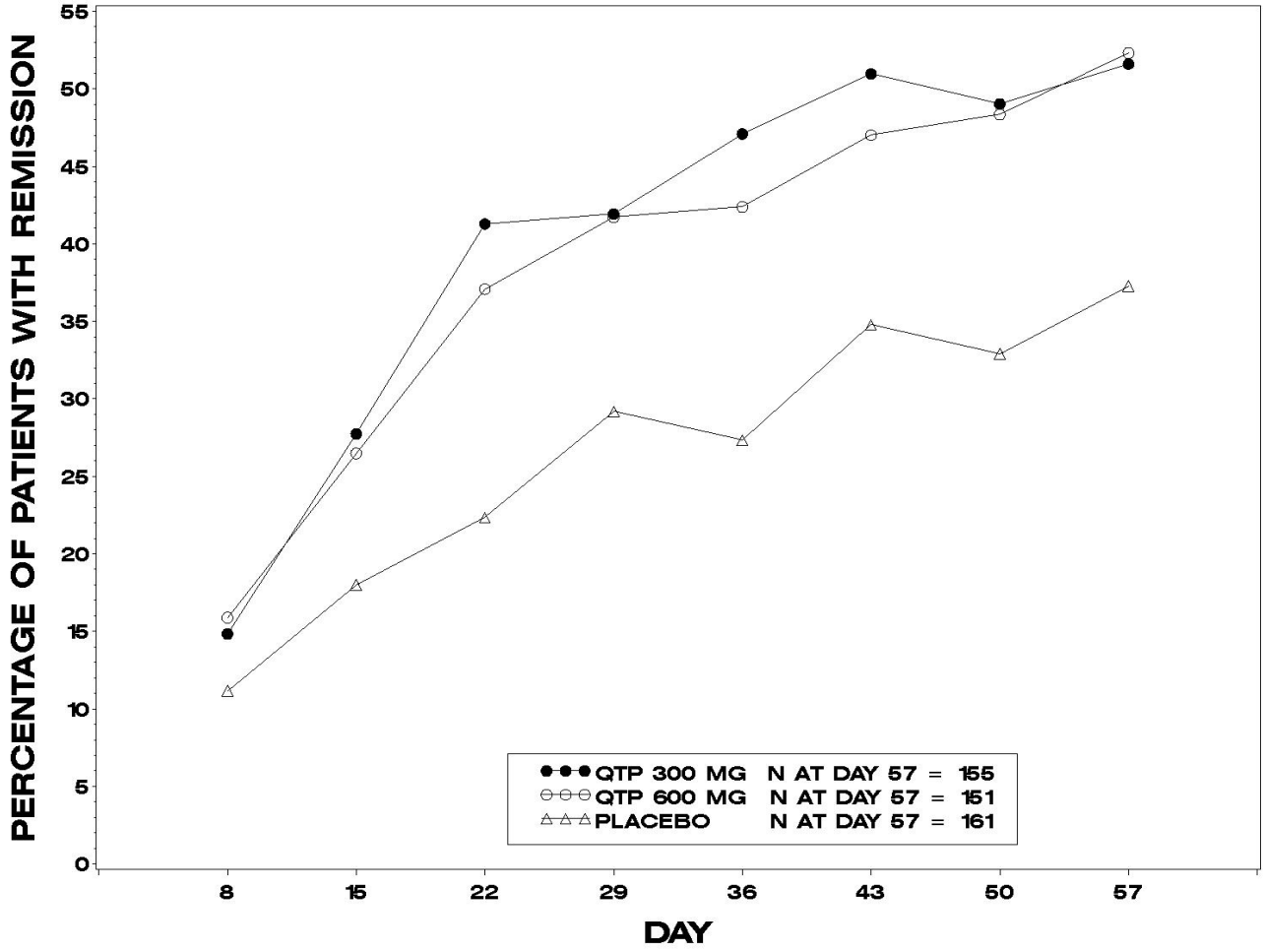

Table 11.2.1.17 MADRS Decision Matrix for the Parallel Weighted Bonferonni Gatekeeping Procedure
Last Observation Carried Forward
Intent to Treat Population

INTERSECTION HYPOTHESIS	RAW P-VALUE / WEIGHT H11	H12	H21	H22	ORIGINAL HYPOTHESIS H11	H12	H21	H22
H1111	<.001	0.001			<.001	<.001	<.001	<.001
H1110	<.001	0.001			<.001	<.001	<.001	0
H1101	<.001	0.001			<.001	<.001	0	<.001
H1100	<.001	0.001			<.001	<.001	0	0
H1011	<.001		0.067	0.272	<.001	0	<.001	<.001
H1010	<.001		0.034		<.001	0	<.001	0
H1001	<.001			0.136	<.001	0	0	<.001
H1000	<.001				<.001	0	0	0
H0111		0.001	0.067	0.272	0	0.001	0.001	0.001
H0110		0.001	0.034		0	0.001	0.001	0
H0101		0.001		0.136	0	0.001	0	0.001
H0100		<.001			0	<.001	0	0
H0011			0.034	0.136	0	0	0.034	0.034
H0010			0.017		0	0	0.017	0
H0001				0.068	0	0	0	0.068
ADJ P-VALUE+					<.001	0.001	0.034	0.068

+ Adjusted p-value for the original hypothesis
H11 are H12 are the hypotheses of MADRS total scores change from baseline for QTP 300 vs PLA and QTP 600 vs PLA.
H21 and H22 are the hypotheses of Q-LES-Q total scores change from baseline for QTP 300 vs PLA and QTP 600 vs PLA.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/MADRS400.SAS
GENERATED: 17NOV2005 13:35:44 iceadmn3

Table 11.2.2.1.1 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	155	24.8	3.39	24.0	20	39	151	24.5	3.06	24.0	20	39	161	24.3	3.27	24.0	15	33
	DAY 1	155	24.9	3.35	25.0	20	36	151	24.3	3.27	24.0	20	38	161	24.3	3.09	24.0	16	33
	DAY 8	153	16.6	5.70	17.0	1	31	147	16.6	5.35	16.0	3	31	161	18.7	6.22	19.0	1	35
	DAY 15	155	13.9	6.26	14.0	1	31	148	14.1	5.91	14.0	2	30	161	16.5	6.53	17.0	0	35
	DAY 22	155	12.7	6.72	12.0	0	31	150	12.9	6.22	12.0	2	29	161	16.0	7.01	17.0	0	37
	DAY 29	155	12.0	6.71	12.0	0	31	150	12.4	6.43	12.0	1	29	161	15.2	7.22	15.0	0	36
	DAY 36	155	11.4	6.90	11.0	0	32	150	11.9	6.63	12.0	0	29	161	14.9	7.12	15.0	0	36
	DAY 43	155	11.3	7.25	11.0	0	32	151	11.5	6.67	11.0	0	33	161	14.9	7.41	15.0	0	36
	DAY 50	155	11.1	7.46	10.0	0	32	151	11.4	6.87	11.0	0	33	161	14.5	7.83	15.0	0	36
	DAY 57	155	10.9	7.47	10.0	0	32	151	11.4	7.23	11.0	0	33	161	14.5	8.03	14.0	0	36
CHG FROM BASELINE	DAY 8	153	-8.3	5.50	-8.0	-26	3	147	-7.7	5.45	-7.0	-21	3	161	-5.6	5.98	-5.0	-25	7
	DAY 15	155	-11.0	6.35	-11.0	-26	6	148	-10.1	6.30	-10.0	-26	5	161	-7.8	6.61	-6.0	-27	7
	DAY 22	155	-12.2	6.78	-12.0	-28	6	150	-11.4	6.31	-12.0	-26	3	161	-8.2	6.93	-7.4	-27	12
	DAY 29	155	-12.9	6.82	-13.0	-27	6	150	-11.9	6.63	-12.0	-27	4	161	-9.1	7.19	-8.0	-28	5
	DAY 36	155	-13.5	7.07	-14.0	-27	6	150	-12.4	6.74	-12.0	-28	2	161	-9.3	7.33	-8.0	-29	5
	DAY 43	155	-13.7	7.24	-14.0	-31	6	151	-12.8	6.79	-13.0	-28	10	161	-9.4	7.49	-8.0	-28	5

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD201.SAS
GENERATED: 17NOV2005 13:49:29 iceadmn3

Table 11.2.2.1.1 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	155	-13.8	7.75	-15.0	-32	6	151	-12.9	6.98	-13.0	-27	10	161	-9.8	7.73	-9.0	-28	5
	DAY 57	155	-14.0	7.51	-15.0	-33	6	151	-12.9	7.16	-13.0	-26	10	161	-9.8	7.86	-10.0	-27	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD201.SAS
GENERATED: 17NOV2005 13:49:29 iceadmn3

Table 11.2.2.1.2 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	155	24.8	3.39	24.0	20	39	151	24.5	3.06	24.0	20	39	161	24.3	3.27	24.0	15	33
	DAY 1	155	24.9	3.35	25.0	20	36	151	24.3	3.27	24.0	20	38	161	24.3	3.09	24.0	16	33
	DAY 8	153	16.6	5.70	17.0	1	31	147	16.6	5.35	16.0	3	31	161	18.7	6.22	19.0	1	35
	DAY 15	134	13.5	6.24	13.0	1	31	126	13.7	5.86	14.0	2	30	146	16.1	6.49	17.0	0	32
	DAY 22	123	11.6	6.24	10.0	0	28	119	11.8	5.86	12.0	2	28	136	15.4	6.87	16.0	0	37
	DAY 29	117	11.0	5.98	11.0	0	25	109	10.9	6.03	10.0	1	29	133	14.2	6.69	15.0	0	32
	DAY 36	111	10.0	6.25	10.0	0	32	104	10.3	6.11	10.0	0	26	124	13.4	6.42	13.0	0	29
	DAY 43	99	9.5	6.44	8.0	0	26	97	9.5	5.62	9.0	0	24	114	12.9	6.49	14.0	0	26
	DAY 50	102	9.2	6.49	8.0	0	24	89	9.1	5.97	8.0	0	24	112	12.5	7.06	12.5	0	30
	DAY 57	97	9.0	6.56	8.0	0	26	86	9.2	6.89	8.0	0	27	103	12.7	7.28	11.0	0	32
CHG FROM BASELINE	DAY 8	153	-8.3	5.50	-8.0	-26	3	147	-7.7	5.45	-7.0	-21	3	161	-5.6	5.98	-5.0	-25	7
	DAY 15	134	-11.5	6.39	-11.0	-26	6	126	-10.5	6.26	-10.5	-26	5	146	-8.2	6.62	-7.0	-27	7
	DAY 22	123	-13.2	6.57	-14.0	-28	5	119	-12.4	5.89	-13.0	-26	3	136	-8.8	6.76	-8.0	-27	12
	DAY 29	117	-13.7	6.43	-14.0	-27	2	109	-13.2	6.30	-14.0	-27	4	133	-9.9	6.92	-9.0	-28	5
	DAY 36	111	-14.7	6.76	-15.0	-27	2	104	-13.7	6.39	-14.5	-28	0	124	-10.8	6.93	-10.5	-29	5
	DAY 43	99	-15.3	6.67	-16.0	-31	-1	97	-14.5	5.98	-15.0	-28	-1	114	-11.1	6.92	-11.0	-28	5

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD200.SAS
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Table 11.2.2.1.2 HAM-D Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	102	-15.4	7.27	-16.0	-32	2	89	-14.8	6.25	-16.0	-27	2	112	-11.7	7.17	-11.0	-28	4
	DAY 57	97	-15.6	6.86	-16.0	-33	1	86	-14.6	6.80	-16.0	-26	4	103	-11.5	7.43	-12.0	-27	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD200.SAS
GENERATED: 17NOV2005 13:49:27 iceadmn3

Table 11.2.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	24.9	3.36	-8.3	5.50	-8.02	0.537	-9.08	-6.95	.
	Q600MG	147	24.3	3.27	-7.7	5.45	-7.88	0.550	-8.97	-6.79	.
	P	161	24.3	3.09	-5.6	5.98	-5.66	0.535	-6.72	-4.60	.
	Q300MG VS P	.	.	.	.	.	-2.36	0.603	-3.54	-1.17	<.001
	Q600MG VS P	.	.	.	.	.	-2.22	0.609	-3.42	-1.03	<.001
DAY 15	Q300MG	155	24.9	3.35	-11.0	6.35	-10.74	0.613	-11.95	-9.52	.
	Q600MG	148	24.3	3.26	-10.1	6.30	-10.44	0.629	-11.69	-9.20	.
	P	161	24.3	3.09	-7.8	6.61	-8.04	0.614	-9.26	-6.82	.
	Q300MG VS P	.	.	.	.	.	-2.70	0.665	-4.01	-1.39	<.001
	Q600MG VS P	.	.	.	.	.	-2.41	0.673	-3.73	-1.08	<.001
DAY 22	Q300MG	155	24.9	3.35	-12.2	6.78	-11.91	0.634	-13.17	-10.66	.
	Q600MG	150	24.3	3.28	-11.4	6.31	-11.68	0.649	-12.97	-10.40	.
	P	161	24.3	3.09	-8.2	6.93	-8.39	0.634	-9.64	-7.13	.
	Q300MG VS P	.	.	.	.	.	-3.53	0.708	-4.92	-2.14	<.001
	Q600MG VS P	.	.	.	.	.	-3.30	0.714	-4.70	-1.89	<.001
DAY 29	Q300MG	155	24.9	3.35	-12.9	6.82	-12.66	0.657	-13.96	-11.36	.
	Q600MG	150	24.3	3.28	-11.9	6.63	-12.22	0.672	-13.55	-10.88	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD204.SAS
GENERATED: 17NOV2005 13:31:48 iceadmn3

Table 11.2.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	24.3	3.09	-9.1	7.19	-9.24	0.657	-10.54	-7.93	.
	Q300MG VS P	.	.	.	.	.	-3.42	0.725	-4.85	-2.00	<.001
	Q600MG VS P	.	.	.	.	.	-2.98	0.731	-4.42	-1.54	<.001
DAY 36	Q300MG	155	24.9	3.35	-13.5	7.07	-13.16	0.658	-14.47	-11.86	.
	Q600MG	150	24.3	3.28	-12.4	6.74	-12.59	0.674	-13.92	-11.25	.
	P	161	24.3	3.09	-9.3	7.33	-9.36	0.658	-10.67	-8.06	.
	Q300MG VS P	.	.	.	.	.	-3.80	0.742	-5.26	-2.34	<.001
	Q600MG VS P	.	.	.	.	.	-3.23	0.748	-4.70	-1.76	<.001
DAY 43	Q300MG	155	24.9	3.35	-13.7	7.24	-13.40	0.674	-14.73	-12.06	.
	Q600MG	151	24.3	3.27	-12.8	6.79	-12.99	0.689	-14.35	-11.62	.
	P	161	24.3	3.09	-9.4	7.49	-9.53	0.674	-10.87	-8.19	.
	Q300MG VS P	.	.	.	.	.	-3.86	0.766	-5.37	-2.36	<.001
	Q600MG VS P	.	.	.	.	.	-3.46	0.771	-4.97	-1.94	<.001
DAY 50	Q300MG	155	24.9	3.35	-13.8	7.75	-13.57	0.708	-14.97	-12.16	.
	Q600MG	151	24.3	3.27	-12.9	6.98	-13.10	0.723	-14.53	-11.66	.
	P	161	24.3	3.09	-9.8	7.73	-9.95	0.708	-11.35	-8.54	.
	Q300MG VS P	.	.	.	.	.	-3.62	0.799	-5.19	-2.05	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD204.SAS
GENERATED: 17NOV2005 13:31:48 iceadmn3

Table 11.2.2.2.1 HAM-D Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-3.15	0.804	-4.73	-1.57	<.001
DAY 57	Q300MG	155	24.9	3.35	-14.0	7.51	-13.81	0.692	-15.18	-12.44	.
	Q600MG	151	24.3	3.27	-12.9	7.16	-12.97	0.707	-14.37	-11.57	.
	P	161	24.3	3.09	-9.8	7.86	-9.92	0.690	-11.29	-8.55	.
	Q300MG VS P	.	.	.	.	.	-3.89	0.821	-5.50	-2.28	<.001
	Q600MG VS P	.	.	.	.	.	-3.05	0.826	-4.68	-1.43	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD204.SAS
GENERATED: 17NOV2005 13:31:48 iceadmn3

Table 11.2.2.2.2 HAM-D Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	24.9	3.36	-8.3	5.50	-8.02	0.537	-9.08	-6.95	.
	Q600MG	147	24.3	3.27	-7.7	5.45	-7.88	0.550	-8.97	-6.79	.
	P	161	24.3	3.09	-5.6	5.98	-5.66	0.535	-6.72	-4.60	.
	Q300MG VS P	.	.	.	.	.	-2.36	0.603	-3.54	-1.17	<.001
	Q600MG VS P	.	.	.	.	.	-2.22	0.609	-3.42	-1.03	<.001
DAY 15	Q300MG	134	25.0	3.39	-11.5	6.39	-11.08	0.665	-12.40	-9.76	.
	Q600MG	126	24.2	3.11	-10.5	6.26	-10.86	0.685	-12.22	-9.50	.
	P	146	24.3	2.96	-8.2	6.62	-8.47	0.658	-9.77	-7.16	.
	Q300MG VS P	.	.	.	.	.	-2.62	0.702	-4.00	-1.24	<.001
	Q600MG VS P	.	.	.	.	.	-2.40	0.707	-3.79	-1.01	<.001
DAY 22	Q300MG	123	24.9	3.38	-13.2	6.57	-12.73	0.681	-14.08	-11.38	.
	Q600MG	119	24.2	3.21	-12.4	5.89	-12.64	0.697	-14.02	-11.25	.
	P	136	24.2	2.95	-8.8	6.76	-8.94	0.664	-10.26	-7.63	.
	Q300MG VS P	.	.	.	.	.	-3.79	0.743	-5.25	-2.33	<.001
	Q600MG VS P	.	.	.	.	.	-3.69	0.748	-5.16	-2.22	<.001
DAY 29	Q300MG	117	24.7	3.43	-13.7	6.43	-13.41	0.692	-14.78	-12.03	.
	Q600MG	109	24.1	3.15	-13.2	6.30	-13.58	0.717	-15.00	-12.16	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD210.SAS
GENERATED: 17NOV2005 13:31:54 iceadmn3

Table 11.2.2.2.2 HAM-D Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	133	24.1	2.89	-9.9	6.92	-10.27	0.668	-11.60	-8.94	.
	Q300MG VS P	.	.	.	.	.	-3.13	0.759	-4.63	-1.64	<.001
	Q600MG VS P	.	.	.	.	.	-3.31	0.769	-4.82	-1.80	<.001
DAY 36	Q300MG	111	24.7	3.46	-14.7	6.76	-14.15	0.702	-15.54	-12.76	.
	Q600MG	104	24.0	2.87	-13.7	6.39	-14.02	0.722	-15.45	-12.59	.
	P	124	24.2	3.07	-10.8	6.93	-10.86	0.679	-12.21	-9.51	.
	Q300MG VS P	.	.	.	.	.	-3.29	0.794	-4.85	-1.73	<.001
	Q600MG VS P	.	.	.	.	.	-3.16	0.801	-4.74	-1.58	<.001
DAY 43	Q300MG	99	24.7	3.42	-15.3	6.67	-14.67	0.703	-16.06	-13.28	.
	Q600MG	97	24.0	2.88	-14.5	5.98	-14.70	0.711	-16.11	-13.29	.
	P	114	24.0	2.89	-11.1	6.92	-11.17	0.669	-12.50	-9.84	.
	Q300MG VS P	.	.	.	.	.	-3.50	0.836	-5.14	-1.85	<.001
	Q600MG VS P	.	.	.	.	.	-3.53	0.835	-5.17	-1.88	<.001
DAY 50	Q300MG	102	24.6	3.38	-15.4	7.27	-14.95	0.739	-16.42	-13.49	.
	Q600MG	89	23.8	2.87	-14.8	6.25	-15.05	0.779	-16.59	-13.51	.
	P	112	24.2	2.95	-11.7	7.17	-11.67	0.718	-13.10	-10.25	.
	Q300MG VS P	.	.	.	.	.	-3.28	0.877	-5.01	-1.56	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD210.SAS
GENERATED: 17NOV2005 13:31:54 iceadmn3

Table 11.2.2.2.2 HAM-D Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-3.38	0.907	-5.16	-1.59	<.001
DAY 57	Q300MG	97	24.6	3.47	-15.6	6.86	-15.29	0.746	-16.77	-13.81	.
	Q600MG	86	23.9	2.96	-14.6	6.80	-14.87	0.792	-16.44	-13.30	.
	P	103	24.2	2.95	-11.5	7.43	-11.49	0.734	-12.95	-10.03	.
	Q300MG VS P	.	.	.	.	.	-3.80	0.962	-5.70	-1.91	<.001
	Q600MG VS P	.	.	.	.	.	-3.38	0.990	-5.33	-1.43	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD210.SAS
GENERATED: 17NOV2005 13:31:54 iceadmn3

FIGURE 11.2.2.3.1 HAM-D TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

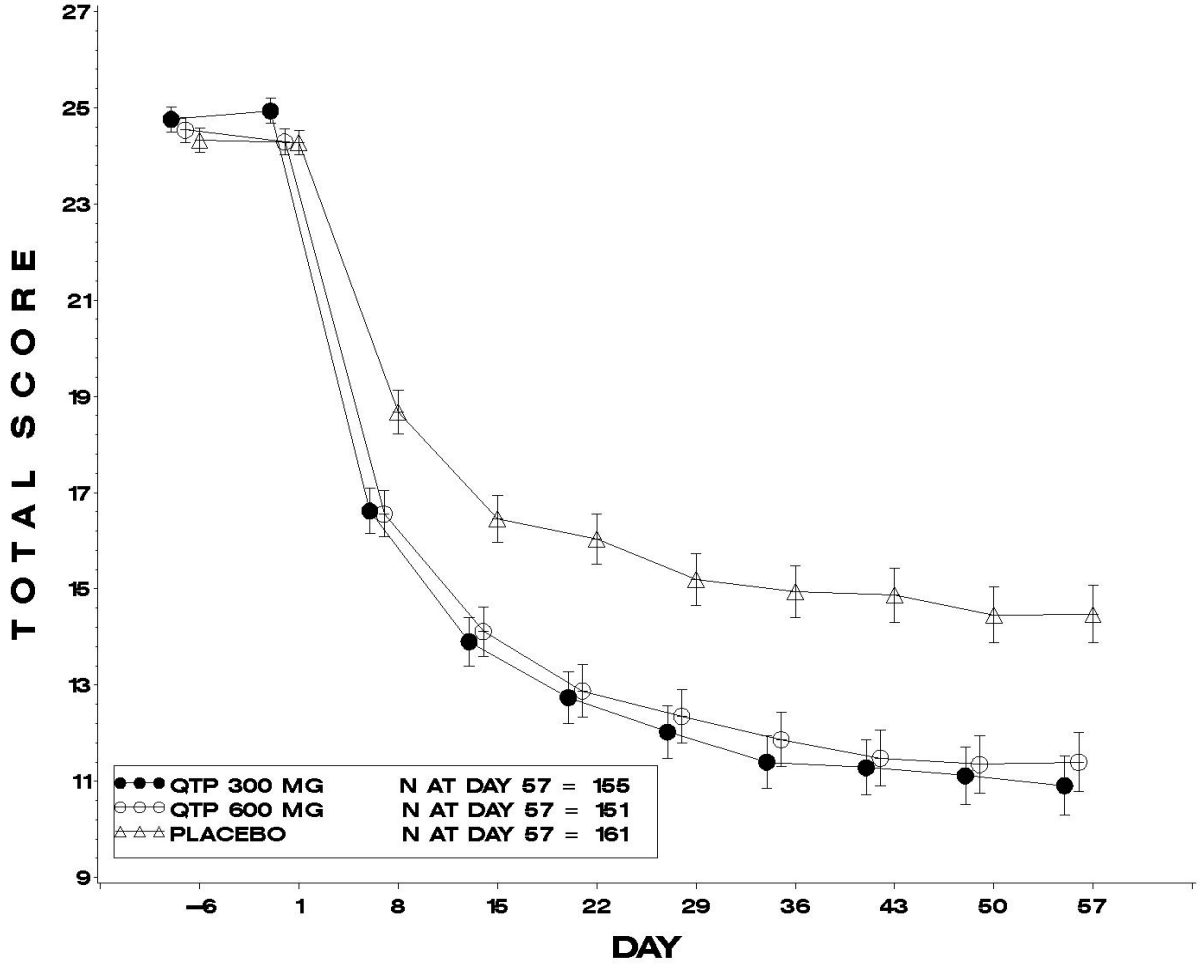

FIGURE 11.2.2.3.2 HAM-D TOTAL SCORE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

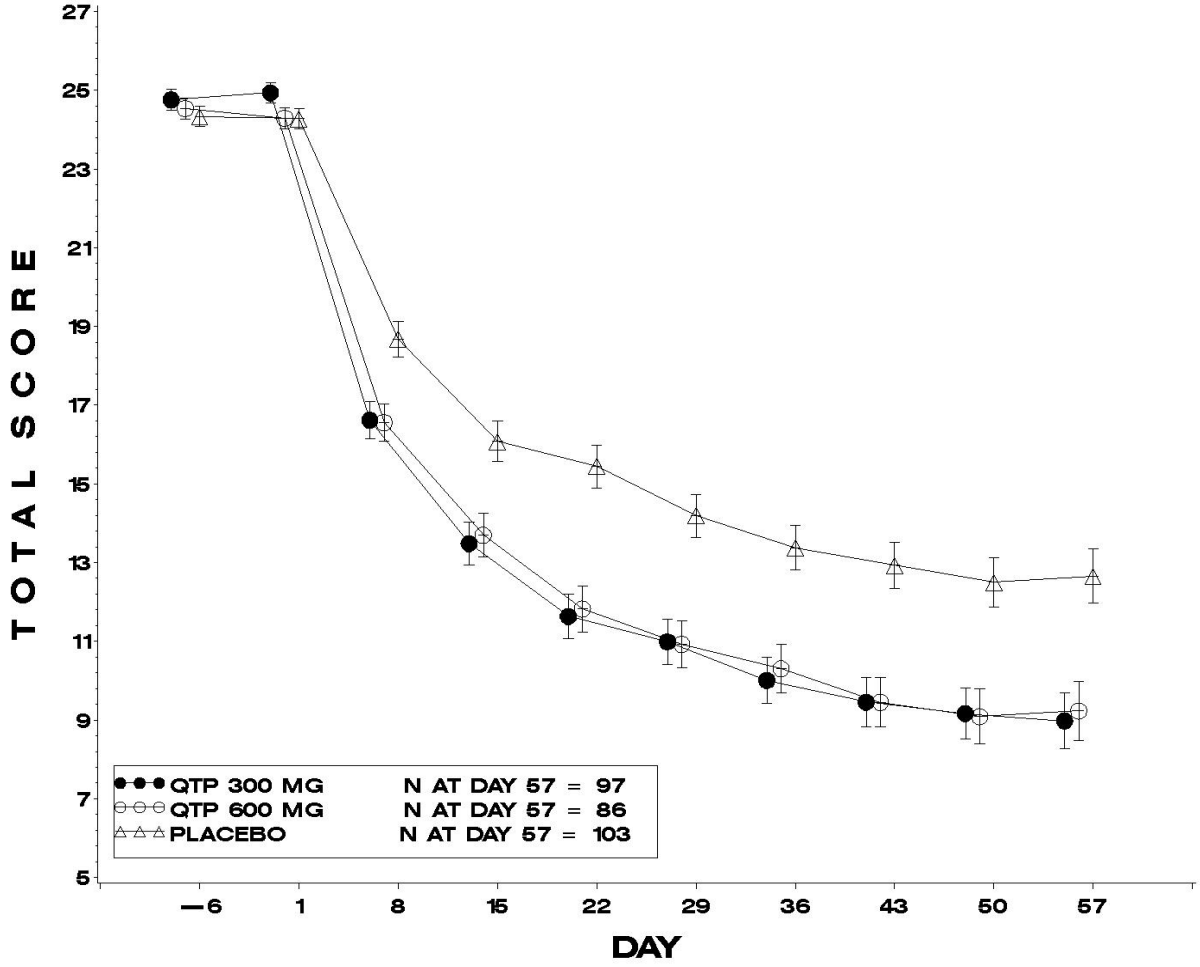

FIGURE 11.2.2.3.3 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN,SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

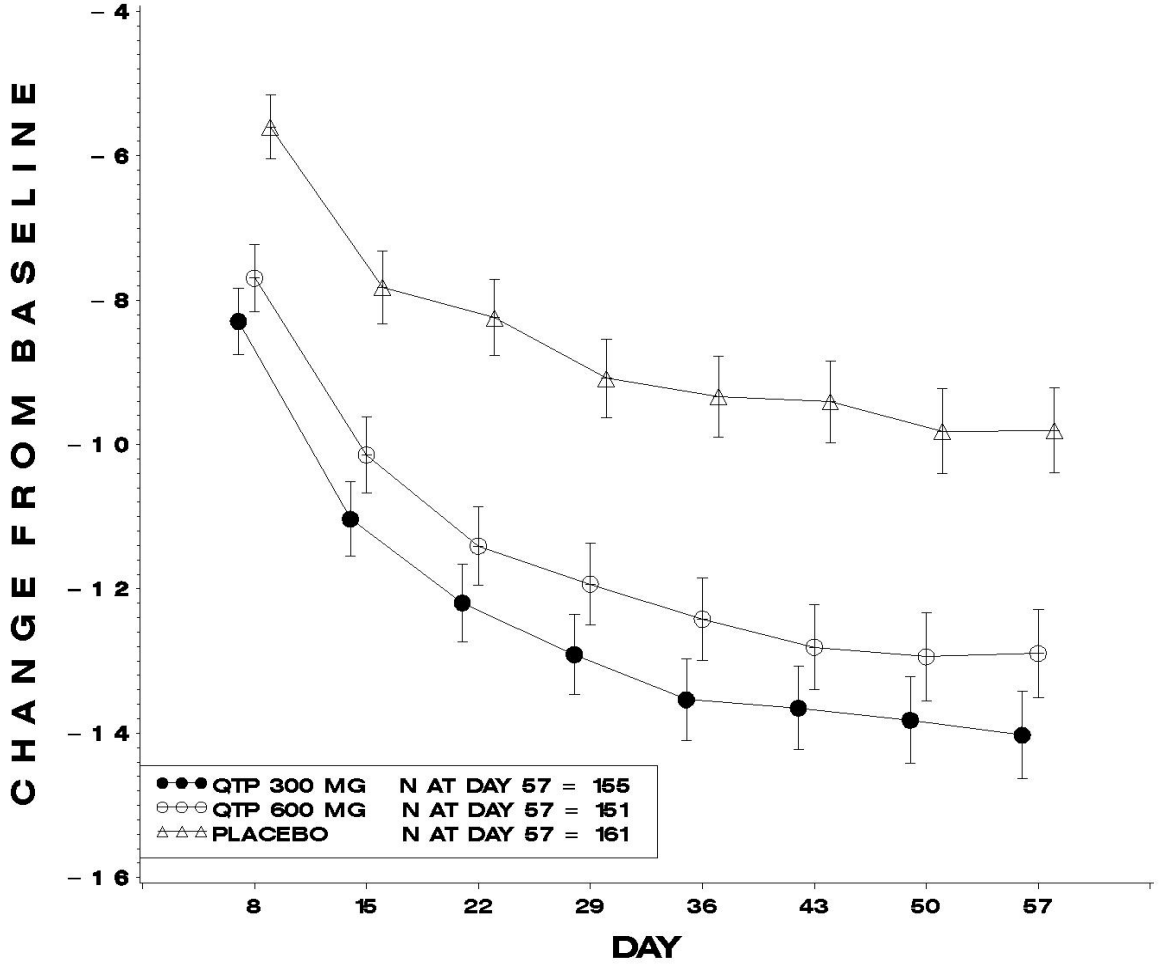

FIGURE 11.2.2.3.4 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(OBSERVED CASES - INTENT TO TREAT)

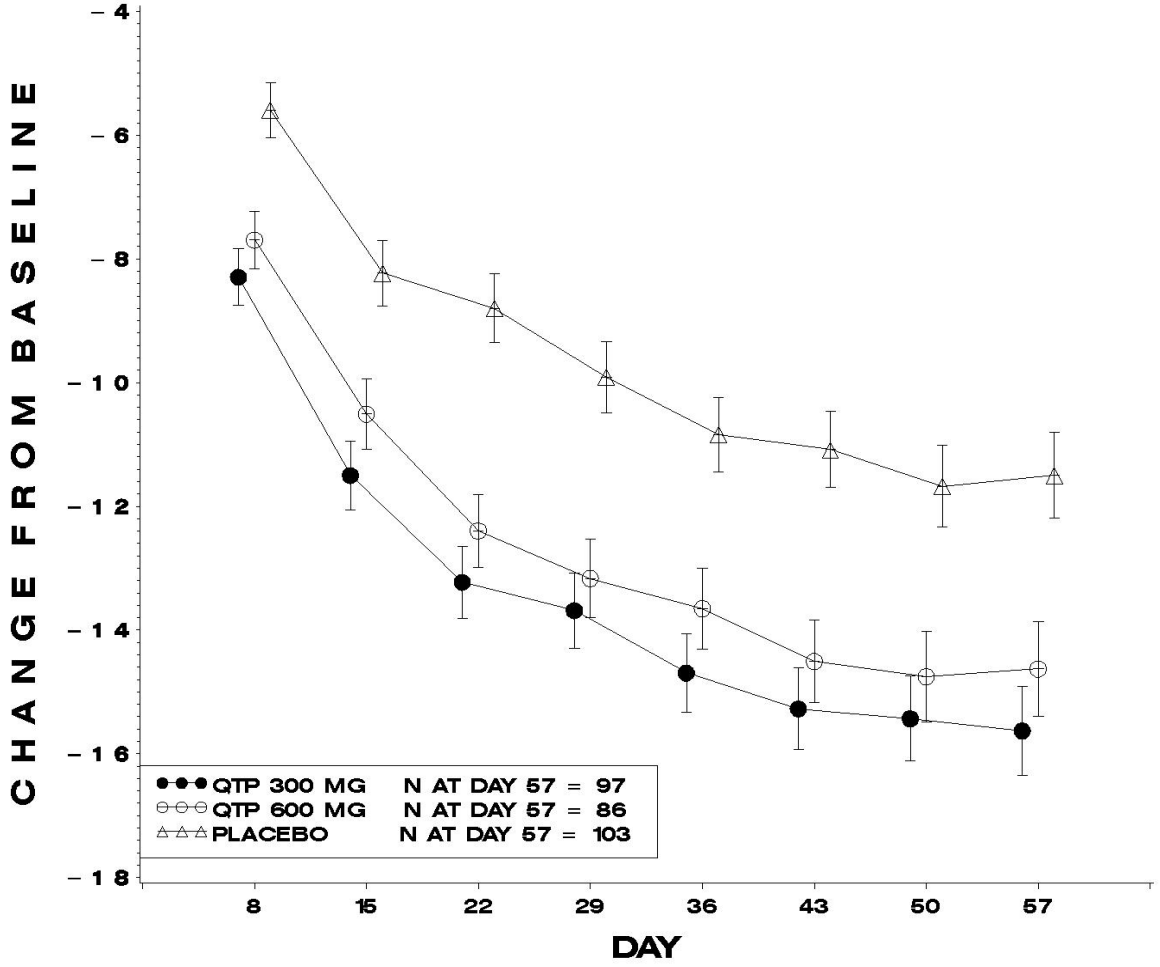

FIGURE 11.2.2.3.5 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

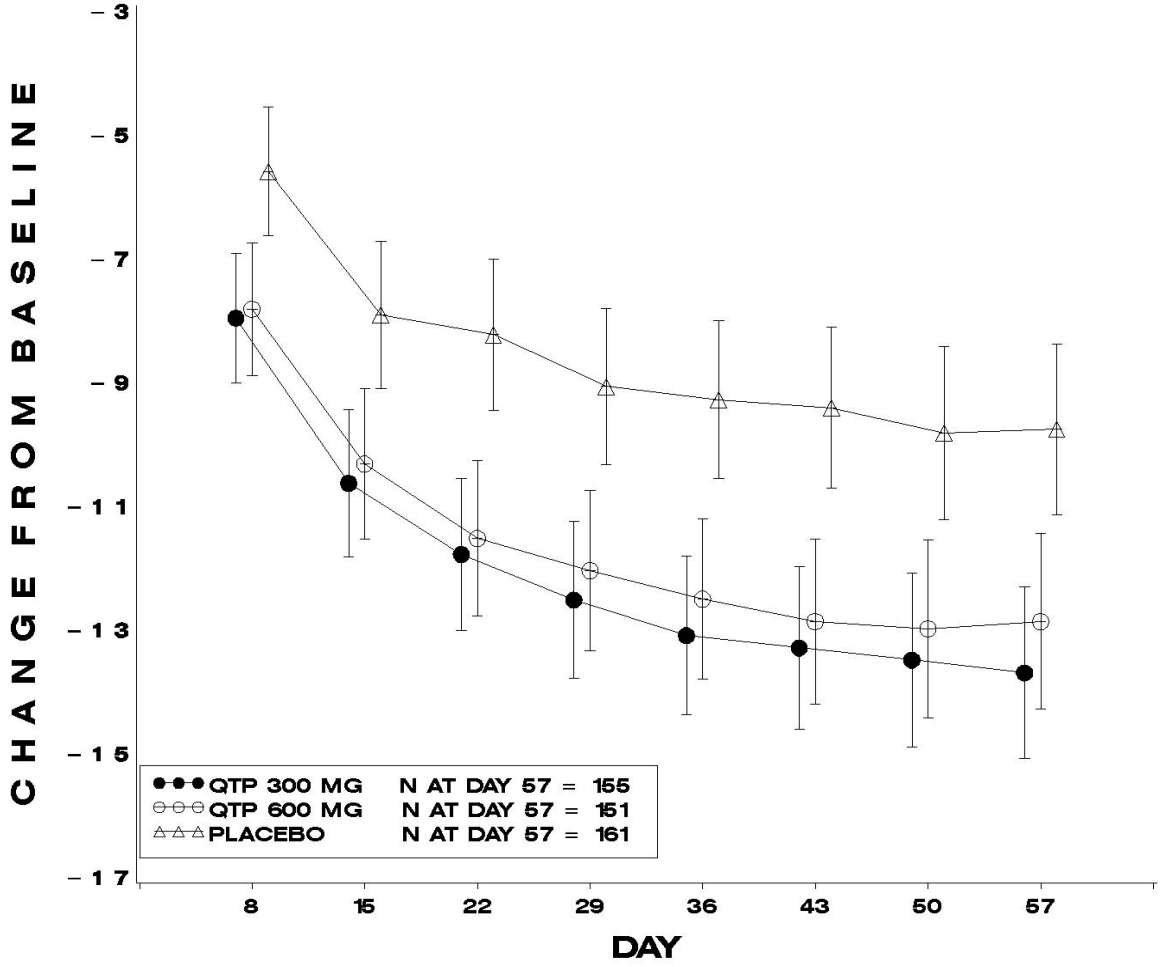

FIGURE 11.2.2.3.6 HAM-D TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(OBSERVED CASES - INTENT TO TREAT)

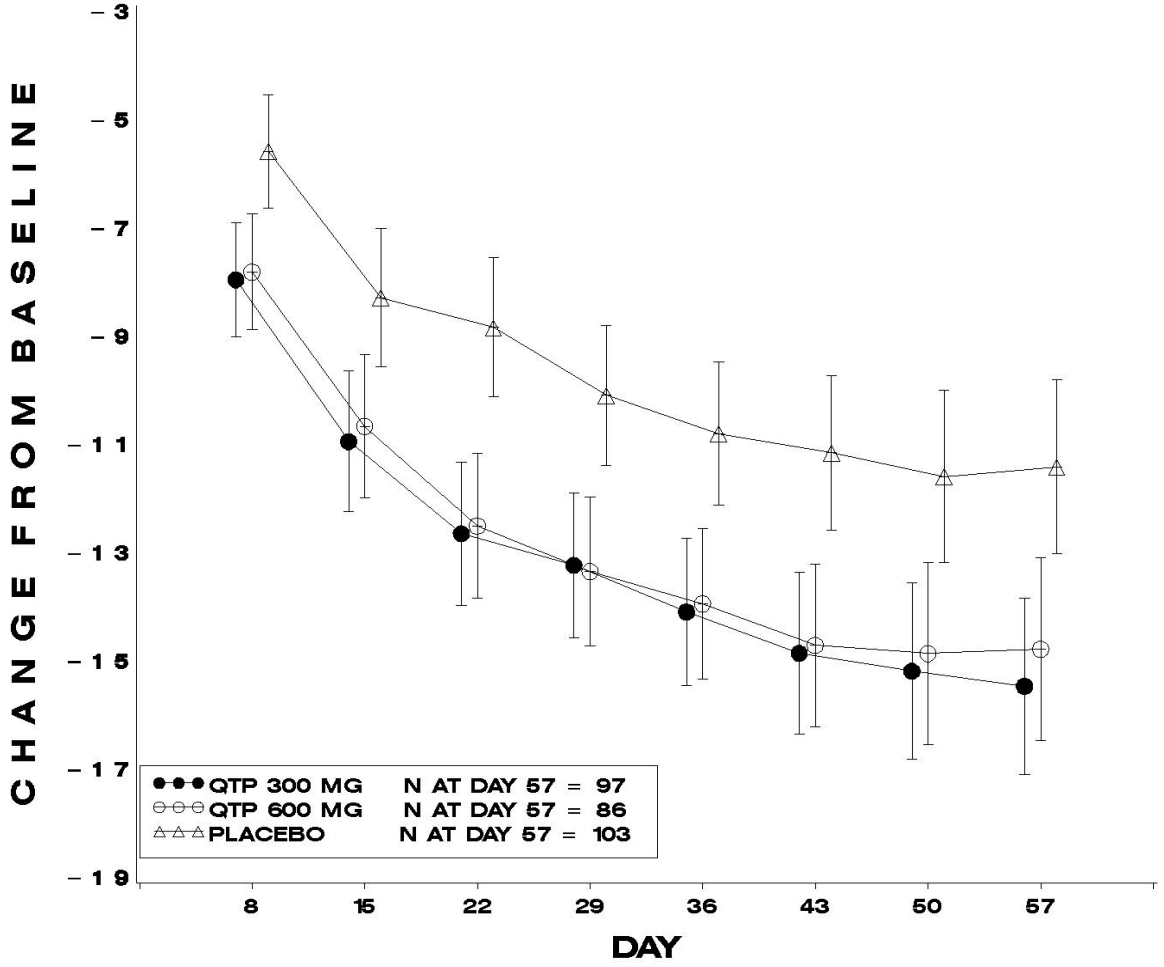

Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	104	25.2	3.63	25.0	20	39	101	25.1	3.08	25.0	20	39	110	24.5	3.56	24.0	15	33
	DAY 1	104	25.4	3.56	25.0	20	36	101	24.6	3.36	24.0	20	38	110	24.4	3.26	24.0	16	33
	DAY 8	102	17.1	6.01	17.0	1	31	98	16.8	5.57	16.0	4	31	110	18.8	6.36	19.0	1	35
	DAY 15	104	14.5	6.81	14.0	1	31	99	13.9	5.97	14.0	2	30	110	16.6	6.74	17.0	0	35
	DAY 22	104	13.1	7.27	12.0	0	31	101	12.9	6.12	12.0	2	29	110	16.3	7.45	17.0	0	37
	DAY 29	104	12.7	6.92	12.0	0	31	101	12.3	6.34	12.0	1	29	110	15.2	7.55	15.0	0	36
	DAY 36	104	11.6	7.29	11.0	0	32	101	11.7	6.49	11.0	0	29	110	15.1	7.51	15.0	0	36
	DAY 43	104	11.8	7.39	11.0	0	32	101	11.5	6.76	11.0	0	33	110	14.9	7.98	14.5	0	36
	DAY 50	104	11.4	7.71	10.0	0	32	101	11.5	6.92	12.0	0	33	110	14.5	8.50	15.0	0	36
	DAY 57	104	11.3	7.72	10.0	0	32	101	11.5	7.27	11.0	0	33	110	14.8	8.71	15.0	0	36
CHG FROM BASELINE	DAY 8	102	-8.3	5.75	-8.0	-26	3	98	-7.8	5.53	-7.5	-20	2	110	-5.6	6.06	-5.0	-25	7
	DAY 15	104	-10.9	6.87	-10.0	-26	6	99	-10.7	6.32	-11.0	-26	5	110	-7.7	6.72	-6.5	-27	7
	DAY 22	104	-12.3	7.37	-12.5	-28	6	101	-11.7	6.15	-12.0	-26	3	110	-8.1	7.28	-7.5	-27	12
	DAY 29	104	-12.7	7.09	-13.0	-26	6	101	-12.3	6.60	-12.0	-27	4	110	-9.1	7.62	-8.0	-28	5
	DAY 36	104	-13.8	7.28	-14.0	-27	6	101	-12.9	6.61	-13.0	-28	1	110	-9.3	7.67	-8.0	-29	5
	DAY 43	104	-13.5	7.37	-14.0	-31	6	101	-13.2	6.88	-13.0	-28	10	110	-9.5	7.97	-8.0	-28	5

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD203.SAS
GENERATED: 17NOV2005 13:49:34 iceadmn3

Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	104	-14.0	8.01	-15.0	-32	6	101	-13.1	7.01	-13.0	-27	10	110	-9.9	8.27	-9.0	-28	5
	DAY 57	104	-14.1	7.74	-15.0	-33	6	101	-13.1	7.28	-13.0	-26	10	110	-9.6	8.47	-9.0	-27	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD203.SAS
GENERATED: 17NOV2005 13:49:34 iceadmn3

Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	51	23.9	2.70	24.0	20	31	50	23.5	2.77	23.0	20	29	51	24.0	2.56	24.0	20	30
	DAY 1	51	24.0	2.70	24.0	20	31	50	23.6	2.98	23.0	20	31	51	24.0	2.70	24.0	20	33
	DAY 8	51	15.7	4.98	16.0	5	23	49	16.1	4.88	16.0	3	25	51	18.5	5.94	19.0	4	29
	DAY 15	51	12.8	4.81	13.0	2	23	49	14.6	5.84	15.0	3	25	51	16.0	6.11	18.0	3	27
	DAY 22	51	12.0	5.40	11.0	3	26	49	12.8	6.47	14.0	2	27	51	15.5	6.00	17.0	3	27
	DAY 29	51	10.7	6.08	11.0	0	26	49	12.4	6.69	11.0	1	27	51	15.1	6.52	16.0	1	28
	DAY 36	51	11.0	6.07	11.0	1	26	49	12.2	6.97	13.0	0	27	51	14.6	6.24	16.0	4	28
	DAY 43	51	10.1	6.89	10.0	0	26	50	11.5	6.55	11.0	0	27	51	14.8	6.08	15.0	3	28
	DAY 50	51	10.5	6.96	10.0	0	26	50	11.0	6.84	9.5	1	27	51	14.4	6.20	14.0	3	28
	DAY 57	51	10.1	6.93	9.0	0	26	50	11.1	7.21	9.0	0	27	51	13.7	6.33	13.0	2	28
CHG FROM BASELINE	DAY 8	51	-8.3	5.02	-9.0	-22	2	49	-7.5	5.35	-7.0	-21	3	51	-5.5	5.85	-4.4	-23	6
	DAY 15	51	-11.3	5.19	-12.0	-22	0	49	-9.0	6.15	-9.0	-23	3	51	-8.0	6.41	-6.0	-21	5
	DAY 22	51	-12.0	5.44	-12.0	-26	1	49	-10.7	6.64	-11.0	-25	2	51	-8.6	6.18	-7.4	-24	3
	DAY 29	51	-13.4	6.29	-13.0	-27	1	49	-11.1	6.68	-11.0	-24	2	51	-9.0	6.24	-8.0	-23	3
	DAY 36	51	-13.1	6.66	-13.0	-27	1	49	-11.4	6.97	-12.0	-26	2	51	-9.4	6.61	-8.0	-21	3
	DAY 43	51	-13.9	7.03	-13.0	-28	1	50	-12.0	6.61	-12.5	-23	2	51	-9.2	6.43	-8.0	-22	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD203.SAS
GENERATED: 17NOV2005 13:49:34 iceadmn3

Table 11.2.2.4.1 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	51	-13.5	7.25	-13.0	-29	2	50	-12.5	6.96	-13.0	-25	2	51	-9.7	6.51	-10.0	-22	3
	DAY 57	51	-13.9	7.11	-14.0	-28	1	50	-12.4	6.96	-13.0	-24	2	51	-10.3	6.39	-11.0	-24	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD203.SAS
GENERATED: 17NOV2005 13:49:34 iceadmn3

Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	104	25.2	3.63	25.0	20	39	101	25.1	3.08	25.0	20	39	110	24.5	3.56	24.0	15	33
	DAY 1	104	25.4	3.56	25.0	20	36	101	24.6	3.36	24.0	20	38	110	24.4	3.26	24.0	16	33
	DAY 8	102	17.1	6.01	17.0	1	31	98	16.8	5.57	16.0	4	31	110	18.8	6.36	19.0	1	35
	DAY 15	88	13.8	6.89	13.5	1	31	88	13.8	5.93	13.5	2	30	100	16.3	6.69	16.0	0	32
	DAY 22	80	11.5	6.64	10.0	0	28	83	12.0	5.63	12.0	2	28	92	15.4	7.39	15.0	0	37
	DAY 29	78	11.4	6.03	11.5	0	25	76	11.2	5.96	11.0	1	29	87	14.1	6.87	15.0	0	32
	DAY 36	74	9.7	6.44	9.5	0	32	71	10.5	5.95	10.0	0	26	81	13.3	6.75	13.0	0	29
	DAY 43	63	9.3	6.20	8.0	0	26	64	9.5	5.72	9.0	0	24	76	12.4	6.94	11.0	0	26
	DAY 50	65	8.9	6.48	7.0	0	24	58	9.5	6.06	9.5	0	24	75	11.9	7.71	11.0	0	30
	DAY 57	61	8.9	6.50	8.0	0	26	57	9.5	6.94	8.0	0	27	69	12.6	8.02	10.0	0	32
CHG FROM BASELINE	DAY 8	102	-8.3	5.75	-8.0	-26	3	98	-7.8	5.53	-7.5	-20	2	110	-5.6	6.06	-5.0	-25	7
	DAY 15	88	-11.6	6.94	-11.0	-26	6	88	-10.7	6.33	-11.0	-26	5	100	-8.1	6.75	-7.5	-27	7
	DAY 22	80	-13.8	6.96	-14.0	-28	5	83	-12.3	5.74	-13.0	-26	3	92	-8.8	7.17	-9.0	-27	12
	DAY 29	78	-13.6	6.50	-14.0	-26	2	76	-13.1	6.38	-13.0	-27	4	87	-10.0	7.35	-9.0	-28	5
	DAY 36	74	-15.4	6.59	-15.0	-27	2	71	-13.6	6.39	-14.0	-28	-1	81	-11.0	7.28	-10.0	-29	5
	DAY 43	63	-15.8	6.24	-16.0	-31	-2	64	-14.5	6.31	-15.0	-28	-1	76	-11.7	7.28	-12.0	-28	5

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD202.SAS
GENERATED: 17NOV2005 13:49:32 iceadmn3

Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	65	-16.1	7.19	-16.0	-32	1	58	-14.6	6.51	-15.0	-27	2	75	-12.3	7.56	-12.0	-28	4
	DAY 57	61	-16.2	6.65	-16.0	-33	-2	57	-14.5	7.17	-16.0	-26	4	69	-11.7	8.07	-12.0	-27	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD202.SAS
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Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-D TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	51	23.9	2.70	24.0	20	31	50	23.5	2.77	23.0	20	29	51	24.0	2.56	24.0	20	30
	DAY 1	51	24.0	2.70	24.0	20	31	50	23.6	2.98	23.0	20	31	51	24.0	2.70	24.0	20	33
	DAY 8	51	15.7	4.98	16.0	5	23	49	16.1	4.88	16.0	3	25	51	18.5	5.94	19.0	4	29
	DAY 15	46	12.8	4.77	13.0	2	23	38	13.5	5.78	14.0	3	25	46	15.7	6.06	18.0	3	27
	DAY 22	43	11.9	5.48	11.0	3	26	36	11.3	6.42	11.0	2	27	44	15.5	5.70	17.0	3	26
	DAY 29	39	10.2	5.87	10.0	0	22	33	10.4	6.24	10.0	1	21	46	14.4	6.40	15.0	1	28
	DAY 36	37	10.6	5.90	10.0	1	23	33	10.0	6.54	9.0	0	20	43	13.5	5.81	13.0	4	28
	DAY 43	36	9.7	6.91	9.0	0	23	33	9.3	5.51	9.0	0	19	38	13.9	5.44	14.0	3	24
	DAY 50	37	9.6	6.59	10.0	0	24	31	8.4	5.83	8.0	1	20	37	13.7	5.41	14.0	3	27
	DAY 57	36	9.2	6.74	7.5	0	23	29	8.7	6.87	7.0	0	27	34	12.9	5.57	12.0	2	28
CHG FROM BASELINE	DAY 8	51	-8.3	5.02	-9.0	-22	2	49	-7.5	5.35	-7.0	-21	3	51	-5.5	5.85	-4.4	-23	6
	DAY 15	46	-11.3	5.24	-12.0	-22	0	38	-10.1	6.14	-10.0	-23	3	46	-8.5	6.39	-6.5	-21	5
	DAY 22	43	-12.2	5.70	-13.0	-26	1	36	-12.7	6.29	-13.5	-25	2	44	-8.7	5.90	-7.7	-24	3
	DAY 29	39	-13.8	6.38	-14.0	-27	0	33	-13.4	6.19	-15.0	-24	0	46	-9.7	6.08	-10.0	-23	3
	DAY 36	37	-13.3	6.96	-14.0	-27	1	33	-13.8	6.49	-16.0	-26	0	43	-10.6	6.31	-11.0	-21	3
	DAY 43	36	-14.3	7.37	-14.0	-28	-1	33	-14.5	5.37	-16.0	-23	-3	38	-9.9	6.08	-9.0	-22	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD202.SAS
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Table 11.2.2.4.2 HAM-D Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	37	-14.3	7.37	-15.0	-29	2	31	-15.1	5.82	-17.0	-25	0	37	-10.3	6.18	-10.0	-22	3
	DAY 57	36	-14.7	7.19	-16.0	-28	1	29	-14.9	6.11	-18.0	-24	0	34	-11.1	5.99	-12.0	-24	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD202.SAS
GENERATED: 17NOV2005 13:49:32 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. DEPRESSED MOOD	WINDOWED VISIT																		
	SCREEN	155	3.0	0.44	3.0	2	4	151	3.0	0.43	3.0	2	4	161	3.0	0.40	3.0	2	4
	DAY 1	155	3.0	0.50	3.0	2	4	151	3.0	0.45	3.0	2	4	161	3.0	0.45	3.0	2	4
	DAY 8	153	2.3	0.98	3.0	0	4	147	2.3	0.90	2.0	0	4	161	2.4	0.91	3.0	0	4
	DAY 15	155	1.8	1.03	2.0	0	4	148	1.9	1.01	2.0	0	4	161	2.1	0.99	2.0	0	4
	DAY 22	155	1.6	1.08	2.0	0	4	150	1.7	1.07	2.0	0	4	161	2.0	1.07	2.0	0	4
	DAY 29	155	1.5	1.07	1.0	0	4	150	1.6	1.08	2.0	0	4	161	1.8	1.09	2.0	0	4
	DAY 36	155	1.4	1.12	1.0	0	4	150	1.5	1.13	1.0	0	4	161	1.9	1.14	2.0	0	4
	DAY 43	155	1.3	1.16	1.0	0	4	151	1.5	1.12	1.0	0	4	161	1.9	1.10	2.0	0	4
	DAY 50	155	1.3	1.16	1.0	0	4	151	1.5	1.13	1.0	0	4	161	1.7	1.19	2.0	0	4
	DAY 57	155	1.3	1.17	1.0	0	4	151	1.4	1.16	1.0	0	4	161	1.7	1.19	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. FEELING OF GUILT	WINDOWED VISIT																		
	SCREEN	155	2.1	0.61	2.0	0	4	151	2.0	0.63	2.0	0	3	161	2.0	0.64	2.0	0	3
	DAY 1	155	2.1	0.58	2.0	0	3	151	2.1	0.63	2.0	0	3	161	1.9	0.68	2.0	0	3
	DAY 8	153	1.4	0.81	2.0	0	3	147	1.5	0.86	2.0	0	3	161	1.4	0.89	2.0	0	3
	DAY 15	155	1.1	0.89	1.0	0	3	148	1.2	0.93	1.0	0	3	161	1.2	0.89	1.0	0	3
	DAY 22	155	1.0	0.89	1.0	0	3	150	1.1	0.97	1.0	0	3	161	1.2	0.93	1.0	0	3
	DAY 29	155	0.9	0.93	1.0	0	3	150	1.0	0.97	1.0	0	3	161	1.2	0.91	1.0	0	3
	DAY 36	155	0.9	0.93	1.0	0	3	150	1.0	0.93	1.0	0	3	161	1.1	0.92	1.0	0	3
	DAY 43	155	0.9	0.92	1.0	0	3	151	0.9	0.95	1.0	0	3	161	1.1	0.94	1.0	0	3
	DAY 50	155	0.8	0.93	1.0	0	3	151	0.9	0.96	1.0	0	3	161	1.1	0.93	1.0	0	3
	DAY 57	155	0.8	0.91	1.0	0	3	151	0.9	0.96	1.0	0	3	161	1.1	0.99	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SUICIDE	WINDOWED VISIT																		
	SCREEN	155	0.9	0.81	1.0	0	3	151	0.8	0.73	1.0	0	2	161	1.0	0.75	1.0	0	2
	DAY 1	155	0.8	0.76	1.0	0	2	151	0.7	0.67	1.0	0	2	161	0.7	0.71	1.0	0	2
	DAY 8	153	0.3	0.58	0.0	0	2	147	0.4	0.71	0.0	0	4	161	0.4	0.64	0.0	0	2
	DAY 15	155	0.3	0.63	0.0	0	3	148	0.3	0.65	0.0	0	4	161	0.4	0.70	0.0	0	2
	DAY 22	155	0.2	0.52	0.0	0	3	150	0.3	0.63	0.0	0	4	161	0.4	0.68	0.0	0	3
	DAY 29	155	0.3	0.57	0.0	0	3	150	0.3	0.61	0.0	0	4	161	0.4	0.67	0.0	0	3
	DAY 36	155	0.3	0.57	0.0	0	3	150	0.3	0.64	0.0	0	4	161	0.4	0.71	0.0	0	3
	DAY 43	155	0.3	0.58	0.0	0	3	151	0.3	0.67	0.0	0	4	161	0.4	0.66	0.0	0	3
	DAY 50	155	0.2	0.52	0.0	0	3	151	0.3	0.66	0.0	0	4	161	0.3	0.65	0.0	0	3
	DAY 57	155	0.2	0.57	0.0	0	3	151	0.3	0.65	0.0	0	4	161	0.4	0.66	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA EARLY	WINDOWED VISIT																		
	SCREEN	155	1.5	0.74	2.0	0	2	151	1.5	0.77	2.0	0	2	161	1.5	0.72	2.0	0	2
	DAY 1	155	1.6	0.70	2.0	0	2	151	1.5	0.74	2.0	0	2	161	1.6	0.68	2.0	0	2
	DAY 8	153	0.5	0.79	0.0	0	2	147	0.5	0.75	0.0	0	2	161	1.0	0.89	1.0	0	2
	DAY 15	155	0.5	0.78	0.0	0	2	148	0.5	0.75	0.0	0	2	161	1.0	0.87	1.0	0	2
	DAY 22	155	0.5	0.79	0.0	0	2	150	0.4	0.72	0.0	0	2	161	0.9	0.91	1.0	0	2
	DAY 29	155	0.4	0.68	0.0	0	2	150	0.5	0.77	0.0	0	2	161	0.9	0.88	1.0	0	2
	DAY 36	155	0.4	0.73	0.0	0	2	150	0.4	0.72	0.0	0	2	161	0.9	0.91	1.0	0	2
	DAY 43	155	0.4	0.73	0.0	0	2	151	0.4	0.74	0.0	0	2	161	0.9	0.90	1.0	0	2
	DAY 50	155	0.5	0.76	0.0	0	2	151	0.4	0.71	0.0	0	2	161	0.9	0.91	1.0	0	2
	DAY 57	155	0.4	0.74	0.0	0	2	151	0.5	0.75	0.0	0	2	161	0.9	0.92	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INSOMNIA MIDDLE	WINDOWED VISIT																		
	SCREEN	155	1.5	0.69	2.0	0	2	151	1.6	0.69	2.0	0	2	161	1.5	0.72	2.0	0	2
	DAY 1	155	1.6	0.60	2.0	0	2	151	1.6	0.67	2.0	0	2	161	1.6	0.63	2.0	0	2
	DAY 8	153	0.6	0.75	0.0	0	2	147	0.5	0.70	0.0	0	2	161	1.1	0.83	1.0	0	2
	DAY 15	155	0.5	0.73	0.0	0	2	148	0.4	0.64	0.0	0	2	161	1.0	0.84	1.0	0	2
	DAY 22	155	0.5	0.73	0.0	0	2	150	0.4	0.68	0.0	0	2	161	1.0	0.84	1.0	0	2
	DAY 29	155	0.5	0.69	0.0	0	2	150	0.4	0.69	0.0	0	2	161	0.9	0.83	1.0	0	2
	DAY 36	155	0.5	0.66	0.0	0	2	150	0.4	0.66	0.0	0	2	161	0.9	0.86	1.0	0	2
	DAY 43	155	0.5	0.69	0.0	0	2	151	0.3	0.60	0.0	0	2	161	0.9	0.85	1.0	0	2
	DAY 50	155	0.5	0.69	0.0	0	2	151	0.4	0.66	0.0	0	2	161	0.9	0.87	1.0	0	2
	DAY 57	155	0.5	0.73	0.0	0	2	151	0.4	0.68	0.0	0	2	161	0.9	0.84	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. INSOMNIA LATE	WINDOWED VISIT																		
	SCREEN	155	1.1	0.84	1.0	0	2	151	1.2	0.86	1.0	0	2	161	1.2	0.82	1.0	0	2
	DAY 1	155	1.3	0.80	2.0	0	2	151	1.3	0.82	2.0	0	2	161	1.2	0.78	1.0	0	2
	DAY 8	153	0.3	0.59	0.0	0	2	147	0.4	0.69	0.0	0	2	161	1.0	0.85	1.0	0	2
	DAY 15	155	0.3	0.54	0.0	0	2	148	0.3	0.60	0.0	0	2	161	0.9	0.82	1.0	0	2
	DAY 22	155	0.3	0.62	0.0	0	2	150	0.3	0.56	0.0	0	2	161	0.9	0.86	1.0	0	2
	DAY 29	155	0.2	0.54	0.0	0	2	150	0.2	0.58	0.0	0	2	161	0.8	0.85	1.0	0	2
	DAY 36	155	0.3	0.59	0.0	0	2	150	0.2	0.55	0.0	0	2	161	0.8	0.84	1.0	0	2
	DAY 43	155	0.3	0.56	0.0	0	2	151	0.3	0.59	0.0	0	2	161	0.8	0.85	1.0	0	2
	DAY 50	155	0.3	0.53	0.0	0	2	151	0.2	0.58	0.0	0	2	161	0.8	0.85	1.0	0	2
	DAY 57	155	0.2	0.51	0.0	0	2	151	0.3	0.61	0.0	0	2	161	0.8	0.86	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
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Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. WORK AND ACTIVITIES	WINDOWED VISIT																		
	SCREEN	155	3.0	0.53	3.0	2	4	151	3.0	0.50	3.0	1	4	161	2.9	0.55	3.0	0	4
	DAY 1	155	3.0	0.59	3.0	0	4	151	3.0	0.48	3.0	2	4	161	3.0	0.49	3.0	2	4
	DAY 8	153	2.3	1.03	3.0	0	4	147	2.3	0.93	3.0	0	4	161	2.4	0.93	3.0	0	4
	DAY 15	155	1.9	1.09	2.0	0	4	148	2.0	1.00	2.0	0	4	161	2.0	1.08	2.0	0	4
	DAY 22	155	1.8	1.17	2.0	0	4	150	1.8	1.10	2.0	0	4	161	2.0	1.11	2.0	0	4
	DAY 29	155	1.8	1.19	2.0	0	4	150	1.7	1.13	2.0	0	4	161	1.8	1.19	2.0	0	4
	DAY 36	155	1.5	1.27	1.0	0	4	150	1.7	1.15	2.0	0	4	161	1.8	1.18	2.0	0	4
	DAY 43	155	1.5	1.26	1.0	0	4	151	1.6	1.16	2.0	0	4	161	1.8	1.19	2.0	0	4
	DAY 50	155	1.5	1.28	1.0	0	4	151	1.5	1.15	2.0	0	4	161	1.7	1.25	2.0	0	4
	DAY 57	155	1.5	1.27	1.0	0	4	151	1.5	1.17	1.0	0	4	161	1.8	1.21	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. RETARDATION	WINDOWED VISIT																		
	SCREEN	155	1.2	0.80	1.0	0	3	151	1.1	0.72	1.0	0	3	161	1.0	0.80	1.0	0	3
	DAY 1	155	1.2	0.80	1.0	0	3	151	1.1	0.70	1.0	0	2	161	1.0	0.80	1.0	0	3
	DAY 8	153	0.9	0.73	1.0	0	3	147	0.9	0.76	1.0	0	4	161	0.7	0.74	1.0	0	3
	DAY 15	155	0.8	0.72	1.0	0	3	148	0.7	0.66	1.0	0	2	161	0.6	0.75	0.0	0	3
	DAY 22	155	0.7	0.78	1.0	0	3	150	0.7	0.68	1.0	0	2	161	0.6	0.74	0.0	0	3
	DAY 29	155	0.6	0.71	0.0	0	3	150	0.7	0.69	1.0	0	2	161	0.6	0.72	0.0	0	3
	DAY 36	155	0.6	0.73	0.0	0	3	150	0.7	0.69	1.0	0	2	161	0.6	0.77	0.0	0	3
	DAY 43	155	0.6	0.74	0.0	0	3	151	0.6	0.65	1.0	0	2	161	0.6	0.75	0.0	0	3
	DAY 50	155	0.6	0.76	0.0	0	3	151	0.6	0.70	0.0	0	2	161	0.6	0.73	0.0	0	3
	DAY 57	155	0.6	0.74	0.0	0	3	151	0.6	0.66	0.0	0	2	161	0.6	0.71	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. AGITATION	WINDOWED VISIT																		
	SCREEN	155	1.3	0.99	1.0	0	4	151	1.3	0.93	1.0	0	4	161	1.3	0.88	1.0	0	4
	DAY 1	155	1.2	0.87	1.0	0	4	151	1.2	0.87	1.0	0	3	161	1.2	0.85	1.0	0	4
	DAY 8	153	0.9	0.76	1.0	0	3	147	0.9	0.92	1.0	0	4	161	1.0	0.89	1.0	0	4
	DAY 15	155	0.7	0.72	1.0	0	3	148	0.8	0.79	1.0	0	3	161	0.9	0.79	1.0	0	3
	DAY 22	155	0.6	0.70	1.0	0	3	150	0.7	0.75	1.0	0	3	161	0.9	0.82	1.0	0	3
	DAY 29	155	0.7	0.70	1.0	0	3	150	0.6	0.73	0.0	0	3	161	0.8	0.82	1.0	0	4
	DAY 36	155	0.6	0.72	0.0	0	3	150	0.6	0.69	0.0	0	3	161	0.9	0.87	1.0	0	4
	DAY 43	155	0.6	0.73	0.0	0	3	151	0.6	0.72	1.0	0	3	161	0.8	0.86	1.0	0	4
	DAY 50	155	0.6	0.69	0.0	0	3	151	0.6	0.74	0.0	0	3	161	0.7	0.80	0.0	0	3
	DAY 57	155	0.6	0.69	0.0	0	3	151	0.6	0.73	0.0	0	3	161	0.7	0.79	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. ANXIETY PSYCHIC	WINDOWED VISIT																		
	SCREEN	155	2.3	0.75	2.0	0	4	151	2.3	0.68	2.0	0	4	161	2.3	0.75	2.0	0	4
	DAY 1	155	2.4	0.61	2.0	1	4	151	2.3	0.73	2.0	0	4	161	2.4	0.71	2.0	0	4
	DAY 8	153	1.8	0.94	2.0	0	4	147	1.7	0.87	2.0	0	4	161	1.9	0.92	2.0	0	4
	DAY 15	155	1.5	1.01	2.0	0	4	148	1.6	0.96	2.0	0	3	161	1.7	0.88	2.0	0	4
	DAY 22	155	1.5	0.96	1.0	0	4	150	1.3	0.91	1.0	0	4	161	1.7	0.93	2.0	0	4
	DAY 29	155	1.4	1.00	1.0	0	4	150	1.3	0.83	1.0	0	3	161	1.5	0.94	2.0	0	4
	DAY 36	155	1.3	0.97	1.0	0	4	150	1.2	0.86	1.0	0	3	161	1.6	0.99	2.0	0	4
	DAY 43	155	1.3	1.03	1.0	0	4	151	1.2	0.88	1.0	0	4	161	1.6	0.97	2.0	0	4
	DAY 50	155	1.3	1.03	1.0	0	4	151	1.2	0.91	1.0	0	4	161	1.7	0.94	2.0	0	4
	DAY 57	155	1.3	1.01	1.0	0	4	151	1.2	0.92	1.0	0	4	161	1.6	0.98	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. ANXIETY SOMATIC	WINDOWED VISIT																		
	SCREEN	155	1.6	0.85	2.0	0	4	151	1.7	0.86	2.0	0	4	161	1.8	0.70	2.0	0	3
	DAY 1	155	1.7	0.80	2.0	0	3	151	1.6	0.85	2.0	0	3	161	1.7	0.76	2.0	0	3
	DAY 8	153	1.4	0.77	1.0	0	3	147	1.4	0.78	2.0	0	3	161	1.4	0.83	2.0	0	3
	DAY 15	155	1.1	0.79	1.0	0	3	148	1.3	0.78	1.0	0	3	161	1.2	0.75	1.0	0	3
	DAY 22	155	1.1	0.77	1.0	0	3	150	1.2	0.80	1.0	0	3	161	1.1	0.81	1.0	0	3
	DAY 29	155	1.0	0.82	1.0	0	3	150	1.2	0.79	1.0	0	3	161	1.1	0.86	1.0	0	3
	DAY 36	155	1.0	0.86	1.0	0	3	150	1.1	0.90	1.0	0	4	161	1.1	0.82	1.0	0	3
	DAY 43	155	1.0	0.84	1.0	0	3	151	1.0	0.86	1.0	0	3	161	1.1	0.85	1.0	0	3
	DAY 50	155	1.0	0.84	1.0	0	3	151	1.1	0.84	1.0	0	3	161	1.1	0.84	1.0	0	3
	DAY 57	155	1.0	0.84	1.0	0	3	151	1.0	0.87	1.0	0	3	161	1.1	0.84	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. SOMATIC SYMPTOMS GASTROINTESTINAL	WINDOWED VISIT																		
	SCREEN	155	0.7	0.69	1.0	0	2	151	0.7	0.70	1.0	0	2	161	0.7	0.68	1.0	0	2
	DAY 1	155	0.8	0.71	1.0	0	2	151	0.7	0.71	1.0	0	2	161	0.7	0.69	1.0	0	2
	DAY 8	153	0.5	0.64	0.0	0	2	147	0.5	0.62	0.0	0	2	161	0.5	0.64	0.0	0	2
	DAY 15	155	0.4	0.59	0.0	0	2	148	0.4	0.61	0.0	0	2	161	0.5	0.63	0.0	0	2
	DAY 22	155	0.4	0.57	0.0	0	2	150	0.4	0.55	0.0	0	2	161	0.4	0.62	0.0	0	2
	DAY 29	155	0.4	0.55	0.0	0	2	150	0.3	0.50	0.0	0	2	161	0.4	0.58	0.0	0	2
	DAY 36	155	0.4	0.52	0.0	0	2	150	0.3	0.52	0.0	0	2	161	0.4	0.57	0.0	0	2
	DAY 43	155	0.3	0.55	0.0	0	2	151	0.3	0.50	0.0	0	2	161	0.4	0.55	0.0	0	2
	DAY 50	155	0.3	0.55	0.0	0	2	151	0.3	0.56	0.0	0	2	161	0.4	0.57	0.0	0	2
	DAY 57	155	0.3	0.53	0.0	0	2	151	0.3	0.49	0.0	0	2	161	0.4	0.55	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. SOMATIC SYMPTOMS GENERAL	WINDOWED VISIT																		
	SCREEN	155	1.7	0.49	2.0	0	2	151	1.8	0.46	2.0	0	2	161	1.7	0.56	2.0	0	2
	DAY 1	155	1.7	0.50	2.0	0	2	151	1.7	0.56	2.0	0	2	161	1.7	0.55	2.0	0	2
	DAY 8	153	1.3	0.73	1.0	0	2	147	1.3	0.68	1.0	0	2	161	1.4	0.72	2.0	0	2
	DAY 15	155	1.2	0.80	1.0	0	2	148	1.1	0.74	1.0	0	2	161	1.2	0.82	1.0	0	2
	DAY 22	155	1.1	0.82	1.0	0	2	150	1.1	0.76	1.0	0	2	161	1.2	0.83	1.0	0	2
	DAY 29	155	1.0	0.84	1.0	0	2	150	1.0	0.77	1.0	0	2	161	1.1	0.84	1.0	0	2
	DAY 36	155	1.0	0.82	1.0	0	2	150	1.0	0.78	1.0	0	2	161	1.1	0.85	1.0	0	2
	DAY 43	155	0.9	0.84	1.0	0	2	151	0.9	0.78	1.0	0	2	161	1.1	0.84	1.0	0	2
	DAY 50	155	0.9	0.84	1.0	0	2	151	0.9	0.80	1.0	0	2	161	1.0	0.86	1.0	0	2
	DAY 57	155	0.9	0.81	1.0	0	2	151	0.9	0.82	1.0	0	2	161	1.1	0.85	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
14. GENITAL SYMPTOMS	WINDOWED VISIT																		
	SCREEN	155	1.2	0.82	1.0	0	2	151	1.1	0.82	1.0	0	2	161	1.2	0.85	1.0	0	2
	DAY 1	155	1.3	0.80	1.0	0	2	151	1.2	0.78	1.0	0	2	161	1.3	0.81	2.0	0	2
	DAY 8	153	1.0	0.85	1.0	0	2	147	0.9	0.82	1.0	0	2	161	1.1	0.87	1.0	0	2
	DAY 15	155	0.9	0.86	1.0	0	2	148	0.8	0.80	1.0	0	2	161	0.9	0.84	1.0	0	2
	DAY 22	155	0.8	0.84	1.0	0	2	150	0.8	0.83	1.0	0	2	161	0.9	0.84	1.0	0	2
	DAY 29	155	0.8	0.82	1.0	0	2	150	0.8	0.82	1.0	0	2	161	0.9	0.85	1.0	0	2
	DAY 36	155	0.7	0.81	0.0	0	2	150	0.8	0.83	1.0	0	2	161	0.8	0.81	1.0	0	2
	DAY 43	155	0.7	0.81	1.0	0	2	151	0.8	0.83	1.0	0	2	161	0.8	0.81	1.0	0	2
	DAY 50	155	0.8	0.84	1.0	0	2	151	0.8	0.83	1.0	0	2	161	0.8	0.83	1.0	0	2
	DAY 57	155	0.7	0.84	0.0	0	2	151	0.8	0.83	1.0	0	2	161	0.8	0.83	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
15. HYPOCHONDRIASIS	WINDOWED VISIT																		
	SCREEN	155	0.9	0.86	1.0	0	3	151	1.0	0.87	1.0	0	4	161	0.9	0.86	1.0	0	3
	DAY 1	155	0.9	0.84	1.0	0	3	151	1.1	0.89	1.0	0	4	161	1.0	0.89	1.0	0	3
	DAY 8	153	0.7	0.78	0.0	0	3	147	0.8	0.84	1.0	0	4	161	0.7	0.84	1.0	0	3
	DAY 15	155	0.5	0.72	0.0	0	3	148	0.7	0.82	1.0	0	4	161	0.6	0.72	0.0	0	3
	DAY 22	155	0.5	0.72	0.0	0	3	150	0.6	0.79	0.0	0	4	161	0.6	0.79	0.0	0	3
	DAY 29	155	0.4	0.70	0.0	0	3	150	0.6	0.81	0.0	0	4	161	0.7	0.75	0.0	0	3
	DAY 36	155	0.4	0.70	0.0	0	3	150	0.6	0.78	0.0	0	4	161	0.6	0.78	0.0	0	3
	DAY 43	155	0.5	0.69	0.0	0	3	151	0.6	0.76	0.0	0	4	161	0.6	0.81	0.0	0	3
	DAY 50	155	0.4	0.70	0.0	0	3	151	0.6	0.75	0.0	0	4	161	0.7	0.84	0.0	0	3
	DAY 57	155	0.4	0.70	0.0	0	3	151	0.6	0.76	0.0	0	4	161	0.6	0.84	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
16a. LOSS OF WEIGHT[HISTORY]	WINDOWED VISIT																		
	SCREEN	155	0.5	0.82	0.0	0	2	151	0.5	0.75	0.0	0	2	161	0.5	0.74	0.0	0	2
	DAY 1	155	0.4	0.73	0.0	0	2	151	0.3	0.63	0.0	0	2	161	0.3	0.63	0.0	0	2
	DAY 8	153	0.2	0.50	0.0	0	2	147	0.1	0.33	0.0	0	2	161	0.2	0.47	0.0	0	2
	DAY 15	155	0.1	0.44	0.0	0	2	148	0.1	0.38	0.0	0	2	161	0.1	0.44	0.0	0	2
	DAY 22	155	0.1	0.43	0.0	0	2	150	0.1	0.26	0.0	0	1	161	0.2	0.46	0.0	0	2
	DAY 29	155	0.1	0.33	0.0	0	2	150	0.1	0.29	0.0	0	2	161	0.2	0.43	0.0	0	2
	DAY 36	155	0.1	0.28	0.0	0	1	150	0.1	0.28	0.0	0	2	161	0.1	0.35	0.0	0	2
	DAY 43	155	0.1	0.37	0.0	0	2	151	0.1	0.27	0.0	0	2	161	0.2	0.50	0.0	0	2
	DAY 50	155	0.1	0.35	0.0	0	2	151	0.1	0.29	0.0	0	2	161	0.1	0.40	0.0	0	2
	DAY 57	155	0.1	0.35	0.0	0	2	151	0.1	0.38	0.0	0	2	161	0.2	0.51	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.1 HAM-D Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
17. INSIGHT	WINDOWED VISIT																		
	SCREEN	155	0.1	0.32	0.0	0	2	151	0.0	0.21	0.0	0	1	161	0.0	0.22	0.0	0	1
	DAY 1	155	0.1	0.28	0.0	0	2	151	0.1	0.22	0.0	0	1	161	0.0	0.17	0.0	0	1
	DAY 8	153	0.0	0.27	0.0	0	2	147	0.0	0.14	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 15	155	0.0	0.20	0.0	0	2	148	0.0	0.12	0.0	0	1	161	0.0	0.19	0.0	0	1
	DAY 22	155	0.0	0.18	0.0	0	2	150	0.0	0.08	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 29	155	0.0	0.18	0.0	0	2	150	0.0	0.12	0.0	0	1	161	0.0	0.19	0.0	0	1
	DAY 36	155	0.0	0.20	0.0	0	2	150	0.0	0.14	0.0	0	1	161	0.0	0.17	0.0	0	1
	DAY 43	155	0.0	0.21	0.0	0	2	151	0.0	0.11	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 50	155	0.0	0.26	0.0	0	2	151	0.0	0.14	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 57	155	0.0	0.25	0.0	0	2	151	0.0	0.11	0.0	0	1	161	0.0	0.17	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD206.SAS
GENERATED: 17NOV2005 13:49:43 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. DEPRESSED MOOD	WINDOWED VISIT																		
	SCREEN	155	3.0	0.44	3.0	2	4	151	3.0	0.43	3.0	2	4	161	3.0	0.40	3.0	2	4
	DAY 1	155	3.0	0.50	3.0	2	4	151	3.0	0.45	3.0	2	4	161	3.0	0.45	3.0	2	4
	DAY 8	153	2.3	0.98	3.0	0	4	147	2.3	0.90	2.0	0	4	161	2.4	0.91	3.0	0	4
	DAY 15	134	1.8	1.00	2.0	0	4	126	1.8	0.99	2.0	0	4	146	2.1	1.01	2.0	0	4
	DAY 22	123	1.5	1.04	2.0	0	4	119	1.6	1.04	2.0	0	3	136	1.9	1.08	2.0	0	4
	DAY 29	117	1.5	1.05	1.0	0	4	109	1.4	1.01	1.0	0	3	133	1.7	1.06	2.0	0	4
	DAY 36	111	1.3	1.10	1.0	0	4	104	1.3	1.08	1.0	0	3	124	1.6	1.11	2.0	0	4
	DAY 43	99	1.1	1.11	1.0	0	3	97	1.3	1.03	1.0	0	3	114	1.6	1.02	2.0	0	4
	DAY 50	102	1.0	1.07	1.0	0	3	89	1.2	1.06	1.0	0	3	112	1.5	1.11	1.0	0	4
	DAY 57	97	1.0	1.12	1.0	0	3	86	1.2	1.10	1.0	0	3	103	1.5	1.09	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. FEELING OF GUILT	WINDOWED VISIT																		
	SCREEN	155	2.1	0.61	2.0	0	4	151	2.0	0.63	2.0	0	3	161	2.0	0.64	2.0	0	3
	DAY 1	155	2.1	0.58	2.0	0	3	151	2.1	0.63	2.0	0	3	161	1.9	0.68	2.0	0	3
	DAY 8	153	1.4	0.81	2.0	0	3	147	1.5	0.86	2.0	0	3	161	1.4	0.89	2.0	0	3
	DAY 15	134	1.1	0.88	1.0	0	3	126	1.2	0.90	1.0	0	3	146	1.2	0.87	1.0	0	3
	DAY 22	123	0.9	0.85	1.0	0	3	119	0.9	0.92	1.0	0	3	136	1.1	0.89	1.0	0	3
	DAY 29	117	0.8	0.87	1.0	0	3	109	0.9	0.89	1.0	0	3	133	1.1	0.84	1.0	0	3
	DAY 36	111	0.7	0.88	0.0	0	3	104	0.8	0.84	1.0	0	3	124	0.9	0.84	1.0	0	3
	DAY 43	99	0.6	0.81	0.0	0	2	97	0.7	0.83	1.0	0	3	114	0.9	0.89	1.0	0	3
	DAY 50	102	0.6	0.80	0.0	0	2	89	0.6	0.82	0.0	0	3	112	0.9	0.88	1.0	0	3
	DAY 57	97	0.6	0.76	0.0	0	2	86	0.6	0.82	0.0	0	3	103	0.9	0.97	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SUICIDE	WINDOWED VISIT																		
	SCREEN	155	0.9	0.81	1.0	0	3	151	0.8	0.73	1.0	0	2	161	1.0	0.75	1.0	0	2
	DAY 1	155	0.8	0.76	1.0	0	2	151	0.7	0.67	1.0	0	2	161	0.7	0.71	1.0	0	2
	DAY 8	153	0.3	0.58	0.0	0	2	147	0.4	0.71	0.0	0	4	161	0.4	0.64	0.0	0	2
	DAY 15	134	0.3	0.63	0.0	0	3	126	0.2	0.50	0.0	0	3	146	0.4	0.67	0.0	0	2
	DAY 22	123	0.1	0.40	0.0	0	2	119	0.2	0.49	0.0	0	2	136	0.4	0.64	0.0	0	3
	DAY 29	117	0.2	0.50	0.0	0	2	109	0.2	0.43	0.0	0	2	133	0.3	0.60	0.0	0	3
	DAY 36	111	0.2	0.50	0.0	0	2	104	0.2	0.51	0.0	0	2	124	0.3	0.61	0.0	0	2
	DAY 43	99	0.2	0.50	0.0	0	3	97	0.2	0.49	0.0	0	2	114	0.2	0.48	0.0	0	2
	DAY 50	102	0.1	0.37	0.0	0	2	89	0.1	0.44	0.0	0	2	112	0.2	0.48	0.0	0	2
	DAY 57	97	0.1	0.47	0.0	0	3	86	0.2	0.43	0.0	0	2	103	0.2	0.50	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA EARLY	WINDOWED VISIT																		
	SCREEN	155	1.5	0.74	2.0	0	2	151	1.5	0.77	2.0	0	2	161	1.5	0.72	2.0	0	2
	DAY 1	155	1.6	0.70	2.0	0	2	151	1.5	0.74	2.0	0	2	160	1.6	0.68	2.0	0	2
	DAY 8	153	0.5	0.79	0.0	0	2	147	0.5	0.75	0.0	0	2	161	1.0	0.89	1.0	0	2
	DAY 15	134	0.5	0.78	0.0	0	2	126	0.4	0.75	0.0	0	2	146	1.0	0.87	1.0	0	2
	DAY 22	123	0.5	0.76	0.0	0	2	119	0.4	0.70	0.0	0	2	136	0.9	0.91	1.0	0	2
	DAY 29	117	0.4	0.64	0.0	0	2	109	0.5	0.77	0.0	0	2	133	0.9	0.87	1.0	0	2
	DAY 36	111	0.4	0.70	0.0	0	2	104	0.4	0.69	0.0	0	2	124	0.8	0.90	0.0	0	2
	DAY 43	99	0.4	0.68	0.0	0	2	97	0.4	0.72	0.0	0	2	114	0.8	0.87	0.0	0	2
	DAY 50	102	0.5	0.73	0.0	0	2	89	0.3	0.65	0.0	0	2	112	0.7	0.89	0.0	0	2
	DAY 57	97	0.3	0.68	0.0	0	2	86	0.4	0.71	0.0	0	2	103	0.7	0.90	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INSOMNIA MIDDLE	WINDOWED VISIT																		
	SCREEN	155	1.5	0.69	2.0	0	2	151	1.6	0.69	2.0	0	2	161	1.5	0.72	2.0	0	2
	DAY 1	155	1.6	0.60	2.0	0	2	151	1.6	0.67	2.0	0	2	161	1.6	0.63	2.0	0	2
	DAY 8	153	0.6	0.75	0.0	0	2	147	0.5	0.70	0.0	0	2	161	1.1	0.83	1.0	0	2
	DAY 15	134	0.5	0.71	0.0	0	2	126	0.4	0.65	0.0	0	2	146	1.0	0.83	1.0	0	2
	DAY 22	123	0.4	0.70	0.0	0	2	119	0.4	0.66	0.0	0	2	136	0.9	0.84	1.0	0	2
	DAY 29	117	0.4	0.66	0.0	0	2	109	0.4	0.66	0.0	0	2	133	0.9	0.83	1.0	0	2
	DAY 36	111	0.4	0.62	0.0	0	2	104	0.4	0.65	0.0	0	2	124	0.8	0.84	1.0	0	2
	DAY 43	99	0.4	0.66	0.0	0	2	97	0.2	0.50	0.0	0	2	114	0.7	0.83	0.5	0	2
	DAY 50	102	0.4	0.65	0.0	0	2	89	0.4	0.61	0.0	0	2	112	0.9	0.87	1.0	0	2
	DAY 57	97	0.5	0.72	0.0	0	2	86	0.4	0.63	0.0	0	2	103	0.8	0.83	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. INSOMNIA LATE	WINDOWED VISIT																		
	SCREEN	155	1.1	0.84	1.0	0	2	151	1.2	0.86	1.0	0	2	161	1.2	0.82	1.0	0	2
	DAY 1	155	1.3	0.80	2.0	0	2	151	1.3	0.82	2.0	0	2	161	1.2	0.78	1.0	0	2
	DAY 8	153	0.3	0.59	0.0	0	2	147	0.4	0.69	0.0	0	2	161	1.0	0.85	1.0	0	2
	DAY 15	134	0.2	0.53	0.0	0	2	126	0.3	0.58	0.0	0	2	146	0.8	0.83	1.0	0	2
	DAY 22	123	0.3	0.62	0.0	0	2	119	0.2	0.51	0.0	0	2	136	0.9	0.87	1.0	0	2
	DAY 29	117	0.2	0.54	0.0	0	2	109	0.2	0.52	0.0	0	2	133	0.8	0.85	0.0	0	2
	DAY 36	111	0.2	0.57	0.0	0	2	104	0.2	0.48	0.0	0	2	124	0.7	0.81	0.0	0	2
	DAY 43	99	0.2	0.51	0.0	0	2	97	0.2	0.54	0.0	0	2	114	0.7	0.83	0.0	0	2
	DAY 50	102	0.2	0.46	0.0	0	2	89	0.2	0.51	0.0	0	2	112	0.8	0.84	0.0	0	2
	DAY 57	97	0.2	0.42	0.0	0	2	86	0.3	0.58	0.0	0	2	103	0.7	0.85	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. WORK AND ACTIVITIES	WINDOWED VISIT																		
	SCREEN	155	3.0	0.53	3.0	2	4	151	3.0	0.50	3.0	1	4	161	2.9	0.55	3.0	0	4
	DAY 1	155	3.0	0.59	3.0	0	4	151	3.0	0.48	3.0	2	4	161	3.0	0.49	3.0	2	4
	DAY 8	153	2.3	1.03	3.0	0	4	147	2.3	0.93	3.0	0	4	161	2.4	0.93	3.0	0	4
	DAY 15	134	1.9	1.08	2.0	0	4	126	2.0	1.01	2.0	0	4	146	2.0	1.06	2.0	0	4
	DAY 22	123	1.6	1.15	2.0	0	4	119	1.7	1.09	2.0	0	4	136	1.9	1.09	2.0	0	4
	DAY 29	117	1.7	1.17	2.0	0	4	109	1.5	1.13	1.0	0	4	133	1.7	1.15	2.0	0	4
	DAY 36	111	1.3	1.25	1.0	0	4	104	1.5	1.16	1.0	0	4	124	1.6	1.14	2.0	0	4
	DAY 43	99	1.2	1.20	1.0	0	4	97	1.3	1.14	1.0	0	4	114	1.6	1.14	2.0	0	4
	DAY 50	102	1.2	1.22	1.0	0	4	89	1.2	1.11	1.0	0	4	112	1.5	1.21	1.0	0	4
	DAY 57	97	1.3	1.20	1.0	0	4	86	1.3	1.17	1.0	0	4	103	1.7	1.15	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. RETARDATION	WINDOWED VISIT																		
	SCREEN	155	1.2	0.80	1.0	0	3	151	1.1	0.72	1.0	0	3	161	1.0	0.80	1.0	0	3
	DAY 1	155	1.2	0.80	1.0	0	3	151	1.1	0.70	1.0	0	2	161	1.0	0.80	1.0	0	3
	DAY 8	153	0.9	0.73	1.0	0	3	147	0.9	0.76	1.0	0	4	161	0.7	0.74	1.0	0	3
	DAY 15	134	0.8	0.71	1.0	0	3	126	0.7	0.63	1.0	0	2	146	0.6	0.72	0.0	0	3
	DAY 22	123	0.6	0.74	0.0	0	3	119	0.6	0.67	1.0	0	2	136	0.6	0.69	0.0	0	2
	DAY 29	117	0.5	0.62	0.0	0	2	109	0.6	0.64	0.0	0	2	133	0.5	0.68	0.0	0	2
	DAY 36	111	0.5	0.66	0.0	0	3	104	0.7	0.65	1.0	0	2	124	0.5	0.74	0.0	0	2
	DAY 43	99	0.5	0.61	0.0	0	2	97	0.5	0.52	1.0	0	2	114	0.5	0.69	0.0	0	2
	DAY 50	102	0.4	0.65	0.0	0	2	89	0.4	0.62	0.0	0	2	112	0.4	0.65	0.0	0	2
	DAY 57	97	0.5	0.63	0.0	0	2	86	0.4	0.54	0.0	0	2	103	0.5	0.64	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. AGITATION	WINDOWED VISIT																		
	SCREEN	155	1.3	0.99	1.0	0	4	151	1.3	0.93	1.0	0	4	161	1.3	0.88	1.0	0	4
	DAY 1	155	1.2	0.87	1.0	0	4	151	1.2	0.87	1.0	0	3	161	1.2	0.85	1.0	0	4
	DAY 8	153	0.9	0.76	1.0	0	3	147	0.9	0.92	1.0	0	4	161	1.0	0.89	1.0	0	4
	DAY 15	134	0.6	0.67	1.0	0	2	126	0.7	0.78	1.0	0	3	146	0.9	0.78	1.0	0	3
	DAY 22	123	0.6	0.66	0.0	0	2	119	0.7	0.75	1.0	0	3	136	0.9	0.81	1.0	0	3
	DAY 29	117	0.6	0.66	1.0	0	2	109	0.6	0.73	0.0	0	3	133	0.7	0.78	1.0	0	4
	DAY 36	111	0.6	0.70	0.0	0	3	104	0.5	0.67	0.0	0	3	124	0.8	0.88	1.0	0	4
	DAY 43	99	0.6	0.72	0.0	0	3	97	0.6	0.68	0.0	0	3	114	0.7	0.83	1.0	0	3
	DAY 50	102	0.5	0.64	0.0	0	2	89	0.5	0.69	0.0	0	3	112	0.6	0.78	0.0	0	3
	DAY 57	97	0.4	0.63	0.0	0	2	86	0.4	0.64	0.0	0	3	103	0.6	0.79	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. ANXIETY PSYCHIC	WINDOWED VISIT																		
	SCREEN	155	2.3	0.75	2.0	0	4	151	2.3	0.68	2.0	0	4	161	2.3	0.75	2.0	0	4
	DAY 1	155	2.4	0.61	2.0	1	4	151	2.3	0.73	2.0	0	4	161	2.4	0.71	2.0	0	4
	DAY 8	153	1.8	0.94	2.0	0	4	147	1.7	0.87	2.0	0	4	161	1.9	0.92	2.0	0	4
	DAY 15	134	1.5	0.98	1.0	0	4	126	1.5	0.97	1.5	0	3	146	1.7	0.88	2.0	0	3
	DAY 22	123	1.3	0.89	1.0	0	4	119	1.2	0.88	1.0	0	4	136	1.6	0.90	2.0	0	4
	DAY 29	117	1.3	0.96	1.0	0	4	109	1.2	0.78	1.0	0	3	133	1.4	0.90	1.0	0	3
	DAY 36	111	1.2	0.90	1.0	0	3	104	1.1	0.80	1.0	0	3	124	1.5	0.98	1.0	0	4
	DAY 43	99	1.1	0.98	1.0	0	3	97	1.0	0.78	1.0	0	3	114	1.5	0.91	2.0	0	3
	DAY 50	102	1.0	0.93	1.0	0	3	89	1.0	0.84	1.0	0	3	112	1.5	0.91	2.0	0	3
	DAY 57	97	1.1	0.93	1.0	0	3	86	1.0	0.85	1.0	0	3	103	1.4	0.94	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
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Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. ANXIETY SOMATIC	WINDOWED VISIT																		
	SCREEN	155	1.6	0.85	2.0	0	4	151	1.7	0.86	2.0	0	4	161	1.8	0.70	2.0	0	3
	DAY 1	155	1.7	0.80	2.0	0	3	151	1.6	0.85	2.0	0	3	161	1.7	0.76	2.0	0	3
	DAY 8	153	1.4	0.77	1.0	0	3	147	1.4	0.78	2.0	0	3	161	1.4	0.83	2.0	0	3
	DAY 15	134	1.1	0.77	1.0	0	3	126	1.2	0.78	1.0	0	3	146	1.2	0.76	1.0	0	3
	DAY 22	123	1.0	0.73	1.0	0	2	119	1.1	0.78	1.0	0	3	136	1.2	0.82	1.0	0	3
	DAY 29	117	0.8	0.76	1.0	0	3	109	1.0	0.75	1.0	0	3	133	1.1	0.83	1.0	0	3
	DAY 36	111	0.9	0.83	1.0	0	3	104	1.0	0.89	1.0	0	4	124	1.0	0.79	1.0	0	3
	DAY 43	99	0.9	0.75	1.0	0	3	97	0.8	0.81	1.0	0	3	114	1.0	0.79	1.0	0	3
	DAY 50	102	0.8	0.75	1.0	0	3	89	0.8	0.76	1.0	0	3	112	1.0	0.79	1.0	0	3
	DAY 57	97	0.8	0.76	1.0	0	3	86	0.8	0.82	1.0	0	3	103	1.0	0.80	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. SOMATIC SYMPTOMS GASTROINTESTINAL	WINDOWED VISIT																		
	SCREEN	155	0.7	0.69	1.0	0	2	151	0.7	0.70	1.0	0	2	161	0.7	0.68	1.0	0	2
	DAY 1	155	0.8	0.71	1.0	0	2	151	0.7	0.71	1.0	0	2	161	0.7	0.69	1.0	0	2
	DAY 8	153	0.5	0.64	0.0	0	2	147	0.5	0.62	0.0	0	2	161	0.5	0.64	0.0	0	2
	DAY 15	134	0.4	0.61	0.0	0	2	126	0.4	0.63	0.0	0	2	146	0.5	0.62	0.0	0	2
	DAY 22	123	0.3	0.55	0.0	0	2	119	0.4	0.56	0.0	0	2	136	0.4	0.60	0.0	0	2
	DAY 29	117	0.3	0.51	0.0	0	2	109	0.3	0.49	0.0	0	2	133	0.4	0.53	0.0	0	2
	DAY 36	111	0.3	0.48	0.0	0	2	104	0.3	0.48	0.0	0	2	124	0.3	0.51	0.0	0	2
	DAY 43	99	0.3	0.53	0.0	0	2	97	0.2	0.44	0.0	0	2	114	0.3	0.49	0.0	0	2
	DAY 50	102	0.3	0.53	0.0	0	2	89	0.3	0.57	0.0	0	2	112	0.3	0.52	0.0	0	2
	DAY 57	97	0.3	0.52	0.0	0	2	86	0.3	0.44	0.0	0	1	103	0.3	0.47	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. SOMATIC SYMPTOMS GENERAL	WINDOWED VISIT																		
	SCREEN	155	1.7	0.49	2.0	0	2	151	1.8	0.46	2.0	0	2	161	1.7	0.56	2.0	0	2
	DAY 1	155	1.7	0.50	2.0	0	2	151	1.7	0.56	2.0	0	2	161	1.7	0.55	2.0	0	2
	DAY 8	153	1.3	0.73	1.0	0	2	147	1.3	0.68	1.0	0	2	161	1.4	0.72	2.0	0	2
	DAY 15	134	1.2	0.80	1.0	0	2	126	1.1	0.75	1.0	0	2	146	1.2	0.81	1.0	0	2
	DAY 22	123	1.0	0.80	1.0	0	2	119	1.0	0.79	1.0	0	2	136	1.1	0.83	1.0	0	2
	DAY 29	117	1.0	0.84	1.0	0	2	109	0.9	0.78	1.0	0	2	133	1.1	0.83	1.0	0	2
	DAY 36	111	0.9	0.82	1.0	0	2	104	0.8	0.78	1.0	0	2	124	1.1	0.85	1.0	0	2
	DAY 43	99	0.7	0.83	0.0	0	2	97	0.8	0.77	1.0	0	2	114	1.0	0.83	1.0	0	2
	DAY 50	102	0.8	0.84	1.0	0	2	89	0.7	0.77	1.0	0	2	112	0.9	0.84	1.0	0	2
	DAY 57	97	0.8	0.79	1.0	0	2	86	0.8	0.84	1.0	0	2	103	1.0	0.83	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
14. GENITAL SYMPTOMS	WINDOWED VISIT																		
	SCREEN	155	1.2	0.82	1.0	0	2	151	1.1	0.82	1.0	0	2	161	1.2	0.85	1.0	0	2
	DAY 1	155	1.3	0.80	1.0	0	2	151	1.2	0.78	1.0	0	2	161	1.3	0.81	2.0	0	2
	DAY 8	153	1.0	0.85	1.0	0	2	147	0.9	0.82	1.0	0	2	161	1.1	0.87	1.0	0	2
	DAY 15	134	0.9	0.86	1.0	0	2	126	0.8	0.81	1.0	0	2	146	0.9	0.83	1.0	0	2
	DAY 22	123	0.7	0.82	1.0	0	2	119	0.7	0.83	0.0	0	2	136	0.9	0.83	1.0	0	2
	DAY 29	117	0.8	0.81	1.0	0	2	109	0.8	0.83	1.0	0	2	133	0.9	0.84	1.0	0	2
	DAY 36	111	0.6	0.76	0.0	0	2	104	0.7	0.83	0.0	0	2	124	0.8	0.78	1.0	0	2
	DAY 43	99	0.6	0.79	0.0	0	2	97	0.7	0.83	0.0	0	2	114	0.8	0.78	1.0	0	2
	DAY 50	102	0.7	0.81	0.0	0	2	89	0.7	0.85	0.0	0	2	112	0.7	0.81	0.0	0	2
	DAY 57	97	0.6	0.83	0.0	0	2	86	0.7	0.84	0.0	0	2	103	0.7	0.81	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
15. HYPOCHONDRIASIS	WINDOWED VISIT																		
	SCREEN	155	0.9	0.86	1.0	0	3	151	1.0	0.87	1.0	0	4	161	0.9	0.86	1.0	0	3
	DAY 1	155	0.9	0.84	1.0	0	3	151	1.1	0.89	1.0	0	4	161	1.0	0.89	1.0	0	3
	DAY 8	153	0.7	0.78	0.0	0	3	147	0.8	0.84	1.0	0	4	161	0.7	0.84	1.0	0	3
	DAY 15	134	0.5	0.72	0.0	0	3	126	0.7	0.83	0.0	0	4	146	0.5	0.71	0.0	0	3
	DAY 22	123	0.4	0.67	0.0	0	3	119	0.5	0.77	0.0	0	4	135	0.6	0.76	0.0	0	3
	DAY 29	117	0.4	0.64	0.0	0	2	109	0.5	0.78	0.0	0	4	133	0.6	0.68	0.0	0	2
	DAY 36	111	0.4	0.66	0.0	0	2	104	0.5	0.67	0.0	0	3	124	0.5	0.73	0.0	0	3
	DAY 43	99	0.4	0.62	0.0	0	2	97	0.4	0.61	0.0	0	2	114	0.5	0.71	0.0	0	3
	DAY 50	102	0.4	0.68	0.0	0	2	89	0.4	0.58	0.0	0	2	112	0.6	0.76	0.0	0	3
	DAY 57	97	0.4	0.67	0.0	0	3	86	0.5	0.65	0.0	0	2	103	0.5	0.76	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
16a. LOSS OF WEIGHT[HISTORY]	WINDOWED VISIT																		
	SCREEN	155	0.5	0.82	0.0	0	2	151	0.5	0.75	0.0	0	2	161	0.5	0.74	0.0	0	2
	DAY 1	155	0.4	0.73	0.0	0	2	151	0.3	0.63	0.0	0	2	161	0.3	0.63	0.0	0	2
	DAY 8	153	0.2	0.50	0.0	0	2	147	0.1	0.33	0.0	0	2	161	0.2	0.47	0.0	0	2
	DAY 15	134	0.1	0.46	0.0	0	2	126	0.1	0.41	0.0	0	2	146	0.1	0.42	0.0	0	2
	DAY 22	123	0.1	0.46	0.0	0	2	119	0.1	0.25	0.0	0	1	136	0.2	0.45	0.0	0	2
	DAY 29	117	0.1	0.33	0.0	0	2	109	0.1	0.30	0.0	0	2	133	0.2	0.42	0.0	0	2
	DAY 36	111	0.1	0.26	0.0	0	1	104	0.1	0.27	0.0	0	2	124	0.1	0.29	0.0	0	2
	DAY 43	99	0.1	0.39	0.0	0	2	97	0.0	0.20	0.0	0	1	114	0.2	0.53	0.0	0	2
	DAY 50	102	0.1	0.35	0.0	0	2	89	0.0	0.24	0.0	0	2	112	0.1	0.39	0.0	0	2
	DAY 57	97	0.1	0.36	0.0	0	2	86	0.1	0.39	0.0	0	2	103	0.2	0.54	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.5.2 HAM-D Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
17. INSIGHT	WINDOWED VISIT																		
	SCREEN	155	0.1	0.32	0.0	0	2	151	0.0	0.21	0.0	0	1	161	0.0	0.22	0.0	0	1
	DAY 1	155	0.1	0.28	0.0	0	2	151	0.1	0.22	0.0	0	1	161	0.0	0.17	0.0	0	1
	DAY 8	153	0.0	0.27	0.0	0	2	147	0.0	0.14	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 15	134	0.0	0.21	0.0	0	2	126	0.0	0.13	0.0	0	1	146	0.0	0.16	0.0	0	1
	DAY 22	123	0.0	0.20	0.0	0	2	119	0.0	0.09	0.0	0	1	135	0.0	0.12	0.0	0	1
	DAY 29	117	0.0	0.21	0.0	0	2	109	0.0	0.13	0.0	0	1	133	0.0	0.17	0.0	0	1
	DAY 36	111	0.0	0.23	0.0	0	2	104	0.0	0.17	0.0	0	1	124	0.0	0.13	0.0	0	1
	DAY 43	99	0.0	0.14	0.0	0	1	97	0.0	0.10	0.0	0	1	114	0.0	0.00	0.0	0	0
	DAY 50	102	0.0	0.24	0.0	0	2	89	0.0	0.15	0.0	0	1	112	0.0	0.00	0.0	0	0
	DAY 57	97	0.0	0.23	0.0	0	2	86	0.0	0.11	0.0	0	1	103	0.0	0.10	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD205.SAS
GENERATED: 17NOV2005 13:49:37 iceadmn3

Table 11.2.2.6.1 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	3.0	0.50	-0.7	0.92	-0.73	0.089	-0.90	-0.55	.
	Q600MG	147	3.0	0.45	-0.7	0.83	-0.73	0.091	-0.92	-0.55	.
	P	161	3.0	0.45	-0.6	0.91	-0.58	0.089	-0.76	-0.41	.
	Q300MG VS P	.	.	.	.	.	-0.14	0.095	-0.33	0.04	0.133
	Q600MG VS P	.	.	.	.	.	-0.15	0.097	-0.34	0.04	0.120
DAY 15	Q300MG	155	3.0	0.50	-1.2	1.03	-1.16	0.101	-1.36	-0.96	.
	Q600MG	148	3.0	0.44	-1.1	1.02	-1.13	0.104	-1.33	-0.92	.
	P	161	3.0	0.45	-0.9	1.04	-0.91	0.102	-1.11	-0.70	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.106	-0.47	-0.05	0.016
	Q600MG VS P	.	.	.	.	.	-0.22	0.108	-0.43	-0.01	0.042
DAY 22	Q300MG	155	3.0	0.50	-1.4	1.13	-1.40	0.104	-1.61	-1.19	.
	Q600MG	150	3.0	0.44	-1.3	1.04	-1.31	0.106	-1.52	-1.09	.
	P	161	3.0	0.45	-1.0	1.10	-1.07	0.104	-1.27	-0.86	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.115	-0.56	-0.11	0.004
	Q600MG VS P	.	.	.	.	.	-0.24	0.116	-0.47	-0.01	0.041
DAY 29	Q300MG	155	3.0	0.50	-1.5	1.11	-1.48	0.104	-1.69	-1.28	.
	Q600MG	150	3.0	0.44	-1.4	1.08	-1.41	0.106	-1.62	-1.20	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD208.SAS
GENERATED: 17NOV2005 13:31:51 iceadmn3

Table 11.2.2.6.1 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	3.0	0.45	-1.2	1.09	-1.19	0.103	-1.40	-0.99	.
	Q300MG VS P	.	.	.	.	.	-0.29	0.116	-0.52	-0.06	0.013
	Q600MG VS P	.	.	.	.	.	-0.22	0.118	-0.45	0.02	0.068
DAY 36	Q300MG	155	3.0	0.50	-1.6	1.20	-1.52	0.114	-1.75	-1.30	.
	Q600MG	150	3.0	0.44	-1.5	1.10	-1.47	0.116	-1.70	-1.24	.
	P	161	3.0	0.45	-1.2	1.22	-1.13	0.114	-1.36	-0.90	.
	Q300MG VS P	.	.	.	.	.	-0.39	0.121	-0.63	-0.15	0.001
	Q600MG VS P	.	.	.	.	.	-0.34	0.123	-0.58	-0.10	0.006
DAY 43	Q300MG	155	3.0	0.50	-1.7	1.19	-1.66	0.109	-1.87	-1.44	.
	Q600MG	151	3.0	0.45	-1.5	1.10	-1.50	0.111	-1.72	-1.28	.
	P	161	3.0	0.45	-1.1	1.13	-1.16	0.109	-1.38	-0.94	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.121	-0.73	-0.26	<.001
	Q600MG VS P	.	.	.	.	.	-0.34	0.123	-0.58	-0.10	0.006
DAY 50	Q300MG	155	3.0	0.50	-1.7	1.20	-1.73	0.110	-1.95	-1.52	.
	Q600MG	151	3.0	0.45	-1.5	1.14	-1.51	0.112	-1.73	-1.29	.
	P	161	3.0	0.45	-1.3	1.19	-1.28	0.110	-1.50	-1.06	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.126	-0.70	-0.20	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD208.SAS
GENERATED: 17NOV2005 13:31:51 iceadmn3

Table 11.2.2.6.1 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.23	0.127	-0.48	0.02	0.075
DAY 57	Q300MG	155	3.0	0.50	-1.8	1.23	-1.76	0.104	-1.96	-1.55	.
	Q600MG	151	3.0	0.45	-1.5	1.15	-1.57	0.106	-1.79	-1.36	.
	P	161	3.0	0.45	-1.3	1.21	-1.29	0.104	-1.50	-1.08	.
	Q300MG VS P	.	.	.	.	.	-0.47	0.130	-0.72	-0.21	<.001
	Q600MG VS P	.	.	.	.	.	-0.28	0.131	-0.54	-0.03	0.030

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD208.SAS
GENERATED: 17NOV2005 13:31:51 iceadmn3

Table 11.2.2.6.2 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
VISIT	TREATMENT	N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
DAY 8	Q300MG	153	3.0	0.50	-0.7	0.92	-0.73	0.089	-0.90	-0.55	.
	Q600MG	147	3.0	0.45	-0.7	0.83	-0.73	0.091	-0.92	-0.55	.
	P	161	3.0	0.45	-0.6	0.91	-0.58	0.089	-0.76	-0.41	.
	Q300MG VS P	.	.	.	.	.	-0.14	0.095	-0.33	0.04	0.133
	Q600MG VS P	.	.	.	.	.	-0.15	0.097	-0.34	0.04	0.120
DAY 15	Q300MG	134	3.0	0.51	-1.2	0.98	-1.17	0.103	-1.37	-0.96	.
	Q600MG	126	3.0	0.40	-1.1	1.01	-1.16	0.106	-1.37	-0.95	.
	P	146	3.0	0.45	-1.0	1.05	-0.95	0.101	-1.15	-0.75	.
	Q300MG VS P	.	.	.	.	.	-0.22	0.114	-0.44	0.01	0.058
	Q600MG VS P	.	.	.	.	.	-0.21	0.115	-0.44	0.02	0.069
DAY 22	Q300MG	123	3.0	0.45	-1.5	1.07	-1.47	0.109	-1.69	-1.26	.
	Q600MG	119	3.0	0.41	-1.4	1.03	-1.40	0.112	-1.62	-1.18	.
	P	136	3.0	0.45	-1.1	1.07	-1.13	0.106	-1.34	-0.92	.
	Q300MG VS P	.	.	.	.	.	-0.35	0.126	-0.59	-0.10	0.006
	Q600MG VS P	.	.	.	.	.	-0.27	0.127	-0.52	-0.02	0.033
DAY 29	Q300MG	117	3.0	0.48	-1.6	1.07	-1.54	0.109	-1.75	-1.32	.
	Q600MG	109	3.0	0.41	-1.5	1.07	-1.57	0.113	-1.79	-1.34	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD212.SAS
GENERATED: 17NOV2005 13:31:57 iceadmn3

Table 11.2.2.6.2 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	133	3.0	0.44	-1.3	1.05	-1.30	0.104	-1.50	-1.09	.
	Q300MG VS P	.	.	.	.	.	-0.24	0.128	-0.49	0.01	0.061
	Q600MG VS P	.	.	.	.	.	-0.27	0.130	-0.53	-0.02	0.037
DAY 36	Q300MG	111	3.0	0.47	-1.7	1.19	-1.62	0.124	-1.87	-1.37	.
	Q600MG	104	3.0	0.40	-1.6	1.08	-1.64	0.128	-1.89	-1.38	.
	P	124	3.0	0.42	-1.4	1.20	-1.32	0.120	-1.56	-1.08	.
	Q300MG VS P	.	.	.	.	.	-0.30	0.139	-0.58	-0.03	0.029
	Q600MG VS P	.	.	.	.	.	-0.32	0.140	-0.60	-0.04	0.023
DAY 43	Q300MG	99	3.0	0.48	-1.9	1.14	-1.84	0.111	-2.06	-1.62	.
	Q600MG	97	2.9	0.43	-1.6	1.06	-1.68	0.113	-1.90	-1.45	.
	P	114	3.0	0.45	-1.4	1.07	-1.34	0.105	-1.55	-1.14	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.143	-0.78	-0.22	<.001
	Q600MG VS P	.	.	.	.	.	-0.33	0.144	-0.62	-0.05	0.022
DAY 50	Q300MG	102	3.0	0.47	-2.0	1.14	-1.96	0.117	-2.19	-1.72	.
	Q600MG	89	2.9	0.41	-1.7	1.13	-1.75	0.124	-2.00	-1.51	.
	P	112	3.0	0.45	-1.5	1.10	-1.54	0.113	-1.76	-1.31	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.145	-0.71	-0.13	0.004

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD212.SAS
GENERATED: 17NOV2005 13:31:57 iceadmn3

Table 11.2.2.6.2 HAM-D Item 1 Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.22	0.151	-0.51	0.08	0.152
DAY 57	Q300MG	97	3.0	0.49	-2.0	1.20	-1.98	0.116	-2.21	-1.76	.
	Q600MG	86	3.0	0.43	-1.8	1.15	-1.83	0.124	-2.08	-1.59	.
	P	103	3.0	0.42	-1.5	1.14	-1.53	0.114	-1.76	-1.31	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.156	-0.76	-0.14	0.004
	Q600MG VS P	.	.	.	.	.	-0.30	0.162	-0.62	0.02	0.065

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMD212.SAS
GENERATED: 17NOV2005 13:31:57 iceadmn3

Table 11.2.3.1.1 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	WINDOWED VISIT																		
	SCREEN	155	4.5	0.56	4.0	4	6	151	4.4	0.57	4.0	3	6	161	4.4	0.55	4.0	3	6
	DAY 1	155	4.6	0.62	5.0	2	6	151	4.4	0.55	4.0	3	6	161	4.5	0.56	4.0	3	6
	DAY 8	153	4.0	0.81	4.0	1	6	146	3.9	0.76	4.0	2	6	161	4.2	0.73	4.0	2	6
	DAY 15	155	3.6	1.00	4.0	0	6	147	3.5	0.87	4.0	1	6	161	3.9	0.82	4.0	1	6
	DAY 22	155	3.4	1.10	3.0	1	6	149	3.3	1.05	3.0	1	6	161	3.7	0.95	4.0	1	6
	DAY 29	155	3.2	1.22	3.0	1	6	149	3.2	1.06	3.0	1	6	161	3.6	1.07	4.0	1	6
	DAY 36	155	3.1	1.27	3.0	1	6	149	3.1	1.12	3.0	1	6	161	3.6	1.11	4.0	1	6
	DAY 43	155	3.0	1.28	3.0	1	6	150	3.0	1.17	3.0	1	6	161	3.5	1.16	4.0	1	6
	DAY 50	155	3.0	1.31	3.0	1	6	150	3.0	1.17	3.0	1	6	161	3.4	1.20	4.0	1	6
	DAY 57	155	2.9	1.41	3.0	1	6	150	2.9	1.21	3.0	1	6	161	3.4	1.20	4.0	1	6
CHANGE FROM BASELINE	DAY 8	153	-0.6	0.78	0.0	-3	1	146	-0.5	0.67	0.0	-2	1	161	-0.3	0.66	0.0	-3	1
	DAY 15	155	-0.9	0.98	-1.0	-4	1	147	-0.9	0.85	-1.0	-4	1	161	-0.6	0.85	0.0	-4	1
	DAY 22	155	-1.2	1.15	-1.0	-4	1	149	-1.1	0.97	-1.0	-4	0	161	-0.8	0.99	0.0	-4	1
	DAY 29	155	-1.4	1.24	-1.0	-5	1	149	-1.2	0.99	-1.0	-4	0	161	-0.9	1.12	-1.0	-5	1
	DAY 36	155	-1.5	1.30	-1.0	-5	1	149	-1.3	1.04	-1.0	-4	0	161	-0.9	1.17	-1.0	-5	1
	DAY 43	155	-1.6	1.29	-2.0	-5	1	150	-1.4	1.10	-1.0	-4	1	161	-1.0	1.19	-1.0	-5	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI201.SAS
GENERATED: 17NOV2005 13:45:15 iceadmn3

Table 11.2.3.1.1 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	WINDOWED VISIT																		
	DAY 50	155	-1.6	1.35	-1.0	-5	1	150	-1.5	1.12	-1.0	-4	1	161	-1.1	1.23	-1.0	-5	1
	DAY 57	155	-1.7	1.41	-2.0	-5	1	150	-1.5	1.14	-1.0	-4	1	161	-1.1	1.21	-1.0	-5	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI201.SAS
GENERATED: 17NOV2005 13:45:15 iceadmn3

Table 11.2.3.1.2 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	WINDOWED VISIT																		
	SCREEN	155	4.5	0.56	4.0	4	6	151	4.4	0.57	4.0	3	6	161	4.4	0.55	4.0	3	6
	DAY 1	155	4.6	0.62	5.0	2	6	151	4.4	0.55	4.0	3	6	161	4.5	0.56	4.0	3	6
	DAY 8	153	4.0	0.81	4.0	1	6	146	3.9	0.76	4.0	2	6	161	4.2	0.73	4.0	2	6
	DAY 15	131	3.5	1.01	4.0	0	6	125	3.5	0.90	4.0	1	6	145	3.9	0.84	4.0	1	6
	DAY 22	123	3.2	1.07	3.0	1	6	119	3.1	1.08	3.0	1	6	136	3.6	0.95	4.0	1	6
	DAY 29	117	3.0	1.19	3.0	1	6	107	3.0	1.06	3.0	1	6	133	3.5	1.03	4.0	1	5
	DAY 36	111	2.7	1.16	3.0	1	6	103	2.9	1.11	3.0	1	5	123	3.4	1.08	4.0	1	6
	DAY 43	98	2.6	1.09	3.0	1	5	96	2.7	1.14	3.0	1	5	114	3.2	1.11	3.0	1	5
	DAY 50	102	2.6	1.11	2.5	1	5	89	2.6	1.14	3.0	1	5	112	3.1	1.16	3.0	1	5
	DAY 57	97	2.4	1.26	2.0	1	6	86	2.6	1.21	3.0	1	5	104	3.2	1.11	3.0	1	5
CHANGE FROM BASELINE	DAY 8	153	-0.6	0.78	0.0	-3	1	146	-0.5	0.67	0.0	-2	1	161	-0.3	0.66	0.0	-3	1
	DAY 15	131	-1.0	0.98	-1.0	-4	1	125	-1.0	0.87	-1.0	-4	1	145	-0.6	0.87	0.0	-4	1
	DAY 22	123	-1.4	1.14	-1.0	-4	1	119	-1.3	0.99	-1.0	-4	0	136	-0.8	1.00	-1.0	-4	1
	DAY 29	117	-1.6	1.18	-1.0	-5	1	107	-1.4	1.02	-1.0	-4	0	133	-1.0	1.12	-1.0	-5	0
	DAY 36	111	-1.8	1.20	-2.0	-5	0	103	-1.6	1.04	-1.0	-4	0	123	-1.0	1.17	-1.0	-5	1
	DAY 43	98	-1.9	1.19	-2.0	-5	0	96	-1.7	1.08	-2.0	-4	0	114	-1.3	1.24	-1.0	-5	1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI200.SAS
GENERATED: 17NOV2005 13:45:12 iceadmn3

Table 11.2.3.1.2 CGI Severity of Illness Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	WINDOWED VISIT																		
	DAY 50	102	-2.0	1.23	-2.0	-5	0	89	-1.8	1.08	-2.0	-4	1	112	-1.3	1.28	-1.0	-5	1
	DAY 57	97	-2.1	1.30	-2.0	-5	1	86	-1.8	1.15	-2.0	-4	0	104	-1.2	1.17	-1.0	-4	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI200.SAS
GENERATED: 17NOV2005 13:45:12 iceadmn3

Table 11.2.3.2.1 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	4.6	0.58	-0.6	0.78	-0.58	0.065	-0.71	-0.45	.
	Q600MG	146	4.4	0.55	-0.5	0.67	-0.57	0.067	-0.70	-0.44	.
	P	161	4.5	0.56	-0.3	0.66	-0.36	0.065	-0.49	-0.23	.
	Q300MG VS P	.	.	.	.	.	-0.22	0.074	-0.37	-0.08	0.003
	Q600MG VS P	.	.	.	.	.	-0.21	0.075	-0.36	-0.07	0.005
DAY 15	Q300MG	155	4.6	0.62	-0.9	0.98	-0.91	0.085	-1.08	-0.75	.
	Q600MG	147	4.4	0.55	-0.9	0.85	-0.98	0.087	-1.15	-0.80	.
	P	161	4.5	0.56	-0.6	0.85	-0.64	0.085	-0.81	-0.47	.
	Q300MG VS P	.	.	.	.	.	-0.27	0.092	-0.45	-0.09	0.003
	Q600MG VS P	.	.	.	.	.	-0.33	0.094	-0.52	-0.15	<.001
DAY 22	Q300MG	155	4.6	0.62	-1.2	1.15	-1.17	0.100	-1.37	-0.97	.
	Q600MG	149	4.4	0.55	-1.1	0.97	-1.23	0.103	-1.43	-1.02	.
	P	161	4.5	0.56	-0.8	0.99	-0.81	0.100	-1.01	-0.61	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.107	-0.57	-0.15	<.001
	Q600MG VS P	.	.	.	.	.	-0.42	0.108	-0.63	-0.21	<.001
DAY 29	Q300MG	155	4.6	0.62	-1.4	1.24	-1.34	0.108	-1.56	-1.13	.
	Q600MG	149	4.4	0.55	-1.2	0.99	-1.29	0.111	-1.51	-1.07	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI215.SAS
GENERATED: 17NOV2005 13:30:47 iceadmn3

Table 11.2.3.2.1 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
VISIT	TREATMENT	N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
DAY 29	P	161	4.5	0.56	-0.9	1.12	-0.96	0.108	-1.18	-0.75	.
	Q300MG VS P	.	.	.	.	.	-0.38	0.117	-0.61	-0.15	0.001
	Q600MG VS P	.	.	.	.	.	-0.32	0.118	-0.56	-0.09	0.006
DAY 36	Q300MG	155	4.6	0.62	-1.5	1.30	-1.45	0.110	-1.67	-1.24	.
	Q600MG	149	4.4	0.55	-1.3	1.04	-1.41	0.113	-1.64	-1.19	.
	P	161	4.5	0.56	-0.9	1.17	-0.96	0.110	-1.18	-0.74	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.123	-0.74	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.46	0.125	-0.70	-0.21	<.001
DAY 43	Q300MG	155	4.6	0.62	-1.6	1.29	-1.56	0.114	-1.79	-1.34	.
	Q600MG	150	4.4	0.55	-1.4	1.10	-1.50	0.117	-1.73	-1.27	.
	P	161	4.5	0.56	-1.0	1.19	-1.06	0.114	-1.29	-0.84	.
	Q300MG VS P	.	.	.	.	.	-0.50	0.127	-0.75	-0.25	<.001
	Q600MG VS P	.	.	.	.	.	-0.44	0.128	-0.69	-0.19	<.001
DAY 50	Q300MG	155	4.6	0.62	-1.6	1.35	-1.57	0.113	-1.79	-1.34	.
	Q600MG	150	4.4	0.55	-1.5	1.12	-1.53	0.116	-1.76	-1.30	.
	P	161	4.5	0.56	-1.1	1.23	-1.10	0.113	-1.33	-0.88	.
	Q300MG VS P	.	.	.	.	.	-0.46	0.132	-0.72	-0.20	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI215.SAS
GENERATED: 17NOV2005 13:30:47 iceadmn3

Table 11.2.3.2.1 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.43	0.134	-0.69	-0.16	0.001
DAY 57	Q300MG	155	4.6	0.62	-1.7	1.41	-1.68	0.119	-1.91	-1.44	.
	Q600MG	150	4.4	0.55	-1.5	1.14	-1.59	0.122	-1.83	-1.35	.
	P	161	4.5	0.56	-1.1	1.21	-1.12	0.119	-1.36	-0.89	.
	Q300MG VS P	.	.	.	.	.	-0.55	0.135	-0.82	-0.29	<.001
	Q600MG VS P	.	.	.	.	.	-0.46	0.136	-0.73	-0.20	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI215.SAS
GENERATED: 17NOV2005 13:30:47 iceadmn3

Table 11.2.3.2.2 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	4.6	0.58	-0.6	0.78	-0.58	0.065	-0.71	-0.45	.
	Q600MG	146	4.4	0.55	-0.5	0.67	-0.57	0.067	-0.70	-0.44	.
	P	161	4.5	0.56	-0.3	0.66	-0.36	0.065	-0.49	-0.23	.
	Q300MG VS P	.	.	.	.	.	-0.22	0.074	-0.37	-0.08	0.003
	Q600MG VS P	.	.	.	.	.	-0.21	0.075	-0.36	-0.07	0.005
DAY 15	Q300MG	131	4.6	0.62	-1.0	0.98	-1.01	0.094	-1.20	-0.82	.
	Q600MG	125	4.4	0.56	-1.0	0.87	-1.06	0.097	-1.25	-0.87	.
	P	145	4.5	0.57	-0.6	0.87	-0.68	0.093	-0.87	-0.50	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.100	-0.53	-0.13	0.001
	Q600MG VS P	.	.	.	.	.	-0.38	0.100	-0.57	-0.18	<.001
DAY 22	Q300MG	123	4.5	0.63	-1.4	1.14	-1.33	0.115	-1.56	-1.10	.
	Q600MG	119	4.4	0.56	-1.3	0.99	-1.38	0.117	-1.61	-1.15	.
	P	136	4.5	0.57	-0.8	1.00	-0.88	0.112	-1.11	-0.66	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.116	-0.67	-0.22	<.001
	Q600MG VS P	.	.	.	.	.	-0.50	0.116	-0.73	-0.27	<.001
DAY 29	Q300MG	117	4.6	0.63	-1.6	1.18	-1.55	0.121	-1.79	-1.31	.
	Q600MG	107	4.4	0.55	-1.4	1.02	-1.49	0.125	-1.74	-1.24	.

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI223.SAS
GENERATED: 17NOV2005 13:30:55 iceadmn3

Table 11.2.3.2.2 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	133	4.5	0.56	-1.0	1.12	-1.08	0.117	-1.31	-0.85	.
	Q300MG VS P	.	.	.	.	.	-0.47	0.129	-0.72	-0.22	<.001
	Q600MG VS P	.	.	.	.	.	-0.41	0.130	-0.66	-0.15	0.002
DAY 36	Q300MG	111	4.5	0.63	-1.8	1.20	-1.74	0.125	-1.98	-1.49	.
	Q600MG	103	4.4	0.55	-1.6	1.04	-1.65	0.128	-1.90	-1.39	.
	P	123	4.4	0.54	-1.0	1.17	-1.09	0.121	-1.33	-0.85	.
	Q300MG VS P	.	.	.	.	.	-0.64	0.138	-0.91	-0.37	<.001
	Q600MG VS P	.	.	.	.	.	-0.55	0.138	-0.83	-0.28	<.001
DAY 43	Q300MG	98	4.5	0.58	-1.9	1.19	-1.88	0.129	-2.13	-1.62	.
	Q600MG	96	4.4	0.56	-1.7	1.08	-1.80	0.130	-2.06	-1.55	.
	P	114	4.4	0.56	-1.3	1.24	-1.31	0.123	-1.55	-1.07	.
	Q300MG VS P	.	.	.	.	.	-0.57	0.148	-0.86	-0.27	<.001
	Q600MG VS P	.	.	.	.	.	-0.49	0.147	-0.78	-0.20	<.001
DAY 50	Q300MG	102	4.5	0.56	-2.0	1.23	-1.93	0.128	-2.18	-1.68	.
	Q600MG	89	4.4	0.56	-1.8	1.08	-1.87	0.134	-2.13	-1.60	.
	P	112	4.4	0.56	-1.3	1.28	-1.35	0.124	-1.59	-1.10	.
	Q300MG VS P	.	.	.	.	.	-0.58	0.153	-0.88	-0.28	<.001

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI223.SAS
GENERATED: 17NOV2005 13:30:55 iceadmn3

Table 11.2.3.2.2 CGI Severity of Illness Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.52	0.157	-0.83	-0.21	0.001
DAY 57	Q300MG	97	4.5	0.54	-2.1	1.30	-2.08	0.135	-2.35	-1.82	.
	Q600MG	86	4.4	0.56	-1.8	1.15	-1.92	0.142	-2.20	-1.64	.
	P	104	4.4	0.55	-1.2	1.17	-1.29	0.133	-1.55	-1.02	.
	Q300MG VS P	.	.	.	.	.	-0.80	0.163	-1.12	-0.48	<.001
	Q600MG VS P	.	.	.	.	.	-0.63	0.165	-0.96	-0.31	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI223.SAS
GENERATED: 17NOV2005 13:30:55 iceadmn3

FIGURE 11.2.3.3.1 CGI SEVERITY OF ILLNESS (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

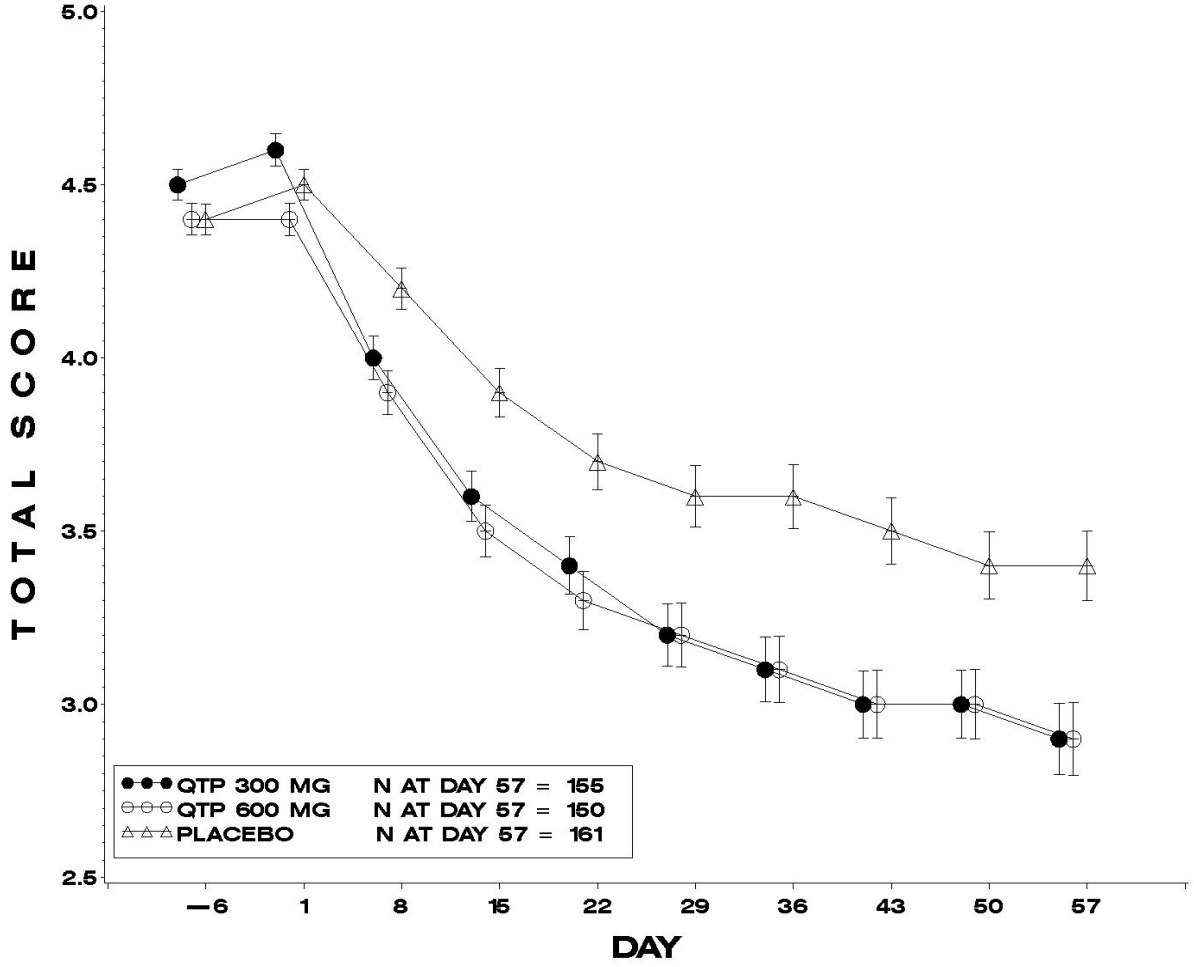

FIGURE 11.2.3.3.2 CGI SEVERITY OF ILLNESS CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

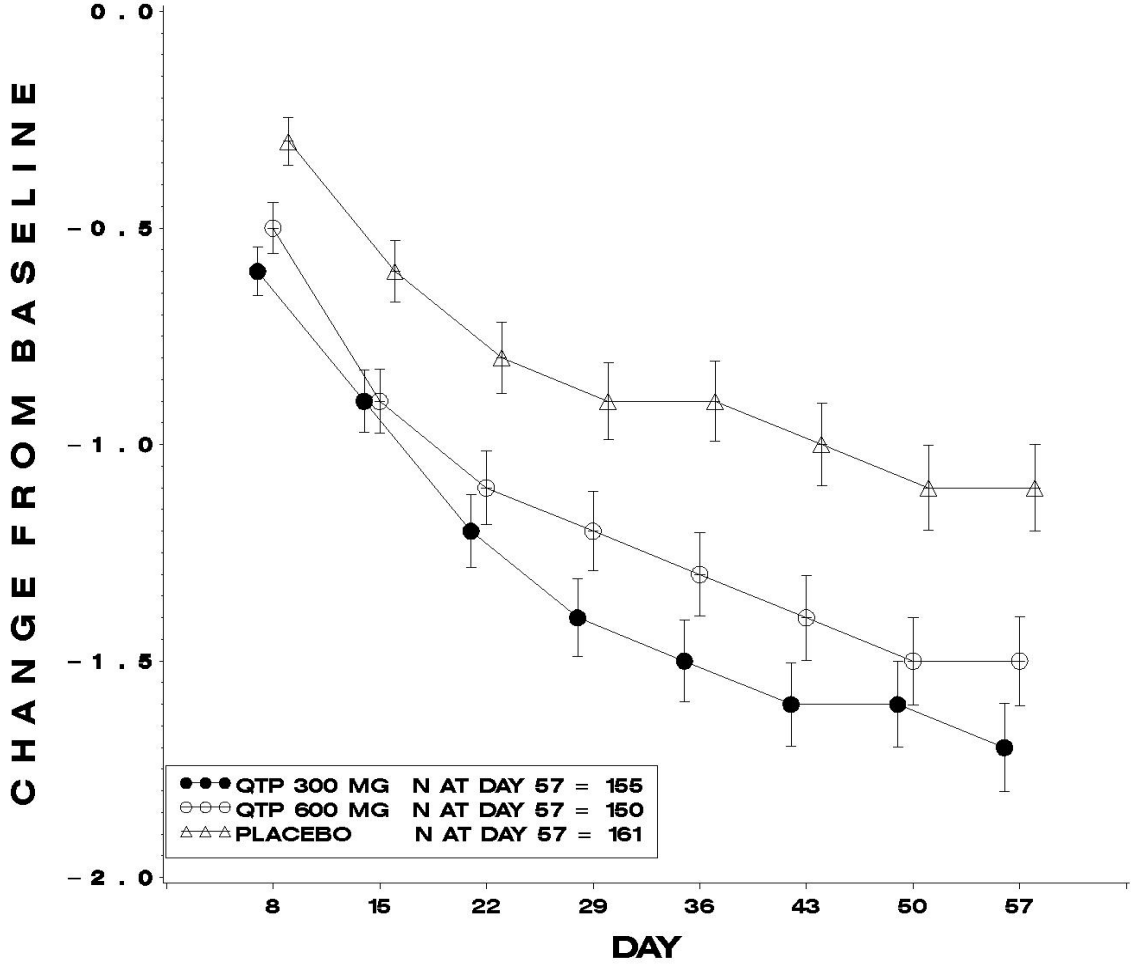

FIGURE 11.2.3.3.3 CGI SEVERITY OF ILLNESS CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

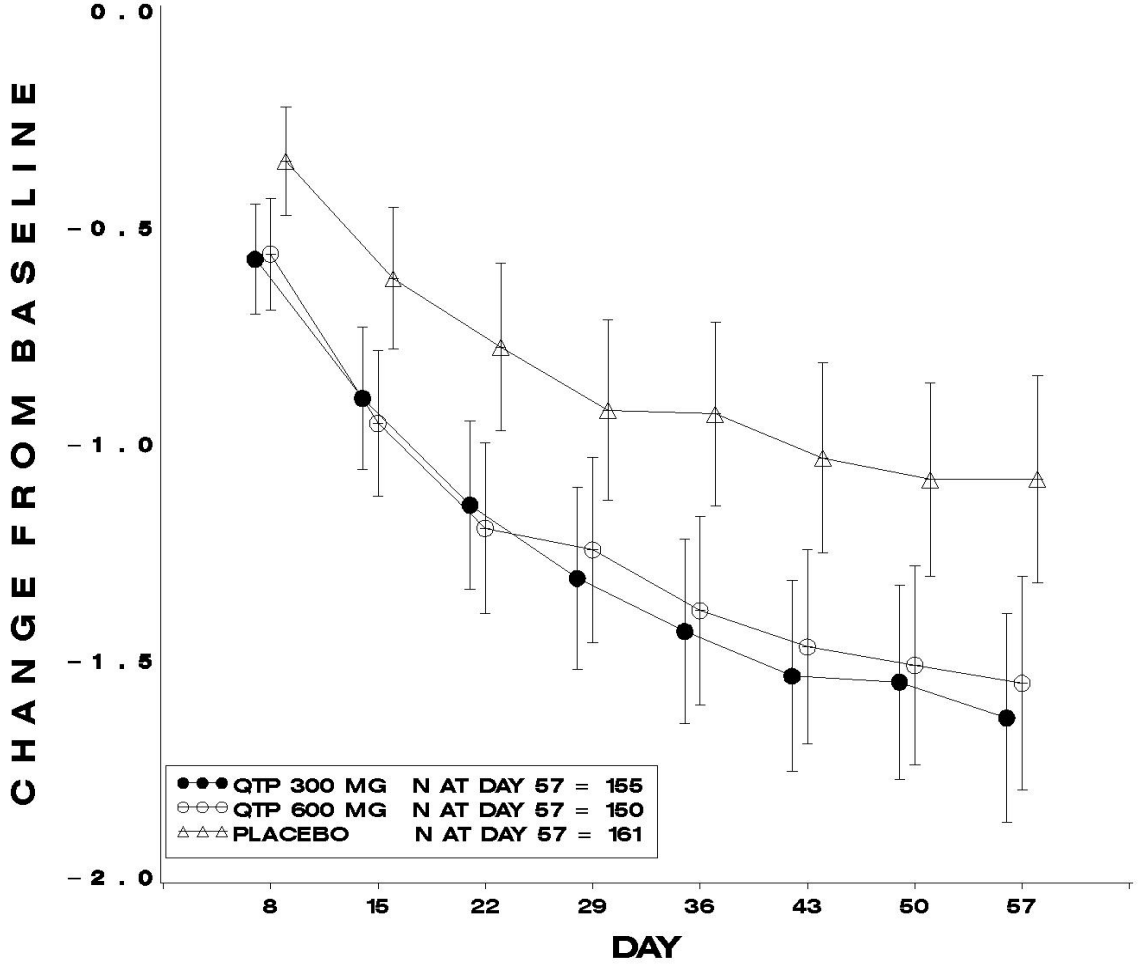

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	WINDOWED VISIT																		
	SCREEN	104	4.6	0.58	5.0	4	6	101	4.5	0.61	4.0	3	6	110	4.5	0.55	4.0	3	6
	DAY 1	104	4.6	0.64	5.0	2	6	101	4.5	0.58	5.0	3	6	110	4.5	0.55	5.0	3	6
	DAY 8	102	4.1	0.85	4.0	1	6	98	4.0	0.79	4.0	2	6	110	4.2	0.75	4.0	2	6
	DAY 15	104	3.7	1.07	4.0	0	6	99	3.6	0.91	4.0	1	6	110	3.9	0.85	4.0	1	5
	DAY 22	104	3.4	1.17	3.5	1	6	101	3.4	1.08	3.0	1	6	110	3.7	1.01	4.0	1	5
	DAY 29	104	3.3	1.26	3.0	1	6	101	3.3	1.09	3.0	1	6	110	3.6	1.12	4.0	1	5
	DAY 36	104	3.1	1.34	3.0	1	6	101	3.1	1.13	3.0	1	6	110	3.6	1.15	4.0	1	6
	DAY 43	104	3.1	1.31	3.0	1	6	101	3.1	1.20	3.0	1	6	110	3.5	1.20	4.0	1	6
	DAY 50	104	3.0	1.39	3.0	1	6	101	3.0	1.18	3.0	1	6	110	3.4	1.27	4.0	1	6
	DAY 57	104	3.0	1.43	3.0	1	6	101	3.0	1.23	3.0	1	6	110	3.5	1.25	4.0	1	6
CHANGE FROM BASELINE	DAY 8	102	-0.6	0.76	0.0	-3	1	98	-0.6	0.67	-1.0	-2	1	110	-0.4	0.71	0.0	-3	1
	DAY 15	104	-0.9	0.98	-1.0	-4	1	99	-1.0	0.86	-1.0	-4	1	110	-0.6	0.89	0.0	-4	1
	DAY 22	104	-1.2	1.19	-1.0	-4	1	101	-1.2	0.98	-1.0	-4	0	110	-0.8	1.02	-1.0	-4	1
	DAY 29	104	-1.3	1.20	-1.0	-4	1	101	-1.2	1.02	-1.0	-4	0	110	-1.0	1.16	-1.0	-4	1
	DAY 36	104	-1.5	1.29	-1.0	-5	1	101	-1.4	1.03	-1.0	-4	0	110	-1.0	1.20	-1.0	-5	1
	DAY 43	104	-1.5	1.25	-1.0	-4	1	101	-1.5	1.12	-1.0	-4	1	110	-1.1	1.24	-1.0	-4	1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI203.SAS
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Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	WINDOWED VISIT																		
	DAY 50	104	-1.6	1.37	-1.0	-5	1	101	-1.5	1.12	-1.0	-4	1	110	-1.1	1.29	-1.0	-4	1
	DAY 57	104	-1.7	1.39	-2.0	-5	1	101	-1.5	1.16	-1.0	-4	1	110	-1.1	1.27	-1.0	-4	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI203.SAS
GENERATED: 17NOV2005 13:45:20 iceadmn3

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	WINDOWED VISIT																		
	SCREEN	51	4.2	0.43	4.0	4	5	50	4.2	0.42	4.0	4	5	51	4.3	0.55	4.0	4	6
	DAY 1	51	4.5	0.54	4.0	4	6	50	4.3	0.44	4.0	4	5	51	4.4	0.56	4.0	4	6
	DAY 8	51	3.8	0.67	4.0	2	5	48	3.8	0.71	4.0	2	5	51	4.1	0.69	4.0	3	6
	DAY 15	51	3.5	0.83	4.0	1	5	48	3.4	0.80	4.0	1	5	51	3.8	0.74	4.0	2	6
	DAY 22	51	3.3	0.93	3.0	1	5	48	3.1	0.97	3.0	1	4	51	3.7	0.83	4.0	2	6
	DAY 29	51	3.0	1.13	3.0	1	5	48	3.1	0.99	3.0	1	5	51	3.6	0.96	4.0	1	6
	DAY 36	51	2.9	1.10	3.0	1	5	48	3.0	1.10	3.0	1	5	51	3.5	1.03	4.0	1	6
	DAY 43	51	2.8	1.21	3.0	1	5	49	2.9	1.11	3.0	1	4	51	3.5	1.08	4.0	1	6
	DAY 50	51	2.8	1.16	3.0	1	5	49	2.9	1.17	3.0	1	5	51	3.4	1.06	3.0	1	6
	DAY 57	51	2.7	1.36	3.0	1	6	49	2.8	1.15	3.0	1	5	51	3.3	1.08	3.0	1	6
CHANGE FROM BASELINE	DAY 8	51	-0.7	0.82	-1.0	-3	1	48	-0.4	0.65	0.0	-2	0	51	-0.2	0.50	0.0	-1	1
	DAY 15	51	-1.0	1.00	-1.0	-4	1	48	-0.8	0.82	-1.0	-3	0	51	-0.5	0.76	0.0	-3	0
	DAY 22	51	-1.2	1.08	-1.0	-4	1	48	-1.1	0.96	-1.0	-3	0	51	-0.6	0.89	0.0	-3	0
	DAY 29	51	-1.5	1.30	-1.0	-5	1	48	-1.1	0.95	-1.0	-3	0	51	-0.7	1.04	0.0	-5	0
	DAY 36	51	-1.5	1.32	-2.0	-5	1	48	-1.2	1.05	-1.0	-3	0	51	-0.8	1.09	0.0	-5	0
	DAY 43	51	-1.7	1.38	-2.0	-5	1	49	-1.3	1.06	-1.0	-4	0	51	-0.9	1.10	-1.0	-5	1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI203.SAS
GENERATED: 17NOV2005 13:45:20 iceadmn3

Table 11.2.3.4.1 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	WINDOWED VISIT																		
	DAY 50	51	-1.6	1.33	-2.0	-5	1	49	-1.4	1.11	-1.0	-4	1	51	-0.9	1.10	-1.0	-5	1
	DAY 57	51	-1.7	1.47	-2.0	-5	1	49	-1.5	1.10	-1.0	-4	0	51	-1.1	1.08	-1.0	-5	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI203.SAS
GENERATED: 17NOV2005 13:45:20 iceadmn3

Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	WINDOWED VISIT																		
	SCREEN	104	4.6	0.58	5.0	4	6	101	4.5	0.61	4.0	3	6	110	4.5	0.55	4.0	3	6
	DAY 1	104	4.6	0.64	5.0	2	6	101	4.5	0.58	5.0	3	6	110	4.5	0.55	5.0	3	6
	DAY 8	102	4.1	0.85	4.0	1	6	98	4.0	0.79	4.0	2	6	110	4.2	0.75	4.0	2	6
	DAY 15	85	3.6	1.11	4.0	0	6	88	3.5	0.92	4.0	1	6	99	3.9	0.88	4.0	1	5
	DAY 22	80	3.2	1.15	3.0	1	6	83	3.2	1.09	3.0	1	6	92	3.6	1.00	4.0	1	5
	DAY 29	78	3.1	1.22	3.0	1	6	74	3.1	1.06	3.0	1	6	87	3.4	1.09	4.0	1	5
	DAY 36	74	2.8	1.26	3.0	1	6	70	2.9	1.06	3.0	1	5	81	3.4	1.17	4.0	1	6
	DAY 43	62	2.6	1.07	3.0	1	5	63	2.7	1.11	3.0	1	5	76	3.1	1.14	3.0	1	5
	DAY 50	65	2.6	1.19	3.0	1	5	58	2.7	1.08	3.0	1	5	75	3.1	1.22	3.0	1	5
	DAY 57	61	2.4	1.24	2.0	1	5	57	2.7	1.20	3.0	1	5	70	3.2	1.17	3.5	1	5
CHANGE FROM BASELINE	DAY 8	102	-0.6	0.76	0.0	-3	1	98	-0.6	0.67	-1.0	-2	1	110	-0.4	0.71	0.0	-3	1
	DAY 15	85	-1.0	0.99	-1.0	-4	1	88	-1.0	0.88	-1.0	-4	1	99	-0.7	0.92	0.0	-4	1
	DAY 22	80	-1.4	1.19	-1.0	-4	1	83	-1.3	1.01	-1.0	-4	0	92	-0.9	1.03	-1.0	-4	1
	DAY 29	78	-1.5	1.15	-1.0	-4	1	74	-1.4	1.05	-1.0	-4	0	87	-1.1	1.14	-1.0	-4	0
	DAY 36	74	-1.8	1.20	-2.0	-5	0	70	-1.6	1.02	-1.5	-4	0	81	-1.1	1.26	-1.0	-5	1
	DAY 43	62	-2.0	1.14	-2.0	-4	0	63	-1.7	1.08	-2.0	-4	0	76	-1.4	1.26	-1.0	-4	0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI202.SAS
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Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	WINDOWED VISIT																		
	DAY 50	65	-2.0	1.29	-2.0	-5	0	58	-1.8	1.06	-2.0	-4	0	75	-1.4	1.33	-1.0	-4	1
	DAY 57	61	-2.1	1.28	-2.0	-5	0	57	-1.8	1.18	-2.0	-4	0	70	-1.3	1.26	-1.0	-4	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI202.SAS
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Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SEVERITY OF ILLNESS	WINDOWED VISIT																		
	SCREEN	51	4.2	0.43	4.0	4	5	50	4.2	0.42	4.0	4	5	51	4.3	0.55	4.0	4	6
	DAY 1	51	4.5	0.54	4.0	4	6	50	4.3	0.44	4.0	4	5	51	4.4	0.56	4.0	4	6
	DAY 8	51	3.8	0.67	4.0	2	5	48	3.8	0.71	4.0	2	5	51	4.1	0.69	4.0	3	6
	DAY 15	46	3.5	0.81	4.0	1	5	37	3.4	0.86	4.0	1	5	46	3.8	0.75	4.0	2	6
	DAY 22	43	3.1	0.91	3.0	1	5	36	2.9	1.04	3.0	1	4	44	3.7	0.85	4.0	2	6
	DAY 29	39	2.8	1.09	3.0	1	5	33	2.9	1.08	3.0	1	5	46	3.5	0.91	4.0	1	5
	DAY 36	37	2.7	0.94	3.0	1	4	33	2.8	1.22	3.0	1	5	42	3.4	0.91	4.0	1	5
	DAY 43	36	2.6	1.13	2.0	1	5	33	2.7	1.21	3.0	1	4	38	3.3	1.06	3.0	1	5
	DAY 50	37	2.6	0.99	2.0	1	5	31	2.5	1.26	3.0	1	5	37	3.3	1.02	3.0	1	5
	DAY 57	36	2.4	1.32	2.0	1	6	29	2.3	1.23	2.0	1	5	34	3.2	1.00	3.0	1	5
CHANGE FROM BASELINE	DAY 8	51	-0.7	0.82	-1.0	-3	1	48	-0.4	0.65	0.0	-2	0	51	-0.2	0.50	0.0	-1	1
	DAY 15	46	-1.0	0.98	-1.0	-4	0	37	-0.9	0.86	-1.0	-3	0	46	-0.6	0.78	0.0	-3	0
	DAY 22	43	-1.3	1.06	-1.0	-4	1	36	-1.4	0.96	-1.0	-3	0	44	-0.6	0.92	0.0	-3	0
	DAY 29	39	-1.7	1.23	-2.0	-5	0	33	-1.4	0.97	-1.0	-3	0	46	-0.8	1.06	-1.0	-5	0
	DAY 36	37	-1.8	1.20	-2.0	-5	0	33	-1.5	1.09	-1.0	-3	0	42	-0.9	0.95	-1.0	-3	0
	DAY 43	36	-1.9	1.29	-2.0	-5	0	33	-1.6	1.08	-2.0	-4	0	38	-1.0	1.17	-1.0	-5	1

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI202.SAS
GENERATED: 17NOV2005 13:45:17 iceadmn3

Table 11.2.3.4.2 CGI Severity of Illness Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHANGE FROM BASELINE	WINDOWED VISIT																		
	DAY 50	37	-1.9	1.14	-2.0	-5	0	31	-1.8	1.15	-2.0	-4	1	37	-1.0	1.15	-1.0	-5	1
	DAY 57	36	-2.1	1.36	-2.0	-5	1	29	-1.9	1.10	-2.0	-4	0	34	-1.1	0.95	-1.0	-3	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI202.SAS
GENERATED: 17NOV2005 13:45:17 iceadmn3

Table 11.2.3.5.1 CGI Severity of Illness Score Summary
Last Observation Carried Forward
Intent-to-Treat Population

	TREATMENT													
	QUETIAPINE 300 MG													
	NOT ASSESSED		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
STUDY DAY / TOTAL	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SCREEN / 155	0	0	0	0	0	0	0	0	86	55.5	64	41.3	5	3.2
DAY 1 / 155	0	0	0	0	1	0.6	1	0.6	70	45.2	77	49.7	6	3.9
DAY 8 / 153	0	0	1	0.7	7	4.6	23	15.0	89	58.2	31	20.3	2	1.3
DAY 15 / 155	1	0.6	3	1.9	15	9.7	42	27.1	72	46.5	19	12.3	3	1.9
DAY 22 / 155	0	0	8	5.2	26	16.8	46	29.7	56	36.1	16	10.3	3	1.9
DAY 29 / 155	0	0	17	11.0	26	16.8	43	27.7	51	32.9	14	9.0	4	2.6
DAY 36 / 155	0	0	23	14.8	25	16.1	47	30.3	43	27.7	13	8.4	4	2.6
DAY 43 / 155	0	0	21	13.5	39	25.2	39	25.2	38	24.5	14	9.0	4	2.6
DAY 50 / 155	0	0	24	15.5	38	24.5	32	20.6	44	28.4	13	8.4	4	2.6
DAY 57 / 155	0	0	35	22.6	29	18.7	35	22.6	37	23.9	14	9.0	5	3.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI206.SAS
GENERATED: 17NOV2005 13:45:25 iceadmn3

Table 11.2.3.5.1 CGI Severity of Illness Score Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 600 MG											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	151	0	0	0	0	1	0.7	92	60.9	53	35.1	5	3.3
DAY 1	151	0	0	0	0	1	0.7	85	56.3	62	41.1	3	2.0
DAY 8	146	0	0	5	3.4	33	22.6	81	55.5	25	17.1	2	1.4
DAY 15	147	3	2.0	14	9.5	47	32.0	71	48.3	11	7.5	1	0.7
DAY 22	149	11	7.4	17	11.4	53	35.6	56	37.6	10	6.7	2	1.3
DAY 29	149	10	6.7	23	15.4	53	35.6	50	33.6	11	7.4	2	1.3
DAY 36	149	15	10.1	26	17.4	51	34.2	44	29.5	12	8.1	1	0.7
DAY 43	150	21	14.0	24	16.0	47	31.3	47	31.3	10	6.7	1	0.7
DAY 50	150	21	14.0	26	17.3	52	34.7	38	25.3	12	8.0	1	0.7
DAY 57	150	24	16.0	25	16.7	52	34.7	35	23.3	13	8.7	1	0.7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI206.SAS
GENERATED: 17NOV2005 13:45:25 iceadmn3

Table 11.2.3.5.1 CGI Severity of Illness Score Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT											
		PLACEBO											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	161	0	0	0	0	1	0.6	95	59.0	61	37.9	4	2.5
DAY 1	161	0	0	0	0	1	0.6	86	53.4	70	43.5	4	2.5
DAY 8	161	0	0	4	2.5	18	11.2	89	55.3	48	29.8	2	1.2
DAY 15	161	1	0.6	7	4.3	35	21.7	84	52.2	33	20.5	1	0.6
DAY 22	161	5	3.1	11	6.8	37	23.0	80	49.7	27	16.8	1	0.6
DAY 29	161	9	5.6	16	9.9	36	22.4	73	45.3	26	16.1	1	0.6
DAY 36	161	12	7.5	11	6.8	42	26.1	69	42.9	25	15.5	2	1.2
DAY 43	161	11	6.8	22	13.7	40	24.8	59	36.6	27	16.8	2	1.2
DAY 50	161	12	7.5	26	16.1	37	23.0	56	34.8	28	17.4	2	1.2
DAY 57	161	12	7.5	27	16.8	36	22.4	57	35.4	27	16.8	2	1.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI206.SAS
GENERATED: 17NOV2005 13:45:25 iceadmn3

Table 11.2.3.5.2 CGI Severity of Illness Score Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT													
		QUETIAPINE 300 MG													
		NOT ASSESSED		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
STUDY DAY	TOTAL	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SCREEN	155	0	0	0	0	0	0	0	0	86	55.5	64	41.3	5	3.2
DAY 1	155	0	0	0	0	1	0.6	1	0.6	70	45.2	77	49.7	6	3.9
DAY 8	153	0	0	1	0.7	7	4.6	23	15.0	89	58.2	31	20.3	2	1.3
DAY 15	131	1	0.8	3	2.3	14	10.7	39	29.8	59	45.0	12	9.2	3	2.3
DAY 22	123	0	0	8	6.5	24	19.5	44	35.8	37	30.1	8	6.5	2	1.6
DAY 29	117	0	0	16	13.7	21	17.9	38	32.5	35	29.9	4	3.4	3	2.6
DAY 36	111	0	0	21	18.9	20	18.0	42	37.8	24	21.6	2	1.8	2	1.8
DAY 43	98	0	0	16	16.3	31	31.6	29	29.6	18	18.4	4	4.1	0	0
DAY 50	102	0	0	21	20.6	30	29.4	26	25.5	23	22.5	2	2.0	0	0
DAY 57	97	0	0	32	33.0	19	19.6	26	26.8	15	15.5	4	4.1	1	1.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI205.SAS
GENERATED: 17NOV2005 13:45:22 iceadmn3

Table 11.2.3.5.2 CGI Severity of Illness Score Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		QUETIAPINE 600 MG											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	151	0	0	0	0	1	0.7	92	60.9	53	35.1	5	3.3
DAY 1	151	0	0	0	0	1	0.7	85	56.3	62	41.1	3	2.0
DAY 8	146	0	0	5	3.4	33	22.6	81	55.5	25	17.1	2	1.4
DAY 15	125	3	2.4	14	11.2	42	33.6	56	44.8	9	7.2	1	0.8
DAY 22	119	11	9.2	17	14.3	46	38.7	37	31.1	6	5.0	2	1.7
DAY 29	107	10	9.3	21	19.6	40	37.4	30	28.0	5	4.7	1	0.9
DAY 36	103	14	13.6	23	22.3	36	35.0	24	23.3	6	5.8	0	0
DAY 43	96	19	19.8	19	19.8	31	32.3	24	25.0	3	3.1	0	0
DAY 50	89	19	21.3	19	21.3	33	37.1	13	14.6	5	5.6	0	0
DAY 57	86	22	25.6	17	19.8	29	33.7	12	14.0	6	7.0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI205.SAS
GENERATED: 17NOV2005 13:45:22 iceadmn3

Table 11.2.3.5.2 CGI Severity of Illness Score Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT											
		PLACEBO											
		NORMAL, NOT AT ALL ILL		BORDERLINE MENTALLY ILL		MILDLY ILL		MODERATELY ILL		MARKEDLY ILL		SEVERELY ILL	
		N	%	N	%	N	%	N	%	N	%	N	%
STUDY DAY	TOTAL												
SCREEN	161	0	0	0	0	1	0.6	95	59.0	61	37.9	4	2.5
DAY 1	161	0	0	0	0	1	0.6	86	53.4	70	43.5	4	2.5
DAY 8	161	0	0	4	2.5	18	11.2	89	55.3	48	29.8	2	1.2
DAY 15	145	1	0.7	7	4.8	34	23.4	73	50.3	29	20.0	1	0.7
DAY 22	136	5	3.7	10	7.4	34	25.0	69	50.7	17	12.5	1	0.7
DAY 29	133	8	6.0	14	10.5	35	26.3	61	45.9	15	11.3	0	0
DAY 36	123	11	8.9	9	7.3	39	31.7	51	41.5	12	9.8	1	0.8
DAY 43	114	11	9.6	20	17.5	31	27.2	43	37.7	9	7.9	0	0
DAY 50	112	12	10.7	22	19.6	27	24.1	41	36.6	10	8.9	0	0
DAY 57	104	8	7.7	23	22.1	24	23.1	40	38.5	9	8.7	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI205.SAS
GENERATED: 17NOV2005 13:45:22 iceadmn3

Table 11.2.3.6 CGI Severity of Illness Shift to Day 57
Last Observation Carried Forward
Intent-to-Treat Population

	QUETIAPINE 300 MG								
	TOTAL	NOT ASSESSED	NORMAL, NOT AT ALL ILL	BORDERLINE MENTALLY ILL	MILDLY ILL	MODERATELY ILL	MARKEDLY ILL	SEVERELY ILL	AMONG THE MOST EXTREMELY ILL
BASELINE									
NOT ASSESSED	0	0	0	0	0	0	0	0	0
NORMAL, NOT AT ALL ILL	0	0	0	0	0	0	0	0	0
BORDERLINE MENTALLY ILL	1	0	1	0	0	0	0	0	0
MILDLY ILL	1	0	0	0	1	0	0	0	0
MODERATELY ILL	70	0	17	17	15	18	3	0	0
MARKEDLY ILL	77	0	15	11	19	19	10	3	0
SEVERELY ILL	6	0	2	1	0	0	1	2	0
AMONG THE MOST EXTREMELY ILL	0	0	0	0	0	0	0	0	0
TOTAL	155	0	35	29	35	37	14	5	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI214.SAS
GENERATED: 17NOV2005 13:45:40 iceadmn3

Table 11.2.3.6 CGI Severity of Illness Shift to Day 57
Last Observation Carried Forward
Intent-to-Treat Population

	QUETIAPINE 600 MG								
	TOTAL	NOT ASSESSED	NORMAL, NOT AT ALL ILL	BORDERLINE MENTALLY ILL	MILDLY ILL	MODERATELY ILL	MARKEDLY ILL	SEVERELY ILL	AMONG THE MOST EXTREMELY ILL
BASELINE									
NOT ASSESSED	0	0	0	0	0	0	0	0	0
NORMAL, NOT AT ALL ILL	0	0	0	0	0	0	0	0	0
BORDERLINE MENTALLY ILL	0	0	0	0	0	0	0	0	0
MILDLY ILL	1	0	0	0	1	0	0	0	0
MODERATELY ILL	85	0	17	19	32	16	1	0	0
MARKEDLY ILL	62	0	7	6	18	18	12	0	0
SEVERELY ILL	3	0	0	0	1	1	0	1	0
AMONG THE MOST EXTREMELY ILL	0	0	0	0	0	0	0	0	0
TOTAL	151	0	24	25	52	35	13	1	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI214.SAS
GENERATED: 17NOV2005 13:45:40 iceadmn3

Table 11.2.3.6 CGI Severity of Illness Shift to Day 57
Last Observation Carried Forward
Intent-to-Treat Population

	PLACEBO								
	TOTAL	NOT ASSESSED	NORMAL, NOT AT ALL ILL	BORDERLINE MENTALLY ILL	MILDLY ILL	MODERATELY ILL	MARKEDLY ILL	SEVERELY ILL	AMONG THE MOST EXTREMELY ILL
BASELINE									
NOT ASSESSED	0	0	0	0	0	0	0	0	0
NORMAL, NOT AT ALL ILL	0	0	0	0	0	0	0	0	0
BORDERLINE MENTALLY ILL	0	0	0	0	0	0	0	0	0
MILDLY ILL	1	0	0	0	1	0	0	0	0
MODERATELY ILL	86	0	6	16	23	41	0	0	0
MARKEDLY ILL	70	0	5	11	11	15	27	1	0
SEVERELY ILL	4	0	1	0	1	1	0	1	0
AMONG THE MOST EXTREMELY ILL	0	0	0	0	0	0	0	0	0
TOTAL	161	0	12	27	36	57	27	2	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI214.SAS
GENERATED: 17NOV2005 13:45:40 iceadmn3

Table 11.2.4.1.1 CGI Improvement Score - Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG																	
		NOT ASSESSED		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE		NOT APPLICABLE	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
WINDOWED VISIT	TOTAL																		
DAY 8	153	0	0	4	2.6	23	15.0	75	49.0	48	31.4	3	2.0	0	0	0	0	0	0
DAY 15	155	0	0	11	7.1	40	25.8	72	46.5	27	17.4	3	1.9	1	0.6	0	0	1	0.6
DAY 22	155	0	0	26	16.8	46	29.7	55	35.5	23	14.8	4	2.6	1	0.6	0	0	0	0
DAY 29	155	0	0	33	21.3	50	32.3	36	23.2	28	18.1	7	4.5	1	0.6	0	0	0	0
DAY 36	155	0	0	42	27.1	47	30.3	37	23.9	22	14.2	6	3.9	1	0.6	0	0	0	0
DAY 43	155	0	0	50	32.3	42	27.1	33	21.3	21	13.5	8	5.2	1	0.6	0	0	0	0
DAY 50	155	0	0	49	31.6	42	27.1	31	20.0	24	15.5	8	5.2	1	0.6	0	0	0	0
DAY 57	155	0	0.0	54	34.8	41	26.5	31	20.0	21	13.5	7	4.5	1	0.6	0	0.0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI211.SAS
GENERATED: 17NOV2005 13:45:31 iceadmn3

Table 11.2.4.1.1 CGI Improvement Score - Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT															
		QUETIAPINE 600 MG															
		NOT ASSESSED		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
WINDOWED VISIT	TOTAL																
DAY 8	146	0	0	3	2.1	26	17.8	58	39.7	58	39.7	1	0.7	0	0	0	0
DAY 15	147	0	0	12	8.2	45	30.6	58	39.5	30	20.4	2	1.4	0	0	0	0
DAY 22	149	0	0	21	14.1	53	35.6	52	34.9	21	14.1	1	0.7	1	0.7	0	0
DAY 29	149	0	0	27	18.1	48	32.2	49	32.9	24	16.1	1	0.7	0	0	0	0
DAY 36	149	0	0	33	22.1	45	30.2	45	30.2	25	16.8	1	0.7	0	0	0	0
DAY 43	150	0	0	38	25.3	47	31.3	43	28.7	20	13.3	1	0.7	1	0.7	0	0
DAY 50	150	0	0	39	26.0	48	32.0	39	26.0	21	14.0	2	1.3	1	0.7	0	0
DAY 57	150	0	0.0	43	28.7	47	31.3	37	24.7	21	14.0	1	0.7	1	0.7	0	0.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI211.SAS
GENERATED: 17NOV2005 13:45:31 iceadmn3

Table 11.2.4.1.1 CGI Improvement Score - Summary
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		PLACEBO																	
		NOT ASSESSED		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
WINDOWED VISIT	TOTAL																		
DAY 8	161	0	0	1	0.6	18	11.2	53	32.9	80	49.7	7	4.3	2	1.2	0	0
DAY 15	161	0	0	2	1.2	33	20.5	58	36.0	63	39.1	4	2.5	1	0.6	0	0
DAY 22	161	0	0	12	7.5	38	23.6	51	31.7	50	31.1	9	5.6	1	0.6	0	0
DAY 29	161	0	0	18	11.2	40	24.8	45	28.0	49	30.4	8	5.0	1	0.6	0	0
DAY 36	161	0	0	16	9.9	37	23.0	49	30.4	48	29.8	9	5.6	2	1.2	0	0
DAY 43	161	0	0	19	11.8	42	26.1	41	25.5	48	29.8	9	5.6	2	1.2	0	0
DAY 50	161	0	0	23	14.3	38	23.6	40	24.8	49	30.4	9	5.6	2	1.2	0	0
DAY 57	161	0	0.0	26	16.1	36	22.4	42	26.1	48	29.8	7	4.3	2	1.2	0	0.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI211.SAS
GENERATED: 17NOV2005 13:45:31 iceadmn3

Table 11.2.4.1.2 CGI Improvement Score - Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG																	
		NOT ASSESSED		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE		NOT APPLICABLE	
WINDOWED VISIT	TOTAL	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
DAY 8	153	0	0	4	2.6	23	15.0	75	49.0	48	31.4	3	2.0	0	0	0	0	0	0
DAY 15	131	0	0	10	7.6	39	29.8	59	45.0	20	15.3	1	0.8	1	0.8	0	0	1	0.8
DAY 22	123	0	0	24	19.5	44	35.8	40	32.5	13	10.6	2	1.6	0	0	0	0	0	0
DAY 29	117	0	0	27	23.1	45	38.5	24	20.5	17	14.5	4	3.4	0	0	0	0	0	0
DAY 36	111	0	0	35	31.5	42	37.8	24	21.6	8	7.2	2	1.8	0	0	0	0	0	0
DAY 43	98	0	0	38	38.8	33	33.7	18	18.4	7	7.1	2	2.0	0	0	0	0	0	0
DAY 50	102	0	0	38	37.3	36	35.3	18	17.6	9	8.8	1	1.0	0	0	0	0	0	0
DAY 57	97	0	0.0	41	42.3	32	33.0	17	17.5	6	6.2	1	1.0	0	0.0	0	0.0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI210.SAS
GENERATED: 17NOV2005 13:45:28 iceadmn3

Table 11.2.4.1.2 CGI Improvement Score - Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 600 MG																	
		NOT ASSESSED		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
WINDOWED VISIT	TOTAL																		
DAY 8	146	0	0	3	2.1	26	17.8	58	39.7	58	39.7	1	0.7	0	0	0	0
DAY 15	125	0	0	12	9.6	43	34.4	47	37.6	21	16.8	2	1.6	0	0	0	0
DAY 22	119	0	0	20	16.8	50	42.0	39	32.8	9	7.6	0	0	1	0.8	0	0
DAY 29	107	0	0	24	22.4	38	35.5	33	30.8	12	11.2	0	0	0	0	0	0
DAY 36	103	0	0	29	28.2	32	31.1	29	28.2	13	12.6	0	0	0	0	0	0
DAY 43	96	0	0	31	32.3	33	34.4	26	27.1	6	6.3	0	0	0	0	0	0
DAY 50	89	0	0	31	34.8	32	36.0	18	20.2	7	7.9	1	1.1	0	0	0	0
DAY 57	86	0	0.0	33	38.4	29	33.7	17	19.8	7	8.1	0	0.0	0	0.0	0	0.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI210.SAS
GENERATED: 17NOV2005 13:45:28 iceadmn3

Table 11.2.4.1.2 CGI Improvement Score - Summary
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		PLACEBO																	
		NOT ASSESSED		VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		VERY MUCH WORSE	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
WINDOWED VISIT	TOTAL																		
DAY 8	161	0	0	1	0.6	18	11.2	53	32.9	80	49.7	7	4.3	2	1.2	0	0
DAY 15	145	0	0	2	1.4	32	22.1	54	37.2	54	37.2	3	2.1	0	0	0	0
DAY 22	136	0	0	12	8.8	34	25.0	47	34.6	36	26.5	7	5.1	0	0	0	0
DAY 29	133	0	0	17	12.8	37	27.8	41	30.8	33	24.8	5	3.8	0	0	0	0
DAY 36	123	0	0	15	12.2	33	26.8	41	33.3	29	23.6	4	3.3	1	0.8	0	0
DAY 43	114	0	0	19	16.7	33	28.9	34	29.8	25	21.9	3	2.6	0	0	0	0
DAY 50	112	0	0	21	18.8	28	25.0	34	30.4	25	22.3	4	3.6	0	0	0	0
DAY 57	104	0	0.0	20	19.2	26	25.0	33	31.7	23	22.1	2	1.9	0	0.0	0	0.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI210.SAS
GENERATED: 17NOV2005 13:45:28 iceadmn3

Table 11.2.4.2.1 CGI Improvement Score (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	4.6	0.58	3.2	0.79	3.16	0.075	3.01	3.31	.
	Q600MG	146	4.4	0.55	3.2	0.81	3.19	0.077	3.04	3.34	.
	P	161	4.5	0.56	3.5	0.82	3.49	0.074	3.34	3.64	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.090	-0.51	-0.15	<.001
	Q600MG VS P	.	.	.	.	.	-0.30	0.091	-0.48	-0.12	0.001
DAY 15	Q300MG	155	4.6	0.62	2.8	0.94	2.82	0.081	2.66	2.98	.
	Q600MG	147	4.4	0.55	2.8	0.92	2.76	0.084	2.59	2.92	.
	P	161	4.5	0.56	3.2	0.87	3.22	0.081	3.06	3.38	.
	Q300MG VS P	.	.	.	.	.	-0.40	0.102	-0.60	-0.20	<.001
	Q600MG VS P	.	.	.	.	.	-0.46	0.103	-0.67	-0.26	<.001
DAY 22	Q300MG	155	4.6	0.62	2.6	1.06	2.60	0.091	2.41	2.78	.
	Q600MG	149	4.4	0.55	2.5	0.97	2.53	0.094	2.35	2.72	.
	P	161	4.5	0.56	3.1	1.06	3.05	0.091	2.87	3.23	.
	Q300MG VS P	.	.	.	.	.	-0.45	0.116	-0.68	-0.23	<.001
	Q600MG VS P	.	.	.	.	.	-0.52	0.117	-0.75	-0.29	<.001
DAY 29	Q300MG	155	4.6	0.62	2.5	1.18	2.53	0.099	2.34	2.73	.
	Q600MG	149	4.4	0.55	2.5	0.99	2.48	0.101	2.28	2.68	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI220.SAS
GENERATED: 17NOV2005 13:30:49 iceadmn3

Table 11.2.4.2.1 CGI Improvement Score (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	4.5	0.56	3.0	1.12	2.94	0.098	2.74	3.13	.
	Q300MG VS P	.	.	.	.	.	-0.40	0.123	-0.65	-0.16	0.001
	Q600MG VS P	.	.	.	.	.	-0.45	0.125	-0.70	-0.21	<.001
DAY 36	Q300MG	155	4.6	0.62	2.4	1.18	2.41	0.100	2.22	2.61	.
	Q600MG	149	4.4	0.55	2.4	1.04	2.45	0.103	2.25	2.66	.
	P	161	4.5	0.56	3.0	1.13	3.04	0.100	2.84	3.24	.
	Q300MG VS P	.	.	.	.	.	-0.63	0.125	-0.87	-0.38	<.001
	Q600MG VS P	.	.	.	.	.	-0.59	0.126	-0.84	-0.34	<.001
DAY 43	Q300MG	155	4.6	0.62	2.3	1.24	2.36	0.106	2.15	2.57	.
	Q600MG	150	4.4	0.55	2.3	1.06	2.37	0.109	2.16	2.59	.
	P	161	4.5	0.56	3.0	1.17	2.98	0.106	2.77	3.19	.
	Q300MG VS P	.	.	.	.	.	-0.62	0.129	-0.88	-0.37	<.001
	Q600MG VS P	.	.	.	.	.	-0.61	0.131	-0.87	-0.35	<.001
DAY 50	Q300MG	155	4.6	0.62	2.4	1.25	2.37	0.104	2.17	2.58	.
	Q600MG	150	4.4	0.55	2.3	1.09	2.36	0.107	2.14	2.57	.
	P	161	4.5	0.56	2.9	1.20	2.94	0.104	2.73	3.14	.
	Q300MG VS P	.	.	.	.	.	-0.56	0.133	-0.82	-0.30	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI220.SAS
GENERATED: 17NOV2005 13:30:49 iceadmn3

Table 11.2.4.2.1 CGI Improvement Score (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.58	0.134	-0.84	-0.32	<.001
DAY 57	Q300MG	155	4.6	0.62	2.3	1.24	2.28	0.104	2.07	2.48	.
	Q600MG	150	4.4	0.55	2.3	1.09	2.29	0.106	2.08	2.50	.
	P	161	4.5	0.56	2.9	1.20	2.88	0.103	2.67	3.08	.
	Q300MG VS P	.	.	.	.	.	-0.60	0.132	-0.86	-0.34	<.001
	Q600MG VS P	.	.	.	.	.	-0.59	0.133	-0.85	-0.33	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI220.SAS
GENERATED: 17NOV2005 13:30:49 iceadmn3

Table 11.2.4.2.2 CGI Improvement Score (ANCOVA)
Observed Cases
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	4.6	0.58	3.2	0.79	3.16	0.075	3.01	3.31	.
	Q600MG	146	4.4	0.55	3.2	0.81	3.19	0.077	3.04	3.34	.
	P	161	4.5	0.56	3.5	0.82	3.49	0.074	3.34	3.64	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.090	-0.51	-0.15	<.001
	Q600MG VS P	.	.	.	.	.	-0.30	0.091	-0.48	-0.12	0.001
DAY 15	Q300MG	131	4.6	0.62	2.7	0.92	2.72	0.087	2.54	2.89	.
	Q600MG	125	4.4	0.56	2.7	0.92	2.65	0.090	2.47	2.83	.
	P	145	4.5	0.57	3.2	0.84	3.15	0.085	2.98	3.32	.
	Q300MG VS P	.	.	.	.	.	-0.43	0.108	-0.65	-0.22	<.001
	Q600MG VS P	.	.	.	.	.	-0.50	0.108	-0.71	-0.28	<.001
DAY 22	Q300MG	123	4.5	0.63	2.4	0.97	2.41	0.100	2.21	2.61	.
	Q600MG	119	4.4	0.56	2.3	0.91	2.33	0.103	2.12	2.53	.
	P	136	4.5	0.57	2.9	1.04	2.92	0.097	2.73	3.11	.
	Q300MG VS P	.	.	.	.	.	-0.51	0.120	-0.75	-0.28	<.001
	Q600MG VS P	.	.	.	.	.	-0.59	0.121	-0.83	-0.36	<.001
DAY 29	Q300MG	117	4.6	0.63	2.4	1.10	2.34	0.106	2.13	2.55	.
	Q600MG	107	4.4	0.55	2.3	0.95	2.28	0.111	2.06	2.50	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI225.SAS
GENERATED: 17NOV2005 13:30:58 iceadmn3

Table 11.2.4.2.2 CGI Improvement Score (ANCOVA)
Observed Cases
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	133	4.5	0.56	2.8	1.07	2.76	0.101	2.56	2.96	.
	Q300MG VS P	.	.	.	.	.	-0.42	0.132	-0.68	-0.16	0.002
	Q600MG VS P	.	.	.	.	.	-0.48	0.135	-0.75	-0.22	<.001
DAY 36	Q300MG	111	4.5	0.63	2.1	0.99	2.12	0.109	1.90	2.34	.
	Q600MG	103	4.4	0.55	2.3	1.01	2.25	0.113	2.02	2.47	.
	P	123	4.4	0.54	2.8	1.08	2.82	0.105	2.61	3.03	.
	Q300MG VS P	.	.	.	.	.	-0.70	0.135	-0.97	-0.44	<.001
	Q600MG VS P	.	.	.	.	.	-0.57	0.136	-0.84	-0.31	<.001
DAY 43	Q300MG	98	4.5	0.58	2.0	1.03	2.03	0.111	1.81	2.25	.
	Q600MG	96	4.4	0.56	2.1	0.92	2.09	0.112	1.87	2.31	.
	P	114	4.4	0.56	2.6	1.08	2.68	0.104	2.47	2.89	.
	Q300MG VS P	.	.	.	.	.	-0.65	0.140	-0.93	-0.38	<.001
	Q600MG VS P	.	.	.	.	.	-0.59	0.140	-0.87	-0.32	<.001
DAY 50	Q300MG	102	4.5	0.56	2.0	1.00	2.02	0.113	1.80	2.24	.
	Q600MG	89	4.4	0.56	2.0	0.99	2.04	0.119	1.80	2.27	.
	P	112	4.4	0.56	2.7	1.13	2.66	0.109	2.44	2.88	.
	Q300MG VS P	.	.	.	.	.	-0.64	0.143	-0.92	-0.36	<.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI225.SAS
GENERATED: 17NOV2005 13:30:58 iceadmn3

Table 11.2.4.2.2 CGI Improvement Score (ANCOVA)
Observed Cases
Intent-to-Treat Population

			SEVERITY BASELINE		IMPROVEMENT		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-0.62	0.148	-0.91	-0.33	<.001
DAY 57	Q300MG	97	4.5	0.54	1.9	0.97	1.89	0.106	1.68	2.10	.
	Q600MG	86	4.4	0.56	2.0	0.96	1.97	0.112	1.75	2.20	.
	P	104	4.4	0.55	2.6	1.09	2.63	0.103	2.42	2.83	.
	Q300MG VS P	.	.	.	.	.	-0.74	0.144	-1.02	-0.45	<.001
	Q600MG VS P	.	.	.	.	.	-0.65	0.147	-0.94	-0.36	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI225.SAS
GENERATED: 17NOV2005 13:30:58 iceadmn3

Table 11.2.4.2.3 CGI Improvement (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA												
DAY 8	BIPOLAR I	16	102	16	23	98	23	14	110	13	.	.	.	.
	BIPOLAR II	11	51	22	6	48	13	5	51	10	.	.	.	.
	ALL	27	153	18	29	146	20	19	161	12	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.146	1.49	0.87	2.58
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.050	1.69	0.99	2.88
DAY 15	BIPOLAR I	31	103	30	43	99	43	27	110	25	.	.	.	.
	BIPOLAR II	20	51	39	14	48	29	8	51	16	.	.	.	.
	ALL	51	154	33	57	147	39	35	161	22	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.024	1.52	1.05	2.21
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.79	1.26	2.55
DAY 22	BIPOLAR I	44	104	42	54	101	53	36	110	33	.	.	.	.
	BIPOLAR II	28	51	55	20	48	42	14	51	27	.	.	.	.
	ALL	72	155	46	74	149	50	50	161	31	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.005	1.49	1.12	1.99
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.60	1.21	2.12
DAY 29	BIPOLAR I	54	104	52	52	101	51	40	110	36	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI222.SAS
GENERATED: 17NOV2005 13:30:52 iceadmn3

Table 11.2.4.2.3 CGI Improvement (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA												
DAY 29	BIPOLAR II	29	51	57	23	48	48	18	51	35	.	.	.	.
	ALL	83	155	54	75	149	50	58	161	36	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.002	1.49	1.15	1.91
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.011	1.40	1.08	1.81
DAY 36	BIPOLAR I	57	104	55	57	101	56	38	110	35	.	.	.	.
	BIPOLAR II	32	51	63	21	48	44	15	51	29	.	.	.	.
	ALL	89	155	57	78	149	52	53	161	33	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.74	1.35	2.26
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.59	1.22	2.08
DAY 43	BIPOLAR I	59	104	57	62	101	61	45	110	41	.	.	.	.
	BIPOLAR II	33	51	65	23	49	47	16	51	31	.	.	.	.
	ALL	92	155	59	85	150	57	61	161	38	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.57	1.24	1.99
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.50	1.18	1.91
DAY 50	BIPOLAR I	57	104	55	62	101	61	42	110	38	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI222.SAS
GENERATED: 17NOV2005 13:30:52 iceadmn3

Table 11.2.4.2.3 CGI Improvement (CMH)
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	34	51	67	25	49	51	19	51	37	.	.	.	.
	ALL	91	155	59	87	150	58	61	161	38	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.55	1.22	1.96
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.53	1.21	1.95
DAY 57	BIPOLAR I	62	104	60	63	101	62	43	110	39	.	.	.	.
	BIPOLAR II	33	51	65	27	49	55	19	51	37	.	.	.	.
	ALL	95	155	61	90	150	60	62	161	39	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.59	1.26	2.01
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.56	1.23	1.97

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI222.SAS
GENERATED: 17NOV2005 13:30:52 iceadmn3

Table 11.2.4.2.4 CGI Improvement (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT									RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P					
VISIT	STRATA	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
DAY 8	BIPOLAR I	16	102	15.7	23	98	23.5	14	110	12.7	.	.	.	.
	BIPOLAR II	11	51	21.6	6	48	12.5	5	51	9.8	.	.	.	.
	ALL	27	153	17.6	29	146	19.9	19	161	11.8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.146	1.49	0.87	2.58
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.050	1.69	0.99	2.88
DAY 15	BIPOLAR I	30	84	35.7	41	88	46.6	27	99	27.3	.	.	.	.
	BIPOLAR II	19	46	41.3	14	37	37.8	7	46	15.2	.	.	.	.
	ALL	49	130	37.7	55	125	44.0	34	145	23.4	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	0.010	1.62	1.12	2.35
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.86	1.31	2.65
DAY 22	BIPOLAR I	41	80	51.3	50	83	60.2	35	92	38.0	.	.	.	.
	BIPOLAR II	27	43	62.8	20	36	55.6	11	44	25.0	.	.	.	.
	ALL	68	123	55.3	70	119	58.8	46	136	33.8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.64	1.23	2.18
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.73	1.31	2.28
DAY 29	BIPOLAR I	47	78	60.3	41	74	55.4	36	87	41.4	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI227.SAS
GENERATED: 17NOV2005 13:31:00 iceadmn3

Table 11.2.4.2.4 CGI Improvement (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 29	BIPOLAR II	25	39	64.1	21	33	63.6	18	46	39.1	.	.	.	.
	ALL	72	117	61.5	62	107	57.9	54	133	40.6	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.52	1.18	1.95
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.008	1.43	1.10	1.85
DAY 36	BIPOLAR I	49	74	66.2	42	70	60.0	34	81	42.0	.	.	.	.
	BIPOLAR II	28	37	75.7	19	33	57.6	14	42	33.3	.	.	.	.
	ALL	77	111	69.4	61	103	59.2	48	123	39.0	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.78	1.38	2.29
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.003	1.51	1.15	1.99
DAY 43	BIPOLAR I	45	62	72.6	44	63	69.8	39	76	51.3	.	.	.	.
	BIPOLAR II	26	36	72.2	20	33	60.6	13	38	34.2	.	.	.	.
	ALL	71	98	72.4	64	96	66.7	52	114	45.6	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.60	1.26	2.03
	Q600 VS P	.	.	.	.	.	.	.	.	.	0.002	1.47	1.15	1.87
DAY 50	BIPOLAR I	44	65	67.7	41	58	70.7	35	75	46.7	.	.	.	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI227.SAS
GENERATED: 17NOV2005 13:31:00 iceadmn3

Table 11.2.4.2.4 CGI Improvement (CMH)
Observed Cases
Intent-to-Treat Population

		TREATMENT										RELATIVE RISK (MANTEL-HAENSEL ADJUSTED)		
		Q300MG			Q600MG			P						
		N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER
VISIT	STRATA													
DAY 50	BIPOLAR II	30	37	81.1	22	31	71.0	14	37	37.8	.	.	.	.
	ALL	74	102	72.5	63	89	70.8	49	112	43.8	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.66	1.30	2.12
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.62	1.26	2.08
DAY 57	BIPOLAR I	45	61	73.8	40	57	70.2	33	70	47.1	.	.	.	.
	BIPOLAR II	28	36	77.8	22	29	75.9	13	34	38.2	.	.	.	.
	ALL	73	97	75.3	62	86	72.1	46	104	44.2	.	.	.	.
	Q300 VS P	.	.	.	.	.	.	.	.	.	<.001	1.71	1.33	2.18
	Q600 VS P	.	.	.	.	.	.	.	.	.	<.001	1.63	1.27	2.10

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI227.SAS
GENERATED: 17NOV2005 13:31:00 iceadmn3

FIGURE 11.2.4.3 PERCENT OF PATIENTS RATED AS "MUCH" OR "VERY MUCH" IMPROVED ON CGI GLOBAL IMPROVEMENT SCALE

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

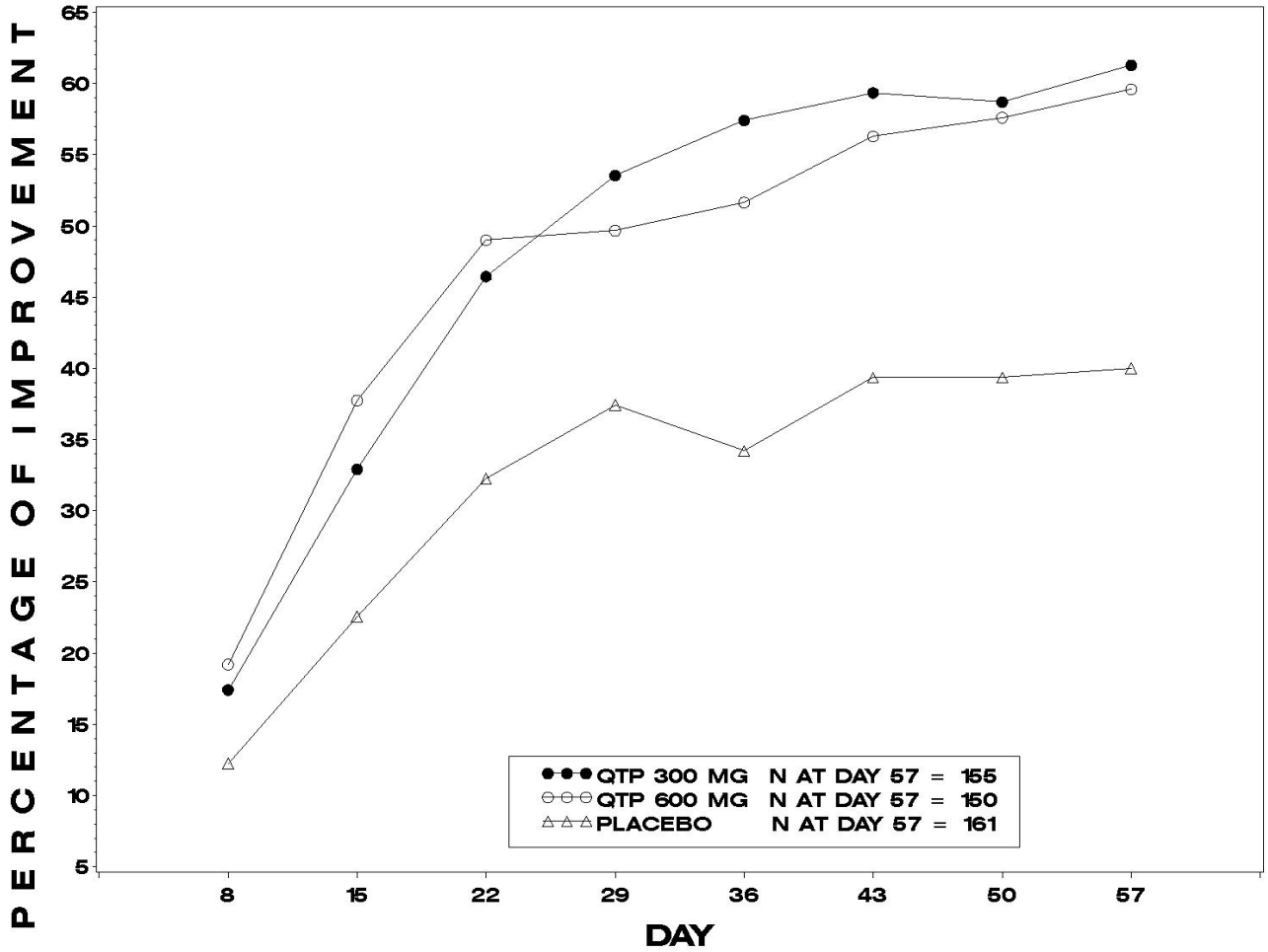

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT													
			QUETIAPINE 300 MG													
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		NOT APPLICABLE	
			N	%	N	%	N	%	N	%	N	%	N	%	N	%
Bipolar I	WINDOWED VISIT	TOTAL														
	DAY 8	102	3	2.9	13	12.7	52	51.0	32	31.4	2	2.0	0	0	0	0
	DAY 15	104	6	5.8	25	24.0	51	49.0	18	17.3	2	1.9	1	1.0	1	1.0
	DAY 22	104	17	16.3	27	26.0	41	39.4	16	15.4	2	1.9	1	1.0	0	0
	DAY 29	104	20	19.2	34	32.7	26	25.0	18	17.3	5	4.8	1	1.0	0	0
	DAY 36	104	27	26.0	30	28.8	28	26.9	14	13.5	4	3.8	1	1.0	0	0
	DAY 43	104	33	31.7	26	25.0	28	26.9	11	10.6	5	4.8	1	1.0	0	0
	DAY 50	104	33	31.7	24	23.1	26	25.0	15	14.4	5	4.8	1	1.0	0	0
	DAY 57	104	36	34.6	26	25.0	22	21.2	15	14.4	4	3.8	1	1.0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI213.SAS
GENERATED: 17NOV2005 13:45:37 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT									
			QUETIAPINE 300 MG									
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE	
			N	%	N	%	N	%	N	%	N	%
Bipolar II	WINDOWED VISIT	TOTAL										
	DAY 8	51	1	2.0	10	19.6	23	45.1	16	31.4	1	2.0
	DAY 15	51	5	9.8	15	29.4	21	41.2	9	17.6	1	2.0
	DAY 22	51	9	17.6	19	37.3	14	27.5	7	13.7	2	3.9
	DAY 29	51	13	25.5	16	31.4	10	19.6	10	19.6	2	3.9
	DAY 36	51	15	29.4	17	33.3	9	17.6	8	15.7	2	3.9
	DAY 43	51	17	33.3	16	31.4	5	9.8	10	19.6	3	5.9
	DAY 50	51	16	31.4	18	35.3	5	9.8	9	17.6	3	5.9
	DAY 57	51	18	35.3	15	29.4	9	17.6	6	11.8	3	5.9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI213.SAS
GENERATED: 17NOV2005 13:45:37 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 600 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
Bipolar I	WINDOWED VISIT	TOTAL												
	DAY 8	98	3	3.1	20	20.4	37	37.8	37	37.8	1	1.0	0	0
	DAY 15	99	8	8.1	35	35.4	36	36.4	18	18.2	2	2.0	0	0
	DAY 22	101	11	10.9	43	42.6	34	33.7	11	10.9	1	1.0	1	1.0
	DAY 29	101	15	14.9	37	36.6	33	32.7	15	14.9	1	1.0	0	0
	DAY 36	101	21	20.8	36	35.6	31	30.7	12	11.9	1	1.0	0	0
	DAY 43	101	24	23.8	38	37.6	25	24.8	12	11.9	1	1.0	1	1.0
	DAY 50	101	24	23.8	38	37.6	25	24.8	11	10.9	2	2.0	1	1.0
	DAY 57	101	25	24.8	38	37.6	25	24.8	11	10.9	1	1.0	1	1.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI213.SAS
GENERATED: 17NOV2005 13:45:37 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT							
			QUETIAPINE 600 MG							
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE	
			N	%	N	%	N	%	N	%
Bipolar II	WINDOWED VISIT	TOTAL								
	DAY 8	48	0	0	6	12.5	21	43.8	21	43.8
	DAY 15	48	4	8.3	10	20.8	22	45.8	12	25.0
	DAY 22	48	10	20.8	10	20.8	18	37.5	10	20.8
	DAY 29	48	12	25.0	11	22.9	16	33.3	9	18.8
	DAY 36	48	12	25.0	9	18.8	14	29.2	13	27.1
	DAY 43	49	14	28.6	9	18.4	18	36.7	8	16.3
	DAY 50	49	15	30.6	10	20.4	14	28.6	10	20.4
	DAY 57	49	18	36.7	9	18.4	12	24.5	10	20.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI213.SAS
GENERATED: 17NOV2005 13:45:37 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT											
			PLACEBO											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
Bipolar I	WINDOWED VISIT	TOTAL												
	DAY 8	110	1	0.9	13	11.8	34	30.9	56	50.9	5	4.5	1	0.9
	DAY 15	110	1	0.9	26	23.6	36	32.7	44	40.0	2	1.8	1	0.9
	DAY 22	110	9	8.2	27	24.5	32	29.1	35	31.8	6	5.5	1	0.9
	DAY 29	110	13	11.8	27	24.5	28	25.5	35	31.8	6	5.5	1	0.9
	DAY 36	110	11	10.0	27	24.5	30	27.3	34	30.9	6	5.5	2	1.8
	DAY 43	110	13	11.8	32	29.1	24	21.8	34	30.9	5	4.5	2	1.8
	DAY 50	110	17	15.5	25	22.7	26	23.6	35	31.8	5	4.5	2	1.8
	DAY 57	110	17	15.5	26	23.6	25	22.7	35	31.8	5	4.5	2	1.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI213.SAS
GENERATED: 17NOV2005 13:45:37 iceadmn3

Table 11.2.4.4.1 CGI Improvement Score by Bipolar Diagnosis - Summary
Last Observation Carried Forward
Intent-to-Treat Population

			TREATMENT											
			PLACEBO											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
Bipolar II	WINDOWED VISIT	TOTAL												
	DAY 8	51	0	0	5	9.8	19	37.3	24	47.1	2	3.9	1	2.0
	DAY 15	51	1	2.0	7	13.7	22	43.1	19	37.3	2	3.9	0	0
	DAY 22	51	3	5.9	11	21.6	19	37.3	15	29.4	3	5.9	0	0
	DAY 29	51	5	9.8	13	25.5	17	33.3	14	27.5	2	3.9	0	0
	DAY 36	51	5	9.8	10	19.6	19	37.3	14	27.5	3	5.9	0	0
	DAY 43	51	6	11.8	10	19.6	17	33.3	14	27.5	4	7.8	0	0
	DAY 50	51	6	11.8	13	25.5	14	27.5	14	27.5	4	7.8	0	0
	DAY 57	51	9	17.6	10	19.6	17	33.3	13	25.5	2	3.9	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI213.SAS
GENERATED: 17NOV2005 13:45:37 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT													
			QUETIAPINE 300 MG													
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE		NOT APPLICABLE	
			N	%	N	%	N	%	N	%	N	%	N	%	N	%
Bipolar I	WINDOWED VISIT	TOTAL														
	DAY 8	102	3	2.9	13	12.7	52	51.0	32	31.4	2	2.0	0	0	0	0
	DAY 15	85	6	7.1	24	28.2	39	45.9	13	15.3	1	1.2	1	1.2	1	1.2
	DAY 22	80	16	20.0	25	31.3	28	35.0	10	12.5	1	1.3	0	0	0	0
	DAY 29	78	18	23.1	29	37.2	16	20.5	11	14.1	4	5.1	0	0	0	0
	DAY 36	74	24	32.4	25	33.8	18	24.3	5	6.8	2	2.7	0	0	0	0
	DAY 43	62	26	41.9	19	30.6	15	24.2	1	1.6	1	1.6	0	0	0	0
	DAY 50	65	26	40.0	18	27.7	15	23.1	5	7.7	1	1.5	0	0	0	0
	DAY 57	61	27	44.3	18	29.5	11	18.0	5	8.2	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI212.SAS
GENERATED: 17NOV2005 13:45:34 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT									
			QUETIAPINE 300 MG									
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE	
			N	%	N	%	N	%	N	%	N	%
Bipolar II	WINDOWED VISIT	TOTAL										
	DAY 8	51	1	2.0	10	19.6	23	45.1	16	31.4	1	2.0
	DAY 15	46	4	8.7	15	32.6	20	43.5	7	15.2	0	0
	DAY 22	43	8	18.6	19	44.2	12	27.9	3	7.0	1	2.3
	DAY 29	39	9	23.1	16	41.0	8	20.5	6	15.4	0	0
	DAY 36	37	11	29.7	17	45.9	6	16.2	3	8.1	0	0
	DAY 43	36	12	33.3	14	38.9	3	8.3	6	16.7	1	2.8
	DAY 50	37	12	32.4	18	48.6	3	8.1	4	10.8	0	0
	DAY 57	36	14	38.9	14	38.9	6	16.7	1	2.8	1	2.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI212.SAS
GENERATED: 17NOV2005 13:45:34 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			QUETIAPINE 600 MG											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
Bipolar I	WINDOWED VISIT	TOTAL												
	DAY 8	98	3	3.1	20	20.4	37	37.8	37	37.8	1	1.0	0	0
	DAY 15	88	8	9.1	33	37.5	30	34.1	15	17.0	2	2.3	0	0
	DAY 22	83	10	12.0	40	48.2	26	31.3	6	7.2	0	0	1	1.2
	DAY 29	74	12	16.2	29	39.2	23	31.1	10	13.5	0	0	0	0
	DAY 36	70	17	24.3	25	35.7	21	30.0	7	10.0	0	0	0	0
	DAY 43	63	18	28.6	26	41.3	14	22.2	5	7.9	0	0	0	0
	DAY 50	58	17	29.3	24	41.4	12	20.7	4	6.9	1	1.7	0	0
	DAY 57	57	17	29.8	23	40.4	13	22.8	4	7.0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI212.SAS
GENERATED: 17NOV2005 13:45:34 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT							
			QUETIAPINE 600 MG							
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE	
			N	%	N	%	N	%	N	%
Bipolar II	WINDOWED VISIT	TOTAL								
	DAY 8	48	0	0	6	12.5	21	43.8	21	43.8
	DAY 15	37	4	10.8	10	27.0	17	45.9	6	16.2
	DAY 22	36	10	27.8	10	27.8	13	36.1	3	8.3
	DAY 29	33	12	36.4	9	27.3	10	30.3	2	6.1
	DAY 36	33	12	36.4	7	21.2	8	24.2	6	18.2
	DAY 43	33	13	39.4	7	21.2	12	36.4	1	3.0
	DAY 50	31	14	45.2	8	25.8	6	19.4	3	9.7
	DAY 57	29	16	55.2	6	20.7	4	13.8	3	10.3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI212.SAS
GENERATED: 17NOV2005 13:45:34 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			PLACEBO											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
Bipolar I	WINDOWED VISIT	TOTAL												
	DAY 8	110	1	0.9	13	11.8	34	30.9	56	50.9	5	4.5	1	0.9
	DAY 15	99	1	1.0	26	26.3	33	33.3	37	37.4	2	2.0	0	0
	DAY 22	92	9	9.8	26	28.3	29	31.5	23	25.0	5	5.4	0	0
	DAY 29	87	12	13.8	24	27.6	25	28.7	22	25.3	4	4.6	0	0
	DAY 36	81	11	13.6	23	28.4	24	29.6	20	24.7	2	2.5	1	1.2
	DAY 43	76	13	17.1	26	34.2	20	26.3	17	22.4	0	0	0	0
	DAY 50	75	16	21.3	19	25.3	22	29.3	17	22.7	1	1.3	0	0
	DAY 57	70	13	18.6	20	28.6	20	28.6	16	22.9	1	1.4	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI212.SAS
GENERATED: 17NOV2005 13:45:34 iceadmn3

Table 11.2.4.4.2 CGI Improvement Score by Bipolar Diagnosis - Summary
Observed Cases
Intent-to-Treat Population

			TREATMENT											
			PLACEBO											
			VERY MUCH IMPROVED		MUCH IMPROVED		MINIMALLY IMPROVED		NO CHANGE		MINIMALLY WORSE		MUCH WORSE	
			N	%	N	%	N	%	N	%	N	%	N	%
Bipolar II	WINDOWED VISIT	TOTAL												
	DAY 8	51	0	0	5	9.8	19	37.3	24	47.1	2	3.9	1	2.0
	DAY 15	46	1	2.2	6	13.0	21	45.7	17	37.0	1	2.2	0	0
	DAY 22	44	3	6.8	8	18.2	18	40.9	13	29.5	2	4.5	0	0
	DAY 29	46	5	10.9	13	28.3	16	34.8	11	23.9	1	2.2	0	0
	DAY 36	42	4	9.5	10	23.8	17	40.5	9	21.4	2	4.8	0	0
	DAY 43	38	6	15.8	7	18.4	14	36.8	8	21.1	3	7.9	0	0
	DAY 50	37	5	13.5	9	24.3	12	32.4	8	21.6	3	8.1	0	0
	DAY 57	34	7	20.6	6	17.6	13	38.2	7	20.6	1	2.9	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CGI212.SAS
GENERATED: 17NOV2005 13:45:34 iceadmn3

Table 11.2.5.1.1 HAM-A Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	155	19.1	5.98	19.0	5	34	151	18.4	5.78	18.0	6	33	161	18.2	5.69	18.0	6	36
	DAY 8	153	13.9	6.19	14.0	2	32	147	13.7	5.98	13.0	1	31	161	15.2	6.74	15.0	0	35
	DAY 29	155	10.9	6.65	10.0	0	32	148	11.0	6.29	10.5	1	26	161	12.6	6.53	12.0	0	35
	DAY 57	155	10.0	6.96	9.0	0	32	149	10.2	6.89	9.0	0	30	161	12.5	7.18	12.0	0	35
CHG FROM BASELINE	DAY 8	153	-5.3	5.41	-5.0	-24	9	147	-4.5	5.60	-4.0	-24	13	161	-3.0	5.59	-3.0	-24	13
	DAY 29	155	-8.3	6.24	-8.0	-24	9	148	-7.2	6.84	-6.5	-27	13	161	-5.6	6.46	-5.0	-31	10
	DAY 57	155	-9.1	6.92	-9.0	-27	9	149	-8.1	7.17	-7.0	-27	13	161	-5.7	7.37	-5.0	-34	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA201.SAS
GENERATED: 17NOV2005 13:49:09 iceadmn3

Table 11.2.5.1.2 HAM-A Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	155	19.1	5.98	19.0	5	34	151	18.4	5.78	18.0	6	33	161	18.2	5.69	18.0	6	36
	DAY 8	153	13.9	6.19	14.0	2	32	147	13.7	5.98	13.0	1	31	161	15.2	6.74	15.0	0	35
	DAY 29	123	9.7	6.31	9.0	0	25	118	10.2	6.24	9.0	1	26	140	12.0	6.16	12.0	0	28
	DAY 57	98	8.1	6.16	7.0	0	22	93	8.0	6.40	6.0	0	30	108	11.0	6.37	10.0	0	30
CHG FROM BASELINE	DAY 8	153	-5.3	5.41	-5.0	-24	9	147	-4.5	5.60	-4.0	-24	13	161	-3.0	5.59	-3.0	-24	13
	DAY 29	123	-9.1	5.96	-9.0	-24	7	118	-8.1	6.85	-7.5	-27	7	140	-6.2	6.49	-5.5	-31	10
	DAY 57	98	-10.7	6.45	-11.0	-27	4	93	-9.9	7.25	-9.0	-27	4	108	-7.0	7.28	-7.0	-34	16

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA200.SAS
GENERATED: 17NOV2005 13:49:06 iceadmn3

Table 11.2.5.1.3 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I DISORDER		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	104	19.2	6.28	19.0	5	34	101	18.6	5.89	19.0	6	30	110	18.0	6.03	17.0	6	36
	DAY 8	102	14.1	6.57	14.0	2	32	98	13.4	6.14	13.5	1	31	110	14.9	6.89	15.0	0	35
	DAY 29	104	11.3	6.97	10.5	0	32	99	10.7	6.00	10.0	1	26	110	12.4	6.79	12.0	0	35
	DAY 57	104	10.4	7.41	9.0	0	32	99	10.1	6.76	9.0	0	30	110	12.8	7.82	13.0	0	35
CHG FROM BASELINE	DAY 8	102	-5.1	5.73	-5.0	-24	9	98	-5.1	5.57	-4.5	-24	9	110	-3.1	5.79	-2.0	-24	13
	DAY 29	104	-7.8	6.44	-8.0	-24	9	99	-7.8	6.68	-7.0	-27	7	110	-5.6	6.87	-5.0	-31	10
	DAY 57	104	-8.8	6.96	-9.0	-26	9	99	-8.5	6.85	-7.0	-27	4	110	-5.2	7.96	-4.0	-34	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA211.SAS
GENERATED: 17NOV2005 13:49:21 iceadmn3

Table 11.2.5.1.3 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II DISORDER		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	51	19.1	5.36	19.0	9	33	50	17.9	5.58	17.0	8	33	51	18.7	4.90	18.0	7	27
	DAY 8	51	13.6	5.37	13.0	2	26	49	14.3	5.68	13.0	3	25	51	15.9	6.41	15.0	4	33
	DAY 29	51	10.0	5.93	10.0	0	23	49	11.6	6.85	12.0	1	25	51	13.1	5.98	12.0	3	25
	DAY 57	51	9.4	5.94	8.0	0	22	50	10.5	7.21	9.5	0	25	51	11.9	5.58	10.0	4	25
CHG FROM BASELINE	DAY 8	51	-5.5	4.73	-6.0	-19	3	49	-3.3	5.50	-3.0	-21	13	51	-2.8	5.16	-3.0	-19	7
	DAY 29	51	-9.1	5.80	-9.0	-23	3	49	-6.0	7.07	-5.0	-21	13	51	-5.6	5.53	-5.0	-16	7
	DAY 57	51	-9.8	6.87	-10.0	-27	4	50	-7.4	7.77	-6.5	-23	13	51	-6.7	5.83	-6.0	-20	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA211.SAS
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Table 11.2.5.1.4 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I DISORDER		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	104	19.2	6.28	19.0	5	34	101	18.6	5.89	19.0	6	30	110	18.0	6.03	17.0	6	36
	DAY 8	102	14.1	6.57	14.0	2	32	98	13.4	6.14	13.5	1	31	110	14.9	6.89	15.0	0	35
	DAY 29	82	9.8	6.40	9.0	0	25	83	10.1	5.95	9.0	1	26	93	11.7	6.39	12.0	0	28
	DAY 57	62	8.0	6.36	6.5	0	22	62	8.2	6.41	6.5	0	30	72	11.0	7.09	11.0	0	30
CHG FROM BASELINE	DAY 8	102	-5.1	5.73	-5.0	-24	9	98	-5.1	5.57	-4.5	-24	9	110	-3.1	5.79	-2.0	-24	13
	DAY 29	82	-8.8	6.01	-8.0	-24	7	83	-8.0	7.03	-7.0	-27	7	93	-6.2	7.04	-6.0	-31	10
	DAY 57	62	-10.6	5.91	-10.5	-26	3	62	-9.5	7.37	-8.0	-27	4	72	-6.6	8.08	-6.5	-34	16

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA210.SAS
GENERATED: 17NOV2005 13:49:19 iceadmn3

Table 11.2.5.1.4 HAM-A Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II DISORDER		TREATMENT															
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HAM-A TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	51	19.1	5.36	19.0	9	33	50	17.9	5.58	17.0	8	33	51	18.7	4.90	18.0	7	27
	DAY 8	51	13.6	5.37	13.0	2	26	49	14.3	5.68	13.0	3	25	51	15.9	6.41	15.0	4	33
	DAY 29	41	9.6	6.20	10.0	0	23	35	10.4	6.95	10.0	1	23	47	12.5	5.68	12.0	3	25
	DAY 57	36	8.2	5.89	7.0	0	18	31	7.7	6.49	6.0	0	25	36	10.8	4.72	9.0	4	21
CHG FROM BASELINE	DAY 8	51	-5.5	4.73	-6.0	-19	3	49	-3.3	5.50	-3.0	-21	13	51	-2.8	5.16	-3.0	-19	7
	DAY 29	41	-9.7	5.88	-10.0	-23	3	35	-8.3	6.49	-9.0	-21	3	47	-6.2	5.32	-5.0	-16	7
	DAY 57	36	-10.9	7.36	-11.0	-27	4	31	-10.8	7.04	-10.0	-23	4	36	-7.7	5.34	-7.0	-20	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA210.SAS
GENERATED: 17NOV2005 13:49:19 iceadmn3

Table 11.2.5.2.1 HAM-A Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	19.2	5.95	-5.3	5.41	-4.98	0.469	-5.91	-4.06	.
	Q600MG	147	18.3	5.67	-4.5	5.60	-4.62	0.481	-5.57	-3.67	.
	P	161	18.2	5.69	-3.0	5.59	-3.06	0.465	-3.98	-2.14	.
	Q300MG VS P	.	.	.	.	.	-1.92	0.573	-3.05	-0.80	<.001
	Q600MG VS P	.	.	.	.	.	-1.56	0.579	-2.70	-0.42	0.007
DAY 29	Q300MG	155	19.1	5.98	-8.3	6.24	-7.91	0.586	-9.07	-6.75	.
	Q600MG	148	18.2	5.66	-7.2	6.84	-7.34	0.601	-8.53	-6.15	.
	P	161	18.2	5.69	-5.6	6.46	-5.69	0.586	-6.85	-4.52	.
	Q300MG VS P	.	.	.	.	.	-2.22	0.629	-3.46	-0.99	<.001
	Q600MG VS P	.	.	.	.	.	-1.65	0.637	-2.90	-0.40	0.010
DAY 57	Q300MG	155	19.1	5.98	-9.1	6.92	-8.78	0.648	-10.07	-7.49	.
	Q600MG	149	18.3	5.74	-8.1	7.17	-8.15	0.664	-9.47	-6.83	.
	P	161	18.2	5.69	-5.7	7.37	-5.80	0.649	-7.09	-4.51	.
	Q300MG VS P	.	.	.	.	.	-2.98	0.702	-4.36	-1.60	<.001
	Q600MG VS P	.	.	.	.	.	-2.35	0.710	-3.75	-0.96	0.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA202.SAS
GENERATED: 17NOV2005 13:31:06 iceadmn3

Table 11.2.5.2.2 HAM-A Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	19.2	5.95	-5.3	5.41	-4.98	0.469	-5.91	-4.06	.
	Q600MG	147	18.3	5.67	-4.5	5.60	-4.62	0.481	-5.57	-3.67	.
	P	161	18.2	5.69	-3.0	5.59	-3.06	0.465	-3.98	-2.14	.
	Q300MG VS P	.	.	.	.	.	-1.92	0.573	-3.05	-0.80	<.001
	Q600MG VS P	.	.	.	.	.	-1.56	0.579	-2.70	-0.42	0.007
DAY 29	Q300MG	123	18.8	5.98	-9.1	5.96	-8.77	0.631	-10.03	-7.52	.
	Q600MG	118	18.3	5.75	-8.1	6.85	-8.11	0.643	-9.38	-6.83	.
	P	140	18.2	5.71	-6.2	6.49	-6.24	0.615	-7.47	-5.02	.
	Q300MG VS P	.	.	.	.	.	-2.53	0.661	-3.83	-1.23	<.001
	Q600MG VS P	.	.	.	.	.	-1.86	0.663	-3.17	-0.56	0.005
DAY 57	Q300MG	98	18.8	5.78	-10.7	6.45	-10.06	0.718	-11.48	-8.63	.
	Q600MG	93	18.0	6.02	-9.9	7.25	-9.96	0.735	-11.42	-8.50	.
	P	108	17.9	5.64	-7.0	7.28	-7.12	0.703	-8.52	-5.72	.
	Q300MG VS P	.	.	.	.	.	-2.93	0.811	-4.53	-1.34	<.001
	Q600MG VS P	.	.	.	.	.	-2.84	0.815	-4.44	-1.23	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA206.SAS
GENERATED: 17NOV2005 13:31:08 iceadmn3

FIGURE 11.2.5.3.1 HAM-A TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

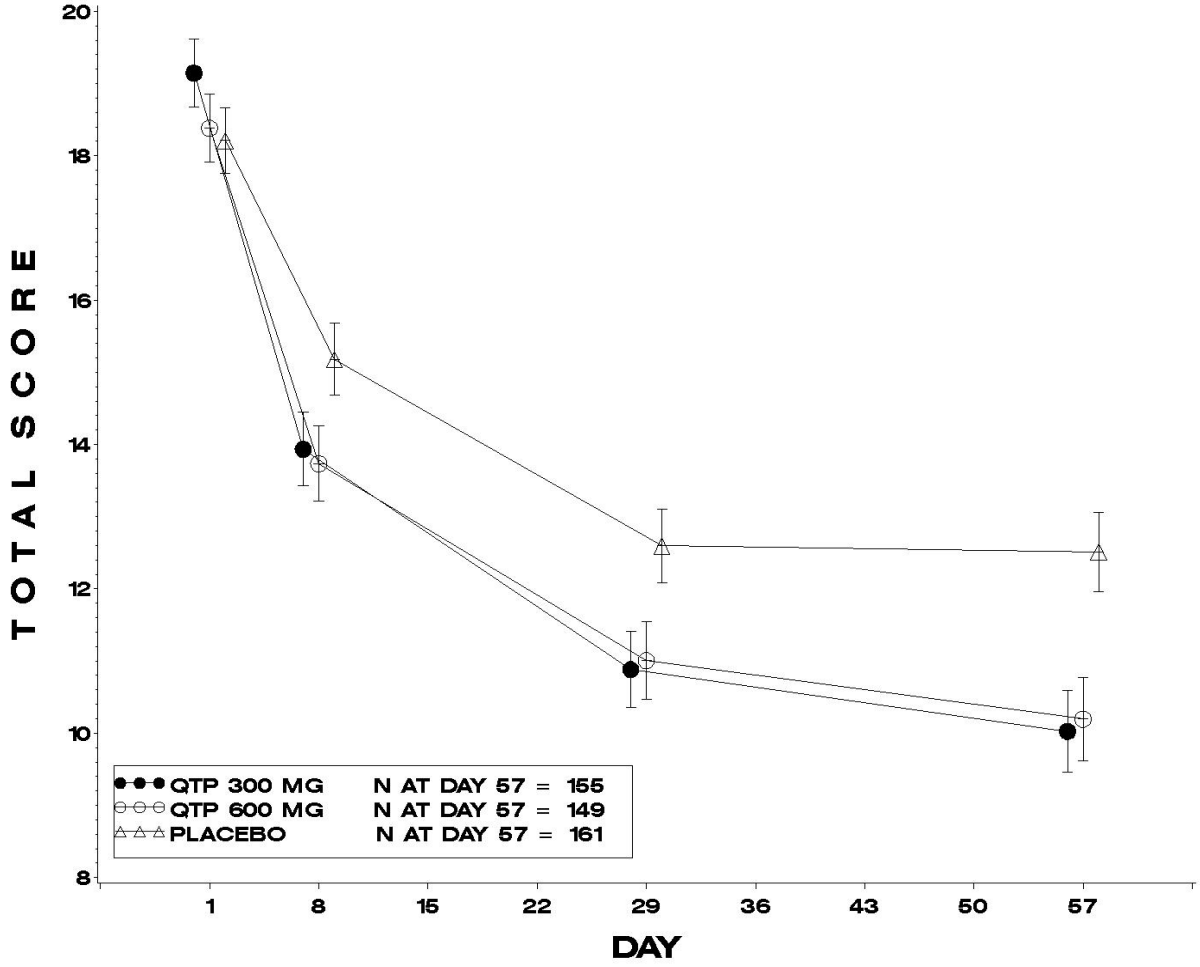

FIGURE 11.2.5.3.2 HAM-A TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

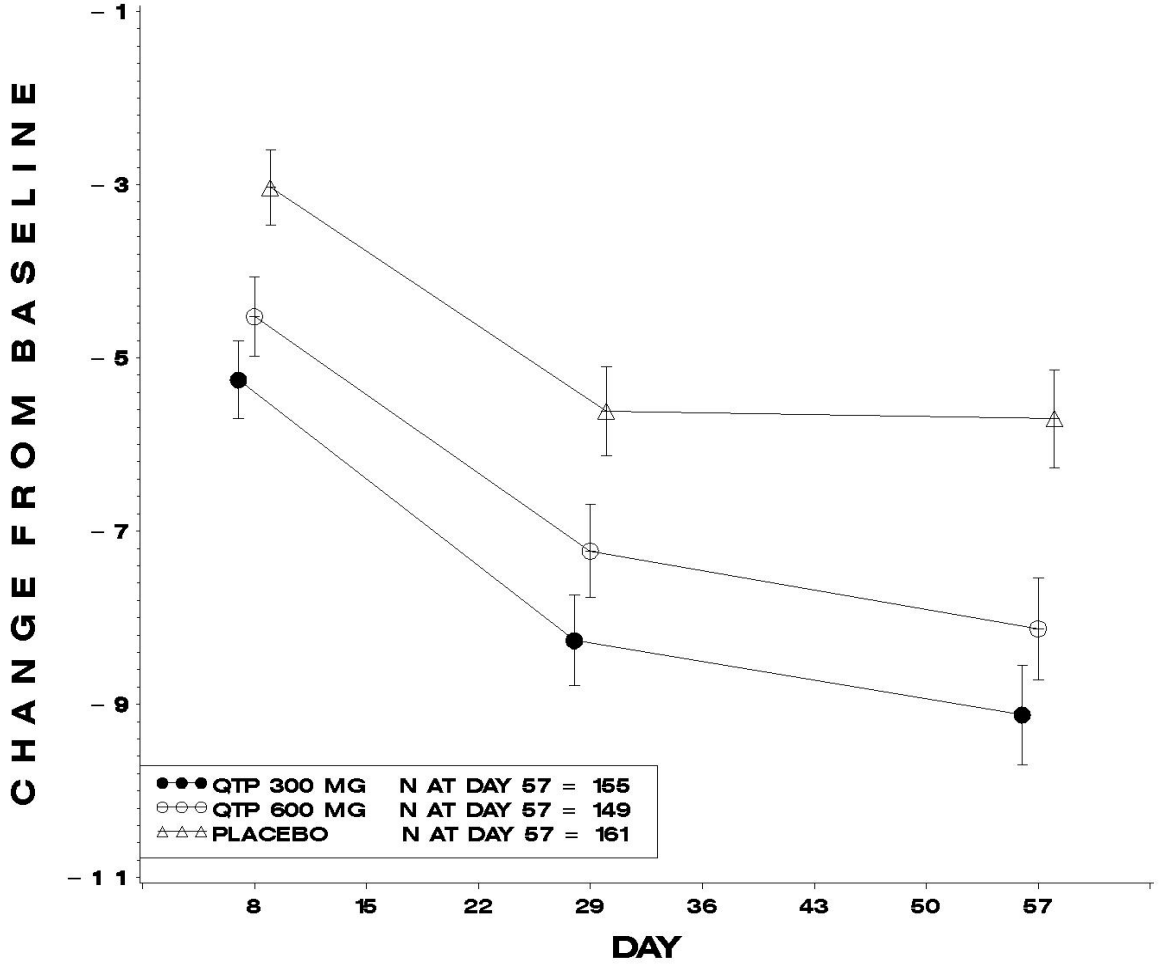

FIGURE 11.2.5.3.3 HAM-A TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

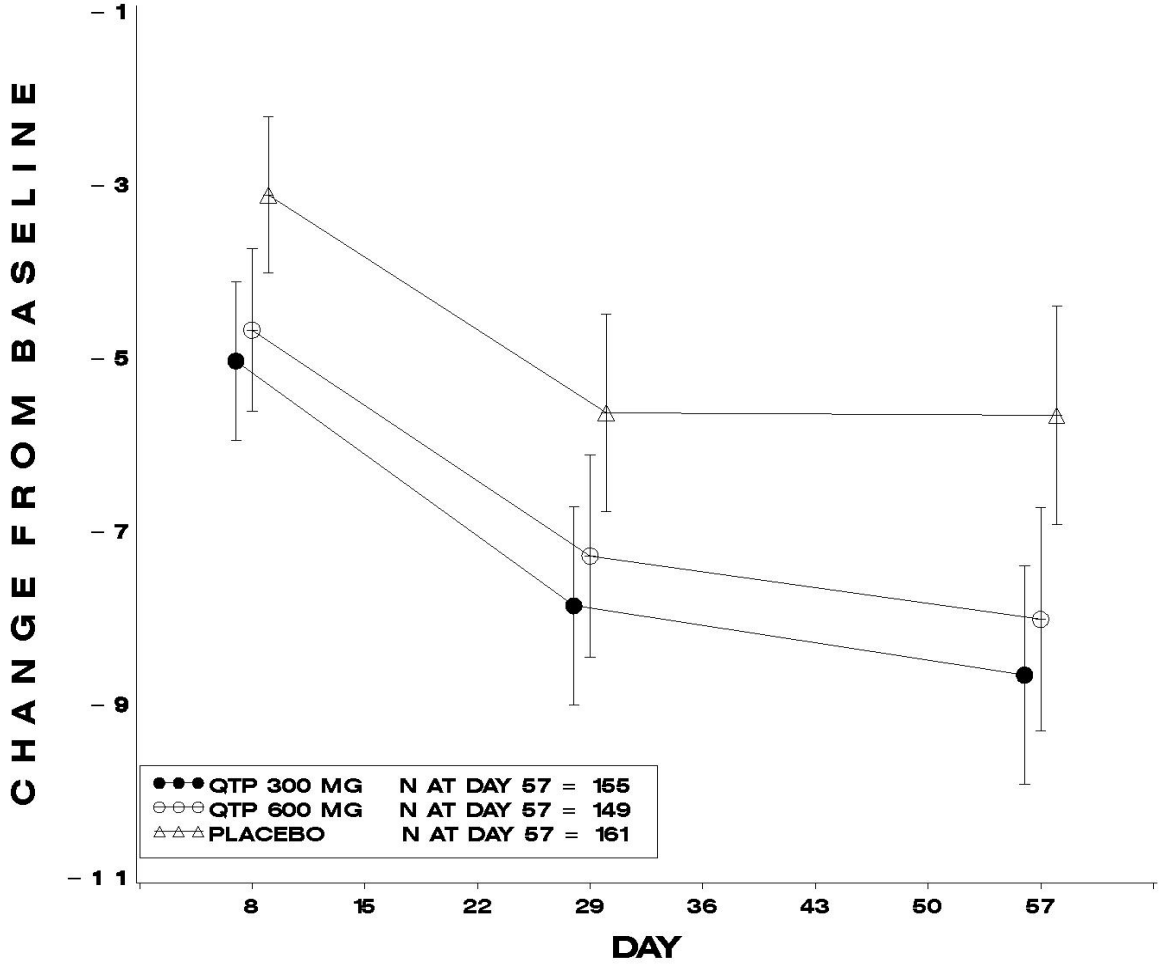

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ANXIOUS MOOD	WINDOWED VISIT																		
	DAY 1	155	2.1	0.74	2.0	0	4	151	2.0	0.71	2.0	0	3	161	2.0	0.74	2.0	0	3
	DAY 8	153	1.6	0.94	2.0	0	4	147	1.6	0.90	2.0	0	3	161	1.7	0.89	2.0	0	4
	DAY 29	155	1.4	0.92	1.0	0	4	148	1.3	0.88	1.0	0	3	161	1.5	0.88	2.0	0	4
	DAY 57	155	1.3	1.01	1.0	0	4	149	1.2	0.92	1.0	0	4	161	1.5	0.91	2.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. TENSION	WINDOWED VISIT																		
	DAY 1	155	2.0	0.80	2.0	0	4	151	1.9	0.78	2.0	0	4	161	1.9	0.71	2.0	0	3
	DAY 8	153	1.6	0.97	2.0	0	4	147	1.5	0.84	1.0	0	4	161	1.7	0.85	2.0	0	3
	DAY 29	155	1.2	0.95	1.0	0	3	148	1.2	0.88	1.0	0	4	161	1.5	0.87	1.0	0	3
	DAY 57	155	1.2	0.95	1.0	0	3	149	1.1	0.87	1.0	0	4	161	1.5	0.92	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. FEARS	WINDOWED VISIT																		
	DAY 1	155	0.5	0.78	0.0	0	3	151	0.5	0.71	0.0	0	3	161	0.5	0.86	0.0	0	3
	DAY 8	153	0.5	0.75	0.0	0	3	147	0.4	0.71	0.0	0	3	161	0.4	0.73	0.0	0	3
	DAY 29	155	0.3	0.57	0.0	0	3	148	0.3	0.57	0.0	0	2	161	0.3	0.62	0.0	0	2
	DAY 57	155	0.4	0.70	0.0	0	3	149	0.2	0.54	0.0	0	2	161	0.3	0.61	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA	WINDOWED VISIT																		
	DAY 1	155	2.4	0.88	2.0	0	4	151	2.3	0.85	2.0	0	4	161	2.3	0.85	2.0	0	4
	DAY 8	153	0.9	0.97	1.0	0	4	147	0.8	0.96	1.0	0	3	161	1.7	1.07	2.0	0	4
	DAY 29	155	0.7	0.97	0.0	0	4	148	0.8	1.00	0.0	0	3	161	1.4	1.09	1.0	0	4
	DAY 57	155	0.7	0.91	0.0	0	4	149	0.8	1.03	0.0	0	4	161	1.5	1.18	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INTELLECTUAL	WINDOWED VISIT																		
	DAY 1	155	1.9	0.76	2.0	0	3	151	1.8	0.81	2.0	0	4	161	1.9	0.77	2.0	0	3
	DAY 8	153	1.5	0.92	1.0	0	4	147	1.5	0.91	2.0	0	4	161	1.6	0.78	2.0	0	3
	DAY 29	155	1.1	0.99	1.0	0	3	148	1.2	0.91	1.0	0	3	161	1.3	0.86	1.0	0	3
	DAY 57	155	1.1	0.98	1.0	0	3	149	1.1	0.95	1.0	0	3	161	1.3	0.92	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. DEPRESSED MOOD	WINDOWED VISIT																		
	DAY 1	155	2.6	0.67	3.0	0	4	151	2.6	0.64	3.0	0	4	161	2.6	0.63	3.0	0	4
	DAY 8	153	1.9	0.86	2.0	0	4	147	1.9	0.91	2.0	0	4	161	2.2	0.78	2.0	0	4
	DAY 29	155	1.4	0.95	1.0	0	4	148	1.4	1.03	1.0	0	4	161	1.7	0.97	2.0	0	3
	DAY 57	155	1.2	1.05	1.0	0	4	149	1.3	1.07	1.0	0	4	161	1.5	1.03	2.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. SOMATIC (MUSCULAR)	WINDOWED VISIT																		
	DAY 1	155	1.1	0.90	1.0	0	3	151	1.1	0.81	1.0	0	3	161	1.0	0.89	1.0	0	3
	DAY 8	153	0.9	0.84	1.0	0	3	147	0.9	0.80	1.0	0	3	161	0.9	0.84	1.0	0	3
	DAY 29	155	0.7	0.78	1.0	0	3	148	0.7	0.79	1.0	0	3	161	0.8	0.81	1.0	0	3
	DAY 57	155	0.7	0.79	0.0	0	3	149	0.6	0.73	0.0	0	3	161	0.8	0.86	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. SOMATIC (SENSORY)	WINDOWED VISIT																		
	DAY 1	155	0.8	0.79	1.0	0	3	151	0.7	0.75	1.0	0	3	161	0.7	0.77	0.0	0	3
	DAY 8	153	0.6	0.73	0.0	0	3	147	0.6	0.71	0.0	0	2	161	0.6	0.72	0.0	0	3
	DAY 29	155	0.4	0.67	0.0	0	3	148	0.5	0.66	0.0	0	2	161	0.4	0.58	0.0	0	2
	DAY 57	155	0.3	0.61	0.0	0	3	149	0.4	0.68	0.0	0	2	161	0.4	0.69	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. CARDIOVASCULAR SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	0.5	0.68	0.0	0	3	151	0.6	0.70	0.0	0	3	161	0.5	0.75	0.0	0	3
	DAY 8	153	0.5	0.73	0.0	0	3	147	0.5	0.69	0.0	0	3	161	0.4	0.69	0.0	0	3
	DAY 29	155	0.3	0.58	0.0	0	3	148	0.3	0.52	0.0	0	2	161	0.4	0.64	0.0	0	3
	DAY 57	155	0.3	0.57	0.0	0	3	149	0.3	0.54	0.0	0	2	161	0.4	0.72	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. RESPIRATORY SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	0.6	0.69	0.0	0	2	151	0.6	0.70	0.0	0	2	161	0.6	0.72	0.0	0	3
	DAY 8	153	0.4	0.68	0.0	0	3	147	0.4	0.64	0.0	0	3	161	0.4	0.60	0.0	0	3
	DAY 29	155	0.4	0.60	0.0	0	3	148	0.3	0.56	0.0	0	3	161	0.4	0.55	0.0	0	2
	DAY 57	155	0.3	0.60	0.0	0	3	149	0.4	0.57	0.0	0	3	161	0.4	0.62	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. GASTROINTESTINAL SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	0.9	0.86	1.0	0	3	151	0.9	0.91	1.0	0	3	161	0.8	0.84	1.0	0	3
	DAY 8	153	0.7	0.80	0.0	0	3	147	0.7	0.80	0.0	0	3	161	0.8	0.85	1.0	0	3
	DAY 29	155	0.6	0.76	0.0	0	3	148	0.6	0.79	0.0	0	3	161	0.6	0.73	0.0	0	3
	DAY 57	155	0.5	0.77	0.0	0	3	149	0.5	0.75	0.0	0	3	161	0.6	0.77	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. GENITOURINARY SYMP	WINDOWED VISIT																		
	DAY 1	155	1.4	1.04	1.0	0	4	151	1.2	1.00	1.0	0	4	161	1.2	1.02	1.0	0	3
	DAY 8	153	1.0	0.99	1.0	0	4	147	1.0	1.00	1.0	0	3	161	1.1	1.03	1.0	0	3
	DAY 29	155	0.9	0.96	1.0	0	3	148	0.9	1.02	1.0	0	3	161	0.9	1.00	1.0	0	3
	DAY 57	155	0.9	1.03	0.0	0	3	149	0.9	1.03	0.0	0	3	161	0.8	0.95	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.1 HAM-A Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. AUTONOMIC SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	1.1	0.82	1.0	0	3	151	1.0	0.80	1.0	0	3	161	1.0	0.84	1.0	0	3
	DAY 8	153	1.0	0.86	1.0	0	4	147	1.0	0.66	1.0	0	3	161	0.8	0.80	1.0	0	3
	DAY 29	155	0.8	0.81	1.0	0	3	148	0.8	0.74	1.0	0	3	161	0.7	0.74	1.0	0	2
	DAY 57	155	0.7	0.76	1.0	0	3	149	0.7	0.79	1.0	0	3	161	0.7	0.72	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA204.SAS
GENERATED: 17NOV2005 13:49:15 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ANXIOUS MOOD	WINDOWED VISIT																		
	DAY 1	155	2.1	0.74	2.0	0	4	151	2.0	0.71	2.0	0	3	161	2.0	0.74	2.0	0	3
	DAY 8	153	1.6	0.94	2.0	0	4	147	1.6	0.90	2.0	0	3	161	1.7	0.89	2.0	0	4
	DAY 29	123	1.3	0.84	1.0	0	3	118	1.2	0.81	1.0	0	3	140	1.4	0.83	1.0	0	3
	DAY 57	98	1.1	0.93	1.0	0	3	93	1.0	0.85	1.0	0	4	108	1.4	0.88	1.5	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. TENSION	WINDOWED VISIT																		
	DAY 1	155	2.0	0.80	2.0	0	4	151	1.9	0.78	2.0	0	4	161	1.9	0.71	2.0	0	3
	DAY 8	153	1.6	0.97	2.0	0	4	147	1.5	0.84	1.0	0	4	161	1.7	0.85	2.0	0	3
	DAY 29	123	1.1	0.91	1.0	0	3	118	1.1	0.85	1.0	0	3	140	1.4	0.83	1.0	0	3
	DAY 57	98	1.0	0.86	1.0	0	3	93	0.9	0.81	1.0	0	3	108	1.3	0.89	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. FEARS	WINDOWED VISIT																		
	DAY 1	155	0.5	0.78	0.0	0	3	151	0.5	0.71	0.0	0	3	161	0.5	0.86	0.0	0	3
	DAY 8	153	0.5	0.75	0.0	0	3	147	0.4	0.71	0.0	0	3	161	0.4	0.73	0.0	0	3
	DAY 29	123	0.2	0.50	0.0	0	3	118	0.3	0.58	0.0	0	2	140	0.3	0.58	0.0	0	2
	DAY 57	98	0.3	0.65	0.0	0	3	93	0.1	0.41	0.0	0	2	108	0.2	0.50	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. INSOMNIA	WINDOWED VISIT																		
	DAY 1	155	2.4	0.88	2.0	0	4	151	2.3	0.85	2.0	0	4	161	2.3	0.85	2.0	0	4
	DAY 8	153	0.9	0.97	1.0	0	4	147	0.8	0.96	1.0	0	3	161	1.7	1.07	2.0	0	4
	DAY 29	123	0.7	0.90	0.0	0	3	118	0.8	0.99	0.0	0	3	140	1.3	1.05	1.0	0	3
	DAY 57	98	0.6	0.75	0.0	0	2	93	0.8	1.06	0.0	0	4	108	1.3	1.15	1.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. INTELLECTUAL	WINDOWED VISIT																		
	DAY 1	155	1.9	0.76	2.0	0	3	151	1.8	0.81	2.0	0	4	161	1.9	0.77	2.0	0	3
	DAY 8	153	1.5	0.92	1.0	0	4	147	1.5	0.91	2.0	0	4	161	1.6	0.78	2.0	0	3
	DAY 29	123	1.0	0.97	1.0	0	3	118	1.1	0.86	1.0	0	3	140	1.2	0.84	1.0	0	3
	DAY 57	98	0.9	0.92	1.0	0	3	93	0.8	0.85	1.0	0	3	108	1.1	0.88	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. DEPRESSED MOOD	WINDOWED VISIT																		
	DAY 1	155	2.6	0.67	3.0	0	4	151	2.6	0.64	3.0	0	4	161	2.6	0.63	3.0	0	4
	DAY 8	153	1.9	0.86	2.0	0	4	147	1.9	0.91	2.0	0	4	161	2.2	0.78	2.0	0	4
	DAY 29	123	1.3	0.94	1.0	0	4	118	1.3	1.00	1.0	0	3	140	1.6	0.96	2.0	0	3
	DAY 57	98	0.9	0.98	1.0	0	3	93	1.0	1.00	1.0	0	3	108	1.3	0.93	1.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. SOMATIC (MUSCULAR)	WINDOWED VISIT																		
	DAY 1	155	1.1	0.90	1.0	0	3	151	1.1	0.81	1.0	0	3	161	1.0	0.89	1.0	0	3
	DAY 8	153	0.9	0.84	1.0	0	3	147	0.9	0.80	1.0	0	3	161	0.9	0.84	1.0	0	3
	DAY 29	123	0.6	0.77	0.0	0	3	118	0.7	0.79	0.0	0	3	140	0.7	0.78	1.0	0	3
	DAY 57	98	0.5	0.76	0.0	0	3	93	0.5	0.65	0.0	0	2	108	0.6	0.78	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. SOMATIC (SENSORY)	WINDOWED VISIT																		
	DAY 1	155	0.8	0.79	1.0	0	3	151	0.7	0.75	1.0	0	3	161	0.7	0.77	0.0	0	3
	DAY 8	153	0.6	0.73	0.0	0	3	147	0.6	0.71	0.0	0	2	161	0.6	0.72	0.0	0	3
	DAY 29	123	0.4	0.59	0.0	0	2	118	0.4	0.63	0.0	0	2	140	0.4	0.56	0.0	0	2
	DAY 57	98	0.2	0.46	0.0	0	2	93	0.2	0.54	0.0	0	2	108	0.4	0.69	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. CARDIOVASCULAR SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	0.5	0.68	0.0	0	3	151	0.6	0.70	0.0	0	3	161	0.5	0.75	0.0	0	3
	DAY 8	153	0.5	0.73	0.0	0	3	147	0.5	0.69	0.0	0	3	161	0.4	0.69	0.0	0	3
	DAY 29	123	0.2	0.50	0.0	0	2	118	0.2	0.43	0.0	0	2	140	0.3	0.63	0.0	0	3
	DAY 57	98	0.2	0.40	0.0	0	2	93	0.1	0.36	0.0	0	2	108	0.3	0.65	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. RESPIRATORY SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	0.6	0.69	0.0	0	2	151	0.6	0.70	0.0	0	2	161	0.6	0.72	0.0	0	3
	DAY 8	153	0.4	0.68	0.0	0	3	147	0.4	0.64	0.0	0	3	161	0.4	0.60	0.0	0	3
	DAY 29	123	0.3	0.52	0.0	0	2	118	0.3	0.56	0.0	0	3	140	0.4	0.54	0.0	0	2
	DAY 57	98	0.2	0.51	0.0	0	2	93	0.3	0.52	0.0	0	2	108	0.3	0.57	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. GASTROINTESTINAL SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	0.9	0.86	1.0	0	3	151	0.9	0.91	1.0	0	3	161	0.8	0.84	1.0	0	3
	DAY 8	153	0.7	0.80	0.0	0	3	147	0.7	0.80	0.0	0	3	161	0.8	0.85	1.0	0	3
	DAY 29	123	0.5	0.69	0.0	0	2	118	0.6	0.79	0.0	0	3	140	0.6	0.72	0.0	0	3
	DAY 57	98	0.4	0.67	0.0	0	3	93	0.4	0.64	0.0	0	2	108	0.5	0.69	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
12. GENITOURINARY SYMP	WINDOWED VISIT																		
	DAY 1	155	1.4	1.04	1.0	0	4	151	1.2	1.00	1.0	0	4	161	1.2	1.02	1.0	0	3
	DAY 8	153	1.0	0.99	1.0	0	4	147	1.0	1.00	1.0	0	3	161	1.1	1.03	1.0	0	3
	DAY 29	123	0.8	0.92	1.0	0	3	118	0.9	1.04	0.5	0	3	140	0.9	0.96	1.0	0	3
	DAY 57	98	0.7	1.01	0.0	0	3	93	0.8	1.03	0.0	0	3	108	0.8	0.87	0.5	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.4.2 HAM-A Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
13. AUTONOMIC SYMPTOMS	WINDOWED VISIT																		
	DAY 1	155	1.1	0.82	1.0	0	3	151	1.0	0.80	1.0	0	3	161	1.0	0.84	1.0	0	3
	DAY 8	153	1.0	0.86	1.0	0	4	147	1.0	0.66	1.0	0	3	161	0.8	0.80	1.0	0	3
	DAY 29	123	0.7	0.80	1.0	0	3	118	0.7	0.73	1.0	0	3	140	0.7	0.73	1.0	0	2
	DAY 57	98	0.6	0.71	0.0	0	2	93	0.6	0.76	0.0	0	3	108	0.7	0.71	1.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA203.SAS
GENERATED: 17NOV2005 13:49:11 iceadmn3

Table 11.2.5.5.1 HAM-A Item 1 (Anxious Mood) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	2.1	0.72	-0.5	0.95	-0.49	0.081	-0.65	-0.33	.
	Q600MG	147	2.0	0.70	-0.4	0.87	-0.48	0.083	-0.64	-0.31	.
	P	161	2.0	0.74	-0.3	0.94	-0.36	0.080	-0.52	-0.20	.
	Q300MG VS P	.	.	.	.	.	-0.13	0.093	-0.31	0.05	0.161
	Q600MG VS P	.	.	.	.	.	-0.12	0.094	-0.30	0.07	0.205
DAY 29	Q300MG	155	2.1	0.74	-0.7	0.97	-0.68	0.078	-0.83	-0.52	.
	Q600MG	148	2.0	0.70	-0.7	0.89	-0.72	0.080	-0.88	-0.57	.
	P	161	2.0	0.74	-0.6	0.95	-0.61	0.078	-0.76	-0.45	.
	Q300MG VS P	.	.	.	.	.	-0.07	0.093	-0.26	0.11	0.425
	Q600MG VS P	.	.	.	.	.	-0.12	0.094	-0.30	0.07	0.208
DAY 57	Q300MG	155	2.1	0.74	-0.8	1.05	-0.76	0.081	-0.92	-0.60	.
	Q600MG	149	2.0	0.70	-0.8	0.95	-0.82	0.083	-0.99	-0.66	.
	P	161	2.0	0.74	-0.5	1.07	-0.59	0.080	-0.75	-0.43	.
	Q300MG VS P	.	.	.	.	.	-0.17	0.102	-0.37	0.03	0.100
	Q600MG VS P	.	.	.	.	.	-0.23	0.103	-0.43	-0.03	0.025

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA212.SAS
GENERATED: 17NOV2005 13:31:11 iceadmn3

Table 11.2.5.5.2 HAM-A Item 2 (Tension) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	2.0	0.80	-0.5	0.86	-0.48	0.070	-0.62	-0.34	.
	Q600MG	147	1.9	0.77	-0.4	0.74	-0.49	0.072	-0.64	-0.35	.
	P	161	1.9	0.71	-0.3	0.86	-0.31	0.070	-0.45	-0.17	.
	Q300MG VS P	.	.	.	.	.	-0.17	0.085	-0.34	-0.00	0.044
	Q600MG VS P	.	.	.	.	.	-0.18	0.086	-0.35	-0.01	0.035
DAY 29	Q300MG	155	2.0	0.80	-0.8	1.01	-0.77	0.085	-0.94	-0.60	.
	Q600MG	148	1.9	0.77	-0.7	0.88	-0.75	0.087	-0.92	-0.57	.
	P	161	1.9	0.71	-0.5	0.99	-0.52	0.085	-0.69	-0.35	.
	Q300MG VS P	.	.	.	.	.	-0.25	0.092	-0.43	-0.07	0.006
	Q600MG VS P	.	.	.	.	.	-0.23	0.093	-0.41	-0.04	0.015
DAY 57	Q300MG	155	2.0	0.80	-0.9	1.00	-0.84	0.086	-1.01	-0.67	.
	Q600MG	149	1.9	0.78	-0.8	0.92	-0.85	0.088	-1.02	-0.67	.
	P	161	1.9	0.71	-0.5	1.04	-0.51	0.086	-0.68	-0.33	.
	Q300MG VS P	.	.	.	.	.	-0.34	0.094	-0.52	-0.15	<.001
	Q600MG VS P	.	.	.	.	.	-0.34	0.095	-0.53	-0.15	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA213.SAS
GENERATED: 17NOV2005 13:31:13 iceadmn3

Table 11.2.5.5.3 HAM-A Item 3 (Fears) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	0.5	0.78	-0.0	0.65	-0.04	0.047	-0.13	0.05	.
	Q600MG	147	0.5	0.71	-0.1	0.64	-0.07	0.048	-0.17	0.03	.
	P	161	0.5	0.86	-0.1	0.68	-0.13	0.047	-0.22	-0.04	.
	Q300MG VS P	.	.	.	.	.	0.09	0.064	-0.04	0.22	0.170
	Q600MG VS P	.	.	.	.	.	0.06	0.065	-0.07	0.19	0.369
DAY 29	Q300MG	155	0.5	0.78	-0.2	0.67	-0.26	0.043	-0.34	-0.17	.
	Q600MG	148	0.5	0.70	-0.2	0.68	-0.24	0.044	-0.33	-0.15	.
	P	161	0.5	0.86	-0.2	0.76	-0.21	0.043	-0.30	-0.13	.
	Q300MG VS P	.	.	.	.	.	-0.04	0.057	-0.15	0.07	0.449
	Q600MG VS P	.	.	.	.	.	-0.03	0.058	-0.14	0.08	0.609
DAY 57	Q300MG	155	0.5	0.78	-0.1	0.81	-0.17	0.047	-0.26	-0.07	.
	Q600MG	149	0.5	0.71	-0.3	0.69	-0.29	0.048	-0.38	-0.19	.
	P	161	0.5	0.86	-0.2	0.79	-0.21	0.047	-0.31	-0.12	.
	Q300MG VS P	.	.	.	.	.	0.05	0.063	-0.08	0.17	0.464
	Q600MG VS P	.	.	.	.	.	-0.07	0.064	-0.20	0.05	0.246

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA214.SAS
GENERATED: 17NOV2005 13:31:16 iceadmn3

Table 11.2.5.5.4 HAM-A Item 4 (Insomnia) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
VISIT	TREATMENT	N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
DAY 8	Q300MG	153	2.4	0.87	-1.5	1.24	-1.42	0.085	-1.59	-1.25	.
	Q600MG	147	2.3	0.86	-1.4	1.13	-1.46	0.087	-1.64	-1.29	.
	P	161	2.3	0.85	-0.6	1.16	-0.59	0.084	-0.75	-0.42	.
	Q300MG VS P	.	.	.	.	.	-0.83	0.111	-1.05	-0.61	<.001
	Q600MG VS P	.	.	.	.	.	-0.88	0.112	-1.10	-0.66	<.001
DAY 29	Q300MG	155	2.4	0.88	-1.6	1.15	-1.57	0.088	-1.75	-1.40	.
	Q600MG	148	2.3	0.86	-1.4	1.13	-1.46	0.090	-1.63	-1.28	.
	P	161	2.3	0.85	-0.8	1.18	-0.85	0.087	-1.03	-0.68	.
	Q300MG VS P	.	.	.	.	.	-0.72	0.111	-0.94	-0.50	<.001
	Q600MG VS P	.	.	.	.	.	-0.60	0.112	-0.82	-0.38	<.001
DAY 57	Q300MG	155	2.4	0.88	-1.7	1.19	-1.62	0.092	-1.80	-1.44	.
	Q600MG	149	2.2	0.85	-1.4	1.17	-1.45	0.094	-1.64	-1.26	.
	P	161	2.3	0.85	-0.8	1.29	-0.79	0.091	-0.97	-0.61	.
	Q300MG VS P	.	.	.	.	.	-0.83	0.115	-1.05	-0.60	<.001
	Q600MG VS P	.	.	.	.	.	-0.66	0.116	-0.89	-0.43	<.001

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA215.SAS
GENERATED: 17NOV2005 13:31:19 iceadmn3

Table 11.2.5.5.5 HAM-A Item 5 (Intellectual) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.9	0.76	-0.4	0.96	-0.38	0.082	-0.54	-0.22	.
	Q600MG	147	1.8	0.82	-0.3	0.96	-0.35	0.084	-0.51	-0.18	.
	P	161	1.9	0.77	-0.3	0.86	-0.22	0.082	-0.38	-0.06	.
	Q300MG VS P	.	.	.	.	.	-0.16	0.087	-0.33	0.01	0.073
	Q600MG VS P	.	.	.	.	.	-0.13	0.088	-0.30	0.05	0.153
DAY 29	Q300MG	155	1.9	0.76	-0.8	1.02	-0.80	0.086	-0.97	-0.63	.
	Q600MG	148	1.8	0.81	-0.7	1.11	-0.72	0.088	-0.89	-0.54	.
	P	161	1.9	0.77	-0.5	0.97	-0.54	0.086	-0.71	-0.37	.
	Q300MG VS P	.	.	.	.	.	-0.26	0.096	-0.44	-0.07	0.008
	Q600MG VS P	.	.	.	.	.	-0.18	0.098	-0.37	0.02	0.074
DAY 57	Q300MG	155	1.9	0.76	-0.9	1.04	-0.83	0.088	-1.00	-0.65	.
	Q600MG	149	1.8	0.82	-0.8	1.13	-0.79	0.090	-0.97	-0.61	.
	P	161	1.9	0.77	-0.6	0.97	-0.55	0.088	-0.72	-0.37	.
	Q300MG VS P	.	.	.	.	.	-0.28	0.099	-0.47	-0.08	0.005
	Q600MG VS P	.	.	.	.	.	-0.24	0.101	-0.44	-0.05	0.016

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA216.SAS
GENERATED: 17NOV2005 13:31:21 iceadmn3

Table 11.2.5.5.6 HAM-A Item 6 (Depressed Mood) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	2.6	0.67	-0.7	0.85	-0.73	0.074	-0.87	-0.58	.
	Q600MG	147	2.6	0.64	-0.6	0.87	-0.65	0.075	-0.80	-0.50	.
	P	161	2.6	0.63	-0.4	0.78	-0.41	0.073	-0.55	-0.26	.
	Q300MG VS P	.	.	.	.	.	-0.32	0.086	-0.49	-0.15	<.001
	Q600MG VS P	.	.	.	.	.	-0.24	0.087	-0.42	-0.07	0.005
DAY 29	Q300MG	155	2.6	0.67	-1.2	1.02	-1.23	0.095	-1.41	-1.04	.
	Q600MG	148	2.6	0.64	-1.1	1.07	-1.16	0.097	-1.36	-0.97	.
	P	161	2.6	0.63	-0.9	1.06	-0.93	0.095	-1.12	-0.74	.
	Q300MG VS P	.	.	.	.	.	-0.29	0.104	-0.50	-0.09	0.005
	Q600MG VS P	.	.	.	.	.	-0.23	0.106	-0.44	-0.03	0.028
DAY 57	Q300MG	155	2.6	0.67	-1.4	1.13	-1.43	0.096	-1.62	-1.24	.
	Q600MG	149	2.6	0.64	-1.3	1.10	-1.30	0.098	-1.50	-1.11	.
	P	161	2.6	0.63	-1.0	1.15	-1.09	0.096	-1.28	-0.90	.
	Q300MG VS P	.	.	.	.	.	-0.34	0.114	-0.57	-0.12	0.003
	Q600MG VS P	.	.	.	.	.	-0.22	0.115	-0.44	0.01	0.062

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA217.SAS
GENERATED: 17NOV2005 13:31:24 iceadmn3

Table 11.2.5.5.7 HAM-A Item 7 (Somatic - Muscular) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.1	0.90	-0.2	0.87	-0.23	0.064	-0.36	-0.10	.
	Q600MG	147	1.1	0.81	-0.2	0.92	-0.21	0.065	-0.34	-0.08	.
	P	161	1.0	0.89	-0.1	0.83	-0.19	0.063	-0.31	-0.06	.
	Q300MG VS P	.	.	.	.	.	-0.04	0.082	-0.20	0.12	0.632
	Q600MG VS P	.	.	.	.	.	-0.02	0.083	-0.19	0.14	0.794
DAY 29	Q300MG	155	1.1	0.90	-0.4	0.98	-0.41	0.070	-0.55	-0.27	.
	Q600MG	148	1.1	0.81	-0.4	1.04	-0.39	0.071	-0.54	-0.25	.
	P	161	1.0	0.89	-0.3	0.96	-0.32	0.069	-0.46	-0.18	.
	Q300MG VS P	.	.	.	.	.	-0.09	0.085	-0.25	0.08	0.307
	Q600MG VS P	.	.	.	.	.	-0.07	0.086	-0.24	0.10	0.398
DAY 57	Q300MG	155	1.1	0.90	-0.5	0.95	-0.45	0.065	-0.58	-0.32	.
	Q600MG	149	1.1	0.81	-0.6	0.95	-0.51	0.067	-0.64	-0.38	.
	P	161	1.0	0.89	-0.2	1.00	-0.28	0.064	-0.41	-0.15	.
	Q300MG VS P	.	.	.	.	.	-0.17	0.085	-0.33	-0.00	0.047
	Q600MG VS P	.	.	.	.	.	-0.23	0.086	-0.40	-0.06	0.008

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA218.SAS
GENERATED: 17NOV2005 13:31:26 iceadmn3

Table 11.2.5.5.8 HAM-A Item 8 (Somatic - Sensory) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	0.8	0.79	-0.2	0.84	-0.19	0.052	-0.29	-0.09	.
	Q600MG	147	0.7	0.75	-0.1	0.69	-0.10	0.053	-0.21	0.00	.
	P	161	0.7	0.77	-0.1	0.63	-0.12	0.051	-0.22	-0.02	.
	Q300MG VS P	.	.	.	.	.	-0.07	0.069	-0.21	0.06	0.289
	Q600MG VS P	.	.	.	.	.	0.02	0.070	-0.12	0.15	0.820
DAY 29	Q300MG	155	0.8	0.79	-0.4	0.80	-0.33	0.059	-0.45	-0.21	.
	Q600MG	148	0.7	0.75	-0.3	0.79	-0.24	0.061	-0.36	-0.12	.
	P	161	0.7	0.77	-0.3	0.75	-0.31	0.059	-0.43	-0.20	.
	Q300MG VS P	.	.	.	.	.	-0.02	0.063	-0.14	0.11	0.773
	Q600MG VS P	.	.	.	.	.	0.07	0.064	-0.05	0.19	0.270
DAY 57	Q300MG	155	0.8	0.79	-0.5	0.87	-0.44	0.059	-0.56	-0.33	.
	Q600MG	149	0.7	0.75	-0.3	0.82	-0.30	0.061	-0.42	-0.18	.
	P	161	0.7	0.77	-0.2	0.80	-0.27	0.059	-0.39	-0.16	.
	Q300MG VS P	.	.	.	.	.	-0.17	0.068	-0.30	-0.04	0.013
	Q600MG VS P	.	.	.	.	.	-0.03	0.069	-0.16	0.11	0.684

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA219.SAS
GENERATED: 17NOV2005 13:31:29 iceadmn3

Table 11.2.5.5.9 HAM-A Item 9 (Cardiovascular Symptoms) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	0.5	0.67	0.0	0.87	-0.01	0.054	-0.11	0.10	.
	Q600MG	147	0.5	0.69	-0.0	0.75	-0.03	0.055	-0.13	0.08	.
	P	161	0.5	0.75	-0.1	0.74	-0.09	0.053	-0.20	0.01	.
	Q300MG VS P	.	.	.	.	.	0.09	0.073	-0.06	0.23	0.242
	Q600MG VS P	.	.	.	.	.	0.07	0.074	-0.08	0.21	0.368
DAY 29	Q300MG	155	0.5	0.68	-0.2	0.85	-0.22	0.052	-0.32	-0.11	.
	Q600MG	148	0.5	0.68	-0.3	0.74	-0.22	0.053	-0.33	-0.12	.
	P	161	0.5	0.75	-0.2	0.85	-0.14	0.051	-0.24	-0.03	.
	Q300MG VS P	.	.	.	.	.	-0.08	0.063	-0.20	0.04	0.203
	Q600MG VS P	.	.	.	.	.	-0.09	0.064	-0.21	0.04	0.166
DAY 57	Q300MG	155	0.5	0.68	-0.2	0.80	-0.27	0.055	-0.38	-0.16	.
	Q600MG	149	0.5	0.69	-0.3	0.79	-0.25	0.056	-0.36	-0.14	.
	P	161	0.5	0.75	-0.1	0.95	-0.09	0.054	-0.20	0.01	.
	Q300MG VS P	.	.	.	.	.	-0.18	0.068	-0.31	-0.04	0.010
	Q600MG VS P	.	.	.	.	.	-0.16	0.069	-0.29	-0.02	0.021

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA220.SAS
GENERATED: 17NOV2005 13:31:32 iceadmn3

Table 11.2.5.5.10 HAM-A Item 10 (Respiratory Symptoms) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	0.6	0.69	-0.1	0.81	-0.13	0.050	-0.23	-0.03	.
	Q600MG	147	0.6	0.68	-0.1	0.66	-0.13	0.051	-0.23	-0.03	.
	P	161	0.6	0.72	-0.2	0.71	-0.15	0.049	-0.25	-0.05	.
	Q300MG VS P	.	.	.	.	.	0.02	0.066	-0.11	0.15	0.773
	Q600MG VS P	.	.	.	.	.	0.02	0.067	-0.12	0.15	0.815
DAY 29	Q300MG	155	0.6	0.69	-0.2	0.82	-0.20	0.049	-0.30	-0.11	.
	Q600MG	148	0.6	0.68	-0.2	0.77	-0.22	0.050	-0.32	-0.12	.
	P	161	0.6	0.72	-0.2	0.73	-0.18	0.048	-0.27	-0.08	.
	Q300MG VS P	.	.	.	.	.	-0.03	0.061	-0.15	0.09	0.677
	Q600MG VS P	.	.	.	.	.	-0.04	0.062	-0.17	0.08	0.471
DAY 57	Q300MG	155	0.6	0.69	-0.3	0.79	-0.25	0.053	-0.36	-0.15	.
	Q600MG	149	0.6	0.69	-0.2	0.78	-0.21	0.055	-0.32	-0.10	.
	P	161	0.6	0.72	-0.2	0.86	-0.18	0.053	-0.28	-0.07	.
	Q300MG VS P	.	.	.	.	.	-0.08	0.065	-0.21	0.05	0.226
	Q600MG VS P	.	.	.	.	.	-0.03	0.066	-0.16	0.10	0.634

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA221.SAS
GENERATED: 17NOV2005 13:31:34 iceadmn3

Table 11.2.5.5.11 HAM-A Item 11 (Gastrointestinal Symptoms) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	0.9	0.86	-0.2	0.96	-0.18	0.065	-0.31	-0.05	.
	Q600MG	147	0.9	0.91	-0.2	0.91	-0.17	0.067	-0.30	-0.04	.
	P	161	0.8	0.84	-0.0	0.83	-0.02	0.064	-0.15	0.10	.
	Q300MG VS P	.	.	.	.	.	-0.15	0.083	-0.32	0.01	0.063
	Q600MG VS P	.	.	.	.	.	-0.14	0.084	-0.31	0.02	0.086
DAY 29	Q300MG	155	0.9	0.86	-0.3	1.01	-0.29	0.067	-0.42	-0.16	.
	Q600MG	148	0.9	0.90	-0.3	1.01	-0.22	0.069	-0.36	-0.08	.
	P	161	0.8	0.84	-0.2	0.90	-0.21	0.067	-0.34	-0.08	.
	Q300MG VS P	.	.	.	.	.	-0.08	0.081	-0.24	0.08	0.326
	Q600MG VS P	.	.	.	.	.	-0.01	0.082	-0.17	0.15	0.896
DAY 57	Q300MG	155	0.9	0.86	-0.4	1.03	-0.32	0.069	-0.46	-0.18	.
	Q600MG	149	0.9	0.91	-0.4	1.04	-0.31	0.071	-0.45	-0.17	.
	P	161	0.8	0.84	-0.2	0.92	-0.21	0.069	-0.35	-0.07	.
	Q300MG VS P	.	.	.	.	.	-0.11	0.082	-0.27	0.05	0.187
	Q600MG VS P	.	.	.	.	.	-0.10	0.083	-0.26	0.07	0.252

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA222.SAS
GENERATED: 17NOV2005 13:31:37 iceadmn3

Table 11.2.5.5.12 HAM-A Item 12 (Genitourinary Symptoms) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.4	1.04	-0.4	0.97	-0.32	0.076	-0.47	-0.17	.
	Q600MG	147	1.2	1.00	-0.2	0.82	-0.26	0.078	-0.41	-0.10	.
	P	161	1.2	1.02	-0.2	1.06	-0.18	0.075	-0.33	-0.03	.
	Q300MG VS P	.	.	.	.	.	-0.14	0.094	-0.32	0.05	0.148
	Q600MG VS P	.	.	.	.	.	-0.07	0.095	-0.26	0.11	0.432
DAY 29	Q300MG	155	1.4	1.04	-0.4	1.09	-0.39	0.082	-0.55	-0.23	.
	Q600MG	148	1.2	1.00	-0.3	1.04	-0.39	0.084	-0.56	-0.23	.
	P	161	1.2	1.02	-0.3	1.18	-0.36	0.081	-0.53	-0.20	.
	Q300MG VS P	.	.	.	.	.	-0.03	0.102	-0.23	0.17	0.802
	Q600MG VS P	.	.	.	.	.	-0.03	0.103	-0.23	0.17	0.767
DAY 57	Q300MG	155	1.4	1.04	-0.5	1.17	-0.44	0.078	-0.59	-0.28	.
	Q600MG	149	1.2	1.00	-0.4	1.01	-0.40	0.080	-0.56	-0.24	.
	P	161	1.2	1.02	-0.4	1.12	-0.46	0.077	-0.61	-0.31	.
	Q300MG VS P	.	.	.	.	.	0.02	0.103	-0.18	0.23	0.826
	Q600MG VS P	.	.	.	.	.	0.06	0.104	-0.14	0.27	0.556

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA223.SAS
GENERATED: 17NOV2005 13:31:40 iceadmn3

Table 11.2.5.5.13 HAM-A Item 13 (Autonomic Symptoms) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.1	0.83	-0.1	0.99	0.02	0.064	-0.11	0.14	.
	Q600MG	147	1.0	0.79	0.0	0.89	-0.02	0.065	-0.14	0.11	.
	P	161	1.0	0.84	-0.2	0.78	-0.17	0.063	-0.30	-0.05	.
	Q300MG VS P	.	.	.	.	.	0.19	0.081	0.03	0.35	0.021
	Q600MG VS P	.	.	.	.	.	0.16	0.082	-0.00	0.32	0.056
DAY 29	Q300MG	155	1.1	0.82	-0.3	0.92	-0.18	0.069	-0.32	-0.05	.
	Q600MG	148	1.0	0.79	-0.2	0.95	-0.18	0.071	-0.32	-0.04	.
	P	161	1.0	0.84	-0.3	0.90	-0.23	0.069	-0.37	-0.09	.
	Q300MG VS P	.	.	.	.	.	0.04	0.079	-0.11	0.20	0.571
	Q600MG VS P	.	.	.	.	.	0.05	0.080	-0.11	0.20	0.559
DAY 57	Q300MG	155	1.1	0.82	-0.4	0.89	-0.32	0.070	-0.46	-0.18	.
	Q600MG	149	1.0	0.79	-0.2	1.03	-0.24	0.072	-0.39	-0.10	.
	P	161	1.0	0.84	-0.3	0.94	-0.27	0.070	-0.41	-0.13	.
	Q300MG VS P	.	.	.	.	.	-0.05	0.079	-0.20	0.11	0.537
	Q600MG VS P	.	.	.	.	.	0.03	0.080	-0.13	0.19	0.733

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA224.SAS
GENERATED: 17NOV2005 13:31:43 iceadmn3

Table 11.2.5.5.14 HAM-A Item 14 (Behavior at Interview) Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	1.3	0.79	-0.3	0.78	-0.31	0.060	-0.43	-0.19	.
	Q600MG	147	1.2	0.70	-0.3	0.77	-0.29	0.062	-0.41	-0.17	.
	P	161	1.2	0.74	-0.2	0.84	-0.22	0.060	-0.33	-0.10	.
	Q300MG VS P	.	.	.	.	.	-0.09	0.075	-0.24	0.05	0.216
	Q600MG VS P	.	.	.	.	.	-0.07	0.076	-0.22	0.08	0.339
DAY 29	Q300MG	155	1.3	0.79	-0.6	0.81	-0.55	0.064	-0.67	-0.42	.
	Q600MG	148	1.2	0.70	-0.5	0.84	-0.52	0.065	-0.65	-0.39	.
	P	161	1.2	0.74	-0.4	0.87	-0.40	0.063	-0.52	-0.27	.
	Q300MG VS P	.	.	.	.	.	-0.15	0.076	-0.30	-0.00	0.048
	Q600MG VS P	.	.	.	.	.	-0.12	0.077	-0.27	0.03	0.123
DAY 57	Q300MG	155	1.3	0.79	-0.7	0.89	-0.63	0.063	-0.76	-0.51	.
	Q600MG	149	1.2	0.70	-0.5	0.83	-0.58	0.065	-0.70	-0.45	.
	P	161	1.2	0.74	-0.4	0.87	-0.44	0.063	-0.56	-0.31	.
	Q300MG VS P	.	.	.	.	.	-0.19	0.074	-0.34	-0.05	0.010
	Q600MG VS P	.	.	.	.	.	-0.14	0.075	-0.28	0.01	0.069

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HAMA225.SAS
GENERATED: 17NOV2005 13:31:45 iceadmn3

Table 11.2.6.1 QLESQ Total Score and Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ TOTAL SCORE		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
QLESQ TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	154	35.4	7.77	36.0	14	52	150	37.5	7.51	37.0	19	57	160	37.8	6.90	38.0	21	55
	DAY 29	126	44.4	9.72	45.0	16	67	131	44.8	9.50	44.0	17	63	149	43.7	8.70	44.0	18	65
	DAY 57	102	47.1	10.28	48.0	23	68	98	49.0	9.03	49.5	22	70	115	46.1	9.54	47.0	23	69
	FINAL	129	46.0	10.65	47.0	18	68	132	46.3	10.52	47.0	14	70	151	44.4	10.05	44.0	18	69
CHG FROM BASELINE	DAY 29	126	8.7	9.47	9.0	-16	34	130	7.2	8.83	7.5	-21	29	148	5.9	8.40	5.0	-13	28
	DAY 57	102	11.1	10.42	11.5	-15	38	97	10.7	9.11	10.0	-9	35	115	8.2	9.47	7.0	-13	31
	FINAL	129	10.3	10.40	10.0	-15	38	131	8.8	10.04	9.0	-21	35	150	6.7	9.82	5.5	-21	31

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ200.SAS
GENERATED: 17NOV2005 13:52:22 iceadmn3

Table 11.2.6.2 QLESQ Total Score Change from Baseline (ANCOVA)
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
VISIT	TREATMENT	N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
DAY 29	Q300MG	126	35.7	7.78	8.7	9.47	8.15	0.798	6.57	9.73	.
	Q600MG	130	37.8	7.49	7.2	8.83	7.51	0.788	5.95	9.07	.
	P	148	37.8	7.08	5.9	8.40	6.20	0.744	4.72	7.68	.
	Q300MG VS P	.	.	.	.	.	1.95	1.005	-0.03	3.92	0.054
	Q600MG VS P	.	.	.	.	.	1.31	0.990	-0.63	3.26	0.186
DAY 57	Q300MG	102	36.0	7.15	11.1	10.42	10.40	0.959	8.50	12.30	.
	Q600MG	97	38.5	7.78	10.7	9.11	11.30	0.984	9.35	13.25	.
	P	115	37.9	7.28	8.2	9.47	8.58	0.917	6.76	10.40	.
	Q300MG VS P	.	.	.	.	.	1.82	1.206	-0.56	4.19	0.133
	Q600MG VS P	.	.	.	.	.	2.72	1.215	0.33	5.11	0.026
FINAL	Q300MG	129	35.6	7.69	10.3	10.40	9.86	0.934	8.01	11.71	.
	Q600MG	131	37.7	7.54	8.8	10.04	9.19	0.933	7.34	11.03	.
	P	150	37.8	7.06	6.7	9.82	7.12	0.884	5.37	8.88	.
	Q300MG VS P	.	.	.	.	.	2.74	1.140	0.50	4.98	0.017
	Q600MG VS P	.	.	.	.	.	2.06	1.128	-0.15	4.28	0.068

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ202.SAS
GENERATED: 17NOV2005 13:35:46 iceadmn3

Table 11.2.6.3 QLESQ %Maximum Total Score and Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ % MAXIMUM TOTAL SCORE		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
QLESQ % MAXIMUM TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	154	38.3	13.93	39.0	0	68	150	41.9	13.41	41.0	9	77	160	42.5	12.29	43.0	13	73
	DAY 29	126	54.3	17.42	55.0	4	95	131	55.0	16.96	54.0	5	88	149	53.1	15.51	54.0	7	91
	DAY 57	102	59.1	18.39	61.0	16	96	98	62.4	16.15	63.5	14	100	115	57.5	16.99	59.0	16	98
	FINAL	129	57.1	19.05	59.0	7	96	132	57.7	18.79	59.0	0	100	151	54.4	17.91	54.0	7	98
CHG FROM BASELINE	DAY 29	126	15.6	16.95	16.0	-29	61	130	12.9	15.79	13.5	-38	52	148	10.6	14.95	9.0	-23	50
	DAY 57	102	19.8	18.71	20.5	-27	68	97	19.1	16.24	18.0	-16	62	115	14.7	16.82	13.0	-23	55
	FINAL	129	18.4	18.65	18.0	-27	68	131	15.8	17.94	16.0	-38	62	150	11.9	17.48	9.5	-37	55

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ205.SAS
GENERATED: 17NOV2005 13:52:26 iceadmn3

Table 11.2.6.4 QLESQ %Maximum Total Score Change from Baseline (ANCOVA)
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	126	38.7	13.95	15.6	16.95	14.57	1.425	11.75	17.39	.
	Q600MG	130	42.4	13.38	12.9	15.79	13.39	1.408	10.61	16.18	.
	P	148	42.6	12.62	10.6	14.95	11.10	1.330	8.46	13.74	.
	Q300MG VS P	.	.	.	.	.	3.47	1.795	-0.06	7.00	0.054
	Q600MG VS P	.	.	.	.	.	2.29	1.768	-1.18	5.77	0.195
DAY 57	Q300MG	102	39.3	12.80	19.8	18.71	18.54	1.708	15.15	21.92	.
	Q600MG	97	43.8	13.87	19.1	16.24	20.17	1.754	16.70	23.65	.
	P	115	42.7	12.96	14.7	16.82	15.36	1.635	12.11	18.61	.
	Q300MG VS P	.	.	.	.	.	3.18	2.154	-1.06	7.42	0.141
	Q600MG VS P	.	.	.	.	.	4.81	2.171	0.54	9.08	0.027
FINAL	Q300MG	129	38.7	13.79	18.4	18.65	17.56	1.670	14.25	20.87	.
	Q600MG	131	42.3	13.47	15.8	17.94	16.38	1.667	13.07	19.68	.
	P	150	42.5	12.57	11.9	17.48	12.75	1.580	9.61	15.89	.
	Q300MG VS P	.	.	.	.	.	4.81	2.035	0.81	8.81	0.019
	Q600MG VS P	.	.	.	.	.	3.63	2.014	-0.33	7.59	0.072

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ204.SAS
GENERATED: 17NOV2005 13:35:49 iceadmn3

Table 11.2.6.5 QLESQ Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Intent-to-Treat Population

BIPOLAR DIAGNOSIS			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
BIPOLAR I	QLESQ TOTAL SCORE	WINDOWED VISIT																		
		DAY 1	103	35.3	8.07	36.0	14	52	100	37.6	7.83	37.0	19	57	109	37.3	6.55	37.0	21	54
		DAY 29	84	43.9	10.01	45.0	16	67	89	44.6	9.99	45.0	17	63	100	43.5	9.06	44.0	18	65
		DAY 57	64	47.6	10.02	48.0	25	68	65	48.8	9.10	51.0	22	67	78	45.7	9.50	47.0	23	69
		FINAL	85	45.9	10.92	47.0	18	68	89	45.7	11.01	47.0	14	67	102	43.6	10.27	44.0	18	69
	CHG FROM BASELINE	DAY 29	84	8.2	9.31	7.5	-13	34	88	6.8	8.74	7.5	-21	28	99	6.3	8.31	5.0	-13	28
		DAY 57	64	11.3	9.65	10.5	-5	38	64	9.6	8.23	9.0	-9	29	78	8.3	9.85	7.0	-13	28
		FINAL	85	10.2	10.03	10.0	-13	38	88	7.9	9.53	8.0	-21	29	101	6.4	10.07	5.0	-21	28
BIPOLAR II	QLESQ TOTAL SCORE	DAY 1	51	35.6	7.17	37.0	15	49	50	37.2	6.89	37.5	24	49	51	39.0	7.53	39.0	24	55
		DAY 29	42	45.4	9.15	46.5	22	62	42	45.3	8.48	43.5	24	63	49	44.2	7.97	44.0	25	57
		DAY 57	38	46.2	10.79	47.5	23	65	33	49.2	9.02	49.0	35	70	37	47.2	9.67	48.0	25	68
		FINAL	44	46.1	10.23	47.0	23	65	43	47.6	9.41	48.0	24	70	49	46.1	9.47	46.0	25	68
	CHG FROM BASELINE	DAY 29	42	9.8	9.80	11.5	-16	28	42	8.2	9.04	7.5	-12	29	49	5.2	8.62	4.0	-10	24
		DAY 57	38	10.8	11.75	12.0	-15	35	33	12.9	10.38	11.0	-4	35	37	8.0	8.73	7.0	-8	31
		FINAL	44	10.5	11.19	11.5	-15	35	43	10.7	10.89	10.0	-12	35	49	7.1	9.37	7.0	-10	31

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ201.SAS
GENERATED: 17NOV2005 13:52:24 iceadmn3

Table 11.2.6.6 QLESQ Individual Item Scores - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 1-PHYSICAL HEALTH	WINDOWED VISIT																		
	DAY 1	155	3.1	0.95	3.0	1	5	151	3.1	0.87	3.0	1	5	160	3.3	0.91	3.0	1	5
	DAY 29	126	3.5	0.87	4.0	1	5	131	3.4	0.91	3.0	1	5	149	3.4	0.86	4.0	1	5
	DAY 57	101	3.6	0.90	4.0	1	5	98	3.6	0.76	4.0	2	5	115	3.6	0.77	4.0	1	5
	FINAL	128	3.5	0.90	4.0	1	5	132	3.5	0.87	4.0	1	5	151	3.5	0.84	4.0	1	5
LEVEL OF SATISFACTION 2-MOOD	DAY 1	155	2.1	0.78	2.0	1	4	151	2.2	0.77	2.0	1	5	160	2.1	0.71	2.0	1	4
	DAY 29	126	3.1	0.92	3.0	1	5	131	3.2	0.86	3.0	1	5	149	2.9	0.87	3.0	1	5
	DAY 57	102	3.3	1.02	3.0	1	5	98	3.4	0.91	4.0	1	5	115	3.1	1.03	3.0	1	5
	FINAL	129	3.2	1.04	3.0	1	5	132	3.3	0.96	3.0	1	5	151	3.0	1.08	3.0	1	5
LEVEL OF SATISFACTION 3-WORK	DAY 1	149	2.2	0.96	2.0	1	4	144	2.3	0.98	2.0	1	5	153	2.3	1.00	2.0	1	5
	DAY 29	121	3.0	1.08	3.0	1	5	126	3.2	0.98	3.0	1	5	147	3.1	1.05	3.0	1	5
	DAY 57	99	3.3	1.07	3.0	1	5	94	3.5	0.91	4.0	1	5	112	3.1	1.08	3.0	1	5
	FINAL	125	3.2	1.09	3.0	1	5	126	3.3	1.02	4.0	1	5	148	3.0	1.09	3.0	1	5
LEVEL OF SATISFACTION 4-HOUSEHOLD	DAY 1	155	2.3	0.91	2.0	1	5	151	2.4	0.95	2.0	1	5	160	2.5	0.91	2.5	1	5
	DAY 29	126	3.0	1.01	3.0	1	5	131	3.2	1.04	3.0	1	5	149	2.9	0.92	3.0	1	5
	DAY 57	102	3.2	0.99	3.0	1	5	98	3.6	0.91	4.0	1	5	115	3.1	0.94	3.0	1	5
	FINAL	129	3.1	1.02	3.0	1	5	132	3.4	1.05	4.0	1	5	151	3.0	0.98	3.0	1	5

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ206.SAS
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Table 11.2.6.6 QLESQ Individual Item Scores - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 5-SOCIAL	WINDOWED VISIT																		
	DAY 1	155	2.3	0.85	2.0	1	4	151	2.4	1.04	2.0	1	5	160	2.4	0.91	2.0	1	5
	DAY 29	126	3.1	1.00	3.0	1	5	130	3.1	1.02	3.0	1	5	149	3.0	0.92	3.0	1	5
	DAY 57	102	3.3	0.96	3.0	1	5	98	3.5	1.03	4.0	1	5	115	3.1	1.07	3.0	1	5
	FINAL	129	3.2	1.01	3.0	1	5	132	3.3	1.11	3.0	1	5	151	3.0	1.09	3.0	1	5
LEVEL OF SATISFACTION 6-FAMILY	DAY 1	154	2.5	0.99	3.0	1	5	151	2.6	0.98	3.0	1	5	159	2.8	1.02	3.0	1	5
	DAY 29	126	3.2	1.13	3.0	1	5	130	3.1	1.04	3.0	1	5	148	3.2	1.00	3.0	1	5
	DAY 57	102	3.3	1.03	3.5	1	5	98	3.4	1.02	4.0	1	5	115	3.3	1.09	3.0	1	5
	FINAL	129	3.3	1.08	3.0	1	5	132	3.3	1.11	4.0	1	5	151	3.2	1.11	3.0	1	5
LEVEL OF SATISFACTION 7-LEISURE	DAY 1	155	2.2	0.86	2.0	1	5	149	2.5	0.99	2.0	1	5	159	2.3	0.88	2.0	1	5
	DAY 29	126	3.1	1.01	3.0	1	5	131	3.1	1.09	3.0	1	5	149	2.8	0.97	3.0	1	5
	DAY 57	102	3.3	0.98	3.0	1	5	98	3.4	0.94	3.0	1	5	115	3.1	1.06	3.0	1	5
	FINAL	129	3.2	1.01	3.0	1	5	132	3.2	1.06	3.0	1	5	151	2.9	1.08	3.0	1	5
LEVEL OF SATISFACTION 8-DAILY LIFE	DAY 1	154	2.6	0.81	3.0	1	4	151	2.7	0.87	3.0	1	5	160	2.7	0.75	3.0	1	4
	DAY 29	125	3.3	0.96	3.0	1	5	131	3.3	0.99	3.0	1	5	149	3.1	0.88	3.0	1	5
	DAY 57	102	3.4	0.89	3.0	1	5	98	3.7	0.87	4.0	1	5	114	3.3	0.91	3.0	1	5
	FINAL	129	3.3	0.97	3.0	1	5	132	3.4	1.01	4.0	1	5	150	3.2	0.98	3.0	1	5

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ206.SAS
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Table 11.2.6.6 QLESQ Individual Item Scores - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 9-SEXUAL INTEREST	WINDOWED VISIT																		
	DAY 1	155	2.2	1.14	2.0	1	5	150	2.4	1.25	2.0	1	5	160	2.1	1.16	2.0	1	5
	DAY 29	126	2.7	1.19	3.0	1	5	130	2.9	1.09	3.0	1	5	149	2.6	1.12	3.0	1	5
	DAY 57	101	3.0	1.27	3.0	1	5	98	3.1	1.12	3.0	1	5	115	2.9	1.14	3.0	1	5
	FINAL	128	3.0	1.27	3.0	1	5	132	2.9	1.18	3.0	1	5	151	2.8	1.17	3.0	1	5
LEVEL OF SATISFACTION 10-ECONOMIC	DAY 1	154	2.0	1.02	2.0	1	5	151	2.3	0.99	2.0	1	5	160	2.4	1.09	2.0	1	5
	DAY 29	126	2.7	1.07	3.0	1	5	131	2.8	0.94	3.0	1	5	149	2.7	1.06	3.0	1	5
	DAY 57	102	2.8	1.03	3.0	1	5	98	3.1	1.00	3.0	1	5	115	2.9	0.91	3.0	1	5
	FINAL	129	2.8	1.01	3.0	1	5	132	2.9	1.02	3.0	1	5	151	2.9	0.96	3.0	1	5
LEVEL OF SATISFACTION 11-LIVING	DAY 1	155	2.6	1.07	3.0	1	5	150	2.9	1.06	3.0	1	5	160	3.1	1.11	3.0	1	5
	DAY 29	126	3.2	0.98	3.0	1	5	131	3.3	1.03	3.0	1	5	149	3.3	1.03	3.0	1	5
	DAY 57	102	3.5	1.01	4.0	1	5	98	3.5	0.91	4.0	1	5	115	3.4	1.00	3.0	1	5
	FINAL	129	3.4	1.04	4.0	1	5	132	3.3	1.04	4.0	1	5	151	3.3	1.03	3.0	1	5
LEVEL OF SATISFACTION 12-GET AROUND	DAY 1	155	3.8	0.99	4.0	1	5	151	3.7	0.95	4.0	1	5	160	4.0	0.97	4.0	1	5
	DAY 29	126	3.9	0.92	4.0	1	5	131	3.6	1.02	4.0	1	5	149	4.0	0.90	4.0	1	5
	DAY 57	102	4.0	0.93	4.0	1	5	98	3.9	0.68	4.0	2	5	115	4.0	0.92	4.0	1	5
	FINAL	129	3.9	0.99	4.0	1	5	132	3.7	0.95	4.0	1	5	151	4.0	0.93	4.0	1	5

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ206.SAS
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Table 11.2.6.6 QLESQ Individual Item Scores - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 13-WORK ABILITY	WINDOWED VISIT																		
	DAY 1	154	3.0	1.15	3.0	1	5	150	3.4	0.97	3.0	1	5	160	3.3	1.03	3.0	1	5
	DAY 29	126	3.6	0.94	4.0	1	5	131	3.6	0.93	4.0	1	5	149	3.5	0.95	4.0	1	5
	DAY 57	102	3.7	0.87	4.0	1	5	98	3.8	0.82	4.0	1	5	115	3.7	0.99	4.0	1	5
	FINAL	129	3.6	0.90	4.0	1	5	132	3.6	0.96	4.0	1	5	151	3.6	0.98	4.0	1	5
LEVEL OF SATISFACTION 14-WELL BEING	DAY 1	155	2.4	0.73	2.0	1	4	151	2.5	0.75	3.0	1	4	160	2.5	0.76	2.5	1	4
	DAY 29	126	3.2	0.89	3.0	1	5	131	3.2	0.86	3.0	1	5	149	3.1	0.94	3.0	1	5
	DAY 57	102	3.4	0.94	4.0	1	5	98	3.6	0.91	4.0	1	5	115	3.3	0.96	3.0	1	5
	FINAL	129	3.3	0.97	3.0	1	5	132	3.4	1.00	4.0	1	5	151	3.2	1.05	3.0	1	5
LEVEL OF SATISFACTION 15-MEDICATIONS	DAY 1	152	0.4	1.15	0.0	0	5	151	0.4	1.14	0.0	0	4	158	0.4	1.16	0.0	0	5
	DAY 29	124	2.9	1.50	3.0	0	5	128	2.9	1.47	3.0	0	5	147	2.8	1.54	3.0	0	5
	DAY 57	101	2.8	1.63	3.0	0	5	97	3.1	1.58	4.0	0	5	115	2.8	1.54	3.0	0	5
	FINAL	128	2.8	1.59	3.0	0	5	130	2.8	1.63	3.0	0	5	149	2.5	1.60	3.0	0	5
PAST WEEK LIFE SATISFACTION	DAY 1	155	2.3	0.73	2.0	1	4	151	2.4	0.76	2.0	1	4	160	2.4	0.75	2.0	1	5
	DAY 29	126	3.2	0.96	3.0	1	5	131	3.2	0.93	3.0	1	5	149	3.0	0.94	3.0	1	5
	DAY 57	102	3.4	0.96	3.5	1	5	98	3.5	0.90	4.0	1	5	115	3.2	0.94	3.0	1	5
	FINAL	129	3.3	1.02	3.0	1	5	132	3.3	0.96	3.0	1	5	151	3.1	1.02	3.0	1	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ206.SAS
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Table 11.2.6.7 QLESQ Individual Item Scores Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 1-PHYSICAL HEALTH	WINDOWED VISIT																		
	DAY 29	126	0.3	1.01	0.0	-3	3	131	0.2	1.00	0.0	-4	3	148	0.1	1.00	0.0	-3	3
	DAY 57	101	0.4	1.07	0.0	-2	3	98	0.4	0.90	0.5	-2	3	115	0.3	0.86	0.0	-2	3
	FINAL	128	0.4	1.11	0.0	-3	3	132	0.3	1.03	0.0	-4	3	150	0.2	0.97	0.0	-3	3
LEVEL OF SATISFACTION 2-MOOD	DAY 29	126	0.9	1.12	1.0	-2	4	131	0.9	0.95	1.0	-2	3	148	0.7	1.04	1.0	-2	3
	DAY 57	102	1.1	1.18	1.0	-2	4	98	1.1	1.11	1.0	-2	3	115	1.0	1.09	1.0	-1	4
	FINAL	129	1.0	1.17	1.0	-2	4	132	1.0	1.07	1.0	-2	3	150	0.8	1.14	1.0	-2	4
LEVEL OF SATISFACTION 3-WORK	DAY 29	118	0.8	1.14	1.0	-2	4	121	0.8	1.14	1.0	-2	3	142	0.7	1.28	1.0	-3	4
	DAY 57	97	1.0	1.18	1.0	-2	4	92	1.1	0.98	1.0	-1	3	107	0.9	1.33	1.0	-3	4
	FINAL	122	0.9	1.14	1.0	-2	4	122	1.0	1.11	1.0	-2	3	142	0.7	1.35	1.0	-3	4
LEVEL OF SATISFACTION 4-HOUSEHOLD	DAY 29	126	0.7	1.10	1.0	-2	3	131	0.8	1.19	1.0	-2	4	148	0.5	1.10	0.0	-3	4
	DAY 57	102	0.9	1.16	1.0	-2	4	98	1.2	1.20	1.0	-1	4	115	0.6	1.07	1.0	-2	3
	FINAL	129	0.8	1.16	1.0	-2	4	132	1.0	1.24	1.0	-2	4	150	0.5	1.16	0.5	-3	4
LEVEL OF SATISFACTION 5-SOCIAL	DAY 29	126	0.7	1.03	1.0	-1	3	130	0.7	1.14	1.0	-2	4	148	0.6	1.02	1.0	-2	3
	DAY 57	102	1.0	1.10	1.0	-2	3	98	1.0	1.24	1.0	-2	4	115	0.6	1.23	0.0	-2	3
	FINAL	129	0.9	1.11	1.0	-2	3	132	0.9	1.23	1.0	-2	4	150	0.5	1.23	0.0	-3	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ207.SAS
GENERATED: 17NOV2005 13:52:32 iceadmn3

Table 11.2.6.7 QLESQ Individual Item Scores Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 6-FAMILY	WINDOWED VISIT																		
	DAY 29	126	0.6	1.26	0.0	-2	4	130	0.5	1.09	0.5	-2	3	146	0.5	1.10	0.0	-2	3
	DAY 57	102	0.8	1.30	1.0	-2	4	98	0.7	1.11	1.0	-2	3	114	0.5	1.24	0.0	-3	3
	FINAL	129	0.7	1.29	1.0	-2	4	132	0.6	1.16	1.0	-2	3	149	0.4	1.23	0.0	-3	3
LEVEL OF SATISFACTION 7-LEISURE	DAY 29	126	1.0	1.04	1.0	-2	3	129	0.6	1.16	1.0	-2	3	147	0.6	1.11	1.0	-2	3
	DAY 57	102	1.1	1.02	1.0	-2	3	97	0.7	1.09	1.0	-2	3	114	0.7	1.14	1.0	-1	4
	FINAL	129	1.1	1.03	1.0	-2	3	130	0.7	1.13	1.0	-2	3	149	0.7	1.13	1.0	-2	4
LEVEL OF SATISFACTION 8-DAILY LIFE	DAY 29	124	0.6	1.07	1.0	-2	4	131	0.6	1.04	1.0	-2	3	148	0.4	0.93	0.0	-2	3
	DAY 57	101	0.7	1.11	1.0	-2	3	98	1.0	1.09	1.0	-1	4	114	0.7	1.04	1.0	-2	3
	FINAL	128	0.6	1.11	1.0	-2	3	132	0.8	1.11	1.0	-2	4	149	0.5	1.07	0.0	-2	3
LEVEL OF SATISFACTION 9-SEXUAL INTEREST	DAY 29	126	0.5	1.18	0.0	-2	3	129	0.5	1.23	0.0	-3	4	148	0.4	1.12	0.0	-2	3
	DAY 57	101	0.8	1.33	1.0	-3	3	98	0.6	1.40	0.0	-3	4	115	0.8	1.31	1.0	-3	4
	FINAL	128	0.8	1.26	1.0	-3	3	131	0.5	1.34	0.0	-3	4	150	0.6	1.26	0.5	-3	4
LEVEL OF SATISFACTION 10-ECONOMIC	DAY 29	126	0.6	1.04	0.0	-2	3	131	0.5	1.06	0.0	-2	3	148	0.3	1.00	0.0	-2	4
	DAY 57	102	0.8	1.11	1.0	-2	4	98	0.8	1.08	1.0	-2	4	115	0.5	1.03	0.0	-2	4
	FINAL	129	0.8	1.08	1.0	-2	4	132	0.6	1.11	0.0	-2	4	150	0.4	0.99	0.0	-2	4

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ207.SAS
GENERATED: 17NOV2005 13:52:32 iceadmn3

Table 11.2.6.7 QLESQ Individual Item Scores Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
LEVEL OF SATISFACTION 11-LIVING	WINDOWED VISIT																		
	DAY 29	126	0.5	1.07	0.0	-3	4	131	0.3	0.96	0.0	-2	3	148	0.2	1.13	0.0	-3	3
	DAY 57	102	0.8	1.16	1.0	-1	4	98	0.5	1.03	0.0	-2	4	115	0.4	1.07	0.0	-2	4
	FINAL	129	0.8	1.12	1.0	-1	4	132	0.3	1.08	0.0	-3	4	150	0.3	1.10	0.0	-3	4
LEVEL OF SATISFACTION 12-GET AROUND	DAY 29	126	0.1	1.14	0.0	-3	3	131	-0.1	1.13	0.0	-4	2	148	0.0	0.91	0.0	-3	3
	DAY 57	102	0.1	1.24	0.0	-4	4	98	0.1	0.90	0.0	-2	2	115	0.2	1.04	0.0	-4	3
	FINAL	129	0.1	1.29	0.0	-4	4	132	-0.0	1.10	0.0	-4	2	150	0.1	1.04	0.0	-4	3
LEVEL OF SATISFACTION 13-WORK ABILITY	DAY 29	126	0.5	1.09	0.0	-2	4	130	0.2	1.04	0.0	-3	3	148	0.2	1.09	0.0	-3	2
	DAY 57	102	0.6	1.17	0.5	-3	4	97	0.4	1.15	0.0	-4	3	115	0.4	1.22	0.0	-3	4
	FINAL	129	0.6	1.18	0.0	-3	4	131	0.2	1.22	0.0	-4	3	150	0.3	1.18	0.0	-3	4
LEVEL OF SATISFACTION 14-WELL BEING	DAY 29	126	0.7	1.02	1.0	-3	3	131	0.7	0.88	1.0	-2	3	148	0.6	1.01	1.0	-2	3
	DAY 57	102	1.0	1.01	1.0	-1	3	98	1.0	0.97	1.0	-2	3	115	0.8	1.07	1.0	-2	3
	FINAL	129	0.9	1.05	1.0	-2	3	132	0.9	1.00	1.0	-2	3	150	0.7	1.12	1.0	-3	3
LEVEL OF SATISFACTION 15-MEDICATIONS	DAY 29	122	2.5	1.99	3.0	-4	5	128	2.5	1.71	3.0	-3	5	145	2.3	1.80	3.0	-2	5
	DAY 57	99	2.3	1.97	3.0	-3	5	97	2.4	1.91	3.0	-3	5	113	2.3	1.86	3.0	-3	5
	FINAL	126	2.3	1.95	3.0	-4	5	130	2.3	1.82	3.0	-3	5	147	2.1	1.85	3.0	-3	5

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ207.SAS
GENERATED: 17NOV2005 13:52:32 iceadmn3

Table 11.2.6.7 QLESQ Individual Item Scores Change from Baseline - Descriptive Statistics
Intent-to-Treat Population

QLESQ INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
PAST WEEK LIFE SATISFACTION	WINDOWED VISIT																		
	DAY 29	126	0.9	1.12	1.0	-2	3	131	0.8	0.99	1.0	-2	4	148	0.5	1.02	1.0	-3	3
	DAY 57	102	1.1	1.05	1.0	-1	4	98	1.1	1.00	1.0	-2	4	115	0.8	0.99	1.0	-2	3
	FINAL	129	1.0	1.14	1.0	-2	4	132	1.0	1.00	1.0	-2	4	150	0.6	1.05	1.0	-3	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/QLESQ207.SAS
GENERATED: 17NOV2005 13:52:32 iceadmn3

Table 11.2.7.1 SDS Total Score And Change From Baseline - Descriptive Statistics
Intent-to-Treat

SDS TOTAL SCORE		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SDS TOTAL SCORE	WINDOWED VISIT																		
	DAY 1	155	18.7	6.26	18.0	0	30	151	17.9	6.58	17.0	3	30	160	18.0	6.20	18.0	2	30
	DAY 29	126	11.8	7.80	11.0	0	30	131	11.2	7.44	11.0	0	30	147	12.2	7.45	12.0	0	30
	DAY 57	101	9.7	7.05	9.0	0	27	98	8.8	6.49	8.0	0	25	115	10.7	7.47	11.0	0	30
	FINAL	129	10.9	7.99	10.0	0	30	132	9.8	7.12	9.0	0	30	150	12.1	8.08	12.0	0	30
CHG FROM BASELINE	DAY 29	126	-6.7	8.22	-6.0	-30	14	131	-6.5	7.55	-6.0	-25	15	146	-5.9	7.95	-5.0	-30	9
	DAY 57	101	-8.6	8.58	-8.0	-30	13	98	-8.4	7.72	-7.5	-28	10	115	-6.8	9.22	-6.0	-27	18
	FINAL	129	-7.6	8.53	-7.0	-30	13	132	-7.9	7.57	-7.0	-28	10	149	-6.0	9.15	-5.0	-27	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS200.SAS
GENERATED: 17NOV2005 13:52:11 iceadmn3

Table 11.2.7.2 SDS Total Score Change From Baseline ANCOVA)
Last Observation Carried Forward
Intent-to-Treat

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	126	18.5	6.47	-6.7	8.22	-6.27	0.693	-7.64	-4.90	.
	Q600MG	131	17.6	6.31	-6.5	7.55	-6.46	0.687	-7.82	-5.10	.
	P	146	18.0	6.27	-5.9	7.95	-5.78	0.657	-7.08	-4.48	.
	Q300MG VS P	.	.	.	.	.	-0.49	0.849	-2.16	1.18	0.562
	Q600MG VS P	.	.	.	.	.	-0.68	0.841	-2.34	0.97	0.419
DAY 57	Q300MG	101	18.2	6.30	-8.6	8.58	-8.11	0.759	-9.62	-6.61	.
	Q600MG	98	17.2	6.40	-8.4	7.72	-8.75	0.776	-10.28	-7.21	.
	P	115	17.5	6.32	-6.8	9.22	-7.14	0.730	-8.58	-5.69	.
	Q300MG VS P	.	.	.	.	.	-0.97	0.932	-2.81	0.86	0.297
	Q600MG VS P	.	.	.	.	.	-1.61	0.939	-3.46	0.24	0.087
FINAL	Q300MG	129	18.5	6.42	-7.6	8.53	-7.30	0.764	-8.81	-5.78	.
	Q600MG	132	17.7	6.38	-7.9	7.57	-7.87	0.765	-9.38	-6.35	.
	P	149	18.0	6.21	-6.0	9.15	-6.03	0.734	-7.49	-4.57	.
	Q300MG VS P	.	.	.	.	.	-1.27	0.871	-2.98	0.44	0.146
	Q600MG VS P	.	.	.	.	.	-1.84	0.866	-3.54	-0.13	0.035

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS209.SAS
GENERATED: 17NOV2005 13:36:10 iceadmn3

Table 11.2.7.3 SDS Individual Items - Descriptive Statistics
Intent-to-Treat

SDS INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. WORK/ SCHOOL	WINDOWED VISIT																		
	DAY 1	120	6.5	2.63	7.0	0	10	112	6.3	2.72	7.0	0	10	129	6.0	2.77	6.0	0	10
	DAY 29	101	3.9	3.07	3.0	0	10	97	3.8	2.73	4.0	0	10	124	4.2	2.68	4.0	0	10
	DAY 57	82	2.9	2.73	2.0	0	10	80	2.9	2.49	2.0	0	10	99	3.3	2.66	3.0	0	10
	FINAL	104	3.5	3.12	2.0	0	10	104	3.2	2.68	3.0	0	10	129	3.9	2.91	4.0	0	10
2. SOCIAL LIFE	DAY 1	155	6.9	2.24	7.0	0	10	151	6.7	2.42	7.0	0	10	160	6.8	2.15	7.0	1	10
	DAY 29	126	4.5	2.90	4.0	0	10	131	4.1	2.87	4.0	0	10	147	4.5	2.96	5.0	0	10
	DAY 57	101	3.7	2.79	3.0	0	10	98	3.3	2.62	3.0	0	10	115	4.0	2.97	4.0	0	10
	FINAL	129	4.2	2.99	4.0	0	10	132	3.7	2.86	3.0	0	10	150	4.5	3.12	4.0	0	10
3. FAMILY LIFE/HOME RESP.	DAY 1	155	6.8	2.21	7.0	0	10	151	6.6	2.46	7.0	0	10	160	6.4	2.24	6.5	0	10
	DAY 29	126	4.2	2.77	4.0	0	10	131	4.3	2.81	4.0	0	10	147	4.2	2.82	4.0	0	10
	DAY 57	101	3.6	2.75	3.0	0	10	98	3.1	2.53	2.5	0	10	115	3.9	2.96	4.0	0	10
	FINAL	129	3.9	2.93	4.0	0	10	132	3.6	2.86	3.0	0	10	150	4.3	3.07	4.0	0	10
4. DAYS LOST	DAY 1	148	2.4	2.41	2.0	0	7	149	2.4	2.51	2.0	0	7	158	2.1	2.27	2.0	0	7
	DAY 29	124	1.3	1.99	0.0	0	7	129	1.3	2.10	0.0	0	7	146	1.2	1.81	0.0	0	7
	DAY 57	99	0.9	1.69	0.0	0	7	98	0.9	1.81	0.0	0	7	112	1.0	1.82	0.0	0	7
	FINAL	127	1.1	1.92	0.0	0	7	131	1.0	2.00	0.0	0	7	148	1.3	1.94	0.0	0	7

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS201.SAS
GENERATED: 17NOV2005 13:52:13 iceadmn3

Table 11.2.7.3 SDS Individual Items - Descriptive Statistics
Intent-to-Treat

SDS INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. DAYS UNDER PRODUCTIVE	WINDOWED VISIT																		
	DAY 1	145	3.8	2.25	4.0	0	7	144	3.9	2.44	4.0	0	7	158	3.5	2.27	3.0	0	7
	DAY 29	123	2.0	2.32	1.0	0	7	126	2.0	2.31	1.0	0	7	143	2.1	2.24	2.0	0	7
	DAY 57	98	1.2	1.93	0.0	0	7	95	1.4	2.15	0.0	0	7	111	1.8	2.21	1.0	0	7
	FINAL	125	1.6	2.19	0.0	0	7	128	1.7	2.27	1.0	0	7	145	2.2	2.37	2.0	0	7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS201.SAS
GENERATED: 17NOV2005 13:52:13 iceadmn3

Table 11.2.7.4.1 SDS Individual Items Change From Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat

SDS INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. WORK/ SCHOOL	WINDOWED VISIT																		
	DAY 29	87	-2.5	3.26	-2.0	-10	7	86	-2.2	2.92	-2.0	-10	5	112	-1.7	3.09	-2.0	-10	6
	DAY 57	73	-3.3	3.53	-3.0	-10	7	65	-3.0	2.99	-3.0	-10	4	82	-2.6	3.54	-3.0	-10	8
	FINAL	90	-3.0	3.48	-3.0	-10	7	89	-2.8	3.05	-2.0	-10	4	111	-2.0	3.54	-2.0	-10	8
2. SOCIAL LIFE	DAY 29	126	-2.3	2.97	-2.0	-10	5	131	-2.5	3.07	-2.0	-10	6	146	-2.3	3.19	-2.0	-10	4
	DAY 57	101	-3.0	3.19	-3.0	-10	8	98	-3.2	2.98	-3.0	-10	6	115	-2.5	3.48	-3.0	-10	9
	FINAL	129	-2.7	3.19	-2.0	-10	8	132	-3.0	2.96	-3.0	-10	6	149	-2.3	3.54	-2.0	-10	9
3. FAMILY LIFE/HOME RESP.	DAY 29	126	-2.5	3.17	-2.0	-10	6	131	-2.3	3.31	-2.0	-10	4	146	-2.2	3.02	-2.0	-10	3
	DAY 57	101	-3.1	3.38	-3.0	-10	5	98	-3.4	3.25	-3.0	-10	4	115	-2.4	3.45	-2.0	-9	9
	FINAL	129	-2.8	3.29	-2.0	-10	5	132	-2.9	3.33	-3.0	-10	4	149	-2.1	3.50	-2.0	-9	10
4. DAYS LOST	DAY 29	120	-1.1	2.46	0.0	-7	7	128	-1.0	2.18	0.0	-7	5	143	-0.8	2.38	0.0	-7	5
	DAY 57	95	-1.3	2.36	0.0	-7	7	96	-1.4	2.21	-0.5	-7	3	111	-1.2	2.56	-1.0	-7	7
	FINAL	122	-1.2	2.44	0.0	-7	7	129	-1.3	2.23	0.0	-7	4	145	-0.8	2.54	0.0	-7	7
5. DAYS UNDER PRODUCTIVE	DAY 29	118	-1.8	2.72	-2.0	-7	7	122	-1.9	2.88	-1.5	-7	7	141	-1.5	2.71	-1.0	-7	7
	DAY 57	94	-2.5	2.48	-2.0	-7	4	92	-2.4	3.15	-2.0	-7	7	109	-1.8	2.81	-2.0	-7	7
	FINAL	119	-2.2	2.63	-2.0	-7	7	123	-2.2	2.92	-2.0	-7	7	143	-1.4	2.80	-1.0	-7	7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS208.SAS
GENERATED: 17NOV2005 13:36:07 iceadmn3

Table 11.2.7.4.2 SDS Individual Items Change From Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat

SDS INDIVIDUAL ITEMS		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. WORK/ SCHOOL	WINDOWED VISIT																		
	DAY 29	87	-2.5	3.26	-2.0	-10	7	86	-2.2	2.92	-2.0	-10	5	112	-1.7	3.09	-2.0	-10	6
	DAY 57	73	-3.3	3.53	-3.0	-10	7	65	-3.0	2.99	-3.0	-10	4	82	-2.6	3.54	-3.0	-10	8
	FINAL	90	-3.0	3.48	-3.0	-10	7	89	-2.8	3.05	-2.0	-10	4	111	-2.0	3.54	-2.0	-10	8
2. SOCIAL LIFE	DAY 29	126	-2.3	2.97	-2.0	-10	5	131	-2.5	3.07	-2.0	-10	6	146	-2.3	3.19	-2.0	-10	4
	DAY 57	101	-3.0	3.19	-3.0	-10	8	98	-3.2	2.98	-3.0	-10	6	115	-2.5	3.48	-3.0	-10	9
	FINAL	129	-2.7	3.19	-2.0	-10	8	132	-3.0	2.96	-3.0	-10	6	149	-2.3	3.54	-2.0	-10	9
3. FAMILY LIFE/HOME RESP.	DAY 29	126	-2.5	3.17	-2.0	-10	6	131	-2.3	3.31	-2.0	-10	4	146	-2.2	3.02	-2.0	-10	3
	DAY 57	101	-3.1	3.38	-3.0	-10	5	98	-3.4	3.25	-3.0	-10	4	115	-2.4	3.45	-2.0	-9	9
	FINAL	129	-2.8	3.29	-2.0	-10	5	132	-2.9	3.33	-3.0	-10	4	149	-2.1	3.50	-2.0	-9	10
4. DAYS LOST	DAY 29	120	-1.1	2.46	0.0	-7	7	128	-1.0	2.18	0.0	-7	5	143	-0.8	2.38	0.0	-7	5
	DAY 57	95	-1.3	2.36	0.0	-7	7	96	-1.4	2.21	-0.5	-7	3	111	-1.2	2.56	-1.0	-7	7
	FINAL	122	-1.2	2.44	0.0	-7	7	129	-1.3	2.23	0.0	-7	4	145	-0.8	2.54	0.0	-7	7
5. DAYS UNDER PRODUCTIVE	DAY 29	118	-1.8	2.72	-2.0	-7	7	122	-1.9	2.88	-1.5	-7	7	141	-1.5	2.71	-1.0	-7	7
	DAY 57	94	-2.5	2.48	-2.0	-7	4	92	-2.4	3.15	-2.0	-7	7	109	-1.8	2.81	-2.0	-7	7
	FINAL	119	-2.2	2.63	-2.0	-7	7	123	-2.2	2.92	-2.0	-7	7	143	-1.4	2.80	-1.0	-7	7

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS202.SAS
GENERATED: 17NOV2005 13:52:16 iceadmn3

Table 11.2.7.5.1 SDS Item 1 Score (Work/School) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	87	6.5	2.66	-2.5	3.26	-2.21	0.311	-2.82	-1.59	.
	Q600MG	86	6.0	2.68	-2.2	2.92	-2.14	0.312	-2.76	-1.52	.
	P	112	5.9	2.75	-1.7	3.09	-1.79	0.281	-2.35	-1.24	.
	Q300MG VS P	.	.	.	.	.	-0.41	0.374	-1.15	0.32	0.271
	Q600MG VS P	.	.	.	.	.	-0.35	0.373	-1.08	0.39	0.356
DAY 57	Q300MG	73	6.2	2.75	-3.3	3.53	-3.08	0.338	-3.75	-2.41	.
	Q600MG	65	5.9	2.83	-3.0	2.99	-3.05	0.357	-3.76	-2.34	.
	P	82	5.9	2.73	-2.6	3.54	-2.72	0.323	-3.36	-2.08	.
	Q300MG VS P	.	.	.	.	.	-0.36	0.415	-1.18	0.45	0.383
	Q600MG VS P	.	.	.	.	.	-0.33	0.425	-1.17	0.51	0.440
FINAL	Q300MG	90	6.5	2.66	-3.0	3.48	-2.72	0.346	-3.40	-2.03	.
	Q600MG	89	6.1	2.68	-2.8	3.05	-2.65	0.348	-3.34	-1.96	.
	P	111	6.0	2.64	-2.0	3.54	-2.09	0.322	-2.73	-1.45	.
	Q300MG VS P	.	.	.	.	.	-0.63	0.394	-1.41	0.14	0.110
	Q600MG VS P	.	.	.	.	.	-0.56	0.391	-1.33	0.21	0.153

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS203.SAS
GENERATED: 17NOV2005 13:35:54 iceadmn3

Table 11.2.7.5.2 SDS Item 2 Score (Social Life) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	126	6.8	2.30	-2.3	2.97	-2.29	0.268	-2.82	-1.76	.
	Q600MG	131	6.6	2.43	-2.5	3.07	-2.55	0.266	-3.07	-2.02	.
	P	146	6.8	2.20	-2.3	3.19	-2.29	0.254	-2.79	-1.78	.
	Q300MG VS P	.	.	.	.	.	-0.00	0.334	-0.66	0.65	0.991
	Q600MG VS P	.	.	.	.	.	-0.26	0.331	-0.91	0.39	0.435
DAY 57	Q300MG	101	6.7	2.29	-3.0	3.19	-2.95	0.297	-3.54	-2.36	.
	Q600MG	98	6.6	2.58	-3.2	2.98	-3.32	0.304	-3.92	-2.71	.
	P	115	6.6	2.25	-2.5	3.48	-2.69	0.285	-3.25	-2.12	.
	Q300MG VS P	.	.	.	.	.	-0.27	0.368	-0.99	0.46	0.472
	Q600MG VS P	.	.	.	.	.	-0.63	0.371	-1.36	0.10	0.091
FINAL	Q300MG	129	6.8	2.29	-2.7	3.19	-2.71	0.285	-3.27	-2.14	.
	Q600MG	132	6.7	2.44	-3.0	2.96	-3.06	0.285	-3.63	-2.50	.
	P	149	6.8	2.20	-2.3	3.54	-2.38	0.273	-2.92	-1.83	.
	Q300MG VS P	.	.	.	.	.	-0.33	0.340	-1.00	0.34	0.332
	Q600MG VS P	.	.	.	.	.	-0.69	0.339	-1.35	-0.02	0.043

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS206.SAS
GENERATED: 17NOV2005 13:36:02 iceadmn3

Table 11.2.7.5.3 SDS Item 3 Score (Family Life/Home Resp) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	126	6.7	2.30	-2.5	3.17	-2.37	0.251	-2.86	-1.87	.
	Q600MG	131	6.5	2.40	-2.3	3.31	-2.29	0.247	-2.78	-1.80	.
	P	146	6.4	2.20	-2.2	3.02	-2.30	0.235	-2.76	-1.83	.
	Q300MG VS P	.	.	.	.	.	-0.07	0.331	-0.72	0.58	0.836
	Q600MG VS P	.	.	.	.	.	0.01	0.328	-0.64	0.65	0.980
DAY 57	Q300MG	101	6.6	2.19	-3.1	3.38	-2.94	0.291	-3.51	-2.36	.
	Q600MG	98	6.5	2.38	-3.4	3.25	-3.38	0.298	-3.97	-2.79	.
	P	115	6.3	2.18	-2.4	3.45	-2.65	0.279	-3.20	-2.10	.
	Q300MG VS P	.	.	.	.	.	-0.29	0.374	-1.02	0.45	0.442
	Q600MG VS P	.	.	.	.	.	-0.73	0.376	-1.47	0.01	0.053
FINAL	Q300MG	129	6.7	2.29	-2.8	3.29	-2.71	0.274	-3.26	-2.17	.
	Q600MG	132	6.5	2.41	-2.9	3.33	-2.97	0.274	-3.51	-2.42	.
	P	149	6.4	2.20	-2.1	3.50	-2.31	0.260	-2.83	-1.80	.
	Q300MG VS P	.	.	.	.	.	-0.40	0.348	-1.08	0.29	0.253
	Q600MG VS P	.	.	.	.	.	-0.65	0.345	-1.33	0.03	0.060

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS204.SAS
GENERATED: 17NOV2005 13:35:57 iceadmn3

Table 11.2.7.5.4 SDS Item 4 Score (Days Lost) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	120	2.3	2.38	-1.1	2.46	-1.02	0.183	-1.38	-0.65	.
	Q600MG	128	2.3	2.48	-1.0	2.18	-0.96	0.179	-1.31	-0.60	.
	P	143	2.1	2.28	-0.8	2.38	-0.93	0.173	-1.27	-0.58	.
	Q300MG VS P	.	.	.	.	.	-0.09	0.216	-0.51	0.34	0.681
	Q600MG VS P	.	.	.	.	.	-0.03	0.213	-0.45	0.39	0.888
DAY 57	Q300MG	95	2.2	2.34	-1.3	2.36	-1.36	0.179	-1.72	-1.01	.
	Q600MG	96	2.3	2.45	-1.4	2.21	-1.38	0.179	-1.73	-1.02	.
	P	111	2.2	2.36	-1.2	2.56	-1.22	0.168	-1.55	-0.88	.
	Q300MG VS P	.	.	.	.	.	-0.15	0.232	-0.60	0.31	0.529
	Q600MG VS P	.	.	.	.	.	-0.16	0.231	-0.62	0.29	0.479
FINAL	Q300MG	122	2.3	2.37	-1.2	2.44	-1.22	0.179	-1.58	-0.87	.
	Q600MG	129	2.3	2.51	-1.3	2.23	-1.26	0.176	-1.61	-0.91	.
	P	145	2.2	2.30	-0.8	2.54	-0.95	0.168	-1.28	-0.61	.
	Q300MG VS P	.	.	.	.	.	-0.28	0.219	-0.71	0.15	0.207
	Q600MG VS P	.	.	.	.	.	-0.32	0.216	-0.74	0.11	0.145

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS205.SAS
GENERATED: 17NOV2005 13:35:59 iceadmn3

Table 11.2.7.5.5 SDS Item 5 Score (Days Underproductive) Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	Q300MG	118	3.8	2.31	-1.8	2.72	-1.66	0.219	-2.10	-1.23	.
	Q600MG	122	3.8	2.41	-1.9	2.88	-1.73	0.216	-2.15	-1.30	.
	P	141	3.6	2.22	-1.5	2.71	-1.50	0.204	-1.91	-1.10	.
	Q300MG VS P	.	.	.	.	.	-0.16	0.274	-0.70	0.38	0.562
	Q600MG VS P	.	.	.	.	.	-0.22	0.272	-0.76	0.31	0.418
DAY 57	Q300MG	94	3.8	2.36	-2.5	2.48	-2.46	0.218	-2.89	-2.03	.
	Q600MG	92	3.8	2.49	-2.4	3.15	-2.38	0.221	-2.81	-1.95	.
	P	109	3.6	2.20	-1.8	2.81	-1.90	0.205	-2.30	-1.50	.
	Q300MG VS P	.	.	.	.	.	-0.56	0.294	-1.14	0.01	0.056
	Q600MG VS P	.	.	.	.	.	-0.48	0.296	-1.06	0.10	0.104
FINAL	Q300MG	119	3.8	2.31	-2.2	2.63	-2.15	0.212	-2.57	-1.73	.
	Q600MG	123	3.9	2.42	-2.2	2.92	-2.13	0.208	-2.54	-1.71	.
	P	143	3.6	2.23	-1.4	2.80	-1.52	0.195	-1.91	-1.13	.
	Q300MG VS P	.	.	.	.	.	-0.63	0.274	-1.17	-0.09	0.022
	Q600MG VS P	.	.	.	.	.	-0.60	0.272	-1.14	-0.07	0.027

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SDS207.SAS
GENERATED: 17NOV2005 13:36:04 iceadmn3

Table 11.3.1.1 Exposure to Randomized Treatment - Descriptive Statistics
Safety Population

		TREATMENT		
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO
DAYS ON RANDOMIZED TREATMENT	N	171	168	167
	MEAN	41.8	39.8	46.0
	SD	20.23	20.91	16.90
	MEDIAN	55.0	54.5	56.0
	MIN	1	1	1
	MAX	62	63	65
DAYS WITH TREATMENT	N	171	168	167
	MEAN	41.1	39.1	45.3
	SD	20.17	20.71	16.76
	MEDIAN	54.3	52.9	55.0
	MIN	1	1	1
	MAX	60	60	64
MEDIAN DOSE OVER STUDY	N	171	168	167
	MEAN	265.2	505.4	0.0
	SD	67.92	153.26	0.00
	MEDIAN	300.0	600.0	0.0
	MIN	0	0	0
	MAX	300	600	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC200.SAS
GENERATED: 17NOV2005 13:48:31 iceadmn3

Table 11.3.1.1 Exposure to Randomized Treatment - Descriptive Statistics
Safety Population

		TREATMENT		
		QUETIAPINE 300 MG	QUETIAPINE 600 MG	PLACEBO
MEAN DOSE OVER STUDY	N	171	168	167
	MEAN	252.6	464.9	0.0
	SD	56.43	136.56	0.00
	MEDIAN	281.7	528.7	0.0
	MIN	25	10	0
	MAX	291	562	0
CUMULATIVE DOSE OVER STUDY	N	171	168	167
	MEAN	11793.3	21191.7	0.0
	SD	6045.05	12311.77	0.00
	MEDIAN	15725.0	29375.0	0.0
	MIN	50	50	0
	MAX	17450	33800	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC200.SAS
GENERATED: 17NOV2005 13:48:31 iceadmn3

Table 11.3.1.2 Total Subject Days on Randomized Treatment - Descriptive Statistics
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N	DAYS	N	DAYS	N	DAYS
TOTAL EXPOSURE	171	7149	168	6686	167	7675

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC204.SAS
GENERATED: 17NOV2005 13:48:40 iceadmn3

Table 11.3.1.3 Subjects with Dose Reduction by Bipolar Diagnosis and Withdrawal Status
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		N	%	N	%	N	%
OVERALL	OVERALL	43	25.1	37	22.0	8	4.8
	COMPLETED	29	17.0	22	13.1	6	3.6
	ALL WITHDRAWALS	14	8.2	15	8.9	2	1.2
	ADVERSE EVENT	1	0.6	2	1.2	0	0
	LACK OF THERAPEUTIC RESPONSE	1	0.6	1	0.6	0	0
	DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	1	0.6	1	0.6	0	0
	SUBJECT NOT WILLING TO CONTINUE STUDY	6	3.5	8	4.8	0	0
	SUBJECT LOST TO FOLLOW-UP	5	2.9	3	1.8	2	1.2
BIPOLAR I	OVERALL	26	15.2	25	14.9	4	2.4
	COMPLETED	17	9.9	16	9.5	4	2.4
	ALL WITHDRAWALS	9	5.3	9	5.4	0	0
	ADVERSE EVENT	1	0.6	1	0.6	0	0
	LACK OF THERAPEUTIC RESPONSE	1	0.6	0	0	0	0
	DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	1	0.6	1	0.6	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC201.SAS
GENERATED: 17NOV2005 13:48:33 iceadmn3

Table 11.3.1.3 Subjects with Dose Reduction by Bipolar Diagnosis and Withdrawal Status
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		N	%	N	%	N	%
BIPOLAR I	SUBJECT NOT WILLING TO CONTINUE STUDY	4	2.3	6	3.6	0	0
	SUBJECT LOST TO FOLLOW-UP	2	1.2	1	0.6	0	0
BIPOLAR II	OVERALL	17	9.9	12	7.1	4	2.4
	COMPLETED	12	7.0	6	3.6	2	1.2
	ALL WITHDRAWALS	5	2.9	6	3.6	2	1.2
	ADVERSE EVENT	0	0	1	0.6	0	0
	LACK OF THERAPEUTIC RESPONSE	0	0	1	0.6	0	0
	SUBJECT NOT WILLING TO CONTINUE STUDY	2	1.2	2	1.2	0	0
	SUBJECT LOST TO FOLLOW-UP	3	1.8	2	1.2	2	1.2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC201.SAS
GENERATED: 17NOV2005 13:48:33 iceadmn3

Table 11.3.1.4 Compliance
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		N	%	N	%	N	%
OVERALL	OVERALL	171	100.0	168	100.0	167	100.0
	COMPLETED	101	59.1	90	53.6	110	65.9
	ALL WITHDRAWALS	70	40.9	78	46.4	57	34.1
	ADVERSE EVENT	14	8.2	19	11.3	2	1.2
	LACK OF THERAPEUTIC RESPONSE	3	1.8	5	3.0	13	7.8
	DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	7	4.1	6	3.6	8	4.8
	SUBJECT NOT WILLING TO CONTINUE STUDY	25	14.6	29	17.3	18	10.8
	SUBJECT LOST TO FOLLOW-UP	21	12.3	19	11.3	14	8.4
	ELIGIBILITY CRITERIA NOT FULFILLED	0	0	0	0	2	1.2
FULL COMPLIANCE (>=80%)	OVERALL	167	97.7	163	97.0	167	100.0
	COMPLETED	101	59.1	90	53.6	110	65.9
	ALL WITHDRAWALS	66	38.6	73	43.5	57	34.1
	ADVERSE EVENT	14	8.2	16	9.5	2	1.2
	LACK OF THERAPEUTIC RESPONSE	3	1.8	5	3.0	13	7.8

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC202.SAS
GENERATED: 17NOV2005 13:48:35 iceadmn3

Table 11.3.1.4 Compliance
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		N	%	N	%	N	%
FULL COMPLIANCE (>=80%)	DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	6	3.5	5	3.0	8	4.8
	SUBJECT NOT WILLING TO CONTINUE STUDY	23	13.5	28	16.7	18	10.8
	SUBJECT LOST TO FOLLOW-UP	20	11.7	19	11.3	14	8.4
	ELIGIBILITY CRITERIA NOT FULFILLED	0	0	0	0	2	1.2
PARTIAL COMPLIANCE (>=70% & <80%)	OVERALL	1	0.6	1	0.6	0	0
	ALL WITHDRAWALS	1	0.6	1	0.6	0	0
	ADVERSE EVENT	0	0	1	0.6	0	0
	SUBJECT LOST TO FOLLOW-UP	1	0.6	0	0	0	0
NON-COMPLIANCE (<70%)	OVERALL	3	1.8	4	2.4	0	0
	ALL WITHDRAWALS	3	1.8	4	2.4	0	0
	ADVERSE EVENT	0	0	2	1.2	0	0
	DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	1	0.6	1	0.6	0	0
	SUBJECT NOT WILLING TO CONTINUE STUDY	2	1.2	1	0.6	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC202.SAS
GENERATED: 17NOV2005 13:48:35 iceadmn3

Table 11.3.1.5 Compliance by Withdrawal Status
Safety Population

	TREATMENT																	
	QUETIAPINE 300 MG (N=171)									QUETIAPINE 600 MG (N=168)								
	>=80			>=70-<80			<70			>=80			>=70-<80			<70		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
OVERALL	171	167	97.7	171	1	0.6	171	3	1.8	168	163	97.0	336	1	0.6	168	4	2.4
COMPLETED	101	101	100.0	0	0	0	0	0	0	90	90	100.0	0	0	0	0	0	0
ALL WITHDRAWALS	70	66	94.3	70	1	1.4	70	3	4.3	78	73	93.6	78	1	1.3	78	4	5.1
ADVERSE EVENT	14	14	100.0	0	0	0	0	0	0	19	16	84.2	19	1	5.3	19	2	10.5
LACK OF THERAPEUTIC RESPONSE	3	3	100.0	0	0	0	0	0	0	5	5	100.0	0	0	0	0	0	0
DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	7	6	85.7	0	0	0	7	1	14.3	6	5	83.3	0	0	0	6	1	16.7
SUBJECT NOT WILLING TO CONTINUE STUDY	25	23	92.0	0	0	0	25	2	8.0	29	28	96.6	0	0	0	29	1	3.4
SUBJECT LOST TO FOLLOW-UP	21	20	95.2	21	1	4.8	0	0	0	19	19	100.0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC203.SAS
GENERATED: 17NOV2005 13:48:38 iceadmn3

Table 11.3.1.5 Compliance by Withdrawal Status
Safety Population

	TREATMENT					
	PLACEBO (N=167)					
	>=80			>=70-<80		
	TOTAL	N	%	TOTAL	N	%
OVERALL	167	167	100.0	167	0	0.0
COMPLETED	110	110	100.0	0	0	0
ALL WITHDRAWALS	57	57	100.0	0	0	0
ELIGIBILITY CRITERIA NOT FULFILLED	2	2	100.0	0	0	0
ADVERSE EVENT	2	2	100.0	0	0	0
LACK OF THERAPEUTIC RESPONSE	13	13	100.0	0	0	0
DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	8	8	100.0	0	0	0
SUBJECT NOT WILLING TO CONTINUE STUDY	18	18	100.0	0	0	0
SUBJECT LOST TO FOLLOW-UP	14	14	100.0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC203.SAS
GENERATED: 17NOV2005 13:48:38 iceadmn3

Table 11.3.1.6 Compliance by Withdrawal Status
Intent-to-treat population

	TREATMENT																	
	QUETIAPINE 300 MG (N=155)									QUETIAPINE 600 MG (N=151)								
	>=80			>=70-<80			<70			>=80			>=70-<80			<70		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
OVERALL	155	152	98.1	155	1	0.6	155	2	1.3	151	146	96.7	302	1	0.7	151	4	2.6
COMPLETED	101	101	100.0	0	0	0	0	0	0	90	90	100.0	0	0	0	0	0	0
ALL WITHDRAWALS	54	51	94.4	54	1	1.9	54	2	3.7	61	56	91.8	61	1	1.6	61	4	6.6
ADVERSE EVENT	10	10	100.0	0	0	0	0	0	0	16	13	81.3	16	1	6.3	16	2	12.5
LACK OF THERAPEUTIC RESPONSE	3	3	100.0	0	0	0	0	0	0	5	5	100.0	0	0	0	0	0	0
DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	5	4	80.0	0	0	0	5	1	20.0	6	5	83.3	0	0	0	6	1	16.7
SUBJECT NOT WILLING TO CONTINUE STUDY	18	17	94.4	0	0	0	18	1	5.6	20	19	95.0	0	0	0	20	1	5.0
SUBJECT LOST TO FOLLOW-UP	18	17	94.4	18	1	5.6	0	0	0	14	14	100.0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC205.SAS
GENERATED: 17NOV2005 13:48:42 iceadmn3

Table 11.3.1.6 Compliance by Withdrawal Status
Intent-to-treat population

	TREATMENT					
	PLACEBO (N=161)					
	>=80			>=70-<80		
	TOTAL	N	%	TOTAL	N	%
OVERALL	161	161	100.0	161	0	0.0
COMPLETED	110	110	100.0	0	0	0
ALL WITHDRAWALS	51	51	100.0	0	0	0
ELIGIBILITY CRITERIA NOT FULFILLED	2	2	100.0	0	0	0
ADVERSE EVENT	2	2	100.0	0	0	0
LACK OF THERAPEUTIC RESPONSE	13	13	100.0	0	0	0
DEVELOPMENT OF STUDY SPECIFIC DISC CRITERIA	8	8	100.0	0	0	0
SUBJECT NOT WILLING TO CONTINUE STUDY	15	15	100.0	0	0	0
SUBJECT LOST TO FOLLOW-UP	11	11	100.0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/DOSC205.SAS
GENERATED: 17NOV2005 13:48:42 iceadmn3

Table 11.3.2.1 Overview of Adverse Events
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SAFETY POPULATION	171	100.0	168	100.0	167	100.0
AT LEAST ONE ADVERSE EVENT	155	90.6	151	89.9	138	82.6
SERIOUS ADVERSE EVENT	3	1.8	7	4.2	1	0.6
ADVERSE EVENT LEADING TO DEATH	0	0	0	0	0	0
STUDY DRUG-RELATED ADVERSE EVENT	149	87.1	134	79.8	94	56.3
DISCONTINUATION DUE TO ADVERSE EVENT	14	8.2	19	11.3	2	1.2

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG200.SAS
GENERATED: 17NOV2005 13:44:22 iceadmn3

Table 11.3.2.2 Overview of Adverse Events by Bipolar Diagnosis
Safety Population

	TREATMENT											
	Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SAFETY POPULATION	112	100.0	112	100.0	112	100.0	59	100.0	56	100.0	55	100.0
AT LEAST ONE ADVERSE EVENT	102	91.1	103	92.0	93	83.0	53	89.8	48	85.7	45	81.8
SERIOUS ADVERSE EVENT	3	2.7	6	5.4	1	0.9	0	0	1	1.8	0	0
ADVERSE EVENT LEADING TO DEATH	0	0	0	0	0	0	0	0	0	0	0	0
STUDY DRUG-RELATED ADVERSE EVENT	97	86.6	90	80.4	65	58.0	52	88.1	44	78.6	29	52.7
DISCONTINUATION DUE TO ADVERSE EVENT	8	7.1	11	9.8	2	1.8	6	10.2	8	14.3	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG201.SAS
GENERATED: 17NOV2005 13:44:25 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY ADVERSE EVENT		155	90.6	151	89.9	138	82.6
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	0	0	1	0.6	0	0
	ANAEMIA	0	0	1	0.6	0	0
CARDIAC DISORDERS	TOTAL	11	6.4	9	5.4	2	1.2
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.6	0	0
	BRADYCARDIA	1	0.6	0	0	0	0
	MITRAL VALVE PROLAPSE	1	0.6	0	0	0	0
	PALPITATIONS	7	4.1	6	3.6	2	1.2
	TACHYCARDIA	2	1.2	2	1.2	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	3	1.8	4	2.4	4	2.4
	EAR CONGESTION	0	0	0	0	1	0.6
	EAR PAIN	0	0	1	0.6	1	0.6
	HYPERACUSIS	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EAR AND LABYRINTH DISORDERS	SENSATION OF PRESSURE IN EAR	0	0	1	0.6	0	0
	TINNITUS	2	1.2	2	1.2	2	1.2
	VERTIGO	1	0.6	0	0	0	0
ENDOCRINE DISORDERS	TOTAL	1	0.6	1	0.6	0	0
	HYPOTHYROIDISM	1	0.6	1	0.6	0	0
EYE DISORDERS	TOTAL	12	7.0	11	6.5	5	3.0
	ALTERED VISUAL DEPTH PERCEPTION	1	0.6	0	0	0	0
	CONJUNCTIVAL HYPERAEMIA	0	0	1	0.6	0	0
	DIPLOPIA	0	0	1	0.6	0	0
	DRY EYE	1	0.6	0	0	0	0
	EYE REDNESS	1	0.6	1	0.6	0	0
	EYE SWELLING	0	0	0	0	1	0.6
	LACRIMATION INCREASED	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	PHOTOPHOBIA	0	0	1	0.6	1	0.6
	VISION BLURRED	7	4.1	5	3.0	4	2.4
	VISUAL DISTURBANCE	3	1.8	1	0.6	0	0
GASTROINTESTINAL DISORDERS	TOTAL	98	57.3	95	56.5	72	43.1
	ABDOMINAL DISCOMFORT	1	0.6	0	0	0	0
	ABDOMINAL DISTENSION	1	0.6	1	0.6	1	0.6
	ABDOMINAL PAIN	4	2.3	2	1.2	4	2.4
	ABDOMINAL PAIN LOWER	0	0	0	0	1	0.6
	ABDOMINAL PAIN UPPER	0	0	2	1.2	4	2.4
	ABDOMINAL TENDERNESS	0	0	1	0.6	0	0
	CONSTIPATION	14	8.2	17	10.1	5	3.0
	DIARRHOEA	4	2.3	8	4.8	11	6.6
	DRY MOUTH	73	42.7	79	47.0	30	18.0
	DYSPEPSIA	12	7.0	11	6.5	8	4.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	DYSPHAGIA	4	2.3	2	1.2	0	0
	ERUCTATION	1	0.6	1	0.6	1	0.6
	FLATULENCE	6	3.5	1	0.6	4	2.4
	FOOD POISONING	1	0.6	0	0	0	0
	GASTRITIS	0	0	1	0.6	0	0
	GASTROOESOPHAGEAL REFLUX DISEASE	2	1.2	6	3.6	2	1.2
	GINGIVAL PAIN	0	0	0	0	1	0.6
	GLOSSODYNIA	1	0.6	0	0	1	0.6
	HYPOAESTHESIA ORAL	1	0.6	0	0	0	0
	IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.6
	LOOSE STOOLS	0	0	0	0	2	1.2
	NAUSEA	13	7.6	18	10.7	22	13.2
	OESOPHAGEAL SPASM	0	0	1	0.6	0	0
	RETCHING	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	SALIVARY HYPERSECRETION	0	0	1	0.6	0	0
	STOMACH DISCOMFORT	1	0.6	2	1.2	1	0.6
	STOMATITIS	0	0	1	0.6	0	0
	TONGUE COATED	1	0.6	0	0	0	0
	TONGUE DISORDER	0	0	1	0.6	0	0
	TOOTHACHE	2	1.2	3	1.8	5	3.0
	VOMITING	9	5.3	9	5.4	10	6.0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	40	23.4	37	22.0	31	18.6
	ASTHENIA	4	2.3	5	3.0	2	1.2
	CHEST DISCOMFORT	0	0	1	0.6	0	0
	CHEST PAIN	0	0	3	1.8	4	2.4
	CHILLS	1	0.6	1	0.6	0	0
	DIFFICULTY IN WALKING	0	0	0	0	1	0.6
	FATIGUE	16	9.4	19	11.3	13	7.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING HOT	0	0	0	0	1	0.6
	FEELING HOT AND COLD	1	0.6	0	0	1	0.6
	FEELING JITTERY	0	0	1	0.6	1	0.6
	GAIT DISTURBANCE	1	0.6	0	0	0	0
	HANGOVER	0	0	0	0	1	0.6
	INFLUENZA LIKE ILLNESS	1	0.6	0	0	5	3.0
	LETHARGY	8	4.7	2	1.2	1	0.6
	MALAISE	0	0	0	0	1	0.6
	NON-CARDIAC CHEST PAIN	0	0	2	1.2	0	0
	OEDEMA PERIPHERAL	4	2.3	2	1.2	2	1.2
	PAIN	4	2.3	1	0.6	1	0.6
	PITTING OEDEMA	0	0	0	0	2	1.2
	PYREXIA	3	1.8	3	1.8	0	0
	SLUGGISHNESS	1	0.6	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	THIRST	2	1.2	0	0	3	1.8
IMMUNE SYSTEM DISORDERS	TOTAL	2	1.2	1	0.6	2	1.2
	DECREASED IMMUNE RESPONSIVENESS	0	0	1	0.6	0	0
	HYPERSENSITIVITY	1	0.6	0	0	2	1.2
	SEASONAL ALLERGY	1	0.6	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	29	17.0	33	19.6	47	28.1
	BRONCHITIS	2	1.2	3	1.8	0	0
	CHLAMYDIAL INFECTION	1	0.6	0	0	0	0
	CONJUNCTIVITIS INFECTIVE	0	0	1	0.6	0	0
	EAR INFECTION	0	0	1	0.6	0	0
	GASTROENTERITIS	2	1.2	0	0	1	0.6
	GASTROENTERITIS VIRAL	1	0.6	2	1.2	1	0.6
	HERPES SIMPLEX	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	INFECTED INSECT BITE	0	0	1	0.6	0	0
	INFLUENZA	2	1.2	4	2.4	4	2.4
	LOCALISED INFECTION	0	0	0	0	1	0.6
	NASOPHARYNGITIS	6	3.5	11	6.5	10	6.0
	OTITIS EXTERNA	0	0	0	0	2	1.2
	PHARYNGITIS	1	0.6	0	0	1	0.6
	PHARYNGITIS STREPTOCOCCAL	0	0	2	1.2	0	0
	PNEUMONIA	2	1.2	0	0	1	0.6
	RESPIRATORY TRACT INFECTION	0	0	0	0	1	0.6
	RHINITIS	2	1.2	0	0	0	0
	SINUSITIS	0	0	1	0.6	5	3.0
	STREPTOCOCCAL INFECTION	1	0.6	0	0	0	0
	TONSILLITIS	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	TOOTH INFECTION	1	0.6	0	0	0	0
	UPPER RESPIRATORY TRACT INFECTION	7	4.1	10	6.0	14	8.4
	URINARY TRACT INFECTION	0	0	1	0.6	2	1.2
	VIRAL INFECTION	0	0	0	0	1	0.6
	VIRAL UPPER RESPIRATORY TRACT INFECTION	1	0.6	1	0.6	3	1.8
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	10	5.8	11	6.5	8	4.8
	ACCIDENTAL OVERDOSE	3	1.8	2	1.2	0	0
	ARTHROPOD BITE	1	0.6	0	0	0	0
	ARTHROPOD STING	0	0	0	0	1	0.6
	BACK INJURY	0	0	0	0	1	0.6
	CHEMICAL INJURY	0	0	1	0.6	0	0
	CONTUSION	2	1.2	3	1.8	0	0
	CORNEAL ABRASION	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FIBULA FRACTURE	0	0	1	0.6	0	0
	FOOT FRACTURE	1	0.6	0	0	0	0
	FRACTURED COCCYX	1	0.6	0	0	0	0
	HAND FRACTURE	0	0	1	0.6	1	0.6
	JOINT DISLOCATION	1	0.6	0	0	0	0
	JOINT SPRAIN	0	0	0	0	2	1.2
	MUSCLE STRAIN	0	0	0	0	1	0.6
	POST PROCEDURAL PAIN	1	0.6	0	0	1	0.6
	RIB FRACTURE	0	0	1	0.6	0	0
	SKIN LACERATION	0	0	2	1.2	0	0
	THERMAL BURN	1	0.6	1	0.6	0	0
	TOOTH INJURY	0	0	0	0	1	0.6
INVESTIGATIONS	TOTAL	12	7.0	13	7.7	8	4.8
	BLOOD PRESSURE INCREASED	0	0	2	1.2	2	1.2

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INVESTIGATIONS	BLOOD PRESSURE SYSTOLIC INCREASED	0	0	1	0.6	0	0
	BLOOD TRIGLYCERIDES INCREASED	1	0.6	0	0	0	0
	BODY TEMPERATURE INCREASED	0	0	0	0	1	0.6
	HEART RATE INCREASED	3	1.8	3	1.8	1	0.6
	HEART RATE IRREGULAR	2	1.2	0	0	0	0
	WEIGHT DECREASED	1	0.6	0	0	2	1.2
	WEIGHT INCREASED	7	4.1	9	5.4	3	1.8
METABOLISM AND NUTRITION DISORDERS	TOTAL	18	10.5	12	7.1	12	7.2
	ANOREXIA	0	0	2	1.2	1	0.6
	DECREASED APPETITE	4	2.3	2	1.2	3	1.8
	FOOD CRAVING	0	0	1	0.6	0	0
	GOUT	0	0	0	0	1	0.6
	HYPERGLYCAEMIA	1	0.6	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
METABOLISM AND NUTRITION DISORDERS	INCREASED APPETITE	13	7.6	7	4.2	7	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	28	16.4	25	14.9	27	16.2
	ARTHRALGIA	5	2.9	5	3.0	2	1.2
	BACK PAIN	8	4.7	3	1.8	13	7.8
	CHEST WALL PAIN	0	0	1	0.6	0	0
	FLANK PAIN	0	0	0	0	2	1.2
	MUSCLE CRAMP	3	1.8	0	0	3	1.8
	MUSCLE SPASMS	1	0.6	1	0.6	2	1.2
	MUSCLE TIGHTNESS	1	0.6	0	0	1	0.6
	MUSCLE TWITCHING	5	2.9	4	2.4	3	1.8
	MUSCULOSKELETAL DISCOMFORT	1	0.6	0	0	0	0
	MUSCULOSKELETAL STIFFNESS	3	1.8	1	0.6	1	0.6
	MYALGIA	3	1.8	5	3.0	4	2.4

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	OSTEOARTHRITIS	0	0	2	1.2	0	0
	PAIN IN EXTREMITY	1	0.6	3	1.8	1	0.6
	POLYMYALGIA	1	0.6	0	0	0	0
	SENSATION OF HEAVINESS	0	0	2	1.2	0	0
	TENDONITIS	0	0	0	0	1	0.6
	TRISMUS	0	0	0	0	1	0.6
NERVOUS SYSTEM DISORDERS	TOTAL	129	75.4	123	73.2	68	40.7
	AKATHISIA	5	2.9	2	1.2	2	1.2
	AMNESIA	1	0.6	0	0	0	0
	APHASIA	0	0	1	0.6	0	0
	ATAXIA	1	0.6	1	0.6	0	0
	BALANCE DISORDER	2	1.2	1	0.6	2	1.2
	CONVULSION	0	0	1	0.6	0	0
	COORDINATION ABNORMAL	1	0.6	2	1.2	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	DISTURBANCE IN ATTENTION	2	1.2	2	1.2	3	1.8
	DIZZINESS	24	14.0	27	16.1	9	5.4
	DIZZINESS POSTURAL	3	1.8	1	0.6	0	0
	DYSARTHRIA	3	1.8	9	5.4	1	0.6
	DYSGEUSIA	0	0	3	1.8	0	0
	DYSKINESIA	2	1.2	0	0	1	0.6
	DYSTONIA	1	0.6	1	0.6	0	0
	EXTRAPYRAMIDAL DISORDER	11	6.4	10	6.0	4	2.4
	HEADACHE	15	8.8	14	8.3	28	16.8
	HYPERSOMNIA	4	2.3	3	1.8	0	0
	HYPOAESTHESIA	2	1.2	4	2.4	3	1.8
	LETHARGY	1	0.6	0	0	2	1.2
	MEMORY IMPAIRMENT	1	0.6	1	0.6	0	0
	MIGRAINE	3	1.8	0	0	3	1.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	2	1.2	8	4.8	3	1.8
	PARAESTHESIA ORAL	0	0	0	0	1	0.6
	RESTLESS LEGS SYNDROME	3	1.8	4	2.4	0	0
	SEDATION	55	32.2	46	27.4	17	10.2
	SINUS HEADACHE	0	0	1	0.6	0	0
	SLEEP TALKING	0	0	1	0.6	0	0
	SOMNOLENCE	51	29.8	50	29.8	8	4.8
	SYNCOPE	1	0.6	3	1.8	1	0.6
	TENSION HEADACHE	1	0.6	2	1.2	0	0
	TREMOR	2	1.2	5	3.0	3	1.8
PSYCHIATRIC DISORDERS	TOTAL	36	21.1	31	18.5	34	20.4
	ABNORMAL DREAMS	1	0.6	3	1.8	1	0.6
	AGGRESSION	1	0.6	0	0	0	0
	AGITATION	1	0.6	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	ANGER	0	0	1	0.6	0	0
	ANORGASMIA	0	0	2	1.2	0	0
	ANXIETY	3	1.8	3	1.8	4	2.4
	BIPOLAR DISORDER	0	0	1	0.6	0	0
	BIPOLAR I DISORDER	1	0.6	0	0	0	0
	BRUXISM	0	0	0	0	1	0.6
	CONFUSIONAL STATE	2	1.2	3	1.8	0	0
	CONSTRICTED AFFECT	1	0.6	0	0	0	0
	DEPRESSION	0	0	0	0	1	0.6
	DISORIENTATION	0	0	0	0	1	0.6
	DISSOCIATION	1	0.6	0	0	0	0
	DYSPHEMIA	0	0	1	0.6	0	0
	ELEVATED MOOD	0	0	1	0.6	0	0
	EUPHORIC MOOD	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	FLAT AFFECT	1	0.6	0	0	0	0
	HALLUCINATION	1	0.6	0	0	0	0
	HALLUCINATION, AUDITORY	1	0.6	0	0	0	0
	HALLUCINATION, VISUAL	1	0.6	1	0.6	0	0
	HOSTILITY	0	0	1	0.6	0	0
	HYPOMANIA	2	1.2	1	0.6	3	1.8
	INITIAL INSOMNIA	1	0.6	0	0	0	0
	INSOMNIA	5	2.9	3	1.8	12	7.2
	IRRITABILITY	7	4.1	8	4.8	3	1.8
	LIBIDO DECREASED	3	1.8	2	1.2	4	2.4
	LIBIDO INCREASED	1	0.6	0	0	0	0
	LOGORRHOEA	0	0	1	0.6	0	0
	LOSS OF LIBIDO	3	1.8	1	0.6	0	0
	MANIA	0	0	0	0	2	1.2

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	NERVOUSNESS	1	0.6	0	0	0	0
	NIGHTMARE	4	2.3	0	0	2	1.2
	OBSESSIVE-COMPULSIVE DISORDER	0	0	1	0.6	0	0
	PANIC ATTACK	3	1.8	0	0	0	0
	PARANOIA	1	0.6	0	0	0	0
	PSYCHOMOTOR RETARDATION	1	0.6	0	0	0	0
	RESTLESSNESS	1	0.6	1	0.6	2	1.2
	SELF ESTEEM INFLATED	0	0	1	0.6	0	0
	SLEEP DISORDER	0	0	0	0	4	2.4
	STRESS SYMPTOMS	1	0.6	0	0	0	0
	SUICIDAL IDEATION	1	0.6	2	1.2	0	0
	SUICIDE ATTEMPT	0	0	1	0.6	0	0
RENAL AND URINARY DISORDERS	TOTAL	8	4.7	3	1.8	9	5.4
	DYSURIA	0	0	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	0	0	0	0	2	1.2
	NOCTURIA	0	0	0	0	1	0.6
	POLLAKIURIA	6	3.5	2	1.2	4	2.4
	URINARY HESITATION	0	0	0	0	1	0.6
	URINARY INCONTINENCE	1	0.6	1	0.6	1	0.6
	URINARY RETENTION	1	0.6	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	5	2.9	6	3.6	11	6.6
	BREAST TENDERNESS	1	0.6	0	0	1	0.6
	DYSMENORRHOEA	0	0	1	0.6	1	0.6
	EJACULATION DELAYED	0	0	0	0	1	0.6
	ERECTILE DYSFUNCTION	1	0.6	2	1.2	3	1.8
	MENORRHAGIA	2	1.2	1	0.6	1	0.6
	MENSTRUATION IRREGULAR	0	0	1	0.6	2	1.2
	SEXUAL DYSFUNCTION	1	0.6	0	0	1	0.6

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	UTERINE CYST	0	0	0	0	1	0.6
	UTERINE SPASM	0	0	1	0.6	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	21	12.3	22	13.1	18	10.8
	CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	1	0.6	0	0	0	0
	COUGH	4	2.3	4	2.4	3	1.8
	DRY THROAT	0	0	0	0	1	0.6
	DYSPNOEA	4	2.3	1	0.6	2	1.2
	EPISTAXIS	0	0	1	0.6	0	0
	LARYNGEAL OEDEMA	1	0.6	0	0	0	0
	NASAL CONGESTION	5	2.9	10	6.0	6	3.6
	NASAL DRYNESS	1	0.6	1	0.6	0	0
	PHARYNGOLARYNGEAL PAIN	5	2.9	5	3.0	7	4.2
	RESPIRATORY TRACT CONGESTION	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
GENERATED: 17NOV2005 13:44:28 iceadmn3

Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	SINUS CONGESTION	1	0.6	2	1.2	1	0.6
	SINUS PAIN	0	0	1	0.6	1	0.6
	THROAT TIGHTNESS	1	0.6	1	0.6	0	0
	YAWNING	1	0.6	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	3	1.8	3	1.8	13	7.8
	ACNE	0	0	0	0	2	1.2
	ALOPECIA	0	0	0	0	2	1.2
	DRY SKIN	0	0	0	0	1	0.6
	HYPERHIDROSIS	2	1.2	1	0.6	2	1.2
	HYPERKERATOSIS	0	0	0	0	1	0.6
	NIGHT SWEATS	0	0	1	0.6	2	1.2
	PHOTOSENSITIVITY REACTION	0	0	0	0	1	0.6
	PRURITUS	0	0	1	0.6	2	1.2
	RASH	1	0.6	1	0.6	3	1.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.3 Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH PRURITIC	0	0	1	0.6	0	0
SURGICAL AND MEDICAL PROCEDURES	TOTAL	1	0.6	0	0	2	1.2
	TOOTH EXTRACTION	1	0.6	0	0	1	0.6
	VASECTOMY	0	0	0	0	1	0.6
VASCULAR DISORDERS	TOTAL	10	5.8	12	7.1	9	5.4
	FLUSHING	0	0	0	0	1	0.6
	HOT FLUSH	2	1.2	0	0	4	2.4
	HYPERTENSION	4	2.3	2	1.2	1	0.6
	ORTHOSTATIC HYPOTENSION	4	2.3	10	6.0	3	1.8

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG202.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY ADVERSE EVENT		102	91.1	103	92.0	93	83.0	53	89.8	48	85.7	45	81.8
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	ANAEMIA	0	0	1	0.9	0	0	0	0	0	0	0	0
CARDIAC DISORDERS	TOTAL	5	4.5	7	6.3	2	1.8	6	10.2	2	3.6	0	0
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.9	0	0	0	0	0	0	0	0
	BRADYCARDIA	1	0.9	0	0	0	0	0	0	0	0	0	0
	MITRAL VALVE PROLAPSE	1	0.9	0	0	0	0	0	0	0	0	0	0
	PALPITATIONS	3	2.7	4	3.6	2	1.8	4	6.8	2	3.6	0	0
	TACHYCARDIA	0	0	2	1.8	0	0	2	3.4	0	0	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	3	2.7	3	2.7	1	0.9	0	0	1	1.8	3	5.5
	EAR CONGESTION	0	0	0	0	0	0	0	0	0	0	1	1.8
	EAR PAIN	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	HYPERACUSIS	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
EAR AND LABYRINTH DISORDERS	SENSATION OF PRESSURE IN EAR	0	0	1	0.9	0	0	0	0	0	0	0	0
	TINNITUS	2	1.8	1	0.9	1	0.9	0	0	1	1.8	1	1.8
	VERTIGO	1	0.9	0	0	0	0	0	0	0	0	0	0
ENDOCRINE DISORDERS	TOTAL	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	HYPOTHYROIDISM	1	0.9	1	0.9	0	0	0	0	0	0	0	0
EYE DISORDERS	TOTAL	6	5.4	6	5.4	3	2.7	6	10.2	5	8.9	2	3.6
	ALTERED VISUAL DEPTH PERCEPTION	1	0.9	0	0	0	0	0	0	0	0	0	0
	CONJUNCTIVAL HYPERAEMIA	0	0	1	0.9	0	0	0	0	0	0	0	0
	DIPLOPIA	0	0	1	0.9	0	0	0	0	0	0	0	0
	DRY EYE	0	0	0	0	0	0	1	1.7	0	0	0	0
	EYE REDNESS	0	0	0	0	0	0	1	1.7	1	1.8	0	0
	EYE SWELLING	0	0	0	0	1	0.9	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	LACRIMATION INCREASED	0	0	0	0	0	0	0	0	1	1.8	0	0
	PHOTOPHOBIA	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	VISION BLURRED	4	3.6	2	1.8	3	2.7	3	5.1	3	5.4	1	1.8
	VISUAL DISTURBANCE	1	0.9	1	0.9	0	0	2	3.4	0	0	0	0
GASTROINTESTINAL DISORDERS	TOTAL	62	55.4	65	58.0	47	42.0	36	61.0	30	53.6	25	45.5
	ABDOMINAL DISCOMFORT	1	0.9	0	0	0	0	0	0	0	0	0	0
	ABDOMINAL DISTENSION	1	0.9	1	0.9	0	0	0	0	0	0	1	1.8
	ABDOMINAL PAIN	2	1.8	2	1.8	3	2.7	2	3.4	0	0	1	1.8
	ABDOMINAL PAIN LOWER	0	0	0	0	1	0.9	0	0	0	0	0	0
	ABDOMINAL PAIN UPPER	0	0	2	1.8	2	1.8	0	0	0	0	2	3.6
	ABDOMINAL TENDERNESS	0	0	0	0	0	0	0	0	1	1.8	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GASTROINTESTINAL DISORDERS	CONSTIPATION	9	8.0	14	12.5	3	2.7	5	8.5	3	5.4	2	3.6
	DIARRHOEA	2	1.8	6	5.4	6	5.4	2	3.4	2	3.6	5	9.1
	DRY MOUTH	44	39.3	52	46.4	19	17.0	29	49.2	27	48.2	11	20.0
	DYSPEPSIA	8	7.1	5	4.5	6	5.4	4	6.8	6	10.7	2	3.6
	DYSPHAGIA	4	3.6	1	0.9	0	0	0	0	1	1.8	0	0
	ERUCTATION	1	0.9	1	0.9	0	0	0	0	0	0	1	1.8
	FLATULENCE	1	0.9	0	0	2	1.8	5	8.5	1	1.8	2	3.6
	FOOD POISONING	1	0.9	0	0	0	0	0	0	0	0	0	0
	GASTRITIS	0	0	1	0.9	0	0	0	0	0	0	0	0
	GASTROOESOPHAGEAL REFLUX DISEASE	1	0.9	5	4.5	2	1.8	1	1.7	1	1.8	0	0
	GINGIVAL PAIN	0	0	0	0	1	0.9	0	0	0	0	0	0
	GLOSSODYNIA	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	HYPOAESTHESIA ORAL	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.9	0	0	0	0	0	0
	LOOSE STOOLS	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	NAUSEA	8	7.1	16	14.3	17	15.2	5	8.5	2	3.6	5	9.1
	OESOPHAGEAL SPASM	0	0	1	0.9	0	0	0	0	0	0	0	0
	RETCHING	0	0	0	0	0	0	0	0	0	0	1	1.8
	SALIVARY HYPERSECRETION	0	0	1	0.9	0	0	0	0	0	0	0	0
	STOMACH DISCOMFORT	0	0	2	1.8	1	0.9	1	1.7	0	0	0	0
	STOMATITIS	0	0	0	0	0	0	0	0	1	1.8	0	0
	TONGUE COATED	0	0	0	0	0	0	1	1.7	0	0	0	0
	TONGUE DISORDER	0	0	0	0	0	0	0	0	1	1.8	0	0
	TOOTHACHE	2	1.8	0	0	5	4.5	0	0	3	5.4	0	0
	VOMITING	5	4.5	5	4.5	5	4.5	4	6.8	4	7.1	5	9.1

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	25	22.3	19	17.0	22	19.6	15	25.4	18	32.1	9	16.4
	ASTHENIA	2	1.8	3	2.7	1	0.9	2	3.4	2	3.6	1	1.8
	CHEST DISCOMFORT	0	0	1	0.9	0	0	0	0	0	0	0	0
	CHEST PAIN	0	0	3	2.7	3	2.7	0	0	0	0	1	1.8
	CHILLS	0	0	0	0	0	0	1	1.7	1	1.8	0	0
	DIFFICULTY IN WALKING	0	0	0	0	1	0.9	0	0	0	0	0	0
	FATIGUE	7	6.3	7	6.3	8	7.1	9	15.3	12	21.4	5	9.1
	FEELING HOT	0	0	0	0	1	0.9	0	0	0	0	0	0
	FEELING HOT AND COLD	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	FEELING JITTERY	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	GAIT DISTURBANCE	1	0.9	0	0	0	0	0	0	0	0	0	0
	HANGOVER	0	0	0	0	1	0.9	0	0	0	0	0	0
	INFLUENZA LIKE ILLNESS	1	0.9	0	0	5	4.5	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	LETHARGY	4	3.6	1	0.9	1	0.9	4	6.8	1	1.8	0	0
	MALAISE	0	0	0	0	1	0.9	0	0	0	0	0	0
	NON-CARDIAC CHEST PAIN	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	OEDEMA PERIPHERAL	2	1.8	2	1.8	1	0.9	2	3.4	0	0	1	1.8
	PAIN	2	1.8	1	0.9	1	0.9	2	3.4	0	0	0	0
	PITTING OEDEMA	0	0	0	0	2	1.8	0	0	0	0	0	0
	PYREXIA	3	2.7	1	0.9	0	0	0	0	2	3.6	0	0
	SLUGGISHNESS	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	THIRST	2	1.8	0	0	2	1.8	0	0	0	0	1	1.8
IMMUNE SYSTEM DISORDERS	TOTAL	2	1.8	1	0.9	1	0.9	0	0	0	0	1	1.8
	DECREASED IMMUNE RESPONSIVENESS	0	0	1	0.9	0	0	0	0	0	0	0	0
	HYPERSENSITIVITY	1	0.9	0	0	1	0.9	0	0	0	0	1	1.8
	SEASONAL ALLERGY	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	TOTAL	18	16.1	22	19.6	30	26.8	11	18.6	11	19.6	17	30.9
	BRONCHITIS	2	1.8	2	1.8	0	0	0	0	1	1.8	0	0
	CHLAMYDIAL INFECTION	1	0.9	0	0	0	0	0	0	0	0	0	0
	CONJUNCTIVITIS INFECTIVE	0	0	1	0.9	0	0	0	0	0	0	0	0
	EAR INFECTION	0	0	1	0.9	0	0	0	0	0	0	0	0
	GASTROENTERITIS	2	1.8	0	0	1	0.9	0	0	0	0	0	0
	GASTROENTERITIS VIRAL	1	0.9	1	0.9	1	0.9	0	0	1	1.8	0	0
	HERPES SIMPLEX	0	0	0	0	0	0	0	0	0	0	1	1.8
	INFECTED INSECT BITE	0	0	1	0.9	0	0	0	0	0	0	0	0
	INFLUENZA	1	0.9	3	2.7	2	1.8	1	1.7	1	1.8	2	3.6
	LOCALISED INFECTION	0	0	0	0	1	0.9	0	0	0	0	0	0
	NASOPHARYNGITIS	2	1.8	7	6.3	5	4.5	4	6.8	4	7.1	5	9.1

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INFECTIONS AND INFESTATIONS	OTITIS EXTERNA	0	0	0	0	2	1.8	0	0	0	0	0	0
	PHARYNGITIS	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	PHARYNGITIS STREPTOCOCCAL	0	0	2	1.8	0	0	0	0	0	0	0	0
	PNEUMONIA	1	0.9	0	0	0	0	1	1.7	0	0	1	1.8
	RESPIRATORY TRACT INFECTION	0	0	0	0	0	0	0	0	0	0	1	1.8
	RHINITIS	1	0.9	0	0	0	0	1	1.7	0	0	0	0
	SINUSITIS	0	0	0	0	3	2.7	0	0	1	1.8	2	3.6
	STREPTOCOCCAL INFECTION	1	0.9	0	0	0	0	0	0	0	0	0	0
	TONSILLITIS	0	0	0	0	1	0.9	0	0	0	0	0	0
	TOOTH INFECTION	1	0.9	0	0	0	0	0	0	0	0	0	0
	UPPER RESPIRATORY TRACT INFECTION	4	3.6	6	5.4	9	8.0	3	5.1	4	7.1	5	9.1
	URINARY TRACT INFECTION	0	0	1	0.9	2	1.8	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	0	0	0	0	0	0	0	0	0	0	1	1.8
	VIRAL UPPER RESPIRATORY TRACT INFECTION	0	0	0	0	3	2.7	1	1.7	1	1.8	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	8	7.1	8	7.1	5	4.5	2	3.4	3	5.4	3	5.5
	ACCIDENTAL OVERDOSE	3	2.7	2	1.8	0	0	0	0	0	0	0	0
	ARTHROPOD BITE	1	0.9	0	0	0	0	0	0	0	0	0	0
	ARTHROPOD STING	0	0	0	0	1	0.9	0	0	0	0	0	0
	BACK INJURY	0	0	0	0	1	0.9	0	0	0	0	0	0
	CHEMICAL INJURY	0	0	1	0.9	0	0	0	0	0	0	0	0
	CONTUSION	1	0.9	2	1.8	0	0	1	1.7	1	1.8	0	0
	CORNEAL ABRASION	0	0	1	0.9	0	0	0	0	0	0	0	0
	FIBULA FRACTURE	0	0	1	0.9	0	0	0	0	0	0	0	0
	FOOT FRACTURE	0	0	0	0	0	0	1	1.7	0	0	0	0
	FRACTURED COCCYX	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HAND FRACTURE	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	JOINT DISLOCATION	1	0.9	0	0	0	0	0	0	0	0	0	0
	JOINT SPRAIN	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	MUSCLE STRAIN	0	0	0	0	0	0	0	0	0	0	1	1.8
	POST PROCEDURAL PAIN	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	RIB FRACTURE	0	0	1	0.9	0	0	0	0	0	0	0	0
	SKIN LACERATION	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	THERMAL BURN	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	TOOTH INJURY	0	0	0	0	1	0.9	0	0	0	0	0	0
INVESTIGATIONS	TOTAL	9	8.0	9	8.0	8	7.1	3	5.1	4	7.1	0	0
	BLOOD PRESSURE INCREASED	0	0	2	1.8	2	1.8	0	0	0	0	0	0
	BLOOD PRESSURE SYSTOLIC INCREASED	0	0	0	0	0	0	0	0	1	1.8	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
INVESTIGATIONS	BLOOD TRIGLYCERIDES INCREASED	1	0.9	0	0	0	0	0	0	0	0	0	0
	BODY TEMPERATURE INCREASED	0	0	0	0	1	0.9	0	0	0	0	0	0
	HEART RATE INCREASED	3	2.7	1	0.9	1	0.9	0	0	2	3.6	0	0
	HEART RATE IRREGULAR	2	1.8	0	0	0	0	0	0	0	0	0	0
	WEIGHT DECREASED	0	0	0	0	2	1.8	1	1.7	0	0	0	0
	WEIGHT INCREASED	5	4.5	8	7.1	3	2.7	2	3.4	1	1.8	0	0
METABOLISM AND NUTRITION DISORDERS	TOTAL	13	11.6	9	8.0	6	5.4	5	8.5	3	5.4	6	10.9
	ANOREXIA	0	0	2	1.8	1	0.9	0	0	0	0	0	0
	DECREASED APPETITE	3	2.7	0	0	1	0.9	1	1.7	2	3.6	2	3.6
	FOOD CRAVING	0	0	1	0.9	0	0	0	0	0	0	0	0
	GOUT	0	0	0	0	0	0	0	0	0	0	1	1.8
	HYPERGLYCAEMIA	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
METABOLISM AND NUTRITION DISORDERS	INCREASED APPETITE	9	8.0	6	5.4	4	3.6	4	6.8	1	1.8	3	5.5
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	15	13.4	19	17.0	20	17.9	13	22.0	6	10.7	7	12.7
	ARTHRALGIA	4	3.6	5	4.5	2	1.8	1	1.7	0	0	0	0
	BACK PAIN	4	3.6	1	0.9	10	8.9	4	6.8	2	3.6	3	5.5
	CHEST WALL PAIN	0	0	1	0.9	0	0	0	0	0	0	0	0
	FLANK PAIN	0	0	0	0	1	0.9	0	0	0	0	1	1.8
	MUSCLE CRAMP	1	0.9	0	0	2	1.8	2	3.4	0	0	1	1.8
	MUSCLE SPASMS	0	0	1	0.9	0	0	1	1.7	0	0	2	3.6
	MUSCLE TIGHTNESS	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	MUSCLE TWITCHING	3	2.7	3	2.7	2	1.8	2	3.4	1	1.8	1	1.8
	MUSCULOSKELETAL DISCOMFORT	1	0.9	0	0	0	0	0	0	0	0	0	0
	MUSCULOSKELETAL STIFFNESS	1	0.9	1	0.9	1	0.9	2	3.4	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	1	0.9	4	3.6	4	3.6	2	3.4	1	1.8	0	0
	OSTEOARTHRITIS	0	0	2	1.8	0	0	0	0	0	0	0	0
	PAIN IN EXTREMITY	1	0.9	2	1.8	1	0.9	0	0	1	1.8	0	0
	POLYMYALGIA	1	0.9	0	0	0	0	0	0	0	0	0	0
	SENSATION OF HEAVINESS	0	0	1	0.9	0	0	0	0	1	1.8	0	0
	TENDONITIS	0	0	0	0	1	0.9	0	0	0	0	0	0
	TRISMUS	0	0	0	0	0	0	0	0	0	0	1	1.8
NERVOUS SYSTEM DISORDERS	TOTAL	86	76.8	84	75.0	42	37.5	43	72.9	39	69.6	26	47.3
	AKATHISIA	2	1.8	1	0.9	1	0.9	3	5.1	1	1.8	1	1.8
	AMNESIA	0	0	0	0	0	0	1	1.7	0	0	0	0
	APHASIA	0	0	0	0	0	0	0	0	1	1.8	0	0
	ATAXIA	0	0	1	0.9	0	0	1	1.7	0	0	0	0
	BALANCE DISORDER	1	0.9	1	0.9	1	0.9	1	1.7	0	0	1	1.8
	CONVULSION	0	0	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NERVOUS SYSTEM DISORDERS	COORDINATION ABNORMAL	1	0.9	1	0.9	0	0	0	0	1	1.8	0	0
	DISTURBANCE IN ATTENTION	1	0.9	2	1.8	1	0.9	1	1.7	0	0	2	3.6
	DIZZINESS	17	15.2	19	17.0	7	6.3	7	11.9	8	14.3	2	3.6
	DIZZINESS POSTURAL	2	1.8	1	0.9	0	0	1	1.7	0	0	0	0
	DYSARTHRIA	2	1.8	5	4.5	1	0.9	1	1.7	4	7.1	0	0
	DYSGEUSIA	0	0	3	2.7	0	0	0	0	0	0	0	0
	DYSKINESIA	1	0.9	0	0	0	0	1	1.7	0	0	1	1.8
	DYSTONIA	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	EXTRAPYRAMIDAL DISORDER	8	7.1	7	6.3	2	1.8	3	5.1	3	5.4	2	3.6
	HEADACHE	8	7.1	10	8.9	14	12.5	7	11.9	4	7.1	14	25.5
	HYPERSOMNIA	2	1.8	2	1.8	0	0	2	3.4	1	1.8	0	0
	HYPOAESTHESIA	2	1.8	2	1.8	2	1.8	0	0	2	3.6	1	1.8
	LETHARGY	1	0.9	0	0	1	0.9	0	0	0	0	1	1.8

(Continued)

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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	MEMORY IMPAIRMENT	0	0	0	0	0	0	1	1.7	1	1.8	0	0
	MIGRAINE	2	1.8	0	0	2	1.8	1	1.7	0	0	1	1.8
	PARAESTHESIA	2	1.8	4	3.6	3	2.7	0	0	4	7.1	0	0
	PARAESTHESIA ORAL	0	0	0	0	1	0.9	0	0	0	0	0	0
	RESTLESS LEGS SYNDROME	2	1.8	1	0.9	0	0	1	1.7	3	5.4	0	0
	SEDATION	35	31.3	31	27.7	13	11.6	20	33.9	15	26.8	4	7.3
	SINUS HEADACHE	0	0	1	0.9	0	0	0	0	0	0	0	0
	SLEEP TALKING	0	0	1	0.9	0	0	0	0	0	0	0	0
	SOMNOLENCE	37	33.0	35	31.3	4	3.6	14	23.7	15	26.8	4	7.3
	SYNCOPE	1	0.9	3	2.7	1	0.9	0	0	0	0	0	0
	TENSION HEADACHE	1	0.9	0	0	0	0	0	0	2	3.6	0	0
	TREMOR	1	0.9	3	2.7	2	1.8	1	1.7	2	3.6	1	1.8
PSYCHIATRIC DISORDERS	TOTAL	25	22.3	19	17.0	23	20.5	11	18.6	12	21.4	11	20.0
	ABNORMAL DREAMS	0	0	1	0.9	1	0.9	1	1.7	2	3.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	AGGRESSION	1	0.9	0	0	0	0	0	0	0	0	0	0
	AGITATION	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	ANGER	0	0	1	0.9	0	0	0	0	0	0	0	0
	ANORGASMIA	0	0	0	0	0	0	0	0	2	3.6	0	0
	ANXIETY	1	0.9	0	0	2	1.8	2	3.4	3	5.4	2	3.6
	BIPOLAR DISORDER	0	0	1	0.9	0	0	0	0	0	0	0	0
	BIPOLAR I DISORDER	1	0.9	0	0	0	0	0	0	0	0	0	0
	BRUXISM	0	0	0	0	0	0	0	0	0	0	1	1.8
	CONFUSIONAL STATE	2	1.8	1	0.9	0	0	0	0	2	3.6	0	0
	CONSTRICTED AFFECT	1	0.9	0	0	0	0	0	0	0	0	0	0
	DEPRESSION	0	0	0	0	0	0	0	0	0	0	1	1.8
	DISORIENTATION	0	0	0	0	0	0	0	0	0	0	1	1.8
	DISSOCIATION	1	0.9	0	0	0	0	0	0	0	0	0	0
	DYSPHEMIA	0	0	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	ELEVATED MOOD	0	0	1	0.9	0	0	0	0	0	0	0	0
	EUPHORIC MOOD	0	0	1	0.9	0	0	0	0	0	0	0	0
	FLAT AFFECT	1	0.9	0	0	0	0	0	0	0	0	0	0
	HALLUCINATION	1	0.9	0	0	0	0	0	0	0	0	0	0
	HALLUCINATION, AUDITORY	1	0.9	0	0	0	0	0	0	0	0	0	0
	HALLUCINATION, VISUAL	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	HOSTILITY	0	0	0	0	0	0	0	0	1	1.8	0	0
	HYPOMANIA	1	0.9	1	0.9	2	1.8	1	1.7	0	0	1	1.8
	INITIAL INSOMNIA	1	0.9	0	0	0	0	0	0	0	0	0	0
	INSOMNIA	4	3.6	3	2.7	8	7.1	1	1.7	0	0	4	7.3
	IRRITABILITY	6	5.4	6	5.4	3	2.7	1	1.7	2	3.6	0	0
	LIBIDO DECREASED	1	0.9	2	1.8	4	3.6	2	3.4	0	0	0	0
	LIBIDO INCREASED	0	0	0	0	0	0	1	1.7	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	LOGORRHOEA	0	0	1	0.9	0	0	0	0	0	0	0	0
	LOSS OF LIBIDO	3	2.7	1	0.9	0	0	0	0	0	0	0	0
	MANIA	0	0	0	0	2	1.8	0	0	0	0	0	0
	NERVOUSNESS	0	0	0	0	0	0	1	1.7	0	0	0	0
	NIGHTMARE	3	2.7	0	0	2	1.8	1	1.7	0	0	0	0
	OBSESSIVE-COMPULSIVE DISORDER	0	0	1	0.9	0	0	0	0	0	0	0	0
	PANIC ATTACK	1	0.9	0	0	0	0	2	3.4	0	0	0	0
	PARANOIA	1	0.9	0	0	0	0	0	0	0	0	0	0
	PSYCHOMOTOR RETARDATION	1	0.9	0	0	0	0	0	0	0	0	0	0
	RESTLESSNESS	0	0	1	0.9	1	0.9	1	1.7	0	0	1	1.8
	SELF ESTEEM INFLATED	0	0	1	0.9	0	0	0	0	0	0	0	0
	SLEEP DISORDER	0	0	0	0	3	2.7	0	0	0	0	1	1.8
	STRESS SYMPTOMS	0	0	0	0	0	0	1	1.7	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	SUICIDAL IDEATION	1	0.9	2	1.8	0	0	0	0	0	0	0	0
	SUICIDE ATTEMPT	0	0	0	0	0	0	0	0	1	1.8	0	0
RENAL AND URINARY DISORDERS	TOTAL	6	5.4	1	0.9	9	8.0	2	3.4	2	3.6	0	0
	DYSURIA	0	0	0	0	1	0.9	0	0	0	0	0	0
	MICTURITION URGENCY	0	0	0	0	2	1.8	0	0	0	0	0	0
	NOCTURIA	0	0	0	0	1	0.9	0	0	0	0	0	0
	POLLAKIURIA	5	4.5	1	0.9	4	3.6	1	1.7	1	1.8	0	0
	URINARY HESITATION	0	0	0	0	1	0.9	0	0	0	0	0	0
	URINARY INCONTINENCE	0	0	0	0	1	0.9	1	1.7	1	1.8	0	0
	URINARY RETENTION	1	0.9	0	0	0	0	0	0	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	3	2.7	4	3.6	7	6.3	2	3.4	2	3.6	4	7.3
	BREAST TENDERNESS	0	0	0	0	1	0.9	1	1.7	0	0	0	0
	DYSMENORRHOEA	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	EJACULATION DELAYED	0	0	0	0	0	0	0	0	0	0	1	1.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	0	0	1	0.9	2	1.8	1	1.7	1	1.8	1	1.8
	MENORRHAGIA	2	1.8	1	0.9	1	0.9	0	0	0	0	0	0
	MENSTRUATION IRREGULAR	0	0	0	0	1	0.9	0	0	1	1.8	1	1.8
	SEXUAL DYSFUNCTION	1	0.9	0	0	0	0	0	0	0	0	1	1.8
	UTERINE CYST	0	0	0	0	1	0.9	0	0	0	0	0	0
	UTERINE SPASM	0	0	1	0.9	0	0	0	0	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	12	10.7	12	10.7	9	8.0	9	15.3	10	17.9	9	16.4
	CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	0	0	0	0	0	1	1.7	0	0	0	0
	COUGH	3	2.7	4	3.6	1	0.9	1	1.7	0	0	2	3.6
	DRY THROAT	0	0	0	0	0	0	0	0	0	0	1	1.8
	DYSPNOEA	1	0.9	1	0.9	1	0.9	3	5.1	0	0	1	1.8
	EPISTAXIS	0	0	0	0	0	0	0	0	1	1.8	0	0
	LARYNGEAL OEDEMA	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	NASAL CONGESTION	3	2.7	5	4.5	4	3.6	2	3.4	5	8.9	2	3.6
	NASAL DRYNESS	1	0.9	0	0	0	0	0	0	1	1.8	0	0
	PHARYNGOLARYNGEAL PAIN	4	3.6	4	3.6	3	2.7	1	1.7	1	1.8	4	7.3
	RESPIRATORY TRACT CONGESTION	0	0	1	0.9	0	0	0	0	0	0	0	0
	SINUS CONGESTION	1	0.9	1	0.9	0	0	0	0	1	1.8	1	1.8
	SINUS PAIN	0	0	1	0.9	0	0	0	0	0	0	1	1.8
	THROAT TIGHTNESS	0	0	0	0	0	0	1	1.7	1	1.8	0	0
	YAWNING	1	0.9	0	0	0	0	0	0	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	2	1.8	2	1.8	9	8.0	1	1.7	1	1.8	4	7.3
	ACNE	0	0	0	0	2	1.8	0	0	0	0	0	0
	ALOPECIA	0	0	0	0	2	1.8	0	0	0	0	0	0
	DRY SKIN	0	0	0	0	0	0	0	0	0	0	1	1.8
	HYPERHIDROSIS	1	0.9	0	0	1	0.9	1	1.7	1	1.8	1	1.8

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	HYPERKERATOSIS	0	0	0	0	1	0.9	0	0	0	0	0	0
	NIGHT SWEATS	0	0	1	0.9	2	1.8	0	0	0	0	0	0
	PHOTOSENSITIVITY REACTION	0	0	0	0	1	0.9	0	0	0	0	0	0
	PRURITUS	0	0	1	0.9	1	0.9	0	0	0	0	1	1.8
	RASH	1	0.9	1	0.9	2	1.8	0	0	0	0	1	1.8
	RASH PRURITIC	0	0	1	0.9	0	0	0	0	0	0	0	0
SURGICAL AND MEDICAL PROCEDURES	TOTAL	1	0.9	0	0	1	0.9	0	0	0	0	1	1.8
	TOOTH EXTRACTION	1	0.9	0	0	1	0.9	0	0	0	0	0	0
	VASECTOMY	0	0	0	0	0	0	0	0	0	0	1	1.8
VASCULAR DISORDERS	TOTAL	5	4.5	9	8.0	6	5.4	5	8.5	3	5.4	3	5.5
	FLUSHING	0	0	0	0	1	0.9	0	0	0	0	0	0
	HOT FLUSH	1	0.9	0	0	2	1.8	1	1.7	0	0	2	3.6
	HYPERTENSION	2	1.8	1	0.9	1	0.9	2	3.4	1	1.8	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.4 Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	2	1.8	8	7.1	2	1.8	2	3.4	2	3.6	1	1.8

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG203.SAS
GENERATED: 17NOV2005 13:44:31 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DRY MOUTH	73	42.7	79	47.0	30	18.0
SEDATION	55	32.2	46	27.4	17	10.2
SOMNOLENCE	51	29.8	50	29.8	8	4.8
DIZZINESS	24	14.0	27	16.1	9	5.4
FATIGUE	16	9.4	19	11.3	13	7.8
HEADACHE	15	8.8	14	8.3	28	16.8
CONSTIPATION	14	8.2	17	10.1	5	3.0
INCREASED APPETITE	13	7.6	7	4.2	7	4.2
NAUSEA	13	7.6	18	10.7	22	13.2
DYSPEPSIA	12	7.0	11	6.5	8	4.8
EXTRAPYRAMIDAL DISORDER	11	6.4	10	6.0	4	2.4
LETHARGY	9	5.3	2	1.2	3	1.8
VOMITING	9	5.3	9	5.4	10	6.0
BACK PAIN	8	4.7	3	1.8	13	7.8

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
GENERATED: 17NOV2005 13:44:35 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
IRRITABILITY	7	4.1	8	4.8	3	1.8
PALPITATIONS	7	4.1	6	3.6	2	1.2
UPPER RESPIRATORY TRACT INFECTION	7	4.1	10	6.0	14	8.4
VISION BLURRED	7	4.1	5	3.0	4	2.4
WEIGHT INCREASED	7	4.1	9	5.4	3	1.8
FLATULENCE	6	3.5	1	0.6	4	2.4
NASOPHARYNGITIS	6	3.5	11	6.5	10	6.0
POLLAKIURIA	6	3.5	2	1.2	4	2.4
AKATHISIA	5	2.9	2	1.2	2	1.2
ARTHRALGIA	5	2.9	5	3.0	2	1.2
INSOMNIA	5	2.9	3	1.8	12	7.2
MUSCLE TWITCHING	5	2.9	4	2.4	3	1.8
NASAL CONGESTION	5	2.9	10	6.0	6	3.6
PHARYNGOLARYNGEAL PAIN	5	2.9	5	3.0	7	4.2

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
GENERATED: 17NOV2005 13:44:35 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ABDOMINAL PAIN	4	2.3	2	1.2	4	2.4
ASTHENIA	4	2.3	5	3.0	2	1.2
COUGH	4	2.3	4	2.4	3	1.8
DECREASED APPETITE	4	2.3	2	1.2	3	1.8
DIARRHOEA	4	2.3	8	4.8	11	6.6
DYSPHAGIA	4	2.3	2	1.2	0	0
DYSPNOEA	4	2.3	1	0.6	2	1.2
HYPERSOMNIA	4	2.3	3	1.8	0	0
HYPERTENSION	4	2.3	2	1.2	1	0.6
NIGHTMARE	4	2.3	0	0	2	1.2
OEDEMA PERIPHERAL	4	2.3	2	1.2	2	1.2
ORTHOSTATIC HYPOTENSION	4	2.3	10	6.0	3	1.8
PAIN	4	2.3	1	0.6	1	0.6
ACCIDENTAL OVERDOSE	3	1.8	2	1.2	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
GENERATED: 17NOV2005 13:44:35 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANXIETY	3	1.8	3	1.8	4	2.4
DIZZINESS POSTURAL	3	1.8	1	0.6	0	0
DYSARTHRIA	3	1.8	9	5.4	1	0.6
HEART RATE INCREASED	3	1.8	3	1.8	1	0.6
LIBIDO DECREASED	3	1.8	2	1.2	4	2.4
LOSS OF LIBIDO	3	1.8	1	0.6	0	0
MIGRAINE	3	1.8	0	0	3	1.8
MUSCLE CRAMP	3	1.8	0	0	3	1.8
MUSCULOSKELETAL STIFFNESS	3	1.8	1	0.6	1	0.6
MYALGIA	3	1.8	5	3.0	4	2.4
PANIC ATTACK	3	1.8	0	0	0	0
PYREXIA	3	1.8	3	1.8	0	0
RESTLESS LEGS SYNDROME	3	1.8	4	2.4	0	0
VISUAL DISTURBANCE	3	1.8	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
GENERATED: 17NOV2005 13:44:35 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BALANCE DISORDER	2	1.2	1	0.6	2	1.2
BRONCHITIS	2	1.2	3	1.8	0	0
CONFUSIONAL STATE	2	1.2	3	1.8	0	0
CONTUSION	2	1.2	3	1.8	0	0
DISTURBANCE IN ATTENTION	2	1.2	2	1.2	3	1.8
DYSKINESIA	2	1.2	0	0	1	0.6
GASTROENTERITIS	2	1.2	0	0	1	0.6
GASTROOESOPHAGEAL REFLUX DISEASE	2	1.2	6	3.6	2	1.2
HEART RATE IRREGULAR	2	1.2	0	0	0	0
HOT FLUSH	2	1.2	0	0	4	2.4
HYPERHIDROSIS	2	1.2	1	0.6	2	1.2
HYPOAESTHESIA	2	1.2	4	2.4	3	1.8
HYPOMANIA	2	1.2	1	0.6	3	1.8
INFLUENZA	2	1.2	4	2.4	4	2.4

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
GENERATED: 17NOV2005 13:44:35 iceadmn3

Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MENORRHAGIA	2	1.2	1	0.6	1	0.6
PARAESTHESIA	2	1.2	8	4.8	3	1.8
PNEUMONIA	2	1.2	0	0	1	0.6
RHINITIS	2	1.2	0	0	0	0
TACHYCARDIA	2	1.2	2	1.2	0	0
THIRST	2	1.2	0	0	3	1.8
TINNITUS	2	1.2	2	1.2	2	1.2
TOOTHACHE	2	1.2	3	1.8	5	3.0
TREMOR	2	1.2	5	3.0	3	1.8
ABDOMINAL DISCOMFORT	1	0.6	0	0	0	0
ABDOMINAL DISTENSION	1	0.6	1	0.6	1	0.6
ABNORMAL DREAMS	1	0.6	3	1.8	1	0.6
AGGRESSION	1	0.6	0	0	0	0
AGITATION	1	0.6	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PREFERRED TERM						
ALTERED VISUAL DEPTH PERCEPTION	1	0.6	0	0	0	0
AMNESIA	1	0.6	0	0	0	0
ARTHROPOD BITE	1	0.6	0	0	0	0
ATAXIA	1	0.6	1	0.6	0	0
BIPOLAR I DISORDER	1	0.6	0	0	0	0
BLOOD TRIGLYCERIDES INCREASED	1	0.6	0	0	0	0
BRADYCARDIA	1	0.6	0	0	0	0
BREAST TENDERNESS	1	0.6	0	0	1	0.6
CHILLS	1	0.6	1	0.6	0	0
CHLAMYDIAL INFECTION	1	0.6	0	0	0	0
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	1	0.6	0	0	0	0
CONSTRICTED AFFECT	1	0.6	0	0	0	0
COORDINATION ABNORMAL	1	0.6	2	1.2	0	0
DISSOCIATION	1	0.6	0	0	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DRY EYE	1	0.6	0	0	0	0
DYSTONIA	1	0.6	1	0.6	0	0
ERECTILE DYSFUNCTION	1	0.6	2	1.2	3	1.8
ERUCTATION	1	0.6	1	0.6	1	0.6
EYE REDNESS	1	0.6	1	0.6	0	0
FEELING HOT AND COLD	1	0.6	0	0	1	0.6
FLAT AFFECT	1	0.6	0	0	0	0
FOOD POISONING	1	0.6	0	0	0	0
FOOT FRACTURE	1	0.6	0	0	0	0
FRACTURED COCCYX	1	0.6	0	0	0	0
GAIT DISTURBANCE	1	0.6	0	0	0	0
GASTROENTERITIS VIRAL	1	0.6	2	1.2	1	0.6
GLOSSODYNIA	1	0.6	0	0	1	0.6
HALLUCINATION	1	0.6	0	0	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
HALLUCINATION, AUDITORY	1	0.6	0	0	0	0
HALLUCINATION, VISUAL	1	0.6	1	0.6	0	0
HYPERGLYCAEMIA	1	0.6	0	0	0	0
HYPERSENSITIVITY	1	0.6	0	0	2	1.2
HYPOAESTHESIA ORAL	1	0.6	0	0	0	0
HYPOTHYROIDISM	1	0.6	1	0.6	0	0
INFLUENZA LIKE ILLNESS	1	0.6	0	0	5	3.0
INITIAL INSOMNIA	1	0.6	0	0	0	0
JOINT DISLOCATION	1	0.6	0	0	0	0
LARYNGEAL OEDEMA	1	0.6	0	0	0	0
LIBIDO INCREASED	1	0.6	0	0	0	0
MEMORY IMPAIRMENT	1	0.6	1	0.6	0	0
MITRAL VALVE PROLAPSE	1	0.6	0	0	0	0
MUSCLE SPASMS	1	0.6	1	0.6	2	1.2

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCLE TIGHTNESS	1	0.6	0	0	1	0.6
MUSCULOSKELETAL DISCOMFORT	1	0.6	0	0	0	0
NASAL DRYNESS	1	0.6	1	0.6	0	0
NERVOUSNESS	1	0.6	0	0	0	0
PAIN IN EXTREMITY	1	0.6	3	1.8	1	0.6
PARANOIA	1	0.6	0	0	0	0
PHARYNGITIS	1	0.6	0	0	1	0.6
POLYMYALGIA	1	0.6	0	0	0	0
POST PROCEDURAL PAIN	1	0.6	0	0	1	0.6
PSYCHOMOTOR RETARDATION	1	0.6	0	0	0	0
RASH	1	0.6	1	0.6	3	1.8
RESTLESSNESS	1	0.6	1	0.6	2	1.2
SEASONAL ALLERGY	1	0.6	0	0	0	0
SEXUAL DYSFUNCTION	1	0.6	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SINUS CONGESTION	1	0.6	2	1.2	1	0.6
SLUGGISHNESS	1	0.6	1	0.6	0	0
STOMACH DISCOMFORT	1	0.6	2	1.2	1	0.6
STREPTOCOCCAL INFECTION	1	0.6	0	0	0	0
STRESS SYMPTOMS	1	0.6	0	0	0	0
SUICIDAL IDEATION	1	0.6	2	1.2	0	0
SYNCOPE	1	0.6	3	1.8	1	0.6
TENSION HEADACHE	1	0.6	2	1.2	0	0
THERMAL BURN	1	0.6	1	0.6	0	0
THROAT TIGHTNESS	1	0.6	1	0.6	0	0
TONGUE COATED	1	0.6	0	0	0	0
TOOTH EXTRACTION	1	0.6	0	0	1	0.6
TOOTH INFECTION	1	0.6	0	0	0	0
URINARY INCONTINENCE	1	0.6	1	0.6	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
URINARY RETENTION	1	0.6	0	0	0	0
VERTIGO	1	0.6	0	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION	1	0.6	1	0.6	3	1.8
WEIGHT DECREASED	1	0.6	0	0	2	1.2
YAWNING	1	0.6	0	0	0	0
ABDOMINAL PAIN UPPER	0	0	2	1.2	4	2.4
ABDOMINAL TENDERNESS	0	0	1	0.6	0	0
ACUTE MYOCARDIAL INFARCTION	0	0	1	0.6	0	0
ANAEMIA	0	0	1	0.6	0	0
ANGER	0	0	1	0.6	0	0
ANOREXIA	0	0	2	1.2	1	0.6
ANORGASMIA	0	0	2	1.2	0	0
APHASIA	0	0	1	0.6	0	0
BIPOLAR DISORDER	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
BLOOD PRESSURE INCREASED	0	0	2	1.2	2	1.2
BLOOD PRESSURE SYSTOLIC INCREASED	0	0	1	0.6	0	0
CHEMICAL INJURY	0	0	1	0.6	0	0
CHEST DISCOMFORT	0	0	1	0.6	0	0
CHEST PAIN	0	0	3	1.8	4	2.4
CHEST WALL PAIN	0	0	1	0.6	0	0
CONJUNCTIVAL HYPERAEMIA	0	0	1	0.6	0	0
CONJUNCTIVITIS INFECTIVE	0	0	1	0.6	0	0
CONVULSION	0	0	1	0.6	0	0
CORNEAL ABRASION	0	0	1	0.6	0	0
DECREASED IMMUNE RESPONSIVENESS	0	0	1	0.6	0	0
DIPLOPIA	0	0	1	0.6	0	0
DYSGEUSIA	0	0	3	1.8	0	0
DYSMENORRHOEA	0	0	1	0.6	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
DYSPHEMIA	0	0	1	0.6	0	0
EAR INFECTION	0	0	1	0.6	0	0
EAR PAIN	0	0	1	0.6	1	0.6
ELEVATED MOOD	0	0	1	0.6	0	0
EPISTAXIS	0	0	1	0.6	0	0
EUPHORIC MOOD	0	0	1	0.6	0	0
FEELING JITTERY	0	0	1	0.6	1	0.6
FIBULA FRACTURE	0	0	1	0.6	0	0
FOOD CRAVING	0	0	1	0.6	0	0
GASTRITIS	0	0	1	0.6	0	0
HAND FRACTURE	0	0	1	0.6	1	0.6
HOSTILITY	0	0	1	0.6	0	0
INFECTED INSECT BITE	0	0	1	0.6	0	0
LACRIMATION INCREASED	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
LOGORRHOEA	0	0	1	0.6	0	0
MENSTRUATION IRREGULAR	0	0	1	0.6	2	1.2
NIGHT SWEATS	0	0	1	0.6	2	1.2
NON-CARDIAC CHEST PAIN	0	0	2	1.2	0	0
OBSESSIVE-COMPULSIVE DISORDER	0	0	1	0.6	0	0
OESOPHAGEAL SPASM	0	0	1	0.6	0	0
OSTEOARTHRITIS	0	0	2	1.2	0	0
PHARYNGITIS STREPTOCOCCAL	0	0	2	1.2	0	0
PHOTOPHOBIA	0	0	1	0.6	1	0.6
PRURITUS	0	0	1	0.6	2	1.2
RASH PRURITIC	0	0	1	0.6	0	0
RESPIRATORY TRACT CONGESTION	0	0	1	0.6	0	0
RIB FRACTURE	0	0	1	0.6	0	0
SALIVARY HYPERSECRETION	0	0	1	0.6	0	0

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SELF ESTEEM INFLATED	0	0	1	0.6	0	0
SENSATION OF HEAVINESS	0	0	2	1.2	0	0
SENSATION OF PRESSURE IN EAR	0	0	1	0.6	0	0
SINUS HEADACHE	0	0	1	0.6	0	0
SINUS PAIN	0	0	1	0.6	1	0.6
SINUSITIS	0	0	1	0.6	5	3.0
SKIN LACERATION	0	0	2	1.2	0	0
SLEEP TALKING	0	0	1	0.6	0	0
STOMATITIS	0	0	1	0.6	0	0
SUICIDE ATTEMPT	0	0	1	0.6	0	0
TONGUE DISORDER	0	0	1	0.6	0	0
URINARY TRACT INFECTION	0	0	1	0.6	2	1.2
UTERINE SPASM	0	0	1	0.6	0	0
ABDOMINAL PAIN LOWER	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ACNE	0	0	0	0	2	1.2
ALOPECIA	0	0	0	0	2	1.2
ARTHROPOD STING	0	0	0	0	1	0.6
BACK INJURY	0	0	0	0	1	0.6
BODY TEMPERATURE INCREASED	0	0	0	0	1	0.6
BRUXISM	0	0	0	0	1	0.6
DEPRESSION	0	0	0	0	1	0.6
DIFFICULTY IN WALKING	0	0	0	0	1	0.6
DISORIENTATION	0	0	0	0	1	0.6
DRY SKIN	0	0	0	0	1	0.6
DRY THROAT	0	0	0	0	1	0.6
DYSURIA	0	0	0	0	1	0.6
EAR CONGESTION	0	0	0	0	1	0.6
EJACULATION DELAYED	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE SWELLING	0	0	0	0	1	0.6
FEELING HOT	0	0	0	0	1	0.6
FLANK PAIN	0	0	0	0	2	1.2
FLUSHING	0	0	0	0	1	0.6
GINGIVAL PAIN	0	0	0	0	1	0.6
GOUT	0	0	0	0	1	0.6
HANGOVER	0	0	0	0	1	0.6
HERPES SIMPLEX	0	0	0	0	1	0.6
HYPERACUSIS	0	0	0	0	1	0.6
HYPERKERATOSIS	0	0	0	0	1	0.6
IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.6
JOINT SPRAIN	0	0	0	0	2	1.2
LOCALISED INFECTION	0	0	0	0	1	0.6
LOOSE STOOLS	0	0	0	0	2	1.2

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MALAISE	0	0	0	0	1	0.6
MANIA	0	0	0	0	2	1.2
MICTURITION URGENCY	0	0	0	0	2	1.2
MUSCLE STRAIN	0	0	0	0	1	0.6
NOCTURIA	0	0	0	0	1	0.6
OTITIS EXTERNA	0	0	0	0	2	1.2
PARAESTHESIA ORAL	0	0	0	0	1	0.6
PHOTOSENSITIVITY REACTION	0	0	0	0	1	0.6
PITTING OEDEMA	0	0	0	0	2	1.2
RESPIRATORY TRACT INFECTION	0	0	0	0	1	0.6
RETCHING	0	0	0	0	1	0.6
SLEEP DISORDER	0	0	0	0	4	2.4
TENDONITIS	0	0	0	0	1	0.6
TONSILLITIS	0	0	0	0	1	0.6

(Continued)

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

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Table 11.3.2.5 Adverse Events by Decreasing Incidence
Safety Population

	TREATMENT					
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
TOOTH INJURY	0	0	0	0	1	0.6
TRISMUS	0	0	0	0	1	0.6
URINARY HESITATION	0	0	0	0	1	0.6
UTERINE CYST	0	0	0	0	1	0.6
VASECTOMY	0	0	0	0	1	0.6
VIRAL INFECTION	0	0	0	0	1	0.6

Note: Table is ordered by decreasing incidence in the Quetiapine 300 mg group.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG204.SAS
GENERATED: 17NOV2005 13:44:35 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS																								
TOTAL	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
ANAEMIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
CARDIAC DISORDERS																								
TOTAL	6	3.5	4	2.3	1	0.6	11	6.4	3	1.8	4	2.4	2	1.2	9	5.4	0	0	2	1.2	0	0	2	1.2
ACUTE MYOCARDIAL INFARCTION	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
BRADYCARDIA	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MITRAL VALVE PROLAPSE	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PALPITATIONS	4	2.3	3	1.8	0	0	7	4.1	3	1.8	3	1.8	0	0	6	3.6	0	0	2	1.2	0	0	2	1.2
TACHYCARDIA	2	1.2	0	0	0	0	2	1.2	0	0	1	0.6	1	0.6	2	1.2	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
EAR AND LABYRINTH DISORDERS																								
TOTAL	2	1.2	1	0.6	0	0	3	1.8	2	1.2	2	1.2	0	0	4	2.4	3	1.8	1	0.6	0	0	4	2.4
EAR CONGESTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
EAR PAIN	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
HYPERACUSIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
SENSATION OF PRESSURE IN EAR	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
TINNITUS	2	1.2	0	0	0	0	2	1.2	0	0	2	1.2	0	0	2	1.2	2	1.2	0	0	0	0	2	1.2
VERTIGO	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ENDOCRINE DISORDERS																								
TOTAL	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
HYPOTHYROIDISM	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
EYE DISORDERS																								
TOTAL	6	3.5	7	4.1	0	0	12	7.0	9	5.4	2	1.2	0	0	11	6.5	3	1.8	2	1.2	0	0	5	3.0
ALTERED VISUAL DEPTH PERCEPTION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CONJUNCTIVAL HYPERAEMIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
DIPLOPIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
DRY EYE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE REDNESS	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
EYE SWELLING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
LACRIMATION INCREASED	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
PHOTOPHOBIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6
VISION BLURRED	4	2.3	3	1.8	0	0	7	4.1	3	1.8	2	1.2	0	0	5	3.0	3	1.8	1	0.6	0	0	4	2.4
VISUAL DISTURBANCE	2	1.2	1	0.6	0	0	3	1.8	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
TOTAL	60	35.1	43	25.1	13	7.6	98	57.3	63	37.5	46	27.4	12	7.1	95	56.5	59	35.3	23	13.8	3	1.8	72	43.1
ABDOMINAL DISCOMFORT	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABDOMINAL DISTENSION	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
ABDOMINAL PAIN	1	0.6	2	1.2	1	0.6	4	2.3	2	1.2	0	0	0	0	2	1.2	2	1.2	1	0.6	1	0.6	4	2.4
ABDOMINAL PAIN LOWER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
ABDOMINAL PAIN UPPER	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2	3	1.8	1	0.6	0	0	4	2.4
ABDOMINAL TENDERNESS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
CONSTIPATION	9	5.3	4	2.3	1	0.6	14	8.2	8	4.8	8	4.8	1	0.6	17	10.1	4	2.4	1	0.6	0	0	5	3.0
DIARRHOEA	2	1.2	2	1.2	0	0	4	2.3	3	1.8	4	2.4	1	0.6	8	4.8	4	2.4	6	3.6	1	0.6	11	6.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
DRY MOUTH	38	22.2	27	15.8	8	4.7	73	42.7	44	26.2	30	17.9	5	3.0	79	47.0	27	16.2	3	1.8	0	0	30	18.0
DYSPEPSIA	7	4.1	3	1.8	2	1.2	12	7.0	5	3.0	6	3.6	0	0	11	6.5	5	3.0	3	1.8	0	0	8	4.8
DYSPHAGIA	1	0.6	3	1.8	0	0	4	2.3	0	0	0	0	2	1.2	2	1.2	0	0	0	0	0	0	0	0
ERUCTATION	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
FLATULENCE	4	2.3	1	0.6	1	0.6	6	3.5	0	0	1	0.6	0	0	1	0.6	4	2.4	0	0	0	0	4	2.4
FOOD POISONING	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GASTRITIS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	1	0.6	0	0	2	1.2	5	3.0	0	0	1	0.6	6	3.6	2	1.2	0	0	0	0	2	1.2
GINGIVAL PAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
GLOSSODYNIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
HYPOAESTHESIA ORAL	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
IRRITABLE BOWEL SYNDROME	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
LOOSE STOOLS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2
NAUSEA	4	2.3	7	4.1	2	1.2	13	7.6	11	6.5	5	3.0	2	1.2	18	10.7	17	10.2	5	3.0	0	0	22	13.2
OESOPHAGEAL SPASM	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
RETCHING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
SALIVARY HYPERSECRETION	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
STOMACH DISCOMFORT	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.2	0	0	1	0.6	0	0	1	0.6
STOMATITIS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
TONGUE COATED	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TONGUE DISORDER	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
TOOTHACHE	0	0	2	1.2	0	0	2	1.2	0	0	2	1.2	1	0.6	3	1.8	3	1.8	1	0.6	1	0.6	5	3.0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS																								
VOMITING	4	2.3	5	2.9	0	0	9	5.3	5	3.0	3	1.8	1	0.6	9	5.4	6	3.6	4	2.4	0	0	10	6.0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
TOTAL	17	9.9	22	12.9	4	2.3	40	23.4	14	8.3	14	8.3	10	6.0	37	22.0	17	10.2	13	7.8	2	1.2	31	18.6
ASTHENIA	2	1.2	2	1.2	0	0	4	2.3	4	2.4	1	0.6	0	0	5	3.0	2	1.2	0	0	0	0	2	1.2
CHEST DISCOMFORT	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
CHEST PAIN	0	0	0	0	0	0	0	0	1	0.6	1	0.6	1	0.6	3	1.8	2	1.2	1	0.6	1	0.6	4	2.4
CHILLS	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
DIFFICULTY IN WALKING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
FATIGUE	5	2.9	8	4.7	3	1.8	16	9.4	3	1.8	8	4.8	8	4.8	19	11.3	6	3.6	6	3.6	1	0.6	13	7.8
FEELING HOT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
FEELING HOT AND COLD	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
FEELING JITTERY	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
GAIT DISTURBANCE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HANGOVER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
INFLUENZA LIKE ILLNESS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	2	1.2	3	1.8	0	0	5	3.0
LETHARGY	2	1.2	4	2.3	2	1.2	8	4.7	1	0.6	1	0.6	0	0	2	1.2	0	0	1	0.6	0	0	1	0.6
MALAISE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NON-CARDIAC CHEST PAIN	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2	0	0	0	0	0	0	0	0
OEDEMA PERIPHERAL	2	1.2	2	1.2	0	0	4	2.3	2	1.2	0	0	0	0	2	1.2	2	1.2	0	0	0	0	2	1.2
PAIN	1	0.6	3	1.8	0	0	4	2.3	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS																								
PITTING OEDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2
PYREXIA	1	0.6	2	1.2	0	0	3	1.8	2	1.2	1	0.6	0	0	3	1.8	0	0	0	0	0	0	0	0
SLUGGISHNESS	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
THIRST	2	1.2	0	0	0	0	2	1.2	0	0	0	0	0	0	0	0	2	1.2	1	0.6	0	0	3	1.8
IMMUNE SYSTEM DISORDERS																								
TOTAL	0	0	2	1.2	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.2
DECREASED IMMUNE RESPONSIVENESS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
HYPERSENSITIVITY	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2
SEASONAL ALLERGY	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS																								
TOTAL	18	10.5	10	5.8	1	0.6	29	17.0	12	7.1	23	13.7	0	0	33	19.6	24	14.4	23	13.8	1	0.6	47	28.1
BRONCHITIS	1	0.6	1	0.6	0	0	2	1.2	1	0.6	2	1.2	0	0	3	1.8	0	0	0	0	0	0	0	0
CHLAMYDIAL INFECTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CONJUNCTIVITIS INFECTIVE	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
EAR INFECTION	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
GASTROENTERITIS	2	1.2	0	0	0	0	2	1.2	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
GASTROENTERITIS VIRAL	0	0	1	0.6	0	0	1	0.6	0	0	2	1.2	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6
HERPES SIMPLEX	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
INFECTED INSECT BITE	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
INFLUENZA	0	0	2	1.2	0	0	2	1.2	1	0.6	3	1.8	0	0	4	2.4	2	1.2	2	1.2	0	0	4	2.4

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS																								
LOCALISED INFECTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NASOPHARYNGITIS	6	3.5	0	0	0	0	6	3.5	6	3.6	5	3.0	0	0	11	6.5	6	3.6	4	2.4	0	0	10	6.0
OTITIS EXTERNA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2
PHARYNGITIS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
PHARYNGITIS STREPTOCOCCAL	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	2	1.2	0	0	0	0	0	0	0	0
PNEUMONIA	0	0	2	1.2	0	0	2	1.2	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
RESPIRATORY TRACT INFECTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
RHINITIS	1	0.6	1	0.6	0	0	2	1.2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SINUSITIS	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	2	1.2	3	1.8	0	0	5	3.0
STREPTOCOCCAL INFECTION	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS																								
TONSILLITIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
TOOTH INFECTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UPPER RESPIRATORY TRACT INFECTION	4	2.3	3	1.8	0	0	7	4.1	4	2.4	6	3.6	0	0	10	6.0	7	4.2	7	4.2	0	0	14	8.4
URINARY TRACT INFECTION	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	2	1.2	0	0	2	1.2
VIRAL INFECTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
VIRAL UPPER RESPIRATORY TRACT INFECTION	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	1	0.6	2	1.2	0	0	3	1.8
INJURY, POISONING AND PROCEDURAL COMPLICATIONS																								
TOTAL	6	3.5	4	2.3	0	0	10	5.8	6	3.6	4	2.4	1	0.6	11	6.5	2	1.2	5	3.0	1	0.6	8	4.8
ACCIDENTAL OVERDOSE	3	1.8	0	0	0	0	3	1.8	1	0.6	0	0	1	0.6	2	1.2	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS																								
ARTHROPOD BITE	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARTHROPOD STING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
BACK INJURY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
CHEMICAL INJURY	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
CONTUSION	1	0.6	1	0.6	0	0	2	1.2	2	1.2	1	0.6	0	0	3	1.8	0	0	0	0	0	0	0	0
CORNEAL ABRASION	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
FIBULA FRACTURE	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
FOOT FRACTURE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FRACTURED COCCYX	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HAND FRACTURE	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6
JOINT DISLOCATION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS																								
JOINT SPRAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	2	1.2
MUSCLE STRAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
POST PROCEDURAL PAIN	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
RIB FRACTURE	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
SKIN LACERATION	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2	0	0	0	0	0	0	0	0
THERMAL BURN	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
TOOTH INJURY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
INVESTIGATIONS																								
TOTAL	9	5.3	4	2.3	0	0	12	7.0	8	4.8	5	3.0	1	0.6	13	7.7	5	3.0	4	2.4	0	0	8	4.8
BLOOD PRESSURE INCREASED	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2	1	0.6	1	0.6	0	0	2	1.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
INVESTIGATIONS																								
BLOOD PRESSURE SYSTOLIC INCREASED	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
BLOOD TRIGLYCERIDES INCREASED	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BODY TEMPERATURE INCREASED	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
HEART RATE INCREASED	3	1.8	0	0	0	0	3	1.8	2	1.2	1	0.6	0	0	3	1.8	1	0.6	0	0	0	0	1	0.6
HEART RATE IRREGULAR	1	0.6	1	0.6	0	0	2	1.2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WEIGHT DECREASED	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2
WEIGHT INCREASED	5	2.9	2	1.2	0	0	7	4.1	6	3.6	3	1.8	0	0	9	5.4	1	0.6	2	1.2	0	0	3	1.8
METABOLISM AND NUTRITION DISORDERS																								
TOTAL	10	5.8	8	4.7	0	0	18	10.5	10	6.0	2	1.2	0	0	12	7.1	9	5.4	2	1.2	1	0.6	12	7.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
METABOLISM AND NUTRITION DISORDERS																								
ANOREXIA	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6
DECREASED APPETITE	2	1.2	2	1.2	0	0	4	2.3	2	1.2	0	0	0	0	2	1.2	3	1.8	0	0	0	0	3	1.8
FOOD CRAVING	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
GOUT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
HYPERGLYCAEMIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INCREASED APPETITE	7	4.1	6	3.5	0	0	13	7.6	6	3.6	1	0.6	0	0	7	4.2	5	3.0	1	0.6	1	0.6	7	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
TOTAL	14	8.2	11	6.4	3	1.8	28	16.4	13	7.7	8	4.8	5	3.0	25	14.9	19	11.4	9	5.4	1	0.6	27	16.2
ARTHRALGIA	2	1.2	3	1.8	0	0	5	2.9	3	1.8	1	0.6	1	0.6	5	3.0	2	1.2	0	0	0	0	2	1.2
BACK PAIN	2	1.2	4	2.3	2	1.2	8	4.7	1	0.6	1	0.6	1	0.6	3	1.8	6	3.6	7	4.2	0	0	13	7.8
CHEST WALL PAIN	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
FLANK PAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2
MUSCLE CRAMP	2	1.2	1	0.6	0	0	3	1.8	0	0	0	0	0	0	0	0	2	1.2	1	0.6	0	0	3	1.8
MUSCLE SPASMS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	2	1.2	0	0	0	0	2	1.2
MUSCLE TIGHTNESS	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
MUSCLE TWITCHING	4	2.3	1	0.6	0	0	5	2.9	3	1.8	1	0.6	0	0	4	2.4	3	1.8	0	0	0	0	3	1.8
MUSCULOSKELETAL DISCOMFORT	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MUSCULOSKELETAL STIFFNESS	2	1.2	1	0.6	0	0	3	1.8	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6
MYALGIA	1	0.6	2	1.2	0	0	3	1.8	2	1.2	1	0.6	2	1.2	5	3.0	4	2.4	0	0	0	0	4	2.4
OSTEOARTHRITIS	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2	0	0	0	0	0	0	0	0
PAIN IN EXTREMITY	0	0	1	0.6	0	0	1	0.6	0	0	3	1.8	0	0	3	1.8	0	0	1	0.6	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS																								
POLYMYALGIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SENSATION OF HEAVINESS	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2	0	0	0	0	0	0	0	0
TENDONITIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
TRISMUS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NERVOUS SYSTEM DISORDERS																								
TOTAL	69	40.4	66	38.6	21	12.3	129	75.4	72	42.9	65	38.7	15	8.9	123	73.2	42	25.1	28	16.8	5	3.0	68	40.7
AKATHISIA	1	0.6	0	0	4	2.3	5	2.9	1	0.6	1	0.6	0	0	2	1.2	1	0.6	0	0	1	0.6	2	1.2
AMNESIA	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
APHASIA	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
ATAXIA	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
BALANCE DISORDER	1	0.6	1	0.6	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6	2	1.2	0	0	0	0	2	1.2
CONVULSION	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
COORDINATION ABNORMAL	0	0	0	0	1	0.6	1	0.6	0	0	1	0.6	1	0.6	2	1.2	0	0	0	0	0	0	0	0
DISTURBANCE IN ATTENTION	1	0.6	0	0	1	0.6	2	1.2	1	0.6	1	0.6	0	0	2	1.2	1	0.6	2	1.2	0	0	3	1.8
DIZZINESS	17	9.9	7	4.1	0	0	24	14.0	13	7.7	11	6.5	3	1.8	27	16.1	8	4.8	1	0.6	0	0	9	5.4
DIZZINESS POSTURAL	2	1.2	1	0.6	0	0	3	1.8	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
DYSARTHRIA	3	1.8	0	0	0	0	3	1.8	5	3.0	3	1.8	1	0.6	9	5.4	0	0	1	0.6	0	0	1	0.6
DYSGEUSIA	0	0	0	0	0	0	0	0	3	1.8	0	0	0	0	3	1.8	0	0	0	0	0	0	0	0
DYSKINESIA	2	1.2	0	0	0	0	2	1.2	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
DYSTONIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
EXTRAPYRAMIDAL DISORDER	3	1.8	7	4.1	1	0.6	11	6.4	5	3.0	4	2.4	1	0.6	10	6.0	3	1.8	1	0.6	0	0	4	2.4
HEADACHE	8	4.7	7	4.1	0	0	15	8.8	8	4.8	5	3.0	1	0.6	14	8.3	12	7.2	13	7.8	3	1.8	28	16.8
HYPERSOMNIA	0	0	3	1.8	1	0.6	4	2.3	0	0	2	1.2	1	0.6	3	1.8	0	0	0	0	0	0	0	0
HYPOAESTHESIA	1	0.6	1	0.6	0	0	2	1.2	3	1.8	1	0.6	0	0	4	2.4	0	0	2	1.2	1	0.6	3	1.8
LETHARGY	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2
MEMORY IMPAIRMENT	0	0	1	0.6	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
MIGRAINE	0	0	1	0.6	2	1.2	3	1.8	0	0	0	0	0	0	0	0	1	0.6	2	1.2	0	0	3	1.8
PARAESTHESIA	0	0	2	1.2	0	0	2	1.2	4	2.4	4	2.4	0	0	8	4.8	2	1.2	1	0.6	0	0	3	1.8
PARAESTHESIA ORAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
RESTLESS LEGS SYNDROME	3	1.8	0	0	0	0	3	1.8	2	1.2	1	0.6	1	0.6	4	2.4	0	0	0	0	0	0	0	0
SEDATION	19	11.1	27	15.8	9	5.3	55	32.2	14	8.3	28	16.7	4	2.4	46	27.4	13	7.8	4	2.4	0	0	17	10.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS																								
SINUS HEADACHE	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
SLEEP TALKING	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
SOMNOLENCE	23	13.5	21	12.3	7	4.1	51	29.8	29	17.3	18	10.7	3	1.8	50	29.8	6	3.6	2	1.2	0	0	8	4.8
SYNCOPE	1	0.6	0	0	0	0	1	0.6	1	0.6	2	1.2	0	0	3	1.8	1	0.6	0	0	0	0	1	0.6
TENSION HEADACHE	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.2	0	0	0	0	0	0	0	0
TREMOR	1	0.6	1	0.6	0	0	2	1.2	4	2.4	1	0.6	0	0	5	3.0	2	1.2	1	0.6	0	0	3	1.8
PSYCHIATRIC DISORDERS																								
TOTAL	13	7.6	17	9.9	11	6.4	36	21.1	16	9.5	10	6.0	8	4.8	31	18.5	21	12.6	13	7.8	3	1.8	34	20.4
ABNORMAL DREAMS	1	0.6	0	0	0	0	1	0.6	1	0.6	2	1.2	0	0	3	1.8	0	0	1	0.6	0	0	1	0.6
AGGRESSION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AGITATION	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
ANGER	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
ANORGASMIA	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2	0	0	0	0	0	0	0	0
ANXIETY	1	0.6	1	0.6	1	0.6	3	1.8	1	0.6	1	0.6	1	0.6	3	1.8	2	1.2	2	1.2	0	0	4	2.4
BIPOLAR DISORDER	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
BIPOLAR I DISORDER	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BRUXISM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
CONFUSIONAL STATE	0	0	1	0.6	1	0.6	2	1.2	1	0.6	2	1.2	0	0	3	1.8	0	0	0	0	0	0	0	0
CONSTRICTED AFFECT	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DEPRESSION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
DISORIENTATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
DISSOCIATION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DYSPHEMIA	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
ELEVATED MOOD	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
EUPHORIC MOOD	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
FLAT AFFECT	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HALLUCINATION	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HALLUCINATION, AUDITORY	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HALLUCINATION, VISUAL	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
HOSTILITY	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
HYPOMANIA	1	0.6	0	0	1	0.6	2	1.2	1	0.6	0	0	0	0	1	0.6	3	1.8	0	0	0	0	3	1.8
INITIAL INSOMNIA	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
INSOMNIA	2	1.2	1	0.6	2	1.2	5	2.9	2	1.2	1	0.6	0	0	3	1.8	8	4.8	3	1.8	1	0.6	12	7.2
IRRITABILITY	1	0.6	4	2.3	2	1.2	7	4.1	4	2.4	2	1.2	2	1.2	8	4.8	2	1.2	1	0.6	0	0	3	1.8
LIBIDO DECREASED	0	0	3	1.8	0	0	3	1.8	1	0.6	1	0.6	0	0	2	1.2	1	0.6	2	1.2	1	0.6	4	2.4

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
LIBIDO INCREASED	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LOGORRHOEA	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
LOSS OF LIBIDO	1	0.6	0	0	2	1.2	3	1.8	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
MANIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	2	1.2
NERVOUSNESS	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NIGHTMARE	3	1.8	1	0.6	0	0	4	2.3	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	2	1.2
OBSESSIVE-COMPULSIVE DISORDER	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0
PANIC ATTACK	0	0	2	1.2	1	0.6	3	1.8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PARANOIA	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PSYCHOMOTOR RETARDATION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESTLESSNESS	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
PSYCHIATRIC DISORDERS																								
SELF ESTEEM INFLATED	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
SLEEP DISORDER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1.8	1	0.6	0	0	4	2.4
STRESS SYMPTOMS	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SUICIDAL IDEATION	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	1	0.6	2	1.2	0	0	0	0	0	0	0	0
SUICIDE ATTEMPT	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
RENAL AND URINARY DISORDERS																								
TOTAL	4	2.3	3	1.8	1	0.6	8	4.7	2	1.2	0	0	1	0.6	3	1.8	6	3.6	3	1.8	1	0.6	9	5.4
DYSURIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
MICTURITION URGENCY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	2	1.2
NOCTURIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
POLLAKIURIA	4	2.3	2	1.2	0	0	6	3.5	1	0.6	0	0	1	0.6	2	1.2	3	1.8	1	0.6	0	0	4	2.4

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RENAL AND URINARY DISORDERS																								
URINARY HESITATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
URINARY INCONTINENCE	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6
URINARY RETENTION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS																								
TOTAL	3	1.8	2	1.2	0	0	5	2.9	3	1.8	2	1.2	1	0.6	6	3.6	6	3.6	4	2.4	1	0.6	11	6.6
BREAST TENDERNESS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
DYSMENORRHOEA	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6
EJACULATION DELAYED	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
ERECTILE DYSFUNCTION	0	0	1	0.6	0	0	1	0.6	1	0.6	0	0	1	0.6	2	1.2	1	0.6	1	0.6	1	0.6	3	1.8
MENORRHAGIA	1	0.6	1	0.6	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	1	0.6

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
REPRODUCTIVE SYSTEM AND BREAST DISORDERS																								
MENSTRUATION IRREGULAR	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	2	1.2	0	0	0	0	2	1.2
SEXUAL DYSFUNCTION	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
UTERINE CYST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6
UTERINE SPASM	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS																								
TOTAL	13	7.6	6	3.5	2	1.2	21	12.3	13	7.7	8	4.8	2	1.2	22	13.1	15	9.0	4	2.4	0	0	18	10.8
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COUGH	4	2.3	0	0	0	0	4	2.3	3	1.8	1	0.6	0	0	4	2.4	2	1.2	1	0.6	0	0	3	1.8
DRY THROAT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
DYSPNOEA	2	1.2	1	0.6	1	0.6	4	2.3	0	0	1	0.6	0	0	1	0.6	2	1.2	0	0	0	0	2	1.2

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS																								
EPISTAXIS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
LARYNGEAL OEDEMA	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NASAL CONGESTION	4	2.3	1	0.6	0	0	5	2.9	6	3.6	4	2.4	0	0	10	6.0	4	2.4	2	1.2	0	0	6	3.6
NASAL DRYNESS	1	0.6	0	0	0	0	1	0.6	0	0	0	0	1	0.6	1	0.6	0	0	0	0	0	0	0	0
PHARYNGOLARYNGEAL PAIN	3	1.8	2	1.2	0	0	5	2.9	2	1.2	2	1.2	1	0.6	5	3.0	7	4.2	0	0	0	0	7	4.2
RESPIRATORY TRACT CONGESTION	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
SINUS CONGESTION	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6
SINUS PAIN	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6
THROAT TIGHTNESS	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	0	0	1	0.6	0	0	0	0	0	0	0	0
YAWNING	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO					
	N=171								N=168								N=167					
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS																								
TOTAL	1	0.6	2	1.2	0	0	3	1.8	2	1.2	1	0.6	0	0	3	1.8	10	6.0	3	1.8	0	0	13	7.8
ACNE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2
ALOPECIA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1.2	0	0	0	0	2	1.2
DRY SKIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
HYPERHIDROSIS	1	0.6	1	0.6	0	0	2	1.2	1	0.6	0	0	0	0	1	0.6	1	0.6	1	0.6	0	0	2	1.2
HYPERKERATOSIS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
NIGHT SWEATS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	2	1.2	0	0	0	0	2	1.2
PHOTOSENSITIVITY REACTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
PRURITUS	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6	2	1.2	0	0	0	0	2	1.2
RASH	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	0	0	1	0.6	1	0.6	2	1.2	0	0	3	1.8
RASH PRURITIC	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0

(Continued)

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.6 Adverse Events by System Organ Class and Intensity
Safety Population

SYSTEM ORGAN CLASS (PREFERRED TERM)	TREATMENT																							
	QUETIAPINE 300 MG								QUETIAPINE 600 MG								PLACEBO							
	N=171								N=168								N=167							
	MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT		MILD		MOD		SEV		TOT	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
SURGICAL AND MEDICAL PROCEDURES																								
TOTAL	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	1	0.6	2	1.2
TOOTH EXTRACTION	0	0	1	0.6	0	0	1	0.6	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
VASECTOMY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	1	0.6
VASCULAR DISORDERS																								
TOTAL	7	4.1	3	1.8	0	0	10	5.8	6	3.6	3	1.8	3	1.8	12	7.1	7	4.2	2	1.2	0	0	9	5.4
FLUSHING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.6	0	0	0	0	1	0.6
HOT FLUSH	1	0.6	1	0.6	0	0	2	1.2	0	0	0	0	0	0	0	0	2	1.2	2	1.2	0	0	4	2.4
HYPERTENSION	3	1.8	1	0.6	0	0	4	2.3	1	0.6	0	0	1	0.6	2	1.2	1	0.6	0	0	0	0	1	0.6
ORTHOSTATIC HYPOTENSION	3	1.8	1	0.6	0	0	4	2.3	5	3.0	3	1.8	2	1.2	10	6.0	3	1.8	0	0	0	0	3	1.8

Note: For each subject, the maximum intensity is chosen if multiple intensities are recorded.
Adverse events with missing intensities are included in the total counts.
Count number of subjects reporting adverse event at least once.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG205.SAS
GENERATED: 17NOV2005 13:44:38 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY ADVERSE EVENT		140	81.9	134	79.8	88	52.7
CARDIAC DISORDERS	TOTAL	6	3.5	6	3.6	1	0.6
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.6	0	0
	PALPITATIONS	5	2.9	3	1.8	1	0.6
	TACHYCARDIA	1	0.6	2	1.2	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	2	1.2	1	0.6	2	1.2
	HYPERACUSIS	0	0	0	0	1	0.6
	TINNITUS	2	1.2	1	0.6	1	0.6
EYE DISORDERS	TOTAL	9	5.3	5	3.0	2	1.2
	ALTERED VISUAL DEPTH PERCEPTION	1	0.6	0	0	0	0
	CONJUNCTIVAL HYPERAEMIA	0	0	1	0.6	0	0
	DRY EYE	1	0.6	0	0	0	0
	EYE REDNESS	1	0.6	1	0.6	0	0
	PHOTOPHOBIA	0	0	0	0	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	VISION BLURRED	4	2.3	2	1.2	1	0.6
	VISUAL DISTURBANCE	3	1.8	1	0.6	0	0
GASTROINTESTINAL DISORDERS	TOTAL	68	39.8	74	44.0	40	24.0
	ABDOMINAL DISTENSION	0	0	1	0.6	1	0.6
	ABDOMINAL PAIN	0	0	1	0.6	0	0
	ABDOMINAL PAIN UPPER	0	0	0	0	1	0.6
	CONSTIPATION	8	4.7	9	5.4	2	1.2
	DIARRHOEA	2	1.2	4	2.4	5	3.0
	DRY MOUTH	58	33.9	62	36.9	18	10.8
	DYSPEPSIA	7	4.1	6	3.6	1	0.6
	DYSPHAGIA	2	1.2	1	0.6	0	0
	FLATULENCE	4	2.3	0	0	3	1.8
	GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	2	1.2	0	0
	GINGIVAL PAIN	0	0	0	0	1	0.6
	HYPOAESTHESIA ORAL	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	LOOSE STOOLS	0	0	0	0	2	1.2
	NAUSEA	6	3.5	9	5.4	9	5.4
	SALIVARY HYPERSECRETION	0	0	1	0.6	0	0
	STOMACH DISCOMFORT	0	0	1	0.6	1	0.6
	TONGUE DISORDER	0	0	1	0.6	0	0
	TOOTHACHE	1	0.6	0	0	2	1.2
	VOMITING	2	1.2	4	2.4	3	1.8
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	29	17.0	25	14.9	12	7.2
	ASTHENIA	4	2.3	3	1.8	1	0.6
	CHEST DISCOMFORT	0	0	1	0.6	0	0
	CHEST PAIN	0	0	1	0.6	0	0
	CHILLS	1	0.6	1	0.6	0	0
	DIFFICULTY IN WALKING	0	0	0	0	1	0.6
	FATIGUE	14	8.2	15	8.9	7	4.2
	FEELING HOT AND COLD	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING JITTERY	0	0	0	0	1	0.6
	GAIT DISTURBANCE	1	0.6	0	0	0	0
	INFLUENZA LIKE ILLNESS	0	0	0	0	1	0.6
	LETHARGY	7	4.1	2	1.2	0	0
	OEDEMA PERIPHERAL	2	1.2	2	1.2	0	0
	PAIN	2	1.2	0	0	0	0
	PYREXIA	1	0.6	1	0.6	0	0
	SLUGGISHNESS	1	0.6	1	0.6	0	0
	THIRST	0	0	0	0	2	1.2
IMMUNE SYSTEM DISORDERS	TOTAL	0	0	1	0.6	0	0
	DECREASED IMMUNE RESPONSIVENESS	0	0	1	0.6	0	0
INFECTIONS AND INFESTATIONS	TOTAL	5	2.9	5	3.0	8	4.8
	BRONCHITIS	0	0	1	0.6	0	0
	HERPES SIMPLEX	0	0	0	0	1	0.6
	INFLUENZA	1	0.6	0	0	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	0	0	1	0.6	1	0.6
	OTITIS EXTERNA	0	0	0	0	1	0.6
	PHARYNGITIS	1	0.6	0	0	1	0.6
	RHINITIS	1	0.6	0	0	0	0
	SINUSITIS	0	0	0	0	1	0.6
	STREPTOCOCCAL INFECTION	1	0.6	0	0	0	0
	UPPER RESPIRATORY TRACT INFECTION	1	0.6	2	1.2	2	1.2
	VIRAL UPPER RESPIRATORY TRACT INFECTION	0	0	1	0.6	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	3	1.8	2	1.2	2	1.2
	ACCIDENTAL OVERDOSE	2	1.2	0	0	0	0
	CONTUSION	0	0	1	0.6	0	0
	FIBULA FRACTURE	0	0	1	0.6	0	0
	POST PROCEDURAL PAIN	1	0.6	0	0	1	0.6
	TOOTH INJURY	0	0	0	0	1	0.6

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
INVESTIGATIONS	TOTAL	3	1.8	8	4.8	3	1.8
	BODY TEMPERATURE INCREASED	0	0	0	0	1	0.6
	HEART RATE INCREASED	3	1.8	3	1.8	1	0.6
	HEART RATE IRREGULAR	1	0.6	0	0	0	0
	WEIGHT DECREASED	0	0	0	0	1	0.6
	WEIGHT INCREASED	0	0	5	3.0	1	0.6
METABOLISM AND NUTRITION DISORDERS	TOTAL	11	6.4	8	4.8	5	3.0
	ANOREXIA	0	0	1	0.6	0	0
	DECREASED APPETITE	2	1.2	1	0.6	2	1.2
	FOOD CRAVING	0	0	1	0.6	0	0
	INCREASED APPETITE	9	5.3	5	3.0	3	1.8
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	12	7.0	12	7.1	7	4.2
	ARTHRALGIA	2	1.2	0	0	1	0.6
	BACK PAIN	2	1.2	1	0.6	2	1.2
	CHEST WALL PAIN	0	0	1	0.6	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	FLANK PAIN	0	0	0	0	1	0.6
	MUSCLE CRAMP	0	0	0	0	1	0.6
	MUSCLE SPASMS	0	0	1	0.6	0	0
	MUSCLE TIGHTNESS	1	0.6	0	0	1	0.6
	MUSCLE TWITCHING	3	1.8	4	2.4	0	0
	MUSCULOSKELETAL STIFFNESS	2	1.2	0	0	1	0.6
	MYALGIA	1	0.6	2	1.2	1	0.6
	OSTEOARTHRITIS	0	0	1	0.6	0	0
	PAIN IN EXTREMITY	0	0	2	1.2	0	0
	POLYMYALGIA	1	0.6	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	112	65.5	104	61.9	34	20.4
	AKATHISIA	5	2.9	2	1.2	0	0
	AMNESIA	1	0.6	0	0	0	0
	APHASIA	0	0	1	0.6	0	0
	ATAXIA	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	BALANCE DISORDER	2	1.2	1	0.6	0	0
	COORDINATION ABNORMAL	1	0.6	2	1.2	0	0
	DISTURBANCE IN ATTENTION	2	1.2	2	1.2	3	1.8
	DIZZINESS	18	10.5	20	11.9	4	2.4
	DYSARTHRIA	2	1.2	8	4.8	0	0
	DYSGEUSIA	0	0	2	1.2	0	0
	DYSKINESIA	2	1.2	0	0	1	0.6
	DYSTONIA	0	0	1	0.6	0	0
	EXTRAPYRAMIDAL DISORDER	8	4.7	7	4.2	3	1.8
	HEADACHE	4	2.3	9	5.4	10	6.0
	HYPERSOMNIA	2	1.2	2	1.2	0	0
	HYPOAESTHESIA	0	0	4	2.4	1	0.6
	MEMORY IMPAIRMENT	1	0.6	1	0.6	0	0
	MIGRAINE	0	0	0	0	2	1.2
	PARAESTHESIA	1	0.6	4	2.4	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	3	1.8	3	1.8	0	0
	SEDATION	50	29.2	41	24.4	10	6.0
	SLEEP TALKING	0	0	1	0.6	0	0
	SOMNOLENCE	43	25.1	42	25.0	8	4.8
	SYNCOPE	0	0	1	0.6	0	0
	TENSION HEADACHE	0	0	1	0.6	0	0
	TREMOR	2	1.2	5	3.0	0	0
PSYCHIATRIC DISORDERS	TOTAL	23	13.5	16	9.5	15	9.0
	ABNORMAL DREAMS	1	0.6	1	0.6	0	0
	AGGRESSION	1	0.6	0	0	0	0
	AGITATION	0	0	0	0	1	0.6
	ANGER	0	0	1	0.6	0	0
	ANORGASMIA	0	0	1	0.6	0	0
	ANXIETY	1	0.6	2	1.2	0	0
	BIPOLAR I DISORDER	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	0	0	1	0.6	0	0
	DEPRESSION	0	0	0	0	1	0.6
	DISORIENTATION	0	0	0	0	1	0.6
	DISSOCIATION	1	0.6	0	0	0	0
	EUPHORIC MOOD	0	0	1	0.6	0	0
	HALLUCINATION	1	0.6	0	0	0	0
	HALLUCINATION, AUDITORY	1	0.6	0	0	0	0
	HALLUCINATION, VISUAL	1	0.6	1	0.6	0	0
	HOSTILITY	0	0	1	0.6	0	0
	HYPOMANIA	2	1.2	0	0	0	0
	INITIAL INSOMNIA	1	0.6	0	0	0	0
	INSOMNIA	4	2.3	0	0	7	4.2
	IRRITABILITY	3	1.8	6	3.6	1	0.6
	LIBIDO DECREASED	1	0.6	0	0	1	0.6
	LOSS OF LIBIDO	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	NIGHTMARE	3	1.8	0	0	1	0.6
	PANIC ATTACK	2	1.2	0	0	0	0
	PARANOIA	1	0.6	0	0	0	0
	PSYCHOMOTOR RETARDATION	1	0.6	0	0	0	0
	RESTLESSNESS	1	0.6	1	0.6	1	0.6
	SLEEP DISORDER	0	0	0	0	3	1.8
	STRESS SYMPTOMS	1	0.6	0	0	0	0
	SUICIDE ATTEMPT	0	0	1	0.6	0	0
RENAL AND URINARY DISORDERS	TOTAL	2	1.2	2	1.2	2	1.2
	NOCTURIA	0	0	0	0	1	0.6
	POLLAKIURIA	1	0.6	2	1.2	1	0.6
	URINARY INCONTINENCE	1	0.6	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	1	0.6	2	1.2	2	1.2
	EJACULATION DELAYED	0	0	0	0	1	0.6
	ERECTILE DYSFUNCTION	1	0.6	2	1.2	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	MENSTRUATION IRREGULAR	0	0	0	0	1	0.6
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	9	5.3	10	6.0	6	3.6
	COUGH	0	0	1	0.6	0	0
	DRY THROAT	0	0	0	0	1	0.6
	DYSPNOEA	2	1.2	1	0.6	0	0
	LARYNGEAL OEDEMA	1	0.6	0	0	0	0
	NASAL CONGESTION	3	1.8	4	2.4	2	1.2
	NASAL DRYNESS	0	0	1	0.6	0	0
	PHARYNGOLARYNGEAL PAIN	1	0.6	1	0.6	2	1.2
	RESPIRATORY TRACT CONGESTION	0	0	1	0.6	0	0
	SINUS CONGESTION	1	0.6	1	0.6	0	0
	SINUS PAIN	0	0	0	0	1	0.6
	THROAT TIGHTNESS	1	0.6	1	0.6	0	0
	YAWNING	1	0.6	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.7 Adverse Events Starting Between Days 1 - 8
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	1	0.6	2	1.2	7	4.2
	ACNE	0	0	0	0	1	0.6
	ALOPECIA	0	0	0	0	1	0.6
	HYPERHIDROSIS	0	0	1	0.6	0	0
	HYPERKERATOSIS	0	0	0	0	1	0.6
	NIGHT SWEATS	0	0	0	0	1	0.6
	PRURITUS	0	0	0	0	2	1.2
	RASH	1	0.6	1	0.6	1	0.6
	RASH PRURITIC	0	0	1	0.6	0	0
VASCULAR DISORDERS	TOTAL	8	4.7	8	4.8	4	2.4
	HOT FLUSH	2	1.2	0	0	1	0.6
	HYPERTENSION	2	1.2	1	0.6	0	0
	ORTHOSTATIC HYPOTENSION	4	2.3	7	4.2	3	1.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG214.SAS
GENERATED: 17NOV2005 13:45:00 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY DRUG RELATED		149	87.1	134	79.8	94	56.3
CARDIAC DISORDERS	TOTAL	7	4.1	8	4.8	2	1.2
	BRADYCARDIA	1	0.6	0	0	0	0
	PALPITATIONS	5	2.9	6	3.6	2	1.2
	TACHYCARDIA	1	0.6	2	1.2	0	0
EAR AND LABYRINTH DISORDERS	TOTAL	2	1.2	2	1.2	2	1.2
	HYPERACUSIS	0	0	0	0	1	0.6
	TINNITUS	1	0.6	2	1.2	1	0.6
	VERTIGO	1	0.6	0	0	0	0
ENDOCRINE DISORDERS	TOTAL	0	0	1	0.6	0	0
	HYPOTHYROIDISM	0	0	1	0.6	0	0
EYE DISORDERS	TOTAL	9	5.3	9	5.4	4	2.4
	ALTERED VISUAL DEPTH PERCEPTION	1	0.6	0	0	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
EYE DISORDERS	CONJUNCTIVAL HYPERAEMIA	0	0	1	0.6	0	0
	DIPLOPIA	0	0	1	0.6	0	0
	EYE REDNESS	0	0	1	0.6	0	0
	EYE SWELLING	0	0	0	0	1	0.6
	PHOTOPHOBIA	0	0	1	0.6	1	0.6
	VISION BLURRED	6	3.5	4	2.4	3	1.8
	VISUAL DISTURBANCE	2	1.2	1	0.6	0	0
GASTROINTESTINAL DISORDERS	TOTAL	87	50.9	87	51.8	55	32.9
	ABDOMINAL DISTENSION	0	0	0	0	1	0.6
	ABDOMINAL PAIN	1	0.6	1	0.6	0	0
	ABDOMINAL PAIN LOWER	0	0	0	0	1	0.6
	ABDOMINAL PAIN UPPER	0	0	2	1.2	3	1.8
	CONSTIPATION	9	5.3	14	8.3	4	2.4
	DIARRHOEA	3	1.8	3	1.8	4	2.4

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	DRY MOUTH	71	41.5	78	46.4	29	17.4
	DYSPEPSIA	10	5.8	10	6.0	5	3.0
	DYSPHAGIA	4	2.3	2	1.2	0	0
	ERUCTATION	0	0	1	0.6	0	0
	FLATULENCE	6	3.5	0	0	3	1.8
	GASTROOESOPHAGEAL REFLUX DISEASE	1	0.6	4	2.4	2	1.2
	GLOSSODYNIA	1	0.6	0	0	0	0
	HYPOAESTHESIA ORAL	1	0.6	0	0	0	0
	IRRITABLE BOWEL SYNDROME	0	0	0	0	1	0.6
	LOOSE STOOLS	0	0	0	0	1	0.6
	NAUSEA	9	5.3	15	8.9	19	11.4
	SALIVARY HYPERSECRETION	0	0	1	0.6	0	0
	STOMACH DISCOMFORT	0	0	2	1.2	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GASTROINTESTINAL DISORDERS	TONGUE COATED	1	0.6	0	0	0	0
	TONGUE DISORDER	0	0	1	0.6	0	0
	VOMITING	4	2.3	6	3.6	4	2.4
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	34	19.9	25	14.9	16	9.6
	ASTHENIA	2	1.2	5	3.0	2	1.2
	CHEST DISCOMFORT	0	0	1	0.6	0	0
	CHEST PAIN	0	0	1	0.6	1	0.6
	DIFFICULTY IN WALKING	0	0	0	0	1	0.6
	FATIGUE	16	9.4	17	10.1	8	4.8
	FEELING HOT AND COLD	1	0.6	0	0	1	0.6
	GAIT DISTURBANCE	1	0.6	0	0	0	0
	HANGOVER	0	0	0	0	1	0.6
	LETHARGY	8	4.7	2	1.2	0	0
	MALAISE	0	0	0	0	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	3	1.8	0	0	2	1.2
	PAIN	1	0.6	0	0	0	0
	PITTING OEDEMA	0	0	0	0	1	0.6
	PYREXIA	1	0.6	0	0	0	0
	SLUGGISHNESS	1	0.6	1	0.6	0	0
	THIRST	2	1.2	0	0	2	1.2
INVESTIGATIONS	TOTAL	10	5.8	10	6.0	5	3.0
	BLOOD TRIGLYCERIDES INCREASED	1	0.6	0	0	0	0
	BODY TEMPERATURE INCREASED	0	0	0	0	1	0.6
	HEART RATE INCREASED	2	1.2	2	1.2	0	0
	WEIGHT DECREASED	0	0	0	0	2	1.2
	WEIGHT INCREASED	7	4.1	8	4.8	3	1.8

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
METABOLISM AND NUTRITION DISORDERS	TOTAL	16	9.4	12	7.1	10	6.0
	ANOREXIA	0	0	2	1.2	1	0.6
	DECREASED APPETITE	3	1.8	2	1.2	2	1.2
	FOOD CRAVING	0	0	1	0.6	0	0
	HYPERGLYCAEMIA	1	0.6	0	0	0	0
	INCREASED APPETITE	12	7.0	7	4.2	7	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	18	10.5	12	7.1	12	7.2
	ARTHRALGIA	3	1.8	2	1.2	0	0
	BACK PAIN	1	0.6	0	0	1	0.6
	MUSCLE CRAMP	2	1.2	0	0	3	1.8
	MUSCLE SPASMS	0	0	1	0.6	2	1.2
	MUSCLE TIGHTNESS	1	0.6	0	0	0	0
	MUSCLE TWITCHING	5	2.9	4	2.4	2	1.2

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	1	0.6	0	0	0	0
	MUSCULOSKELETAL STIFFNESS	3	1.8	0	0	1	0.6
	MYALGIA	1	0.6	2	1.2	2	1.2
	OSTEOARTHRITIS	0	0	1	0.6	0	0
	PAIN IN EXTREMITY	1	0.6	1	0.6	1	0.6
	POLYMYALGIA	1	0.6	0	0	0	0
	SENSATION OF HEAVINESS	0	0	2	1.2	0	0
	TRISMUS	0	0	0	0	1	0.6
NERVOUS SYSTEM DISORDERS	TOTAL	125	73.1	115	68.5	50	29.9
	AKATHISIA	3	1.8	2	1.2	1	0.6
	APHASIA	0	0	1	0.6	0	0
	ATAXIA	1	0.6	1	0.6	0	0
	BALANCE DISORDER	2	1.2	0	0	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	CONVULSION	0	0	1	0.6	0	0
	COORDINATION ABNORMAL	1	0.6	1	0.6	0	0
	DISTURBANCE IN ATTENTION	1	0.6	1	0.6	2	1.2
	DIZZINESS	23	13.5	24	14.3	7	4.2
	DIZZINESS POSTURAL	3	1.8	1	0.6	0	0
	DYSARTHRIA	2	1.2	8	4.8	0	0
	DYSGEUSIA	0	0	2	1.2	0	0
	DYSKINESIA	0	0	0	0	1	0.6
	DYSTONIA	1	0.6	1	0.6	0	0
	EXTRAPYRAMIDAL DISORDER	10	5.8	10	6.0	3	1.8
	HEADACHE	11	6.4	11	6.5	17	10.2
	HYPERSOMNIA	4	2.3	3	1.8	0	0
	HYPOAESTHESIA	0	0	2	1.2	0	0
	LETHARGY	1	0.6	0	0	2	1.2

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	MEMORY IMPAIRMENT	1	0.6	1	0.6	0	0
	MIGRAINE	1	0.6	0	0	1	0.6
	PARAESTHESIA	2	1.2	6	3.6	2	1.2
	PARAESTHESIA ORAL	0	0	0	0	1	0.6
	RESTLESS LEGS SYNDROME	2	1.2	4	2.4	0	0
	SEDATION	54	31.6	46	27.4	16	9.6
	SLEEP TALKING	0	0	1	0.6	0	0
	SOMNOLENCE	51	29.8	48	28.6	8	4.8
	SYNCOPE	0	0	2	1.2	0	0
	TREMOR	1	0.6	4	2.4	3	1.8
PSYCHIATRIC DISORDERS	TOTAL	25	14.6	17	10.1	15	9.0
	ABNORMAL DREAMS	1	0.6	3	1.8	1	0.6
	AGGRESSION	1	0.6	0	0	0	0
	AGITATION	1	0.6	0	0	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	ANGER	0	0	1	0.6	0	0
	ANORGASMIA	0	0	2	1.2	0	0
	ANXIETY	2	1.2	1	0.6	0	0
	BRUXISM	0	0	0	0	1	0.6
	CONFUSIONAL STATE	2	1.2	1	0.6	0	0
	CONSTRICTED AFFECT	1	0.6	0	0	0	0
	DISORIENTATION	0	0	0	0	1	0.6
	DISSOCIATION	1	0.6	0	0	0	0
	EUPHORIC MOOD	0	0	1	0.6	0	0
	FLAT AFFECT	1	0.6	0	0	0	0
	HALLUCINATION	1	0.6	0	0	0	0
	HALLUCINATION, AUDITORY	1	0.6	0	0	0	0
	HALLUCINATION, VISUAL	1	0.6	1	0.6	0	0
	INSOMNIA	2	1.2	1	0.6	4	2.4

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	IRRITABILITY	4	2.3	5	3.0	1	0.6
	LIBIDO DECREASED	3	1.8	2	1.2	2	1.2
	LOSS OF LIBIDO	1	0.6	1	0.6	0	0
	MANIA	0	0	0	0	1	0.6
	NERVOUSNESS	1	0.6	0	0	0	0
	NIGHTMARE	3	1.8	0	0	2	1.2
	PANIC ATTACK	2	1.2	0	0	0	0
	PARANOIA	1	0.6	0	0	0	0
	RESTLESSNESS	1	0.6	1	0.6	1	0.6
	SLEEP DISORDER	0	0	0	0	1	0.6
RENAL AND URINARY DISORDERS	TOTAL	5	2.9	2	1.2	2	1.2
	MICTURITION URGENCY	0	0	0	0	1	0.6
	POLLAKIURIA	3	1.8	2	1.2	1	0.6
	URINARY INCONTINENCE	1	0.6	0	0	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RENAL AND URINARY DISORDERS	URINARY RETENTION	1	0.6	0	0	0	0
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	TOTAL	2	1.2	5	3.0	5	3.0
	BREAST TENDERNESS	0	0	0	0	1	0.6
	EJACULATION DELAYED	0	0	0	0	1	0.6
	ERECTILE DYSFUNCTION	1	0.6	2	1.2	1	0.6
	MENORRHAGIA	0	0	1	0.6	0	0
	MENSTRUATION IRREGULAR	0	0	1	0.6	2	1.2
	SEXUAL DYSFUNCTION	1	0.6	0	0	0	0
	UTERINE SPASM	0	0	1	0.6	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	8	4.7	5	3.0	2	1.2
	COUGH	0	0	0	0	1	0.6
	DYSPNOEA	2	1.2	0	0	0	0
	NASAL CONGESTION	3	1.8	4	2.4	1	0.6

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	NASAL DRYNESS	0	0	1	0.6	0	0
	SINUS CONGESTION	1	0.6	0	0	0	0
	THROAT TIGHTNESS	1	0.6	0	0	0	0
	YAWNING	1	0.6	0	0	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	2	1.2	2	1.2	9	5.4
	ACNE	0	0	0	0	2	1.2
	ALOPECIA	0	0	0	0	2	1.2
	DRY SKIN	0	0	0	0	1	0.6
	HYPERHIDROSIS	2	1.2	1	0.6	2	1.2
	NIGHT SWEATS	0	0	0	0	2	1.2
	PHOTOSENSITIVITY REACTION	0	0	0	0	1	0.6
	PRURITUS	0	0	0	0	2	1.2
	RASH	0	0	1	0.6	0	0

(Continued)

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.2.8 Possibly Study Drug-Related Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH PRURITIC	0	0	1	0.6	0	0
VASCULAR DISORDERS	TOTAL	4	2.3	10	6.0	5	3.0
	HOT FLUSH	2	1.2	0	0	2	1.2
	HYPERTENSION	0	0	1	0.6	0	0
	ORTHOSTATIC HYPOTENSION	2	1.2	9	5.4	3	1.8

Note: Table includes adverse events with a causality assessment of yes.
Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG206.SAS
GENERATED: 17NOV2005 13:44:41 iceadmn3

Table 11.3.3.1 Deaths

NOTE:

NO DATA MEETS THE CRITERIA FOR ENTRY INTO THIS TABLE.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG213.SAS
GENERATED: 17NOV2005 13:44:58 iceadmn3

Table 11.3.3.2 Adverse Events that Lead to Death

NOTE: THERE WERE NO ADVERSE EVENTS THAT LEAD TO DEATH.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG101.SAS
GENERATED: 17NOV2005 13:44:09 iceadmn3

11.3.3.3 Narratives of deaths

There were no deaths reported in this study.

Table 11.3.4.1.1 Serious Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY SERIOUS EVENT		3	1.8	7	4.2	1	0.6
CARDIAC DISORDERS	TOTAL	1	0.6	1	0.6	0	0
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.6	0	0
	MITRAL VALVE PROLAPSE	1	0.6	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	0	0	0	0	1	0.6
	TONSILLITIS	0	0	0	0	1	0.6
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	1	0.6	0	0
	ACCIDENTAL OVERDOSE	0	0	1	0.6	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	0	0	2	1.2	0	0
	CONVULSION	0	0	1	0.6	0	0
	SYNCOPE	0	0	1	0.6	0	0
PSYCHIATRIC DISORDERS	TOTAL	2	1.2	3	1.8	0	0
	BIPOLAR I DISORDER	1	0.6	0	0	0	0
	SUICIDAL IDEATION	1	0.6	2	1.2	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG207.SAS
GENERATED: 17NOV2005 13:44:44 iceadmn3

Table 11.3.4.1.1 Serious Adverse Events by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
PSYCHIATRIC DISORDERS	SUICIDE ATTEMPT	0	0	1	0.6	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG207.SAS
GENERATED: 17NOV2005 13:44:44 iceadmn3

Table 11.3.4.1.2 Serious Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY SERIOUS EVENT		3	2.7	6	5.4	1	0.9	0	0	1	1.8	0	0
CARDIAC DISORDERS	TOTAL	1	0.9	1	0.9	0	0	0	0	0	0	0	0
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.9	0	0	0	0	0	0	0	0
	MITRAL VALVE PROLAPSE	1	0.9	0	0	0	0	0	0	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	0	0	0	0	1	0.9	0	0	0	0	0	0
	TONSILLITIS	0	0	0	0	1	0.9	0	0	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	ACCIDENTAL OVERDOSE	0	0	1	0.9	0	0	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	0	0	2	1.8	0	0	0	0	0	0	0	0
	CONVULSION	0	0	1	0.9	0	0	0	0	0	0	0	0
	SYNCOPE	0	0	1	0.9	0	0	0	0	0	0	0	0
PSYCHIATRIC DISORDERS	TOTAL	2	1.8	2	1.8	0	0	0	0	1	1.8	0	0
	BIPOLAR I DISORDER	1	0.9	0	0	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG208.SAS
GENERATED: 17NOV2005 13:44:47 iceadmn3

Table 11.3.4.1.2 Serious Adverse Events by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
PSYCHIATRIC DISORDERS	SUICIDAL IDEATION	1	0.9	2	1.8	0	0	0	0	0	0	0	0
	SUICIDE ATTEMPT	0	0	0	0	0	0	0	0	1	1.8	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG208.SAS
GENERATED: 17NOV2005 13:44:47 iceadmn3

Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0015008	37 YRS BLACK MALE	23DEC2004-29DEC2004	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH PLAN]	7	9	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0033007	39 YRS BLACK MALE	17JAN2005-18JAN2005	ON	MITRAL VALVE PROLAPSE (Cardiac disorders) [MITRAL VALVE PROLAPSE WORSENING]	2	55	SEV	N	N	Y	N	N	N	NO NO	None
	E0034010	58 YRS BLACK FEMALE	06MAY2005-12MAY2005	ON	BIPOLAR I DISORDER (Psychiatric disorders) [WORSENING OF BIPOLAR I DISORDER , MIXED WITH ASSOCIATED PSYCHOTIC FEATURES]	7	4	SEV	N	N	Y	N	N	N	YES NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG102.SAS
GENERATED: 17NOV2005 13:44:11 iceadmn3

Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0015005	42 YRS CAUCASIAN FEMALE	07OCT2004-07OCT2004	ON	SYNCOPE (Nervous system disorders) [SYNCOPE NOT DUE TO ORTHOSTATIC HYPOTENSION]	1	11	MIL	N	N	Y	N	N	N	NO YES	None
	E0020032	33 YRS CAUCASIAN MALE	11FEB2005-14FEB2005	ON	CONVULSION (Nervous system disorders) [SEIZURE WITH ASSOCIATED ASPIRATION/BRONCHOSPASM]	4	33	SEV	N	N	Y	N	N	N	YES YES	Permanently Stopped
	E0020037	30 YRS CAUCASIAN FEMALE	01MAR2005-09MAR2005	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH PLAN]	9	22	SEV	N	N	Y	N	N	N	NO NO	None
	E0027016	21 YRS CAUCASIAN FEMALE	04JAN2005-08FEB2005	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	36	61	MIL	N	N	Y	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG102.SAS
GENERATED: 17NOV2005 13:44:11 iceadmn3

Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0028013	26 YRS CAUCASIAN MALE	28MAR2005-29MAR2005	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [SUSPECTED UNINTENTIONAL OVERDOSE OF STUDY DRUG]	2	36	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0046012	60 YRS CAUCASIAN MALE	16FEB2005-03MAR2005	ON	ACUTE MYOCARDIAL INFARCTION (Cardiac disorders) [ACUTE INFERIOR WALL MYOCARDIAL INFARCTION]	16	2	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

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GENERATED: 17NOV2005 13:44:11 iceadmn3

Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0025045	24 YRS BLACK FEMALE	01MAR2005-02MAR2005	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT INTENTIONAL OVERDOSE (NON - STUDY DRUG)]	2	2	SEV	N	N	Y	N	N	N	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG102.SAS
GENERATED: 17NOV2005 13:44:11 iceadmn3

Table 11.3.4.2 Serious Adverse Events

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0014020	20 YRS CAUCASIAN FEMALE	08JUN2005-15JUN2005	ON	TONSILLITIS (Infections and infestations) [TONSILLITIS ASSOCIATED WITH STREP INFECTION]	8	37	SEV	N	N	Y	N	N	N	YES NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG102.SAS
GENERATED: 17NOV2005 13:44:11 iceadmn3

11.3.4.3 Narratives of serious adverse events other than death

Study D1447C00135 Patient 0014/020 Placebo

Serious: Tonsillitis

This narrative concerns a 20-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of tonsillitis associated with strep infection (MedDRA: tonsillitis) on Day 37 of randomized treatment to placebo that was considered by the investigator to be severe in intensity. Eight days after the last dose of study medication, the patient informed the site that she had been hospitalized from three days after the last dose of study medication to six days after the last dose of study medication because of tonsillitis and a streptococcal infection. According to the patient, she was treated with ibuprofen and an unknown antibiotic for the tonsillitis. The patient provided the site written consent to obtain hospital records related to the hospitalization, but the hospital denied admitting or having treated the patient during the referenced time period. Attempts by telephone and certified letter to contact the patient and schedule a follow-up evaluation and resolve the confusion about the hospitalization did not succeed. The patient did not return for a premature discontinuation visit. The investigator withdrew study treatment due to this event and the patient's last dose of study medication was on Day 38.

The patient had non-serious adverse events of worsening of migraines (MedDRA: migraine) from Day 5 to Day 8, considered by the investigator to be mild in intensity, and nausea from Day 6 to Day 8, considered by the investigator to be moderate in intensity. The investigator considered both non-serious adverse events to be related to study treatment. Before and during the study, the patient was treated with acetaminophen (TYLENOL®, McNeil Consumer) and aspirin as needed for migraines. The patient had a current medical history of migraines and seasonal allergies. The screening visit physical examination was normal.

The investigator considered tonsillitis to be not related to study treatment.

Study D1447C00135 Patient 0015/005 Quetiapine 600 mg/day

Serious: Syncope

This narrative concerns a 42-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of syncope not due to orthostatic hypotension (MedDRA: syncope) one day after the last dose of randomized treatment of 600 mg that was considered by the investigator to be mild in intensity. One day after the last dose of study medication, she was hospitalized after a syncopal event and complaints of Right Upper Quadrant (RUQ) pain. Evaluations during the 24-hour hospitalization are listed in Table 1. The patient was not treated with medications for syncope or RUQ pain during the hospital stay and left after one day against medical advice. The patient took her last dose of study medication on Day 10 and withdrew consent five days later.

Table 1 Clinical Assessments Patient 0015/005

Study day	Assessment	Results
One day after last dose	AST	64 U/L
	ALT	74 U/L
	Hepatitis panel	Negative
	C-reactive protein	12.9 mg/L
	CT scan, abdomen	Sigmoid diverticula, Right Lower Lobe atelectasis
	Urinalysis	Positive for blood
	Pregnancy test	Negative
	Cardiac enzyme panel	Negative
	Urine culture	No growth
	Chest X-ray	Basilar infiltrates, bilateral

The patient had non-serious adverse events of dry mouth (Day 3 to Day 10), increased appetite for sweets (MedDRA: food craving) (Day 2 to Day 10), and rib pain (MedDRA: chest wall pain) (Day 7, ongoing as of final visit). The investigator considered the dry mouth and increased appetite for sweets to be mild in intensity and related to study treatment and the rib pain to be moderate in intensity and not related to study treatment. Before entering the study, the patient had been treated with lansoprazole (PREVACID®, TAP Pharmaceuticals) as needed for gastroesophageal reflux disease (GERD). During the study the patient was treated by her primary care physician with propoxyphene napsylate / acetaminophen (DARVOCET-N®, aaiPharma) as needed for rib pain from Day 8 to Day 10. The patient had a current medical history of GERD. The screening visit and final visit physical examinations were normal.

The investigator considered syncope to be related to study treatment

Study D1447C00135 Patient 0015/008 Quetiapine 300 mg/day

Serious: Suicidal Ideation

This narrative concerns a 37-year-old black man with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation with plan (MedDRA: suicidal ideation) two days after the last dose of randomized treatment 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient was admitted to the hospital with complaints of feeling depressed and because he reported feeling suicidal and described having a plan. Evaluations during the hospitalization are shown in Table 2. The patient was treated with quetiapine fumarate (SEROQUEL®, AstraZeneca) 100 mg, (two days after the last dose to 12 days after the last dose), divalproex sodium (DEPAKOTE ER®, Abbott) 1500 mg (two days after the last dose and ongoing at the final visit), and sertraline hydrochloride (ZOLOFT®, Pfizer) 50 mg (two days after the last dose and ongoing at the final visit). His depression came under control and suicidal ideation resolved eight days after the last dose of study medication. The patient was discharged eight days after the last dose of study medication. The patient took his last dose of study medication on Day 7 and an early discontinuation visit was performed 13 days later.

Table 2 Clinical Assessments Patient 0015/008

Study day	Assessment	Results
9	CK	460 U/L (decreased to 266 U/L after IV hydration)
9-15*	CT scan, head	Normal
	Cocaine level	Positive
14	Depakote level	78.8 mcg/mL

*Exact study day unknown

The patient had a non-serious adverse event of lightheadedness not due to orthostatic hypotension (MedDRA: dizziness) from Day 4 to four days after the last dose of study medication that was considered by the investigator to be mild in intensity and related to study treatment. Before entering the study, the patient had been treated with divalproex sodium (DEPAKOTE ER®, Abbott) 1000 mg, and sertraline hydrochloride (ZOLOFT®, Pfizer) 50 mg for bipolar disorder. Both medications were discontinued 14 days before the first dose of study treatment. The patient had a past medical history of cocaine abuse, cannabis abuse, alcohol abuse, status post cerebral vascular accident, diverticulitis, left side migraine with some parasthesias, asthma, and allergies to fruits and nuts. The screening visit and final visit physical examinations were normal.

The investigator considered suicidal ideation to be not related to study treatment.

Study D1447C00135 Patient 0020/032 Quetiapine 600 mg/day

Serious: Convulsion

This narrative concerns a 33-year-old white man with bipolar I disorder.

The patient had a serious adverse event of seizure with associated bronchospasm/aspiration (MedDRA: convulsion) that started one day after the last dose of randomized treatment 600

mg that was considered by the investigator to be severe in intensity. The patient experienced twitching and a fall while drinking (alcohol) with friends. He vomited and may have briefly stopped breathing. He was transported to the emergency room by ambulance and admitted with the presumptive diagnosis of a seizure with aspiration. In the emergency room, the patient had significant wheezing and an arterial blood gas showed respiratory acidosis (pH=7.12). Evaluations during the hospitalization are shown in Table 3. The patient had no seizure activity during the hospitalization. The patient was treated with levofloxacin (LEVAQUIN®, Ortho-McNeil) 500 mg and clindamycin 1200 mg for aspiration prophylaxis, prednisone 40 mg and ipratropium bromide / albuterol sulfate (COMBIVENT®, Boehringer Ingelheim) 8 puffs as needed for bronchospasm associated with seizure, and benzodiazapine for seizure prophylaxis. He was discharged four days after the last dose of study medication with seizure precautions. The patient's last dose of study medication was on Day 32. One day after the last dose of study medication, the investigator withdrew study treatment due to this event.

Table 3 Clinical Assessments Patient 0020/032

Study day	Assessment	Results
33	CBC, PTT, INH	Normal
	Serum chemistry	Normal
	CXR	Normal
	Alcohol level	Negative
	CT scan, head	No intracranial abnormality
	Tricyclic level	Positive
35	CXR	Interstitial infiltrates
36	EEG	Normal

The patient had the following non-serious adverse events during study treatment: umbilical pain (MedDRA: abdominal pain), Day 1 to Day 13, considered by the investigator to be mild in intensity and not related to study treatment; cough (start date Feb 2005 and ongoing as of last patient contact), considered by the investigator to be moderate in intensity and not related to study treatment; dry mouth (Day 9 to Day 13 and Day 16 and ongoing as of last patient contact); drowsiness morning (MedDRA: somnolence) (Day 2 and ongoing as of last patient contact); and worsening of decreased libido (MedDRA: libido decreased) (Day 15 and ongoing as of last patient contact). The investigator considered both episodes of dry mouth, drowsiness morning, and worsening of decreased libido to be mild in intensity and related to study treatment. During the study, the patient was treated with benzonatate (TESSALON® PERLES, Forest) 600 mg for cough, start date Feb 2005 and ongoing as of last patient contact. The patient had a relevant medical history of cocaine abuse (non-dependent), alcohol abuse, and a childhood seizure (not reported during the study enrollment history but included in the

medical history obtained by the hospital). The screening visit physical examination was normal.

The investigator considered convulsion to be related to study treatment.

Study D1447C00135 Patient 0020/037 Quetiapine 600 mg/day

Serious: Suicidal Ideation

This narrative concerns a 30-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation with plan (MedDRA: suicidal ideation) 25 days after the last dose of randomized treatment 600 mg that was considered by the investigator to be severe in intensity. Twenty-five days after the last dose of study medication, the patient was seen at the study site for a follow-up visit and was evaluated for depression and fearfulness and was felt to be in crisis because of the loss of custody of her two daughters. She stated during this clinic visit, "There is a 9mm in the drawer calling my name." Under authority of the State of Florida's Baker Act, she was involuntarily admitted to the hospital for approximately 48 hours. At discharge, the hospital provided a follow-up care plan. The patient expressed anger over the involvement of the site in invoking the Baker Act. With a care plan known to be in place, attempts to reestablish a relationship to obtain additional information on the event were not felt to be in the patient's interest.

During the study, the patient had non-serious adverse events of diffuse rash (MedDRA: rash) (began Day 3) and itching associated with diffuse rash (MedDRA: rash pruritic) (began two days after the last dose of study medication). The investigator considered both diffuse rash and itching associated with diffuse rash to be moderate in intensity and related to study treatment. The investigator withdrew the subject from the study due to the event of diffuse rash and the patient's last dose of study medication was on Day 3. A final study visit was performed four days after the last dose of study drug. Both events resolved 25 days after the last dose of study medication. Other non-serious adverse events during the study were vomiting and nausea that both began and ended one day after the last dose of study medication and were considered by the investigator to be mild in intensity and related to study treatment. The patient was not treated with any concomitant medications before or during study treatment. The patient was treated with diphenhydramine hydrochloride (BENADRYL®, Pfizer Consumer) 25 mg (starting and ending one day after the last dose of study medication), 125 mg (starting and ending two days after the last dose of study medication), and 150 mg (three days after the last dose of study medication and ongoing as of last patient contact) for diffuse rash. At the final visit, four days after the last dose of study medication, the patient was treated with clonazepam (KLONOPIN®, Roche) 0.25 mg as needed for anxiety/agitation associated with bipolar disorder. The patient had a current medical history of allergies to oxcarbazepine (TRILEPTAL®, Novartis Pharmaceuticals), divalproex sodium (DEPAKOTE®, Abbott), penicillin, and aspirin, environmental allergies, right ovarian cyst, arthritis of the knees, ankles, and wrists, and migraine headaches. The screening visit physical examination was normal. The final visit physical examination revealed a fine erythematous wheel like rash over inner arms and inner thighs.

The investigator considered suicidal ideation to be not related to study treatment.

Study D1447C00135 Patient 0025/045 Quetiapine 600 mg/day

Serious: Suicide Attempt

This narrative concerns a 24-year-old black woman with bipolar II disorder.

The patient had a serious adverse event of suicide attempt – intentional overdose (non-study drug) (MedDRA: suicide attempt) on Day 2 of randomized treatment 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. The patient was evaluated and treated in an emergency room where she was taken by ambulance after her boyfriend found her in a sleepy/groggy state. Per hospital records, the patient had taken 35 tablets of naproxen (NAPROSYN®, Roche) (500 mg), 8 tablets of zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) (10 mg), 6 tablets of oxcarbazepine (TRILEPTAL®, Novartis) (unknown strength), 10 tablets of atenolol (50 mg), and 10 tablets of hydrochlorthiazide (25 mg) approximately two hours before being found by her boyfriend. Treatment in the emergency room included stomach pumping and oral charcoal. Evaluation included vital sign monitoring, ECG, and clinical laboratory tests, all of which were unremarkable. A serum ethanol level was positive. In consultation with the Poison Control Center, the managing physicians determined it was unlikely the patient ingested the drugs and doses listed because of the lack of metabolic changes and stable vital signs. The patient agreed to a no-harm contract, refused hospital admission, and was discharged from the emergency room. The patient took a single dose of study medication on Day 1, no study medications on Day 2, and resumed study medication on Days 3, 4, 5, 6, and 7. The patient's last dose of study medication was on Day 7. The patient's final study visit occurred nine days after the last dose of study medication.

The patient had non-serious adverse events of dry mouth (Day 3 to four days after the last dose of study medication) and sedation (Day 1 and ongoing as of the final visit, nine days after the last dose of study medication). The investigator considered both non-serious adverse events to be mild in intensity and related to study treatment. Before entering the study, the patient had been treated with oxcarbazepine (TRILEPTAL®, Novartis) 1 tablet/day and risperidone (RISPERDAL®, Janssen) 1 tablet/day for anxiety. Per patient report, zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) and oxcarbazepine (TRILEPTAL®, Novartis) were previously prescribed to the patient and other drugs taken as part of the non-accidental overdose [naproxen (NAPROSYN®, Roche), atenolol, and hydrochlorthiazide] were her boyfriend's. The patient had a current medical history of thalassemia and obesity. The screening visit and final visit physical examinations were normal.

The investigator considered suicide attempt to be not related to study treatment.

Study D1447C00135 Patient 0027/016 Quetiapine 600 mg/day

Serious: Suicidal Ideation

This narrative concerns a 21-year-old white woman with bipolar I disorder.

The patient had a serious adverse event of suicidal ideation 15 days after the last dose of randomized treatment 600 mg that was considered by the investigator to be mild in intensity. The patient was discontinued from the study on Day 47. The patient was prescribed open-label quetiapine fumarate (SEROQUEL®, AstraZeneca), 300 mg BID at study termination. Fifteen days after the last dose of study medication, the patient's family called the site to report the patient had not been taking the prescribed medication properly and was psychiatrically unstable. The site recommended evaluation in an emergency room. In the emergency room the patient was diagnosed with suicidal ideation and admitted to the hospital. The hospitalization continued for a total of 33 days in two hospitals, and concluded with transfer to a chronic care facility. At the first acute care hospital, the patient was discovered to be pregnant (6 weeks gestation). The patient underwent elective termination of pregnancy (see separate pregnancy report). At hospital discharge, the patient was being treated with divalproex sodium (DEPAKOTE ER®, Abbott) 1000 mg/day and risperidone (RISPERDAL®, Janssen) 3 mg/day for bipolar disorder.

During the study, the patient had non-serious adverse events of palpitation (MedDRA: palpitations), double vision (MedDRA: diplopia), weakness (MedDRA: asthenia), anorexia, and sleepiness (MedDRA: somnolence). All of these events, except sleepiness, began on Day 19, resolved on Day 33, and were considered by the investigator to be mild in intensity and related to study treatment. Sleepiness began on Day 24, resolved on Day 33, and was considered by the investigator to be moderate in intensity and related to study treatment. Before entering the study, the patient had been treated with divalproex sodium (DEPAKOTE ER®, Abbott) 1500 mg/day and risperidone (RISPERDAL®, Janssen) 2 mg/day for bipolar disorder. No conditions were reported in the medical history. The screening visit and final visit physical examinations were normal.

The investigator considered suicidal ideation to be not related to study treatment.

Study D1447C00135 Patient 0028/013 Quetiapine 600 mg/day

Serious: Accidental Overdose

This narrative concerns a 26-year-old white man with bipolar I disorder.

The patient had a serious adverse event of suspected unintentional overdose of study drug (MedDRA: accidental overdose) one day after the last confirmed dose of randomized treatment 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from treatment due to this event. The patient's last confirmed dose was on Day 35. The study site contacted the patient's mother when the patient missed his Visit 7 appointment. She reported that the patient had taken an overdose of study medication combined with alcohol. The site recommended calling the paramedics who transported the patient to the emergency room where he was admitted for 24 hours of observation. In the emergency room, the patient reported taking a double dose of study medication (8 tablets) and drinking 7-8 beers to ensure sleep. Suicidal intentions were denied. Per hospital records, the patient had one prior overdose with suicidal intent. Evaluations included hematology and serum chemistry screens (unremarkable) and toxicology screens (positive only for benzodiazepines). The patient was treated with stomach pumping, naloxone

hydrochloride (NARCAN®, Endo) 2 mg, charcoal 50 g, sorbitol 50 g, and intravenous saline 125 cc. An early discontinuation visit was performed 24 days after the last confirmed dose of study medication.

The patient had non-serious adverse events of restless legs – not EPS (extrapyramidal symptoms) (MedDRA: restless legs syndrome) (Day 9 to 24 days after last confirmed dose of study medication) and intermittent dizziness – due to possible orthostatic hypotension (MedDRA: orthostatic hypotension) (Day 4 to 24 days after the last confirmed dose of study medication). Both non-serious adverse events were considered by the investigator to be mild in intensity and related to study treatment. Before entering the study, the patient was treated with albuterol as needed for asthma. This medication was ongoing at the final study visit. The patient was not treated with additional medications during the study. The patient had a current medical history of allergic to eggs and asthma. The screening visit and final visit physical examinations were normal.

The investigator considered accidental overdose to be not related to study treatment.

Study D1447C00135 Patient 0033/007 Quetiapine 300 mg/day

Serious: Mitral Valve Prolapse

This narrative concerns a 39-year-old black man with bipolar I disorder.

The patient had a serious adverse event of mitral valve prolapse worsening (MedDRA: mitral valve prolapse) on Day 55 of randomized treatment 300 mg that was considered by the investigator to be severe in intensity. The patient was evaluated in an emergency room and admitted to the hospital after experiencing chest pain, palpitations, and lightheadedness approximately 1.5 hours after taking study medication, drinking 10 cups of coffee and one soda on Day 55. Evaluations during the 24-hour hospital stay are shown in Table 4. During the hospitalization, the patient was treated with aspirin (ECOTRIN®, GlaxoSmithKline) 325 mg and nitroglycerin. The patient was discharged the day after admission against medical advice. The final study visit was performed four days after the last dose of study medication.

Table 4 Clinical Assessments Patient 0033/007

Study day	Assessment	Results
One day after last dose of study medication	ECG	No significant abnormality
	Ventilation/ perfusion scan	Normal
	echocardiogram	No pericardial effusion; minimal anterior leaf prolapse of the mitral valve with trace regurgitation
	CXR	Normal
	Arterial blood gas	Normal

Table 4 Clinical Assessments Patient 0033/007

Study day	Assessment	Results
Two days after last dose of study medication	Cardiac stress test	Normal

During the study the patient had non-serious adverse events of weight gain (MedDRA: weight increased) from Day 36 to Day 43, considered by the investigator to be mild in intensity and grogginess in the morning (MedDRA: somnolence) from Day 2 to Day 4, considered by the investigator to be moderate in intensity. The investigator considered both events to be related to study treatment. The patient did not take any other relevant concomitant medications before or during the study. The patient had a past medical history of bacterial pericarditis and staph infection on left leg, and a current medical history of occasional headaches, intermittent lower back pain, abdominal scar, dysconjugate gaze, and mitral valve prolapse. The screening visit and final visit physical examinations revealed dysconjugate gaze and a scar from a knife wound right lower quadrant.

The investigator considered the mitral valve prolapse to be not related to study treatment.

Study D1447C00135 Patient 0034/010 Quetiapine 300 mg/day

Serious: Bipolar I Disorder

This narrative concerns a 58-year-old black woman with bipolar I disorder.

The patient had a serious adverse event of worsening of bipolar I disorder, mixed with associated psychotic features (MedDRA: bipolar I disorder) one day after the last dose of randomized treatment 300 mg that was considered by the investigator to be severe in intensity. The patient was hospitalized one day after the last dose of study medication because of agitation, hostility, and aggressive behaviors. During the hospitalization, the patient was treated with risperidone (RISPERDAL®, Janssen) 2 mg for bipolar mood disorder and lorazepam (ATIVAN®, Biovail Pharmaceuticals, Inc.) 1 mg for anxiety. The patient remained in the hospital for six days and, at discharge, was receiving risperidone (RISPERDAL®, Janssen) 2 mg for bipolar mood disorder and hydroclorothiazide 12.5 mg for hypertension. The serious adverse event resolved seven days after the last dose of study medication. The patient was judged medically stable and was discharged with a recommendation to follow-up with the Partial Hospitalization Program and a primary care physician that same day. The investigator withdrew study treatment due to this event and the patient's last dose of study medication was on Day 3.

The patient had a non-serious adverse event of back pain that began four days after the last dose of study medication and resolved five days after the last dose of study medication. The investigator considered the back pain to be mild in intensity and not related to study treatment. Before entering the study, the patient had been treated with divalproex sodium

(DEPAKOTE®, Abbott) 1000 mg, then 500 mg, and ziprasidone hydrochloride (GEODON®, Pfizer) 160 mg, then 80 mg for bipolar mood disorder, and trazadone 100 mg then 50 mg for insomnia. The patient discontinued these medications eight days before study treatment. Before and during the study, the patient was treated with pioglitazone (ACTOS®, Takeda) 15 mg for NIDDM. While being hospitalized for bipolar I disorder, the patient was treated with hydrochlorothiazide 12.5 mg and clonidine 2 mg and 0.1 mg for hypertension, potassium (K-DUR®, Key) 20 meq for low potassium, and acetaminophen (TYLENOL®, McNeil Consumer) 650 mg for back pain. The patient had a current medical history of non-insulin dependent diabetes mellitus (NIDDM), hypertension, and an allergy to penicillin. The screening visit and final visit physical examinations were normal.

The investigator considered bipolar I disorder to be not related to study treatment.

Study D1447C00135 Patient 0046/012 Quetiapine 600 mg/day

Serious: Acute Myocardial Infarction

This narrative concerns a 60-year-old white man with bipolar I disorder.

The patient had a serious adverse event of acute inferior wall myocardial infarction (MedDRA: acute myocardial infarction) that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event. On Day 2 of randomized treatment 600 mg, the patient described experiencing a “pressure on my chest” radiating to the patient’s neck and left arm and shortness of breath. The patient took his last dose of study medication on Day 6 and returned to the clinic one day later for evaluation. During the evaluation, the patient stated that the symptoms had been present off and on since Day 2 (total of five days) and resembled the symptoms of a previous episode that had resulted in cardiac stenting. An ECG at the site was consistent with an acute inferior myocardial infarction. The patient was referred to an emergency room and admitted for management of myocardial infarction. The patient arrived at the emergency department three to four hours into an acute myocardial infarction. The patient was admitted and underwent emergency stenting of his right coronary artery. About three hours after the procedure, the patient had a monitored VF arrest and was returned to the cardiac catheterization laboratory. Procedures of coronary angiography, left ventriculography, and PCI of right coronary artery were performed. Though the right coronary artery had been successfully unoccluded, the angiogram revealed the patient had untreated high-grade LAD bifurcation diagonal disease. The patient slowly recovered and stabilized in the coronary care unit. Eight days later a coronary angiography and PCI of the LAD were performed resulting in additional placement of stents. The patient returned to the care of the hospital for recovery. On the following day, the patient was reported to have some brief runs of non-sustained ventricular arrhythmias after the PCI procedure. The patient also reported some dizziness upon standing, but no palpitations. After consultation with cardiology, an ECG, physical exam, telemetry, and additional labs were conducted and results reviewed. The patient was prescribed amiodarone and it was decided he did not need a defibrillator at that time. The serious adverse event resolved 11 days after the last dose of study medication. The patient was reported to be in stable condition at discharge, two days after the PCI procedure. The patient returned for

follow-up with the cardiologist 13 days after discharge and continued to be medically stable. The patient was treated with clopidogrel bisulfate (PLAVIX®, Bristol-Myers Squibb and Sanofi-Synthelabo) 75 mg, aspirin 325 mg, and amiodarone 400 mg for cardiac prophylaxis, metoprolol 150 mg and lisinopril 2.5 mg for hypertension, simvastatin (ZOCOR®, Merck) 20 mg for hyperlipidemia, famotidine (PEPCID®, Merck) 20 mg for gastrointestinal bleeding prophylaxis, and cefuroxime 2250 mg for infection prophylaxis. The patient was discharged with all of the above noted medications (except for famotidine (PEPCID®, Merck) and cefuroxime) with the following noted dose changes: amiodarone 200 mg for cardiac prophylaxis, metoprolol 100 mg then 50 mg for hypertension, and simvastatin (ZOCOR®, Merck) 40 mg for hyperlipidemia. Additionally, upon discharge the patient was treated with pantoprazole sodium (PROTONIX®, Wyeth) 40 mg for gastrointestinal bleeding prophylaxis. No study medication was taken after Day 6 and the patient returned to the study site for an early termination visit 13 days after discharge from the hospital, which was 24 days after the last dose of study medication.

The patient had non-serious adverse events of chest pain, sedation, restlessness not due to EPS (MedDRA: restlessness), and shortness of breath (MedDRA: dyspnea). All non-serious adverse events began on Day 2 and resolved two days after the last dose of study medication. The chest pain and shortness of breath were considered by the investigator to be moderate in intensity and not related to study treatment. The sedation and restlessness not due to EPS were considered by the investigator to be mild in intensity and related to study treatment. Before entering the study, the patient had been treated with atenolol 50 mg for hypertension and aspirin 80 mg for general heart health. The patient discontinued use of atenolol on Day 6. Asprin was ongoing at the patient's final study visit. The patient had a past medical history of angina without myocardial infarction, benign colon polyp, glucose intolerance, and bilateral retinal detachment. The patient had a current medical history of hypertension, hyperlipidemia, intermittent rectal bleeding, hemorrhoids, reduced sensation both feet, headaches, and mild loss of hearing right ear. The screening visit and final visit physical examinations were normal.

The investigator considered acute myocardial infarction to be not related to study treatment.

Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
ANY EVENT LEADING TO DISCONTINUATION		14	8.2	19	11.3	2	1.2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	0	0	1	0.6	0	0
	ANAEMIA	0	0	1	0.6	0	0
CARDIAC DISORDERS	TOTAL	0	0	2	1.2	0	0
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.6	0	0
	TACHYCARDIA	0	0	1	0.6	0	0
EYE DISORDERS	TOTAL	0	0	1	0.6	0	0
	VISION BLURRED	0	0	1	0.6	0	0
GASTROINTESTINAL DISORDERS	TOTAL	2	1.2	1	0.6	0	0
	DRY MOUTH	0	0	1	0.6	0	0
	NAUSEA	2	1.2	0	0	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	1	0.6	4	2.4	0	0
	CHEST DISCOMFORT	0	0	1	0.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG209.SAS
GENERATED: 17NOV2005 13:44:50 iceadmn3

Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	0	0	3	1.8	0	0
	LETHARGY	1	0.6	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	0	0	0	0	1	0.6
	TONSILLITIS	0	0	0	0	1	0.6
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	1	0.6	0	0
	ACCIDENTAL OVERDOSE	0	0	1	0.6	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	10	5.8	10	6.0	0	0
	AKATHISIA	1	0.6	0	0	0	0
	CONVULSION	0	0	1	0.6	0	0
	DIZZINESS	1	0.6	2	1.2	0	0
	EXTRAPYRAMIDAL DISORDER	0	0	1	0.6	0	0
	HYPERSOMNIA	0	0	1	0.6	0	0
	HYPOAESTHESIA	0	0	1	0.6	0	0
	SEDATION	8	4.7	6	3.6	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG209.SAS
GENERATED: 17NOV2005 13:44:50 iceadmn3

Table 11.3.5.1.1 Adverse Events Leading to Discontinuation by System Organ Class
Safety Population

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
SYSTEM ORGAN CLASS	PREFERRED TERM	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	0	0	1	0.6	0	0
PSYCHIATRIC DISORDERS	TOTAL	4	2.3	1	0.6	0	0
	BIPOLAR I DISORDER	1	0.6	0	0	0	0
	DISSOCIATION	1	0.6	0	0	0	0
	HYPOMANIA	1	0.6	0	0	0	0
	PANIC ATTACK	1	0.6	0	0	0	0
	SUICIDAL IDEATION	1	0.6	0	0	0	0
	SUICIDE ATTEMPT	0	0	1	0.6	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	0	0	1	0.6	1	0.6
	RASH	0	0	1	0.6	1	0.6
VASCULAR DISORDERS	TOTAL	0	0	1	0.6	0	0
	HYPERTENSION	0	0	1	0.6	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG209.SAS
GENERATED: 17NOV2005 13:44:50 iceadmn3

Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
ANY EVENT LEADING TO DISCONTINUATION		8	7.1	11	9.8	2	1.8	6	10.2	8	14.3	0	0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	ANAEMIA	0	0	1	0.9	0	0	0	0	0	0	0	0
CARDIAC DISORDERS	TOTAL	0	0	2	1.8	0	0	0	0	0	0	0	0
	ACUTE MYOCARDIAL INFARCTION	0	0	1	0.9	0	0	0	0	0	0	0	0
	TACHYCARDIA	0	0	1	0.9	0	0	0	0	0	0	0	0
EYE DISORDERS	TOTAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	VISION BLURRED	0	0	1	0.9	0	0	0	0	0	0	0	0
GASTROINTESTINAL DISORDERS	TOTAL	1	0.9	1	0.9	0	0	1	1.7	0	0	0	0
	DRY MOUTH	0	0	1	0.9	0	0	0	0	0	0	0	0
	NAUSEA	1	0.9	0	0	0	0	1	1.7	0	0	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	0	0	1	0.9	0	0	1	1.7	3	5.4	0	0
	CHEST DISCOMFORT	0	0	1	0.9	0	0	0	0	0	0	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG210.SAS
GENERATED: 17NOV2005 13:44:53 iceadmn3

Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	0	0	0	0	0	0	0	0	3	5.4	0	0
	LETHARGY	0	0	0	0	0	0	1	1.7	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	0	0	0	0	1	0.9	0	0	0	0	0	0
	TONSILLITIS	0	0	0	0	1	0.9	0	0	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	ACCIDENTAL OVERDOSE	0	0	1	0.9	0	0	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	6	5.4	5	4.5	0	0	4	6.8	5	8.9	0	0
	AKATHISIA	0	0	0	0	0	0	1	1.7	0	0	0	0
	CONVULSION	0	0	1	0.9	0	0	0	0	0	0	0	0
	DIZZINESS	0	0	2	1.8	0	0	1	1.7	0	0	0	0
	EXTRAPYRAMIDAL DISORDER	0	0	1	0.9	0	0	0	0	0	0	0	0
	HYPERSOMNIA	0	0	1	0.9	0	0	0	0	0	0	0	0
	HYPOAESTHESIA	0	0	1	0.9	0	0	0	0	0	0	0	0
	SEDATION	6	5.4	1	0.9	0	0	2	3.4	5	8.9	0	0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG210.SAS
GENERATED: 17NOV2005 13:44:53 iceadmn3

Table 11.3.5.1.2 Adverse Events Leading to Discontinuation by System Organ Class and Bipolar Diagnosis
Safety Population

		TREATMENT											
		Q300-BPI		Q600-BPI		P-BPI		Q300-BPII		Q600-BPII		P-BPII	
		N=112		N=112		N=112		N=59		N=56		N=55	
		NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%	NO.OF PTS	%
SYSTEM ORGAN CLASS	PREFERRED TERM												
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	0	0	1	0.9	0	0	0	0	0	0	0	0
PSYCHIATRIC DISORDERS	TOTAL	3	2.7	0	0	0	0	1	1.7	1	1.8	0	0
	BIPOLAR I DISORDER	1	0.9	0	0	0	0	0	0	0	0	0	0
	DISSOCIATION	1	0.9	0	0	0	0	0	0	0	0	0	0
	HYPOMANIA	0	0	0	0	0	0	1	1.7	0	0	0	0
	PANIC ATTACK	1	0.9	0	0	0	0	0	0	0	0	0	0
	SUICIDAL IDEATION	1	0.9	0	0	0	0	0	0	0	0	0	0
	SUICIDE ATTEMPT	0	0	0	0	0	0	0	0	1	1.8	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL	0	0	1	0.9	1	0.9	0	0	0	0	0	0
	RASH	0	0	1	0.9	1	0.9	0	0	0	0	0	0
VASCULAR DISORDERS	TOTAL	0	0	1	0.9	0	0	0	0	0	0	0	0
	HYPERTENSION	0	0	1	0.9	0	0	0	0	0	0	0	0

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG210.SAS
GENERATED: 17NOV2005 13:44:53 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0008009	34 YRS CAUCASIAN FEMALE	26JAN2005-31JAN2005	ON	SEDATION (Nervous system disorders) [SEDATION]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0008010	31 YRS ORIENTAL FEMALE	01FEB2005-06FEB2005	ON	NAUSEA (Gastrointestinal disorders) [NAUSEA]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	6	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0010017	29 YRS CAUCASIAN MALE	14MAY2005-30MAY2005	ON	SEDATION (Nervous system disorders) [SEDATION]	17	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			15MAY2005-24MAY2005	ON	DISSOCIATION (Psychiatric disorders) [INTERMITTENT DISASSOCIATION]	10	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG103.SAS
GENERATED: 17NOV2005 13:44:13 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0010017	29 YRS CAUCASIAN MALE	15MAY2005-27MAY2005	ON	PANIC ATTACK (Psychiatric disorders) [INTERMITTENT PANIC ATTACK]	13	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0013006	36 YRS CAUCASIAN FEMALE	06OCT2004-09OCT2004	ON	SEDATION (Nervous system disorders) [SEDATION]	4	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0014010	45 YRS OTHER MALE	04JAN2005-06FEB2005	ON	SEDATION (Nervous system disorders) [EARLY MORNING SEDATION]	34	2	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0015008	37 YRS BLACK MALE	23DEC2004-29DEC2004	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH PLAN]	7	9	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG103.SAS
GENERATED: 17NOV2005 13:44:13 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR I)	E0034010	58 YRS BLACK FEMALE	06MAY2005-12MAY2005	ON	BIPOLAR I DISORDER (Psychiatric disorders) [WORSENING OF BIPOLAR I DISORDER, MIXED WITH ASSOCIATED PSYCHOTIC FEATURES]	7	4	SEV	YES	N	N	Y	N	N	N	YES NO	None
	E0039023	35 YRS BLACK FEMALE	06APR2005-14APR2005	ON	SEDATION (Nervous system disorders) [SEDATION]	9	1	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG103.SAS
GENERATED: 17NOV2005 13:44:13 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0007002	35 YRS CAUCASIAN FEMALE	13OCT2004-21OCT2004	ON	SEDATION (Nervous system disorders) [SEDATION]	9	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0008007	34 YRS CAUCASIAN FEMALE	19JAN2005-25JAN2005	ON	SEDATION (Nervous system disorders) [SEDATION]	7	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0011024	22 YRS BLACK MALE	15MAR2005-16MAR2005	ON	DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	2	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					NAUSEA (Gastrointestinal disorders) [NAUSEA]	2	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0014005	42 YRS CAUCASIAN MALE	30AUG2004-CONTINUE	ON	LETHARGY (General disorders and administration site conditions) [LETHARGY]	UNK	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG103.SAS
GENERATED: 17NOV2005 13:44:13 iceadmn3

Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 300 MG (BIPOLAR II)	E0030023	31 YRS BLACK FEMALE	10DEC2004-CONTINUE	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	UNK	2	SEV	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0037021	54 YRS CAUCASIAN MALE	27MAR2005-29MAR2005	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	3	6	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE @ SER=SERIOUS
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Table 11.3.5.2 Adverse Events Leading to Discontinuation

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0006017	51 YRS CAUCASIAN FEMALE	22OCT2004-CONTINUE	ON	HYPERTENSION (Vascular disorders) [HYPERTENSION]	UNK	8	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0012004	43 YRS BLACK MALE	28AUG2004-CONTINUE	ON	ANAEMIA (Blood and lymphatic system disorders) [WORSENING ANEMIA]	UNK	30	MIL	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0014023	39 YRS CAUCASIAN FEMALE	15JUL2005-CONTINUE	ON	VISION BLURRED (Eye disorders) [BLURRED VISION]	UNK	23	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0020032	33 YRS CAUCASIAN MALE	11FEB2005-14FEB2005	ON	CONVULSION (Nervous system disorders) [SEIZURE WITH ASSOCIATED ASPIRATION/BRONCHOSPASM]	4	33	SEV	YES	N	N	Y	N	N	N	YES YES	Permanently Stopped
	E0020037	30 YRS CAUCASIAN FEMALE	10FEB2005-07MAR2005	ON	RASH (Skin and subcutaneous tissue disorders) [DIFFUSE RASH]	26	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0028013	26 YRS CAUCASIAN MALE	28MAR2005-29MAR2005	ON	ACCIDENTAL OVERDOSE (Injury, poisoning and procedural complications) [SUSPECTED UNINTENTIONAL OVERDOSE OF STUDY DRUG]	2	36	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped
	E0030016	56 YRS BLACK MALE	04NOV2004-CONTINUE	ON	HYPOAESTHESIA (Nervous system disorders) [NUMBNESS IN FINGERS]	UNK	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			04NOV2004-06NOV2004	ON	CHEST DISCOMFORT (General disorders and administration site conditions) [TIGHTNESS IN CHEST NOT DUE TO EPS]	3	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					DIZZINESS (Nervous system disorders) [DIZZINESS NOT DUE TO ORTHOSTATIC HYPOTENSION]	3	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0032010	55 YRS CAUCASIAN FEMALE	09MAR2005-27MAR2005	ON	SEDATION (Nervous system disorders) [SEDATION]	19	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			10MAR2005-27MAR2005	ON	DRY MOUTH (Gastrointestinal disorders) [DRY MOUTH]	18	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
			18MAR2005-27MAR2005	ON	HYPERSOMNIA (Nervous system disorders) [OVERSLEEPING]	10	11	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0042020	43 YRS CAUCASIAN FEMALE	16APR2005-16APR2005	ON	DIZZINESS (Nervous system disorders) [DIZZINESS DUE TO EPS NOT DUE TO ORTHOSTATIC HYPOTENSION]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [INVOLUNTARY TONGUE MOVEMENT DUE TO EPS]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR I)	E0042020	43 YRS CAUCASIAN FEMALE	16APR2005-16APR2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE ACHES/DUE TO EPS]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE STIFFNESS DUE TO EPS]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [SLURRED SPEECH DUE TO EPS]	1	6	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					TACHYCARDIA (Cardiac disorders) [TACHYCARDIA]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0042021	33 YRS CAUCASIAN FEMALE	26APR2005-CONTINUE	ON	SOMNOLENCE (Nervous system disorders) [DROWSINESS]	UNK	14	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR I)	E0046012	60 YRS CAUCASIAN MALE	16FEB2005-03MAR2005	ON	ACUTE MYOCARDIAL INFARCTION (Cardiac disorders) [ACUTE INFERIOR WALL MYOCARDIAL INFARCTION]	16	2	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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QUETIAPINE 600 MG (BIPOLAR II)	E0010011	54 YRS CAUCASIAN MALE	05FEB2005-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0011006	38 YRS CAUCASIAN FEMALE	05OCT2004-06OCT2004	ON	SEDATION (Nervous system disorders) [SEDATION]	2	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0011013	32 YRS CAUCASIAN FEMALE	01DEC2004-03DEC2004	ON	SEDATION (Nervous system disorders) [SEDATION]	3	3	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0012003	34 YRS CAUCASIAN FEMALE	30JUL2004-09AUG2004	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	11	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
					SEDATION (Nervous system disorders) [SEDATION]	11	2	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
QUETIAPINE 600 MG (BIPOLAR II)	E0014009	22 YRS CAUCASIAN FEMALE	11DEC2004-CONTINUE	ON	SEDATION (Nervous system disorders) [SEDATION]	UNK	3	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0025002	24 YRS BLACK MALE	18AUG2004-21AUG2004	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	4	2	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0025032	30 YRS CAUCASIAN FEMALE	10JAN2005-11JAN2005	ON	FATIGUE (General disorders and administration site conditions) [FATIGUE]	2	1	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
	E0025045	24 YRS BLACK FEMALE	01MAR2005-02MAR2005	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT INTENTIONAL OVERDOSE (NON - STUDY DRUG)]	2	2	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
PLACEBO (BIPOLAR I)	E0008011	24 YRS CAUCASIAN FEMALE	10MAR2005-CONTINUE	ON	RASH (Skin and subcutaneous tissue disorders) [RASH]	UNK	37	MOD	NO	N	N	N	N	N	N	YES NO	Permanently Stopped
	E0014020	20 YRS CAUCASIAN FEMALE	08JUN2005-15JUN2005	ON	TONSILLITIS (Infections and infestations) [TONSILLITIS ASSOCIATED WITH STREP INFECTION]	8	37	SEV	YES	N	N	Y	N	N	N	YES NO	None

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11.3.5.3 Narratives of discontinuations due to adverse events

Study D1447C00135 Patient 0006/017 Quetiapine 600 mg/day

Withdrawal: Hypertension

This narrative concerns a 51-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of hypertension on Day 8 of randomized treatment of 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's vital signs at the time of enrollment (seven days before the first dose of study medication), onset of the adverse event, and at the final study visit is listed below in Table 1. The patient's final dose of study medication was on Day 14. The non-serious adverse event of hypertension was unresolved at the time of the final visit, four days after the last dose of study medication.

Table 1 Clinical Assessments Patient 0006/017

Study Day	Supine Blood Pressure	Heart Rate (BPM)
Seven days before first dose of study medication	122/82	65
Day 8	160/120	89
Four days after the last dose of study medication	172/106	86

The patient had a non-serious adverse event of somnolence on Day 4 of randomized treatment that was considered by the investigator to be moderate in intensity and related to study treatment. The investigator reduced the dose of study medication from 4 to 3 tablets per day on Day 8 due to this event. This dose reduction was continued through the last dose. Two days after the final dose of study medication, the patient had a non-serious adverse event of nausea that was considered by the investigator to be mild in intensity and not related to study treatment. At the time of the final visit, four days after the last dose of study medication, the nausea and somnolence were ongoing. Before entering the study, the patient had been treated with ibuprofen 1000 mg / day (as needed) for intermittent tension headaches, which was ongoing at the final study visit. During the study, the patient was treated with hydrochlorothiazide 50 mg / day for hypertension starting on Day 8. This medication was ongoing at the final study visit. The patient had a medical history of current intermittent tension headaches. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered hypertension to be related to study treatment.

Study D1447C00135 Patient 0007/002 Quetiapine 300 mg/day

Withdrawal: Sedation

This narrative concerns a 35-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's final dose of study medication was on Day 7. The non-serious adverse event of sedation resolved two days after the last dose of study medication.

The patient had non-serious adverse events of urinary tract infection (starting 11 days prior to study treatment and ending seven days prior to study treatment) and headache (starting nine days prior to study treatment and ending on Day 6). The urinary tract infection and headache were considered by the investigator to be moderate in intensity and not related to study treatment. The patient also had non-serious adverse events of blurred vision (MedDRA: vision blurred), dry mouth, indigestion (MedDRA: dyspepsia), and decreased appetite, all starting on Day 1 of randomized treatment and ending two days after the last dose of study medication. The blurred vision and dry mouth were considered by the investigator to be moderate in intensity and related to study treatment. The indigestion and decreased appetite were considered by the investigator to be mild in intensity and related to study treatment. The patient had a non-serious adverse event of muscle stiffness not due to EPS (MedDRA: musculoskeletal stiffness) starting on Day 5 and ending two days after the last dose of study treatment. The event was considered by the investigator to be moderate in intensity and related to study treatment. Before entering the study, the patient had been treated with escitalopram oxalate (LEXAPRO®, Forest) 20 mg for bipolar disorder, which was stopped 15 days prior to study treatment. Fourteen days prior to study treatment, the patient had been treated with escitalopram oxalate (LEXAPRO®, Forest) 10 mg for bipolar disorder, which was stopped ten days prior to study treatment. Before entering the study, the patient had been treated with trazodone 50 mg for sleep, which was stopped 11 days prior to study treatment, and fluticasone propionate / salmeterol (ADVAIR DISKUS®, GlaxoSmithKline) two puffs / day for asthma. This medication was ongoing at the final visit. The patient was treated with ciprofloxacin (CIPRO®, Bayer) 1000 mg for a urinary tract infection, from 11 days to seven days prior to study treatment, and acetaminophen (EXTRA STRENGTH TYLENOL®, McNeil Consumer) 1500 mg for headache, beginning nine days prior to study treatment. This medication was ongoing at the final visit, one day after the last dose of study medication. The patient had a medical history of current asthma. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered sedation to be related to study treatment

Study D1447C00135 Patient 0008/007 Quetiapine 300 mg/day

Withdrawal: Sedation

This narrative concerns a 34-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment and the patient's final dose of study medication was on Day 3. Sedation resolved four days after the last dose of study medication.

The patient had a non-serious adverse event of orthostatic hypotension that began five days after the last dose of study medication and had not resolved as of the final visit, five days after the last dose of study medication. This adverse event was considered by the investigator to be mild in intensity and not related to study treatment. The patient was treated with levonorgestrel / ethinyl estradiol (SEASONALE®, Barr Laboratories, Inc.) before study treatment and this medication was ongoing at the final study visit. The patient had a current medical history of irregular periods. The screening and final visit physical examinations were unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0008/009 Quetiapine 300 mg/day

Withdrawal: Sedation

This narrative concerns a 34-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 2 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment and the patient's final dose of study medication was on Day 4. The sedation resolved three days after the last dose of study medication.

The patient had a non-serious adverse event of pharyngitis that began one day after the last dose of study medication and had not resolved as of the final visit, four days after the last dose of study medication. This adverse event was considered by the investigator to be mild in intensity and not related to study medication. Before and during study treatment, the patient was treated with acetaminophen (TYLENOL®, McNeil Consumer) 2 tablets/day for headaches and ibuprofen (ADVIL®, Wyeth Consumer) 400 mg as needed for headaches. During the study, the patient was treated for pharyngitis with acetaminophen (TYLENOL ES®, McNeil Consumer) 2000 mg that started one day before the last dose of study medication and ended two days after the last dose of study medication. The patient's relevant current medical history revealed intermittent chest pain (stress-related), intermittent stomach pain, headaches, and migraines. The patient had a past medical history of Bell's palsy and dysplasia (cervical). The screening and final visit physical examinations were unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0008/010 Quetiapine 300 mg/day

Withdrawal: Sedation and Nausea

This narrative concerns a 31-year-old Oriental woman with bipolar I disorder.

The patient had non-serious adverse events of sedation and nausea that began on Day 2 of randomized treatment of 300 mg and were both considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to these events and the patient's final dose of study medication was on Day 6. The sedation and nausea resolved one day after the last dose of study medication.

Seventeen days prior to randomized treatment, the patient was treated with penicillin 2000 mg and ibuprofen 800 mg as needed for abscessed tooth and left hip pain, respectively. The penicillin was discontinued seven days prior to randomized treatment and the ibuprofen was ongoing at the subject's final study visit, two days after the last dose of study medication. The patient's relevant current medical history revealed left hip arthritis, seasonal allergies, insomnia, abscessed tooth, and hypertension. The patient had a past medical history of heat stroke and anemia. The screening and final visit physical examinations revealed obesity.

The investigator considered sedation and nausea to be related to study treatment.

Study D1447C00135 Patient 0008/011 Placebo

Withdrawal: Rash

This narrative concerns a 24-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of rash that began on Day 37 of randomized treatment to placebo that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 37. The rash had not resolved as of the patient's final study visit, five days after the last dose of study treatment.

Other non-serious adverse events during the study included upper respiratory infection (MedDRA: upper respiratory tract infection) and rash that both began on Day 6 of randomized treatment and resolved on Day 15. Both were considered by the investigator to be moderate in intensity and not related to study treatment. From Day 11 to Day 15, the patient was treated with azithromycin (ZITHROMAX®, Pfizer) 250 mg/day for upper respiratory infection. No other relevant medications were taken during the study. The patient's current medical history revealed anxiety-related chest pain, heartburn, headaches, migraines, and insomnia. The patient's past medical history revealed anemia. The screening visit physical examination was unremarkable. The final visit physical examination revealed a fine, pruritic rash on the face, upper chest, and arms.

The investigator considered rash to be not related to study treatment

Study D1447C00135 Patient 0010/011 Quetiapine 600 mg/day

Withdrawal: Sedation

This narrative concerns a 54-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of sedation that began on Day 3 of randomized treatment of 600 mg that was considered by the investigator to be moderate in intensity. The investigator temporarily stopped study treatment due to this event on Day 6 (titration was not completed). The investigator resumed study treatment of four tablets on Day 8. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 12. The sedation had not resolved as of the patient's final visit, nine days after the last dose of study medication.

The patient had non-serious adverse events of akathisia (began Day 8, resolved two days after the last dose of study medication, considered by the investigator to be moderate in intensity and related to study treatment) and dizziness due to orthostatic hypotension [MedDRA: orthostatic hypotension] (began Day 8, resolved two days after the last dose of study medication, considered by the investigator to be moderate in intensity and related to study treatment). Other non-serious adverse events during the study included: dry mouth (Day 3, and ongoing at the final visit, considered by the investigator to be severe in intensity and related to study treatment); nausea (Day 3, and ongoing at the final visit, considered by the investigator to be moderate in intensity and related to study treatment); numbness in facial muscles [MedDRA: hypoaesthesia] (Day 3 to Day 5, considered by the investigator to be mild in intensity and not related to study treatment); difficulty swallowing due to EPS [MedDRA: extrapyramidal disorder] (Day 3 to Day 5, and Day 8 to two days after the last dose of study medication, both episodes considered by the investigator to be mild in intensity and related to study treatment); dizziness due to orthostatic hypotension [MedDRA: orthostatic hypotension] (Day 3 to Day 5, considered by the investigator to be severe in intensity and related to study treatment). Before and during the study, the patient was treated with aspirin as needed for headaches, melatonin 3 mg/day for insomnia, and metamucil as needed for irritable bowel syndrome. The patient's current relevant medical history revealed a penicillin allergy, numbness of the left leg and foot, headaches, irritable bowel syndrome, shoulder pain, and insomnia. The patient's past medical history revealed hepatitis A and pericarditis. The screening visit physical examination revealed an occasional wheeze in the left upper posterior chest, cleared with cough. The final visit physical examination was unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0010/017 Quetiapine 300 mg/day

Withdrawal: Sedation, Panic Attack, and Dissociation

This narrative concerns a 29-year-old white man with bipolar I disorder.

The patient had non-serious adverse events of sedation, intermittent panic attack [MedDRA: panic attack], and intermittent disassociation [MedDRA: dissociation]. Sedation began on Day 2 of randomized treatment of 300 mg and was considered by the investigator to be moderate in intensity. Intermittent panic attack and intermittent disassociation both began on Day 3 of randomized treatment and were considered by the investigator to be moderate in intensity. The investigator reduced the dose of study medication to three tablets on Day 8 (titration was not completed). The investigator withdrew study treatment due to these events and the patient's final dose of study medication was on Day 12. The sedation resolved

six days after the last dose of study medication, the intermittent panic attack resolved three days after the last dose of study medication, and the intermittent disassociation resolved on Day 12.

Other non-serious adverse events during the study included dry mouth (Day 4 to six days after the last dose of study medication), occasional muscle twitches due to EPS [MedDRA: extrapyramidal disorder] (Day 1, not resolved as of the final visit, 17 days after the last dose of study medication), and increased irritability [MedDRA: irritability] (Day 3 to six days after the last dose of study medication). The investigator considered the dry mouth, occasional muscle twitches due to EPS, and increased irritability to be moderate in intensity and related to study treatment. Before entering the study, the patient was treated with diphenhydramine hydrochloride (SOMINEX®, GlaxoSmithKline) 25 mg/day for insomnia, and Nyquil (NYQUIL®, Vicks) 50 ml/day and penicillin 500 mg/day for a sinus cold. The patient discontinued treatment with diphenhydramine hydrochloride (SOMINEX®, GlaxoSmithKline) seven days before study treatment. The patient discontinued treatment with Nyquil (NYQUIL®, Vicks) and penicillin eight days before study treatment. The patient did not take any concomitant medications during the study. The patient's relevant current medical history revealed a sinus cold, hypoglycemia, hypertension, and insomnia. The screening visit and final visit physical examinations were unremarkable.

The investigator considered sedation, panic attack, and dissociation to be related to study treatment.

Study D1447C00135 Patient 0011/006 Quetiapine 600 mg/day

Withdrawal: Sedation

This narrative concerns a 38-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 6 of randomized treatment of 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 5. The non-serious adverse event of sedation resolved two days after the last dose of study medication.

The patient had a non-serious adverse event of sedation on Day 2 that resolved on Day 3 and was considered by the investigator to be moderate in intensity and related to study treatment. The patient also had a non-serious adverse event of bronchitis that started eight days prior to randomized treatment, which was ongoing at the final visit. This event was considered by the investigator to be moderate in intensity and not related to study treatment. Before entering the study, the patient had been treated with albuterol inhaler 2 puffs/day for bronchitis, eight days prior to study treatment. This medication was ongoing at the final visit, three days after the last dose of study medication. The patient had a current medical history of mitral valve prolapse and headaches. The patient's screening and final visit physical examinations were unremarkable. No additional concomitant medications were given prior to or during study treatment.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0011/013 Quetiapine 600 mg/day

Withdrawal: Sedation

This narrative concerns a 32-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 3 of randomized treatment of 600 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's final dose of study medication was on Day 3. The non-serious adverse event of sedation resolved two days after the last dose of study medication.

The patient had a non-serious adverse event of dry mouth starting on Day 2 and ending four days after the last dose of study medication. This event was considered by the investigator to be mild in intensity and related to study treatment. On Day 2, the patient had a non-serious adverse event of inorgasmia (MedDRA: anorgasmia) that was considered by the investigator to be moderate in intensity and related to study treatment. Inorgasmia was ongoing at the final study visit, five days after the last dose of study medication. The patient was not treated with any concomitant medications prior to or during study treatment. The patient had a medical history of past asthma and past bladder infection. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0011/024 Quetiapine 300 mg/day

Withdrawal: Nausea and Dizziness

This narrative concerns a 22-year-old black man with bipolar II disorder.

The patient had non-serious adverse events of nausea and dizziness not due to orthostatic hypotension (MedDRA: dizziness) on Day 2 of randomized treatment of 300 mg that were both considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to these events. The patient's final dose of study medication was on Day 3. The non-serious adverse events of nausea and dizziness resolved that same day.

Twenty-six days prior to study treatment, the patient had been treated with acetaminophen / diphenhydramine hydrochloride (TYLENOL® PM, McNeil Consumer) one tablet / day for insomnia related to bipolar depression. The patient discontinued this medication nine days prior to study treatment. The patient was not treated with any concomitant medications during study treatment. The patient had a medical history of current muscular chest pain and current food-related heartburn. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered nausea and dizziness to be related to study treatment.

Study D1447C00135 Patient 0012/003 Quetiapine 600 mg/day

Withdrawal: Fatigue and Sedation

This narrative concerns a 34-year-old white woman with bipolar II disorder.

The patient had non-serious adverse events of fatigue and sedation on Day 2 of randomized treatment of 600 mg that were both considered by the investigator to be moderate in intensity. The investigator withdrew the patient from study treatment due to these events. The patient's final dose of study medication was on Day 6. The non-serious adverse events of fatigue and sedation resolved six days after the last dose of study medication.

The patient had a non-serious adverse event of partial numbness both legs (MedDRA: hypoaesthesia) starting on Day 6 and ending six days after the last dose of study medication. This event was considered by the investigator to be mild in intensity and related to study treatment. The patient also had a non-serious adverse event of feelings of hostility (MedDRA: hostility) from Day 2 to Day 6 that was considered by the investigator to be moderate in intensity and not related to study treatment. Before and during the study the patient was treated with vitamins, 1 tab/day, for general health. The patient's current medical history included migraines, benign thyroid tumors, and seasonal allergies. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered fatigue and sedation to be related to study treatment.

Study D1447C00135 Patient 0012/004 Quetiapine 600 mg/day

Withdrawal: Anaemia

This narrative concerns a 43-year-old black man with bipolar I disorder.

The patient had a non-serious adverse event of worsening anemia [MedDRA: anaemia] on Day 30 of randomized treatment of 600 mg that was considered by the investigator to be mild in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 35. Significant lab values obtained at enrollment (seven days before the first dose of study medication) and discontinuation (one day after the last dose of study medication) are listed in Table 2 below. The event of worsening anemia had not resolved at the time of the patient's final visit, one day later.

Table 2 Clinical Assessments Patient 0012/004

Assessment	Enrollment result	Discontinuation result	Normal range
Hemoglobin	9.2 g/dL	7.4 g/dL	12.7 – 18.1 g/dL
Hematocrit	32%	26%	39 – 54 %
Red Blood Cells	4.6 x 106/µL	3.7 x 106/µL	4.5 – 6.4 x 106/µL

Other non-serious adverse events during the study included dry mouth that began on Day 25 and drowsy [MedDRA: somnolence] that began on Day 4. Dry mouth and drowsy were considered by the investigator to be mild in intensity and related to study treatment. These events were not resolved at the patient's final visit, one day after the last dose of study medication. The patient was not treated with any medications before or during study treatment. The patient had a current medical history of anemia. The screening visit and final visit physical examinations were unremarkable.

The investigator considered anaemia to be not related to study treatment.

Study D1447C00135 Patient 0013/006 Quetiapine 300 mg/day

Withdrawal: Sedation

This narrative concerns a 36-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's final dose of study medication was on Day 3. The non-serious adverse event of sedation resolved one day after the last dose of study medication.

The patient had non-serious adverse events of blurred vision (MedDRA: vision blurred), dry mouth, and increased urinary frequency (MedDRA: pollakiuria), all starting on Day 1 of randomized treatment and ending one day after the last dose of study medication. Blurred vision and dry mouth were considered by the investigator to be mild in intensity and related to study treatment. Increased urinary frequency was considered by the investigator to be mild in intensity and not related to study treatment. The patient had a non-serious adverse event of bilateral arm weakness (MedDRA: asthenia) starting one day after the last dose of medication and ending three days after the last dose of study medication. This event was considered by the investigator to be mild in intensity and not related to study treatment. Before entering the study, the patient had been treated with hydrochlorothiazide as needed for lower extremity edema. This medication was ongoing at the final study visit. The patient had a current medical history of migraine, tension, sinus, and cluster headaches, hypercholesterolemia, gastroesophageal reflux disease, lower extremity edema, and allergies to codeine and demerol. The patient had a past medical history of cholelithiasis, cerebral aneurysm, generalized seizure, ovarian cyst, tubal pregnancy, and kidney infection. The patient's screening physical examination revealed 1+ pitting edema in both lower extremities. The patient's final visit physical examination was unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0014/005 Quetiapine 300 mg/day

Withdrawal: Lethargy

This narrative concerns a 42-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of lethargy on Day 1 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's final dose of study medication was on Day 15. The non-serious adverse event of lethargy was not resolved at the time of the final visit, two days after the last dose of study medication.

The patient had non-serious adverse events of dry mouth, fatigue, tightness in body not due to EPS (MedDRA: muscle tightness), dizziness not due to orthostatic hypotension (MedDRA: dizziness), memory loss (MedDRA: amnesia), and decreased concentration (MedDRA: disturbance in attention), all starting on Day 1, that were not resolved at the time of the final visit, two days after the last dose of study medication. Dry mouth, fatigue, and tightness in body not due to EPS were considered by the investigator to be severe in intensity and related to study treatment. Dizziness not due to orthostatic hypotension was considered by the investigator to be moderate in intensity and related to study treatment. Memory loss and decreased concentration were considered by the investigator to be severe in intensity and not related to study treatment. The patient had a non-serious adverse event of diarrhea (MedDRA: diarrhoea) on Day 6, that was not resolved at the final study visit. This event was considered by the investigator to moderate in intensity and related to study treatment. The patient had a non-serious adverse event of increased gas (MedDRA: flatulence) on Day 10, that was not resolved at the final study visit. This event was considered by the investigator to be severe in intensity and related to study treatment. Before entering the study, the patient had been treated with fluticasone propionate (FLONASE®, GlaxoSmithKline) one spray / day for environmental allergies, and ibuprofen as needed for intermittent back pain and intermittent headaches. These medications were ongoing at the patient's final visit. The patient had been treated with divalproex sodium (DEPAKOTE®, Abbott) 1500 mg for mood stabilization, which was stopped 15 days prior to study treatment, and propoxyphene one tablet / day for intermittent back pain, which stopped 16 days prior to study treatment. The patient had been treated with divalproex sodium (DEPAKOTE®, Abbott) 1000 mg for mood stabilization, which was stopped 12 days prior to study treatment, and divalproex sodium (DEPAKOTE®, Abbott) 500 mg for mood stabilization, which was stopped nine days prior to study treatment. During the study, the patient was treated with loperamide hydrochloride (IMODIUM®, McNeil Consumer) one tablet / day for diarrhea on Day 6 as needed for diarrhea beginning on Day 8. Treatment with loperamide hydrochloride (IMODIUM®, McNeil Consumer) was ongoing at the final visit. The patient had a current medical history of environmental allergies, lactose intolerance, intermittent lower back pain, and intermittent headaches. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered lethargy to be related to study treatment.

Study D1447C00135 Patient 0014/009 Quetiapine 600 mg/day

Withdrawal: Sedation

This narrative concerns a 22-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of sedation on Day 3 of randomized treatment of 600 mg that was considered by the investigator to be severe in intensity. The patient's dose of

study medication was reduced from 4 to 3 tablets per day on Day 9 and the patient continued the reduced dose until her final dose of study medication on Day 18. The investigator withdrew the patient from study treatment due to this event. The sedation had not resolved at the time of the final visit, one day after the last dose of study medication.

The patient had a non-serious adverse event of lethargy on Day 3, which had not resolved at the final study visit, one day after the last dose of study medication. The patient also had a non-serious adverse event of increased heart rate (MedDRA: heart rate increased) that began and resolved on Day 4. These events were considered by the investigator to be moderate in intensity and related to study treatment. Before and during study treatment, the patient had been treated with acetaminophen / aspirin / caffeine (EXCEDRIN®, Bristol-Myers) as needed and ibuprofen as needed for intermittent migraines. These medications were ongoing at the final study visit. The patient had a medical history of current intermittent migraines and current allergy to penicillin. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0014/010 Quetiapine 300 mg/day

Withdrawal: Sedation

This narrative concerns a 45-year-old hispanic man with bipolar I disorder.

The patient had a non-serious adverse event of early morning sedation (MedDRA: sedation) on Day 2 of randomized treatment of 300 mg that was considered by the investigator to be mild in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's final dose of study medication was on Day 35. The non-serious adverse event of early morning sedation resolved on Day 35.

The patient had non-serious adverse events of sinus infection (MedDRA: sinusitis), 17 days prior to study treatment and ending on Day 14, dry mouth from Day 4 to Day 32, increased heart rate (MedDRA: heart rate increased) from Day 1 to Day 32, irregular heart beat (MedDRA: heart rate irregular) from Day 1 to Day 32, muscle stiffness not due to EPS (MedDRA: musculoskeletal stiffness) from Day 1 and ongoing at the final visit, eye lid twitching not due to EPS (MedDRA: muscle twitching) from Day 15 to Day 32, restless legs not due to EPS (MedDRA: restless legs syndrome) from Day 4 to Day 15, and visual hallucinations (MedDRA: hallucination, visual) from Day 3 to Day 5. All events were considered by the investigator to be mild in intensity. Sinus infection, increased heart rate, irregular heart beat, and restless legs not due to EPS, were considered by the investigator to be not related to study treatment. Muscle stiffness not due to EPS, eye lid twitching not due to EPS, dry mouth, and visual hallucinations were considered by the investigator to be related to study treatment. Before entering the study, the patient had been treated with Maalox (MAALOX®, Novartis Consumer) as needed for upset stomach, hydrocodone / potassium guaiacolsulfonate (PROLEX-DH®, Blansett Pharmacal) as needed for sinus infection, phenylephrine hydorcloride / chlorpheniramine maleate / methscopolamine nitrate (DURAHIST™ PE, ProEthic Laboratories) as needed for sinus infection, irbesartan /

hydrochlorothiazide (AVALIDE® 300, Bristol-Myers Squibb) 12.5 mg for high blood pressure, bupropion hydrocholride (WELLBUTRIN XL®, GlaxoSmithKline) 300 mg for depression, and olopatadine hydrochloride (PATANOL®, Alcon) 4 drops / day for itching eyes. All concomitant medications were discontinued prior to study treatment, except for irbesartan / hydrochlorothiazide (AVALIDE® 300, Bristol-Myers Squibb), which was ongoing at the final study visit. During the study, the patient had been treated with olopatadine hydrochloride (PATANOL®, Alcon) 4 drops / day for itching eyes from Day 2 to Day 3 and aspirin as needed for stiff muscles on Day 37 only. Glucosamine sulfate 1500 mg for knee pain was given starting Day 1 and was ongoing as of the final study visit. The patient had a medical history of current high blood pressure, current itching eyes, past acid reflux, past hypercholesterolemia, and past arthritis. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered sedation to be related to study treatment.

Study D1447C00135 Patient 0014/020 Placebo

Withdrawal: Tonsillitis

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0014/023 Quetiapine 600 mg/day

Withdrawal: Vision Blurred

This narrative concerns a 39-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of blurred vision [MedDRA: vision blurred] that began on Day 23 of randomized treatment of 600 mg and was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 41. At the time of the final visit, one day after the final dose of study medication, the blurred vision was ongoing.

Other non-serious adverse events during the study included abdominal bloating [MedDRA: abdominal distension] (began Day 1 and was ongoing at the final visit), back cramps due to EPS [MedDRA: extrapyramidal disorder] (began Day 2 and was ongoing at the final visit), sedation (began Day 1 and was ongoing at the final visit), and more frequent urination [MedDRA: pollakiuria] (began Day 1 and resolved on Day 21). The investigator considered the abdominal bloating to be mild in intensity and not related to study treatment. The investigator considered the back cramps due to EPS to be moderate in intensity and related to study treatment. Sedation and more frequent urination were considered by the investigator to be mild in intensity and related to study treatment. The patient discontinued treatment with olanzapine (ZYPREXA®, Eli Lilly) 5 mg/day for bipolar disorder nine days before study treatment. During the study the patient was treated with ibuprofen (ADVIL®, Wyeth Consumer) as needed for back cramps from Day 2 through Day 27. The patient was treated with naproxen sodium (ALEVE®, Bayer Consumer) as needed for back cramps on Day 19. The patient took benztropine mesylate (COGENTIN®, Merck) 1 mg from Day 8 to Day 12 and 2 mg from Day 13 to Day 41 for back cramps. The patient's medical history revealed past

migraines and current Kienbock's disease and seasonal allergies. The screening visit and final visit physical examinations were unremarkable.

The investigator considered vision blurred to be related to study treatment.

Study D1447C00135 Patient 0015/008 Quetiapine 300 mg/day

Withdrawal: Suicidal Ideation

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0020/032 Quetiapine 600 mg/day

Withdrawal: Convulsion

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0020/037 Quetiapine 600 mg/day

Withdrawal: Rash

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0025/002 Quetiapine 600 mg/day

Withdrawal: Fatigue

This narrative concerns a 24-year-old black man with bipolar II disorder.

The patient had a non-serious adverse event of fatigue that began on Day 2 of randomized treatment of 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 3. The fatigue resolved two days after the last dose of study medication.

No medications were taken prior to or given during study treatment. The patient had no relevant medical history. The screening visit and final visit physical examinations were unremarkable.

The investigator considered fatigue to be related to study treatment.

Study D1447C00135 Patient 0025/032 Quetiapine 600 mg/day

Withdrawal: Fatigue

This narrative concerns a 30-year-old white woman with bipolar II disorder.

The patient had a non-serious adverse event of fatigue that began on Day 1 of randomized treatment of 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 1. The fatigue resolved one day after the last dose of study medication.

The patient had a non-serious adverse event of restless legs not due to EPS (MedDRA: restless legs syndrome) that began on Day 1 of randomized treatment and resolved one day after the last dose of study medication. The investigator considered this event to be severe in intensity and related to study treatment. No medications were taken prior to or given during study treatment. No conditions were reported in the medical history. The screening visit and final visit physical examinations were unremarkable.

The investigator considered fatigue to be related to study treatment.

Study D1447C00135 Patient 0025/045 Quetiapine 600 mg/day

Withdrawal: Suicide Attempt

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0028/013 Quetiapine 600 mg/day

Withdrawal: Accidental Overdose

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0030/016 Quetiapine 600 mg/day

Withdrawal: Chest Discomfort, Dizziness, and Hypoaesthesia

This narrative concerns a 56-year-old black man with bipolar I disorder.

The patient had non-serious adverse events of tightness in chest not due to EPS (MedDRA: chest discomfort), dizziness not due to orthostatic hypotension (MedDRA: dizziness), and numbness in fingers (MedDRA: hypoaesthesia) all beginning on Day 2 of randomized treatment of 600 mg. Tightness in chest not due to EPS and dizziness not due to orthostatic hypotension were considered by the investigator to be severe in intensity. The investigator considered numbness in fingers to be moderate in intensity. The investigator withdrew study treatment due to these events and the patient's final dose of study medication was on Day 2. The events of tightness in chest not due to EPS and dizziness not due to orthostatic hypotension resolved two days after the last dose of study medication. At the time of the final visit, six days after the last dose of study medication, the numbness in fingers was ongoing.

The patient had non-serious adverse events of cold virus symptoms (MedDRA: nasopharyngitis) and drowsiness (MedDRA: somnolence). The cold virus symptoms began five days after the last dose of study medication, and were ongoing at the time of the final visit. The drowsiness began on Day 2 and ended one day after the last dose of study medication. Both events were considered by the investigator to be mild in intensity. Cold virus symptoms were considered by the investigator to be not related to study treatment and drowsiness was considered by the investigator to be related to study treatment. Before entering the study treatment, the patient was treated with diphenhydramine hydrochloride (BENADRYL ALLERGY®, Pfizer Consumer) one capsule for cold virus symptoms, which was discontinued nine days before study treatment. The patient was also treated with clonazepam (KLONOPIN®, Roche) 1 mg for insomnia and discontinued this medication ten

days before study treatment. During the study, the patient was treated with diphenhydramine hydrochloride (BENADRYL ALLERGY®, Pfizer Consumer) one capsule for cold virus symptoms which started and ended five days after the last dose of study medication. The patient had a current medical history of cold virus symptoms and insomnia. The screening visit and final visit physical examinations were unremarkable.

The investigator considered chest discomfort, dizziness, and hypoaesthesia to be related to study treatment.

Study D1447C00135 Patient 0030/023 Quetiapine 300 mg/day

Withdrawal: Hypomania

This narrative concerns a 31-year-old black woman with bipolar II disorder.

The patient had a non-serious adverse event of hypomania that began on Day 2 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew study treatment due to this event and the patient's final dose of study medication was on Day 7. Hypomania had not resolved as of the final visit, one day after the last dose of study medication.

The patient had a non-serious adverse event of drowsiness (MedDRA: somnolence) that began on Day 1 of randomized treatment and resolved two days after the last dose of study medication. The event was considered by the investigator to be severe in intensity and related to study treatment. The patient was not treated with any medications before or during study treatment. The patient had no relevant medical history. The screening visit and final visit physical examinations revealed obesity.

The investigator considered hypomania to be not related to study treatment.

Study D1447C00135 Patient 0032/010 Quetiapine 600 mg/day

Withdrawal: Sedation, Dry Mouth, and Hypersomnia

This narrative concerns a 55-year-old white woman with bipolar I disorder.

The patient had non-serious adverse events of sedation on Day 2 of randomized treatment of 600 mg, dry mouth on Day 3 of randomized treatment, and oversleeping (MedDRA: hypersomnia) on Day 11 of randomized treatment that were considered by the investigator to be moderate in intensity. The investigator temporarily stopped study treatment due to these events on Day 12 and resumed study treatment of four tablets on Day 13. The investigator withdrew the patient from study treatment due to these events and the patient's final dose of study medication was on Day 16. The sedation, dry mouth, and oversleeping all resolved four days after the last dose of study medication.

The patient had a serious adverse event of acute epiglottitis (MedDRA: epiglottitis) that started five days prior to study treatment and ended on Day 15. This event was considered by the investigator to be severe in intensity and not related to study treatment. Before entering

the study, the patient had been treated with tramadol hydrochloride (ULTRAM®, Ortho-McNeil) 50 mg / day for degenerative arthritis of the knee, which stopped seven days prior to study treatment. The patient had also been treated with travoprost (TRAVATAN®, Alcon) 1 drop / day and timolol (BETIMOL®, Santen) 1 drop / day for glaucoma, naproxen sodium (ALEVE®, Bayer Consumer) 400 mg / day for degenerative arthritis of the knee, and naproxen sodium (ALEVE®, Bayer Consumer) 400 mg / day for degenerative arthritis. These concomitant medications were ongoing at the final study visit. On Day 8 of study treatment, the patient had been treated with morphine (unknown total daily dose), and promethazine hydrochloride (PHENERGAN®, Wyeth) (unknown total daily dose) for acute epiglottitis, that were stopped on the same day. The patient had taken prednisone (unknown total daily dose), morphine (unknown total daily dose), ampicillin (UNASYN®, Roerig) 6 grams / day, and dexamethasone (DECADRON®, Merck) 30 mg / day for acute epiglottitis. These concomitant medications all started on Day 8 and were stopped on Day 9 of study treatment. The patient was treated with amoxicillin / clavulanate potassium (AUGMENTIN®, GlaxoSmithKline) 2 tablets / day, which started on Day 9 and stopped three days after the final dose of study medication. The patient had a current medical history of back pain due to a herniated disc, degenerative arthritis of the knee, glaucoma-right eye blind, occasional anxiety attacks, allergy to sulfa, and blindness in the left eye. The patient had a past medical history of sinus infections and high liver enzymes. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered sedation, dry mouth, and hypersomnia to be related to study treatment.

Study D1447C00135 Patient 0034/010 Quetiapine 300 mg/day

Withdrawal: Bipolar I Disorder

See Serious Adverse Event narrative section regarding withdrawal for this event.

Study D1447C00135 Patient 0037/021 Quetiapine 300 mg/day

Withdrawal: Akathisia

This narrative concerns a 54-year-old white man with bipolar II disorder.

The patient had a non-serious adverse event of akathisia on Day 7 of randomized treatment of 300 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's first dose of study medication was on Day 2 of randomized treatment. The patient's final dose of study medication was on Day 8. The non-serious adverse event of akathisia resolved one day after the last dose of study medication.

Before study treatment, the patient had non-serious adverse events of headaches, one episode starting and ending five days prior to study treatment and the second episode starting and ending two days prior to study treatment. Both events were considered by the investigator to be mild in intensity and not related to study treatment. The patient had two additional non-serious adverse events of headaches during study treatment on Day 4 and Day 8 only. Both

events were considered by the investigator to be mild in intensity and related to study treatment. Other non-serious adverse events included dry mouth (Day 2 to one day after the last dose of study medication), drowsiness (MedDRA: somnolence) (Day 2 to two days after the last dose of study medication), and constriction in throat not due to EPS (MedDRA: throat tightness) (Day 2 to one day after the last dose of study medication), all considered by the investigator to be severe in intensity and related to study treatment. Before entering the study, the patient had been treated with atenolol / chlortalidone one tablet / day for hypertension, cetirizine hydrochloride (ZYRTEC®, Pfizer) 10 mg for allergies, pantoprazole sodium (PROTONIX®, Wyeth-Ayerst) 40 mg for indigestion. These medications were all ongoing at the final study visit, ten days after the last dose of study medication. Sertraline hydrochloride (ZOLOFT®, Pfizer) 50 mg for bipolar disorder was stopped 11 days prior to study treatment and alprazolam (XANAX®, Pharmacia and Upjohn) as needed for depression-related insomnia was stopped 13 days prior to study treatment. The patient had been treated with acetaminophen (TYLENOL®, McNeil Consumer) 500 mg, once five days prior to study treatment and once two days prior to study treatment, for headaches. During the study, the patient had been treated with acetaminophen (TYLENOL®, McNeil Consumer) 1000 mg for headache on Day 8 only. The patient had a current medical history of controlled indigestion, controlled hypertension, and allergies to dust, tomatoes, dairy, and chocolate. The patient had a past medical history of tonsillitis, bones missing, middle ear (right), and kidney stones. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered akathisia to be related to study treatment.

Study D1447C00135 Patient 0039/023 Quetiapine 300 mg/day

Withdrawal: Sedation

This narrative concerns a 35-year-old black woman with bipolar I disorder.

The patient had a non-serious adverse event of sedation on Day 1 of randomized treatment of 300 mg that was considered by the investigator to be moderate in intensity. The investigator withdrew study treatment due to this event and the patient's last dose of study medication was on Day 7. The sedation resolved two days after the last dose of study medication.

The patient had non-serious adverse events of dry mouth, constipation, nausea, diarrhea (MedDRA: diarrhoea) and increased appetite that all started on Day 1 of study treatment and were all considered by the investigator to be moderate in intensity and related to study treatment. Dry mouth and constipation were ongoing at the time of the patient's final visit, one day after the last dose of study medication. Nausea resolved on Day 4, diarrhea resolved three days after the last dose of study medication. Increased appetite resolved two days after the last dose of study medication. Before entering the study, the patient had been treated with acetaminophen/aspirin/caffeine (EXCEDRIN MIGRAINE®, Bristol-Myers) as needed for headaches and ibuprofen as needed for back pain, neck pain, and headaches. These medications were all ongoing as of the patient's final visit. The patient was also treated with NyQuil (NYQUIL®, Vicks) as needed for insomnia and discontinued this medication 35 days prior to study treatment. The patient had a current medical history of occasional dizziness, occasional shortness of breath, headaches, back pain, neck pain, insomnia, and internal

vaginal cyst. The patient had past medical history of heartburn, hypertension and breast lumps. The patient's screening and final visit physical examinations revealed obesity.

The investigator considered the sedation to be related to study treatment.

Study D1447C00135 Patient 0042/020 Quetiapine 600 mg/day

Withdrawal: Dizziness, Extrapyramidal Disorder, Tachycardia, Extrapyramidal Disorder, Extrapyramidal Disorder, and Extrapyramidal Disorder

This narrative concerns a 43-year-old white woman with bipolar I disorder.

The patient had non-serious adverse events of dizziness due to EPS not due to orthostatic hypotension (MedDRA: dizziness), involuntary tongue movement due to EPS (MedDRA: extrapyramidal disorder), tachycardia, muscle aches due to EPS (MedDRA: extrapyramidal disorder), muscle stiffness due to EPS (MedDRA: extrapyramidal disorder), and slurred speech due to EPS (MedDRA: extrapyramidal disorder) on Day 6 of randomized treatment of 600 mg that were considered by the investigator to be moderate in intensity, except or slurred speech, which was mild in intensity. The investigator withdrew the patient from study treatment due to these events. The patient's final dose of study medication was on Day 6. The non-serious adverse events of dizziness due to EPS not due to orthostatic hypotension, involuntary tongue movement due to EPS, tachycardia, muscle aches due to EPS, muscle stiffness due to EPS, and slurred speech due to EPS resolved the day of the last dose of study medication.

Fifteen days prior to study treatment, the patient had been treated with fexofenadine hydrochloride / pseudoephedrine hydrocholoride (ALLEGRA-D®, Aventis) as needed for nasal congestion. This medication was ongoing at the final study visit, two days after the last dose of study medication. The patient was also treated with hydrocodone as needed for hip pain, 15 days prior to study treatment only, sertraline hydrochloride (ZOLOFT®, Pfizer) 150 mg for depressed mood, which stopped prior to study treatment, and aspirin 81 mg as prophylaxis, which was ongoing at the final study visit. During the study, the patient had been treated with diphenhydramine hydrochloride (BENADRYL ALLERGY®, Pfizer Consumer) 75 mg as needed for EPS reaction on Day 6 and one day after the last dose of study medication. The patient's medical history revealed a current allergy to codeine, past hip pain, and past nasal congestion. The patient's screening and final visit physical examinations were unremarkable.

The investigator considered dizziness, extrapyramidal disorder, tachycardia, extrapyramidal disorder, extrapyramidal disorder, and extrapyramidal disorder to be related to study treatment.

Study D1447C00135 Patient 0042/021 Quetiapine 600 mg/day

Withdrawal: Somnolence

This narrative concerns a 33-year-old white woman with bipolar I disorder.

The patient had a non-serious adverse event of drowsiness (MedDRA: somnolence) on Day 14 of randomized treatment of 600 mg that was considered by the investigator to be severe in intensity. The investigator withdrew the patient from study treatment due to this event. The patient's final dose of study medication was on Day 14. The drowsiness had not resolved at the time of the site personnel's last contact with the patient, two days after the last dose of study medication.

The patient had non-serious adverse events of dry mouth (on Day 4 and ongoing at the final contact), nausea (on Day 14 and ongoing at the final contact), and AM drowsiness (MedDRA: somnolence) (on Day 2 and ongoing at the final contact). All events were considered by the investigator to be moderate in intensity and related to study treatment. Before entering the study, the patient had been treated with acetaminophen (EXTRA STRENGTH TYLENOL®, McNeil Consumer) 2 tablets / day as needed and ibuprofen 600 mg as needed for occasional headaches, ibuprofen 600 mg as needed for menstrual cramps, and norgestimate / ethinyl estradiol (Ortho Tri-Cyclen Lo®, Ortho-McNeil) 1 tablet /day as needed for birth control. These concomitant medications were ongoing at the last contact with the patient, two days after the last dose of study medication. Prior to study treatment, the patient was treated with zolpidem tartrate (AMBIEN®, Sanofi-Synthelabo) 10 mg as needed for insomnia related to bipolar disorder. This medication stopped 15 days prior to study treatment. The patient had a medical history of current mitral valve prolapse, current occasional headaches, current menstrual cramps, past neck injury at C4, and past breast augmentation. The patient's screening physical examination was unremarkable. The final visit physical examination was not performed.

The investigator considered somnolence to be related to study treatment.

Study D1447C00135 Patient 0046/012 Quetiapine 600 mg/day

Withdrawal: Acute Myocardial Infarction

See Serious Adverse Event narrative section regarding withdrawal for this event.

Table 11.3.6.1 Other Adverse Events of Interest

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO. of PTS	%	NO. of PTS	%	NO. of PTS	%
ANY ADVERSE EVENT	PREFERRED TERM						
		27	15.8	21	12.5	15	9.0
EPS	TOTAL	21	12.3	17	10.1	11	6.6
	AKATHISIA	5	2.9	2	1.2	2	1.2
	DYSKINESIA	2	1.2	0	0	1	0.6
	DYSTONIA	1	0.6	1	0.6	0	0
	EXTRAPYRAMIDAL DISORDER	11	6.4	10	6.0	4	2.4
	RESTLESSNESS	1	0.6	1	0.6	2	1.2
	TREMOR	2	1.2	5	3.0	3	1.8
DIABETES	TOTAL	3	1.8	0	0	3	1.8
	HYPERGLYCAEMIA	1	0.6	0	0	0	0
	THIRST	2	1.2	0	0	3	1.8
SUICIDALITY	TOTAL	1	0.6	3	1.8	0	0
	SUICIDAL IDEATION	1	0.6	2	1.2	0	0
	SUICIDE ATTEMPT	0	0	1	0.6	0	0
TREATMENT EMERGENT MANIA	TOTAL	2	1.2	1	0.6	5	3.0

(Continued)

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG212.SAS
GENERATED: 17NOV2005 13:44:55 iceadmn3

Table 11.3.6.1 Other Adverse Events of Interest

		TREATMENT					
		QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
		N=171		N=168		N=167	
		NO. of PTS	%	NO. of PTS	%	NO. of PTS	%
TREATMENT EMERGENT MANIA	PREFERRED TERM						
	HYPOMANIA	2	1.2	1	0.6	3	1.8
	MANIA	0	0	0	0	2	1.2

Note: This table includes adverse events which occurred from start of study treatment to last dose plus 30 days.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG212.SAS
GENERATED: 17NOV2005 13:44:55 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0010017	29 YRS CAUCASIAN MALE	13MAY2005-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [OCCASIONAL MUSCLE TWITCHES - DUE TO EPS]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0012010	50 YRS CAUCASIAN FEMALE	10SEP2004-10SEP2004	ON	DYSKINESIA (Nervous system disorders) [TWITCHY (UNCONTROLLED MUSCLE MOVEMENTS) NOT DUE TO EPS]	1	3	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0014018	22 YRS CAUCASIAN MALE	29APR2005-CONTINUE	ON	TREMOR (Nervous system disorders) [HAND TREMOR NOT DUE TO EPS (RIGHT HAND)]	UNK	4	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0016001	37 YRS CAUCASIAN FEMALE	02SEP2004-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE SPASMS DUE TO EPS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
		E0020002	32 YRS CAUCASIAN MALE	26JUL2004-15AUG2004	ON	AKATHISIA (Nervous system disorders) [NOCTURNAL AKATHISIA]	21	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
				17AUG2004-23AUG2004	ON	AKATHISIA (Nervous system disorders) [NOCTURNAL AKATHISIA]	7	23	MIL	NO	N	N	N	N	N	N	NO YES	None
				02SEP2004-05SEP2004	ON	AKATHISIA (Nervous system disorders) [NOCTURNAL AKATHISIA]	4	39	SEV	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0020002	32 YRS CAUCASIAN MALE	21SEP2004-22SEP2004	ON	AKATHISIA (Nervous system disorders) [NOCTURNAL AKATHISIA]	2	58	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0020013	32 YRS CAUCASIAN FEMALE	11NOV2004-26DEC2004	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCULAR TENSION DUE TO EPS]	46	30	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0020038	35 YRS CAUCASIAN MALE	14FEB2005-11APR2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [INTERMITTENT RESTLESS LEGS DUE TO EPS]	57	1	MOD	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0020038	35 YRS CAUCASIAN MALE	16FEB2005-16FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [JERKY MOVEMENTS ARMS DUE TO EPS]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
						EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [JERKY MOVEMENTS LEGS DUE TO EPS]	1	3	MIL	NO	N	N	N	N	N	N	NO YES	None
				22MAR2005-29MAR2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE JERKS DUE TO EPS]	8	37	MIL	NO	N	N	N	N	N	N	NO YES	None
				24MAR2005-29MAR2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [LOWER LIP TREMOR DUE TO EPS]	6	39	MIL	NO	N	N	N	N	N	N	NO YES	None

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# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0021009	24 YRS ORIENTAL MALE	01OCT2004-04NOV2004	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	35	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0024002	23 YRS CAUCASIAN FEMALE	20AUG2004-26AUG2004	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [TWITCHING IN BOTH LEGS DUE TO EPS]	7	2	MIL	NO	N	N	N	N	N	N	NO YES	None
				27AUG2004-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [TWITCHING IN BODY AND LIMBS DUE TO EPS]	UNK	9	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
		E0039010	33 YRS CAUCASIAN MALE	12OCT2004-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [RESTLESSNESS DUE TO EPS]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR I)	E0039012	41 YRS CAUCASIAN FEMALE	30OCT2004-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [RESTLESS LEGS DUE TO EPS]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0040017	37 YRS CAUCASIAN FEMALE	13JUL2005-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [EYE TWITCHING RELATED TO EPS]	UNK	50	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0043001	23 YRS CAUCASIAN MALE	05SEP2004-20SEP2004	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	16	27	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
\# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION, DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY, ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR II)	E0003002	41 YRS BLACK FEMALE	26AUG2004-08SEP2004	ON	DYSKINESIA (Nervous system disorders) [GENERAL BODY MUSCLE JERKING (INVOLUNTARY MUSCLE MOVEMENTS) NOT DUE TO EPS]	14	3	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0010005	34 YRS OTHER FEMALE	27OCT2004-30OCT2004	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	4	2	SEV	NO	N	N	N	N	N	N	NO NO	None
				27OCT2004-08NOV2004	ON	TREMOR (Nervous system disorders) [TREMOR NOT DUE TO EPS]	13	2	MOD	NO	N	N	N	N	N	N	NO NO	None
				31OCT2004-02DEC2004	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	33	6	MOD	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
^ SERIOUS REASON: DT=DEATH, LT=LIFE-THREATENING, RH=REQUIRES OR PROLONGS HOSPITALIZATION,
DI=CAUSING PERSISTENT DISABILITY OR INCAPACITY, CA=CONGENITAL ABNORMALITY,
ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

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GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR II)	E0010007	59 YRS OTHER MALE	10NOV2004-12NOV2004	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	3	3	SEV	NO	N	N	N	N	N	N	NO NO	None
				13NOV2004-16NOV2004	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	4	6	MOD	NO	N	N	N	N	N	N	NO NO	None
		E0011001	36 YRS CAUCASIAN FEMALE	16JUL2004-CONTINUE	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT DUE TO EPS]	UNK	1	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
		E0020028	43 YRS CAUCASIAN FEMALE	22DEC2004-29DEC2004	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [INTERMITTENT MUSCLE TENSION DUE TO EPS]	8	8	MIL	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 300 MG (BIPOLAR II)	E0031002	36 YRS CAUCASIAN FEMALE	29JUL2004-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [DUE TO EXTRA PYRAMIDAL SYMPTOMS AKATHESIA]	UNK	3	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0036002	28 YRS CAUCASIAN MALE	29JAN2005-04FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [STIFFNESS IN LEGS (QUADS) DUE TO EPS]	7	18	SEV	NO	N	N	N	N	N	N	NO YES	None
		E0037021	54 YRS CAUCASIAN MALE	27MAR2005-29MAR2005	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	3	6	SEV	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0003011	49 YRS CAUCASIAN MALE	03JAN2005-CONTINUE	ON	TREMOR (Nervous system disorders) [SHAKING OF BILATERAL EXTREMITIES NOT DUE TO EPS]	UNK	4	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0004022	35 YRS OTHER FEMALE	02FEB2005-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [DECREASED MUSCLE COORDINATION DUE TO EPS]	UNK	8	MOD	NO	N	N	N	N	N	N	NO YES	None
				10FEB2005-28FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [BILATERAL LEG TWITCHING AT NIGHT DUE TO EPS]	19	16	MIL	NO	N	N	N	N	N	N	NO YES	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0010016	30 YRS OTHER FEMALE	17MAY2005-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [STIFFNESS IN UPPER EXTREMITIES - DUE TO EPS]	UNK	13	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0014013	33 YRS CAUCASIAN MALE	03MAR2005-13MAR2005	ON	DYSTONIA (Nervous system disorders) [DYSTONIA]	11	4	SEV	NO	N	N	N	N	N	N	NO YES	None
		E0014023	39 YRS CAUCASIAN FEMALE	24JUN2005-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [BACK CRAMPS DUE TO EPS]	UNK	2	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0020048	39 YRS CAUCASIAN MALE	21JUN2005-21JUL2005	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	31	8	MIL	NO	N	N	N	N	N	N	NO YES	None

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0033008	48 YRS CAUCASIAN FEMALE	15DEC2004-23DEC2004	ON	TREMOR (Nervous system disorders) [BILATERAL HAND TREMORS NOT DUE TO EPS]	9	7	MOD	NO	N	N	N	N	N	N	NO YES	Dose Changed
				13JAN2005-09FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [COGWHEEL RIGIDITY IN BILATERAL ELBOW DUE TO EXTRAPYRAMIDAL SYMPTOMS]	28	36	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0037017	24 YRS OTHER MALE	24FEB2005-24FEB2005	ON	TREMOR (Nervous system disorders) [TREMORS NOT DUE TO EPS]	1	7	MIL	NO	N	N	N	N	N	N	NO YES	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0039002	50 YRS CAUCASIAN FEMALE	14SEP2004-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [RESTLESS FEET DUE TO EPS]	UNK	15	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0039007	19 YRS CAUCASIAN FEMALE	04OCT2004-31OCT2004	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [RESTLESS LEGS DUE TO EPS]	28	5	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0042020	43 YRS CAUCASIAN FEMALE	16APR2005-16APR2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [INVOLUNTARY TONGUE MOVEMENT DUE TO EPS]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped

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EPS	QUETIAPINE 600 MG (BIPOLAR I)	E0042020	43 YRS CAUCASIAN FEMALE	16APR2005-16APR2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE ACHES/DUE TO EPS]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
						EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [MUSCLE STIFFNESS DUE TO EPS]	1	6	MOD	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
						EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [SLURRED SPEECH DUE TO EPS]	1	6	MIL	NO	N	N	N	N	N	N	YES YES	Permanently Stopped
		E0046012	60 YRS CAUCASIAN MALE	16FEB2005-22FEB2005	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT DUE TO EPS]	7	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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EPS	QUETIAPINE 600 MG (BIPOLAR II)	E0010011	54 YRS CAUCASIAN MALE	05FEB2005-07FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [DIFFICULTY SWALLOWING DUE TO EPS]	3	3	MIL	NO	N	N	N	N	N	N	NO YES	None
				10FEB2005-16FEB2005	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	7	8	MOD	NO	N	N	N	N	N	N	NO YES	None
						EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [DIFFICULTY SWALLOWING DUE TO EPS]	7	8	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0010015	51 YRS CAUCASIAN FEMALE	24FEB2005-24FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [DIFFICULTY SWALLOWING DUE TO EPS]	1	2	MOD	NO	N	N	N	N	N	N	NO YES	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	QUETIAPINE 600 MG (BIPOLAR II)	E0036007	52 YRS CAUCASIAN MALE	18MAR2005-CONTINUE	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [STUMBLING WHEN WALKING DUE TO EPS]	UNK	1	SEV	NO	N	N	N	N	N	N	NO YES	None
		E0046001	25 YRS CAUCASIAN FEMALE	16NOV2004-25NOV2004	ON	TREMOR (Nervous system disorders) [INTERMITTENT TREMOR NOT DUE TO EPS]	10	7	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0046007	49 YRS CAUCASIAN FEMALE	06JAN2005-14JAN2005	ON	TREMOR (Nervous system disorders) [INTERMITTENT TREMOR OF HANDS NOT DUE TO EPS]	9	3	MIL	NO	N	N	N	N	N	N	NO YES	None

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CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
EPS	PLACEBO (BIPOLAR I)	E0004007	45 YRS OTHER MALE	29SEP2004-02OCT2004	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [FEELING OF PARALYSIS OF EXTREMITIES (HEAVINESS IN THE LIMBS) DUE TO EPS]	4	58	MOD	NO	N	N	N	N	N	N	NO NO	None
		E0004008	33 YRS CAUCASIAN FEMALE	07OCT2004-16OCT2004	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	10	58	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0012026	38 YRS CAUCASIAN FEMALE	28JUN2005-01JUL2005	ON	TREMOR (Nervous system disorders) [SHAKES NOT DUE TO EPS]	4	14	MIL	NO	N	N	N	N	N	N	NO YES	None
				20JUL2005-CONTINUE	ON	TREMOR (Nervous system disorders) [SHAKES NOT DUE TO EPS]	UNK	36	MIL	NO	N	N	N	N	N	N	NO YES	None

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EPS	PLACEBO (BIPOLAR I)	E0020036	43 YRS CAUCASIAN MALE	22FEB2005-22FEB2005	ON	TREMOR (Nervous system disorders) [HAND TREMORS NOT DUE TO EPS]	1	16	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0034013	42 YRS CAUCASIAN MALE	04JUN2005-16JUN2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [RESTLESSNESS DUE TO EPS]	13	2	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0040013	49 YRS CAUCASIAN FEMALE	06APR2005-27MAY2005	ON	RESTLESSNESS (Psychiatric disorders) [RESTLESSNESS NOT RELATED TO EPS]	52	6	MOD	NO	N	N	N	N	N	N	NO YES	None

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EPS	PLACEBO (BIPOLAR II)	E0010010	32 YRS OTHER FEMALE	29JAN2005-14FEB2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [DYSPHAGIA DUE TO EPS]	17	2	MIL	NO	N	N	N	N	N	N	NO YES	None
				07FEB2005-10FEB2005	ON	AKATHISIA (Nervous system disorders) [AKATHISIA]	4	11	SEV	NO	N	N	N	N	N	N	NO YES	None
		E0014016	24 YRS CAUCASIAN MALE	21MAR2005-21MAR2005	ON	DYSKINESIA (Nervous system disorders) [MUSCLE JERK IN RIGHT ARM NOT DUE TO EPS (MUSCLE MOVEMENT)]	1	5	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0020026	55 YRS CAUCASIAN FEMALE	21DEC2004-04JAN2005	ON	EXTRAPYRAMIDAL DISORDER (Nervous system disorders) [RESTLESS LEGS DUE TO EPS]	15	6	MIL	NO	N	N	N	N	N	N	NO YES	None

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EPS	PLACEBO (BIPOLAR II)	E0025001	37 YRS CAUCASIAN MALE	18SEP2004-21SEP2004	ON	TREMOR (Nervous system disorders) [TREMORS NOT DUE TO EPS]	4	62	MOD	NO	N	N	N	N	N	N	NO YES	None
		E0027015	20 YRS CAUCASIAN FEMALE	24NOV2004-CONTINUE	ON	RESTLESSNESS (Psychiatric disorders) [FIDGITINESS]	UNK	43	MIL	NO	N	N	N	N	N	N	NO NO	None

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ME=MEDICAL EVENT THAT MAY JEOPARDIZE PATIENT OR REQUIRE MEDICAL INTERVENTION.
** WD=WITHDRAWN.
Note: The adverse events are coded using MedDRA version 7.1.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/AELOG106.SAS
GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
DIABETES	QUETIAPINE 300 MG (BIPOLAR I)	E0012020	43 YRS BLACK MALE	25JAN2005-22MAR2005	ON	THIRST (General disorders and administration site conditions) [EXCESSIVE THIRST]	57	16	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0021008	44 YRS CAUCASIAN MALE	25OCT2004-01NOV2004	ON	HYPERGLYCAEMIA (Metabolism and nutrition disorders) [HYPERGLYCEMIA]	8	29	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0037028	55 YRS BLACK FEMALE	25MAY2005-08JUN2005	ON	THIRST (General disorders and administration site conditions) [THIRSTY]	15	17	MIL	NO	N	N	N	N	N	N	NO YES	None

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# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
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GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
DIABETES	PLACEBO (BIPOLAR I)	E0004007	45 YRS OTHER MALE	29SEP2004-02OCT2004	ON	THIRST (General disorders and administration site conditions) [EXTREME THIRST]	4	58	MOD	NO	N	N	N	N	N	N	NO NO	None
		E0020036	43 YRS CAUCASIAN MALE	08FEB2005-03MAR2005	ON	THIRST (General disorders and administration site conditions) [THIRST INCREASED]	24	2	MIL	NO	N	N	N	N	N	N	NO YES	None

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Note: The adverse events are coded using MedDRA version 7.1.

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GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURA-TION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
DIABETES	PLACEBO (BIPOLAR II)	E0014016	24 YRS CAUCASIAN MALE	17MAR2005-CONTINUE	ON	THIRST (General disorders and administration site conditions) [INCREASED THIRST]	UNK	1	MIL	NO	N	N	N	N	N	N	NO YES	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 300 MG (BIPOLAR I)	E0015008	37 YRS BLACK MALE	23DEC2004-29DEC2004	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH PLAN]	7	9	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 600 MG (BIPOLAR I)	E0020037	30 YRS CAUCASIAN FEMALE	01MAR2005-09MAR2005	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION WITH PLAN]	9	22	SEV	YES	N	N	Y	N	N	N	NO NO	None
		E0027016	21 YRS CAUCASIAN FEMALE	04JAN2005-08FEB2005	ON	SUICIDAL IDEATION (Psychiatric disorders) [SUICIDAL IDEATION]	36	61	MIL	YES	N	N	Y	N	N	N	NO NO	None

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GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
SUICIDALITY	QUETIAPINE 600 MG (BIPOLAR II)	E0025045	24 YRS BLACK FEMALE	01MAR2005-02MAR2005	ON	SUICIDE ATTEMPT (Psychiatric disorders) [SUICIDE ATTEMPT INTENTIONAL OVERDOSE (NON - STUDY DRUG)]	2	2	SEV	YES	N	N	Y	N	N	N	YES NO	Permanently Stopped

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# INT=INTENSITY: MIL=MILD, MOD=MODERATE, SEV=SEVERE. @ SER=SERIOUS
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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/ POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
TREATMENT EMERGENT MANIA	QUETIAPINE 300 MG (BIPOLAR I)	E0046008	34 YRS CAUCASIAN MALE	21JAN2005-21JAN2005	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	1	3	MIL	NO	N	N	N	N	N	N	NO NO	None
				23JAN2005-23JAN2005	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	1	5	MIL	NO	N	N	N	N	N	N	NO NO	None

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
TREATMENT EMERGENT MANIA	QUETIAPINE 300 MG (BIPOLAR II)	E0030023	31 YRS BLACK FEMALE	10DEC2004-CONTINUE	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	UNK	2	SEV	NO	N	N	N	N	N	N	YES NO	Permanently Stopped

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Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
TREATMENT EMERGENT MANIA	QUETIAPINE 600 MG (BIPOLAR I)	E0046004	33 YRS CAUCASIAN FEMALE	23DEC2004-31DEC2004	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	9	22	MIL	NO	N	N	N	N	N	N	NO NO	None

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GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
TREATMENT EMERGENT MANIA	PLACEBO (BIPOLAR I)	E0034013	42 YRS CAUCASIAN MALE	20JUN2005-15JUL2005	ON	MANIA (Psychiatric disorders) [TREATMENT EMERGENT MANIA]	26	18	MOD	NO	N	N	N	N	N	N	NO NO	None
		E0010001	26 YRS CAUCASIAN MALE	10SEP2004-CONTINUE	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	UNK	45	MIL	NO	N	N	N	N	N	N	NO NO	None
		E0033009	50 YRS CAUCASIAN MALE	27JAN2005-01MAR2005	ON	MANIA (Psychiatric disorders) [TREATMENT EMERGENT MANIA]	34	50	MIL	NO	N	N	N	N	N	N	NO YES	None
		E0046017	34 YRS CAUCASIAN FEMALE	13JUL2005-25JUL2005	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	13	52	MIL	NO	N	N	N	N	N	N	NO NO	None

* POST=ADVERSE EVENTS OCCURRING MORE THAN 30 DAYS AFTER LAST TREATMENT.
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GENERATED: 17NOV2005 13:44:20 iceadmn3

Table 11.3.6.2 Other Adverse Events of Interest

CATEGORY	TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	AGE RACE SEX	START DATE-STOP DATE	ON/POST TRT*	PREFERRED TERM (SYSTEM ORGAN CLASS) [INVESTIGATOR TERM]	AE DURATION (DAYS)	ONSET EXP (DAYS)	INT#	SER@	SERIOUS REASON^ DT	LT	RH	DI	CA	ME	WD**/ DRUG RELATED	ACTION TAKEN
TREATMENT EMERGENT MANIA	PLACEBO (BIPOLAR II)	E0037025	51 YRS BLACK FEMALE	20APR2005-26JUL2005	ON	HYPOMANIA (Psychiatric disorders) [HYPOMANIA]	98	24	MIL	NO	N	N	N	N	N	N	NO NO	None

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11.3.6.3 Narratives of other significant adverse events

No narratives of other significant adverse events are included in this clinical study report.

Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
Hematocrit	FEMALE	18-65	%	34	48	0.01	Vol Fraction	0.34	0.48
	FEMALE	58-58	%	35.0	45.0	0.01	Vol Fraction	0.35	0.45
	MALE	59-63	%	37	51	0.01	Vol Fraction	0.37	0.51
	MALE	18-58	%	39	54	0.01	Vol Fraction	0.39	0.54
Hemoglobin	FEMALE	59-65	g/dL	11.5	15.8	1	G/DL	11.50	15.80
	FEMALE	18-58	g/dL	11.6	16.4	1	G/DL	11.60	16.40
	FEMALE	58-58	G/DL	12.3	15.3	1	G/DL	12.30	15.30
	MALE	59-63	g/dL	12.5	17.0	1	G/DL	12.50	17.00
	MALE	18-58	g/dL	12.7	18.1	1	G/DL	12.70	18.10
RBC	FEMALE	59-65	x10^6/uL	3.9	5.5	1	X10E12/L	3.90	5.50
	MALE	59-63	x10^6/uL	4.0	5.8	1	X10E12/L	4.00	5.80
	FEMALE	58-58	/CMM	4.10	5.10	1	X10E12/L	4.10	5.10
	FEMALE	18-58	x10^6/uL	4.1	5.6	1	X10E12/L	4.10	5.60
	MALE	18-58	x10^6/uL	4.5	6.4	1	X10E12/L	4.50	6.40
Platelets	BOTH	60-65	x10^3/uL	130	394	1	X10E9/L	130.00	394.00
	BOTH	18-59	x10^3/uL	140	400	1	X10E9/L	140.00	400.00
	FEMALE	58-58	/CMM	172	450	1	X10E9/L	172.00	450.00
WBC	BOTH	18-65	x10^3/uL	3.80	10.70	1	X10E9/L	3.80	10.70
	FEMALE	58-58	/CMM	4.4	11.3	1	X10E9/L	4.40	11.30
Neutrophils (%)	BOTH	18-65	%	40.5	75.0	1	%	40.50	75.00
	FEMALE	58-58	%	44	80	1	%	44.00	80.00
Total Abs. Neutrophil Count	BOTH	18-65	x10^3/uL	1.96	7.23	1	X10E9/L	1.96	7.23
Eosinophils (%)	BOTH	18-65	%	0.0	6.8	1	%	0.00	6.80
	BOTH	58-58	%	0	8	1	%	0.00	8.00
Eosinophils	BOTH	18-65	x10^3/uL	0.00	0.57	1	X10E9/L	0.00	0.57
Basophils (%)	BOTH	18-65	%	0.0	2.0	1	%	0.00	2.00
Basophils	BOTH	18-65	x10^3/uL	0.00	0.20	1	X10E9/L	0.00	0.20

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA200.SAS
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Table 11.3.7.1.1.1 Hematology Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	*REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
Lymphocytes (%)	FEMALE	58-58	%	13	43	1	%	13.00	43.00
	BOTH	18-65	%	15.4	48.5	1	%	15.40	48.50
Lymphocytes	BOTH	59-65	x10^3/uL	0.80	3.00	1	X10E9/L	0.80	3.00
	BOTH	18-58	x10^3/uL	0.91	4.28	1	X10E9/L	0.91	4.28
Monocytes (%)	FEMALE	58-58	%	2	11	1	%	2.00	11.00
	BOTH	18-65	%	2.6	10.1	1	%	2.60	10.10
Monocytes	BOTH	18-65	x10^3/uL	0.12	0.92	1	X10E9/L	0.12	0.92

*SI conversion factors for differentials not measured as absolutes are dependent on WBC.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA200.SAS
GENERATED: 17NOV2005 13:50:05 iceadmn3

Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
HEMATOCRIT (VOL. FRACTION)	BSLN	138	0.44	0.04	0.4	0.3	0.5	138	0.43	0.04	0.4	0.3	0.5	154	0.44	0.04	0.4	0.3	0.6
	VISIT 10	138	0.43	0.04	0.4	0.2	0.5	138	0.42	0.04	0.4	0.3	0.5	154	0.43	0.04	0.4	0.3	0.5
	FINAL	138	0.43	0.04	0.4	0.2	0.5	138	0.42	0.04	0.4	0.3	0.5	154	0.43	0.04	0.4	0.3	0.5
	CHG FRM BSLN	138	-0.01	0.03	-0.0	-0.2	0.1	138	-0.01	0.03	-0.0	-0.1	0.1	154	-0.01	0.03	-0.0	-0.1	0.1
HEMOGLOBIN (G/DL)	BSLN	138	14.54	1.48	14.6	10.1	18.2	138	14.22	1.48	14.3	9.2	17.7	154	14.48	1.50	14.6	9.5	18.5
	VISIT 10	138	14.23	1.69	14.3	6.6	18.7	138	13.77	1.57	13.6	7.4	17.2	154	14.25	1.40	14.3	11.4	18.2
	FINAL	138	14.23	1.69	14.3	6.6	18.7	138	13.77	1.57	13.6	7.4	17.2	154	14.25	1.40	14.3	11.4	18.2
	CHG FRM BSLN	138	-0.31	0.89	-0.3	-6.2	1.9	138	-0.45	0.83	-0.3	-3.9	1.4	154	-0.23	0.75	-0.3	-2.2	2.6
TOTAL RBC COUNT (10**12-/L)	BSLN	138	4.99	0.48	5.0	3.5	6.3	138	4.94	0.47	4.9	3.8	6.5	154	4.94	0.47	4.9	3.6	6.3
	VISIT 10	138	4.90	0.54	4.9	2.6	6.9	138	4.81	0.48	4.8	3.7	6.3	154	4.88	0.46	4.9	3.7	6.1
	FINAL	138	4.90	0.54	4.9	2.6	6.9	138	4.81	0.48	4.8	3.7	6.3	154	4.88	0.46	4.9	3.7	6.1
	CHG FRM BSLN	138	-0.09	0.31	-0.1	-2.3	0.7	138	-0.13	0.29	-0.1	-1.4	0.5	154	-0.06	0.26	-0.1	-0.7	0.7
PLATELETS (10**9/-L)	BSLN	137	285.22	68.88	277.0	140.0	587.0	137	291.64	80.84	290.0	126.0	675.0	154	275.44	63.29	267.0	152.0	496.0
	VISIT 10	137	272.66	66.82	264.0	140.0	479.0	137	281.84	73.51	276.0	125.0	503.0	154	272.21	59.76	261.5	141.0	456.0
	FINAL	137	272.66	66.82	264.0	140.0	479.0	137	281.84	73.51	276.0	125.0	503.0	154	272.21	59.76	261.5	141.0	456.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA201.SAS
GENERATED: 17NOV2005 13:50:08 iceadmn3

Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
PLATELETS (10**9/L)	CHG FRM BSLN	137	-12.55	49.03	-15.0	-227.0	118.0	137	-9.80	51.12	-10.0	-172.0	234.0	154	-3.23	35.44	-3.0	-148.0	83.0
TOTAL WBC COUNT (10**9/L)	BSLN	138	7.21	2.10	7.0	3.1	18.4	138	7.33	2.05	7.0	3.7	14.3	154	7.16	2.07	6.9	3.3	13.1
	VISIT 6	136	7.12	2.34	7.1	1.4	19.4	134	6.88	2.02	6.6	3.3	13.4	150	6.96	1.92	6.6	2.8	13.7
	VISIT 10	103	6.88	2.34	6.4	3.3	14.4	97	6.42	1.69	6.3	2.7	11.6	113	7.04	1.79	6.9	3.3	14.2
	FINAL	138	6.80	2.20	6.5	3.3	14.4	138	6.60	1.96	6.3	2.7	13.4	154	6.95	1.90	6.6	2.8	14.2
	CHG FRM BSLN	138	-0.40	1.99	-0.3	-5.9	7.5	138	-0.73	1.75	-0.6	-7.5	4.1	154	-0.20	1.65	-0.2	-6.0	5.9
NEUTROPHILS (%)	BSLN	138	59.87	9.54	60.0	35.9	80.4	138	60.49	8.99	60.5	39.7	81.1	154	60.99	8.44	61.2	39.1	81.2
	VISIT 6	136	60.11	10.15	60.9	31.0	82.3	134	59.60	9.30	59.8	19.0	82.2	150	59.86	8.81	61.4	28.2	81.1
	VISIT 10	103	60.17	9.41	60.4	32.5	79.4	97	58.64	8.17	59.5	35.0	75.7	113	60.83	8.23	61.2	42.7	79.2
	FINAL	138	60.06	9.46	60.4	32.5	80.7	138	59.31	8.37	59.8	35.0	82.2	154	60.54	8.47	61.3	28.2	79.2
	CHG FRM BSLN	138	0.18	8.68	0.0	-23.1	27.7	138	-1.19	8.41	-1.0	-24.8	19.3	154	-0.44	8.22	-1.1	-35.5	31.8
NEUTROPHILS (10**9/L)	BSLN	138	4.40	1.71	4.3	1.1	11.6	138	4.51	1.73	4.3	1.7	10.5	154	4.44	1.64	4.2	1.6	9.8
	VISIT 6	136	4.40	1.97	4.2	1.1	15.0	134	4.20	1.69	3.9	0.8	10.5	150	4.24	1.53	4.1	0.8	9.6
	VISIT 10	103	4.26	1.98	3.8	1.3	11.4	97	3.82	1.32	3.7	1.6	8.1	113	4.35	1.45	4.1	1.7	9.2
	FINAL	138	4.20	1.89	3.8	1.3	11.4	138	3.99	1.61	3.8	1.6	10.5	154	4.28	1.49	4.1	0.8	9.6

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA201.SAS
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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
NEUTROP-HILS (10**9/-L)	CHG FRM BSLN	138	-0.20	1.80	-0.2	-5.6	6.9	138	-0.52	1.54	-0.4	-5.7	3.4	154	-0.16	1.47	-0.1	-6.6	5.5
EOSINOP-HILS (%)	BSLN	138	1.95	1.20	1.7	0.0	6.8	138	2.01	1.41	1.6	0.0	7.9	154	2.01	1.45	1.7	0.0	7.2
	VISIT 6	136	2.38	1.67	2.0	0.0	11.2	134	2.49	1.84	2.1	0.0	12.4	150	2.13	1.33	1.9	0.4	10.4
	VISIT 10	103	2.27	1.52	2.0	0.4	9.6	97	2.50	1.79	2.1	0.1	11.0	113	1.97	1.33	1.7	0.0	9.8
	FINAL	138	2.23	1.47	1.9	0.1	9.6	138	2.47	1.86	2.0	0.1	12.4	154	1.98	1.31	1.7	0.0	9.8
	CHG FRM BSLN	138	0.28	1.21	0.1	-4.8	4.8	138	0.46	1.54	0.2	-3.2	9.2	154	-0.02	1.17	0.0	-6.3	2.6
EOSINOP-HILS (10**9/-L)	BSLN	138	0.13	0.08	0.1	0.0	0.5	138	0.14	0.10	0.1	0.0	0.6	154	0.14	0.10	0.1	0.0	0.6
	VISIT 6	136	0.16	0.13	0.1	0.0	1.1	134	0.17	0.16	0.1	0.0	1.5	150	0.15	0.10	0.1	0.0	0.7
	VISIT 10	103	0.15	0.09	0.1	0.0	0.6	97	0.16	0.11	0.1	0.0	0.6	113	0.14	0.10	0.1	0.0	0.6
	FINAL	138	0.14	0.09	0.1	0.0	0.6	138	0.16	0.16	0.1	0.0	1.5	154	0.14	0.11	0.1	0.0	0.7
	CHG FRM BSLN	138	0.01	0.07	0.0	-0.2	0.3	138	0.02	0.12	0.0	-0.2	1.0	154	-0.00	0.07	0.0	-0.3	0.2
BASOPHI-LS (%)	BSLN	138	0.65	0.41	0.6	0.0	2.8	138	0.66	0.34	0.6	0.0	1.5	154	0.66	0.41	0.6	0.0	2.9
	VISIT 6	136	0.58	0.34	0.5	0.0	1.9	134	0.62	0.34	0.6	0.0	2.3	150	0.63	0.32	0.6	0.0	2.0
	VISIT 10	103	0.63	0.34	0.6	0.0	2.1	97	0.63	0.41	0.6	0.0	2.9	113	0.67	0.38	0.6	0.0	2.7
	FINAL	138	0.63	0.36	0.6	0.0	2.1	138	0.65	0.39	0.6	0.0	2.9	154	0.65	0.36	0.6	0.0	2.7

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA201.SAS
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Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
BASOPHILS (%)	CHG FRM BSLN	138	-0.02	0.45	0.0	-2.2	1.1	138	-0.00	0.43	0.0	-1.2	1.9	154	-0.01	0.44	0.0	-1.8	1.6
BASOPHILS (10**9/L)	BSLN	138	0.05	0.03	0.0	0.0	0.2	138	0.05	0.03	0.0	0.0	0.1	154	0.05	0.03	0.0	0.0	0.2
	VISIT 6	136	0.04	0.03	0.0	0.0	0.2	134	0.04	0.02	0.0	0.0	0.1	150	0.04	0.03	0.0	0.0	0.1
	VISIT 10	103	0.04	0.02	0.0	0.0	0.1	97	0.04	0.02	0.0	0.0	0.2	113	0.05	0.03	0.0	0.0	0.1
	FINAL	138	0.04	0.02	0.0	0.0	0.1	138	0.04	0.02	0.0	0.0	0.2	154	0.04	0.02	0.0	0.0	0.1
	CHG FRM BSLN	138	-0.00	0.03	0.0	-0.1	0.1	138	-0.01	0.03	-0.0	-0.1	0.1	154	-0.00	0.03	0.0	-0.1	0.1
LYMPHOCYTES (%)	BSLN	138	32.39	8.75	31.4	15.0	54.8	138	31.51	8.55	31.0	14.2	52.0	154	31.19	7.86	30.6	13.8	52.0
	VISIT 6	136	31.48	9.05	30.8	12.7	59.7	134	31.59	8.94	31.0	12.6	70.0	150	32.15	8.25	30.6	14.1	62.8
	VISIT 10	103	31.57	8.54	30.9	13.4	58.3	97	32.40	7.38	32.1	14.9	54.7	113	31.39	7.79	30.8	14.3	51.8
	FINAL	138	31.69	8.51	31.3	13.4	58.3	138	31.80	7.84	31.8	12.6	54.7	154	31.60	8.14	30.8	14.3	62.8
	CHG FRM BSLN	138	-0.70	7.73	-1.6	-22.3	18.1	138	0.29	7.52	0.4	-25.0	21.1	154	0.41	7.33	0.5	-28.7	33.4
LYMPHOCYTES (10**9/L)	BSLN	138	2.27	0.70	2.2	1.2	5.4	138	2.25	0.70	2.1	0.8	4.1	154	2.17	0.70	2.1	0.8	5.4
	VISIT 6	136	2.15	0.64	2.1	0.2	4.2	134	2.09	0.61	2.1	1.0	4.6	150	2.18	0.67	2.1	0.9	5.9
	VISIT 10	103	2.07	0.60	2.0	1.0	3.9	97	2.04	0.59	2.0	0.9	3.8	113	2.16	0.62	2.1	0.8	4.6
	FINAL	138	2.06	0.59	2.0	1.0	3.9	138	2.03	0.57	2.1	0.9	3.8	154	2.14	0.65	2.1	0.8	4.6

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA201.SAS
GENERATED: 17NOV2005 13:50:08 iceadmn3

Table 11.3.7.1.1.2 Hematology - Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG					QUETIAPINE 600 MG					PLACEBO				
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
LYMPHOCYTES (10**9/L)	CHG FRM BSLN	138	-0.20	0.50	-0.2	-2.0	1.4	138	-0.21	0.47	-0.2	-2.1	0.7	154	-0.03	0.47	-0.0	-1.6	1.4
MONOCYTES (%)	BSLN	138	5.12	1.50	4.8	2.0	10.2	138	5.33	1.65	5.1	0.0	10.4	154	5.16	1.63	4.9	2.6	11.7
	VISIT 6	136	5.41	1.90	5.1	2.0	14.0	134	5.69	1.77	5.4	2.0	14.0	150	5.23	1.44	5.0	2.0	11.0
	VISIT 10	103	5.33	1.51	5.1	1.0	9.3	97	5.77	1.72	5.6	2.0	10.2	113	5.15	1.37	5.0	2.8	9.5
	FINAL	138	5.37	1.63	5.1	1.0	13.0	138	5.74	1.70	5.5	2.0	10.2	154	5.23	1.31	5.1	2.6	9.5
	CHG FRM BSLN	138	0.25	1.47	0.1	-4.3	5.5	138	0.41	1.85	0.4	-5.0	10.0	154	0.07	1.46	0.3	-5.0	3.6
MONOCYTES (10**9/L)	BSLN	138	0.36	0.12	0.3	0.1	1.0	138	0.38	0.12	0.4	0.0	0.7	154	0.36	0.12	0.3	0.1	0.9
	VISIT 6	136	0.37	0.15	0.3	0.1	1.2	134	0.38	0.14	0.4	0.1	0.8	150	0.35	0.11	0.3	0.1	0.8
	VISIT 10	103	0.35	0.12	0.3	0.1	0.9	97	0.36	0.12	0.4	0.1	1.0	113	0.35	0.10	0.3	0.2	0.8
	FINAL	138	0.35	0.12	0.3	0.1	0.9	138	0.37	0.13	0.4	0.1	1.0	154	0.36	0.11	0.3	0.1	0.8
	CHG FRM BSLN	138	-0.01	0.14	-0.0	-0.8	0.4	138	-0.01	0.12	-0.0	-0.3	0.5	154	-0.00	0.11	0.0	-0.4	0.4

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA201.SAS
GENERATED: 17NOV2005 13:50:08 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
HEMATOCRIT	BASELINE												
	LOW	3	1	2	0	1	1	0	0	2	0	2	0
	NOT CLINICALLY IMPORTANT	130	2	128	0	135	2	133	0	150	0	150	0
	HIGH	5	0	4	1	2	0	2	0	2	0	2	0
HEMOGLOBIN	LOW	5	4	1	0	7	7	0	0	2	0	2	0
	NOT CLINICALLY IMPORTANT	130	3	126	1	130	4	126	0	151	2	149	0
	HIGH	3	0	1	2	1	0	1	0	1	0	0	1
TOTAL RBC COUNT	LOW	2	2	0	0	3	2	1	0	6	3	3	0
	NOT CLINICALLY IMPORTANT	134	3	130	1	133	8	125	0	148	3	144	1
	HIGH	2	0	1	1	2	0	2	0	0	0	0	0
PLATELETS	LOW	0	0	0	0	3	0	3	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	129	0	125	4	123	3	118	2	148	0	146	2
	HIGH	8	0	8	0	11	0	6	5	6	0	2	4

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA202.SAS
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Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL WBC COUNT	BASELINE												
	LOW	3	3	0	0	1	0	1	0	3	1	2	0
	NOT CLINICALLY IMPORTANT	128	2	119	7	128	5	119	4	139	1	137	1
	HIGH	7	0	4	3	9	0	5	4	12	0	7	5
NEUTROPHILS (%)	LOW	5	2	3	0	1	0	1	0	2	0	2	0
	NOT CLINICALLY IMPORTANT	128	1	120	7	128	3	124	1	146	1	142	3
	HIGH	5	0	5	0	9	0	6	3	6	0	5	1
NEUTROPHILS (10**9/L)	LOW	7	4	3	0	2	0	2	0	4	1	3	0
	NOT CLINICALLY IMPORTANT	122	3	111	8	124	5	115	4	139	3	132	4
	HIGH	9	0	7	2	12	0	8	4	11	0	10	1
EOSINOPHILS (%)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	136	2	136	0	132	4	151	0	151	0
	HIGH	0	0	0	0	2	0	2	0	3	0	2	1

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA202.SAS
GENERATED: 17NOV2005 13:50:14 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
EOSINOPHILS (10**9/L)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	137	1	137	0	136	1	153	0	150	3
	HIGH	0	0	0	0	1	0	1	0	1	0	1	0
BASOPHILS (%)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	136	0	135	1	138	0	136	2	152	0	151	1
	HIGH	2	0	2	0	0	0	0	0	2	0	2	0
BASOPHILS (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	138	0	138	0	138	0	154	0	154	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHOCYTES (%)	LOW	1	0	1	0	2	0	2	0	3	0	3	0
	NOT CLINICALLY IMPORTANT	130	3	125	2	133	3	128	2	146	1	141	4
	HIGH	7	0	5	2	3	0	3	0	5	0	5	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA202.SAS
GENERATED: 17NOV2005 13:50:14 iceadmn3

Table 11.3.7.1.1.3.1 Hematology Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
LYMPHOCYTES (10**9/L)	BASELINE												
	LOW	0	0	0	0	1	0	1	0	1	1	0	0
	NOT CLINICALLY IMPORTANT	137	0	137	0	137	1	136	0	150	0	149	1
	HIGH	1	0	1	0	0	0	0	0	3	0	2	1
MONOCYTES (%)	LOW	3	1	2	0	2	0	2	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	134	2	131	1	135	1	133	1	153	0	153	0
	HIGH	1	0	1	0	1	0	1	0	1	0	1	0
MONOCYTES (10**9/L)	LOW	0	0	0	0	1	0	1	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	137	0	137	0	137	1	135	1	154	0	154	0
	HIGH	1	0	1	0	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA202.SAS
GENERATED: 17NOV2005 13:50:14 iceadmn3

Table 11.3.7.1.1.3.2 Hematology Findings Exceeding Laboratory Norms
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300mg n/N (%)	QUETIAPINE 600mg n/N (%)	PLACEBO n/N (%)
Hematocrit	2/135 (1.5%)	2/137 (1.5%)	0/152 (0.0%)	0/133 (0.0%)	0/136 (0.0%)	0/152 (0.0%)
Hemoglobin	3/133 (2.3%)	4/131 (3.1%)	2/152 (1.3%)	1/135 (0.7%)	0/137 (0.0%)	0/153 (0.0%)
RBC	3/136 (2.2%)	8/135 (5.9%)	3/148 (2.0%)	1/136 (0.7%)	0/136 (0.0%)	1/154 (0.6%)
Platelets	0/137 (0.0%)	3/134 (2.2%)	0/154 (0.0%)	4/129 (3.1%)	2/126 (1.6%)	2/148 (1.4%)
WBC	2/135 (1.5%)	5/137 (3.6%)	1/151 (0.7%)	7/131 (5.3%)	4/129 (3.1%)	1/142 (0.7%)
Neutrophils (%)	1/133 (0.8%)	3/137 (2.2%)	1/152 (0.7%)	7/133 (5.3%)	1/129 (0.8%)	3/148 (2.0%)
Total Abs. Neutrophil Count	3/131 (2.3%)	5/136 (3.7%)	3/150 (2.0%)	8/129 (6.2%)	4/126 (3.2%)	4/143 (2.8%)
Eosinophils (%)	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)	2/138 (1.4%)	4/136 (2.9%)	0/151 (0.0%)
Eosinophils	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)	1/138 (0.7%)	1/137 (0.7%)	3/153 (2.0%)
Basophils (%)	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)	1/136 (0.7%)	2/138 (1.4%)	1/152 (0.7%)
Basophils	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)
Lymphocytes (%)	3/137 (2.2%)	3/136 (2.2%)	1/151 (0.7%)	2/131 (1.5%)	2/135 (1.5%)	4/149 (2.7%)
Lymphocytes	0/138 (0.0%)	1/137 (0.7%)	0/153 (0.0%)	0/137 (0.0%)	0/138 (0.0%)	1/151 (0.7%)
Monocytes (%)	2/135 (1.5%)	1/136 (0.7%)	0/154 (0.0%)	1/137 (0.7%)	1/137 (0.7%)	0/153 (0.0%)
Monocytes	0/138 (0.0%)	1/137 (0.7%)	0/154 (0.0%)	0/137 (0.0%)	1/138 (0.7%)	0/154 (0.0%)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA205.SAS
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Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
HEMATOCRIT	BASELINE												
	LOW	1	1	0	0	1	1	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	134	2	132	0	136	0	136	0	151	0	151	0
	HIGH	3	0	2	1	1	0	1	0	2	0	2	0
HEMOGLOBIN	LOW	1	1	0	0	1	1	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	135	2	132	1	137	2	135	0	152	0	152	0
	HIGH	2	0	0	2	0	0	0	0	1	0	1	0
TOTAL RBC COUNT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	137	1	136	0	136	0	136	0	151	0	151	0
	HIGH	1	0	0	1	2	0	1	1	3	0	2	1
PLATELETS	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	137	0	137	0	136	0	136	0	154	0	154	0
	HIGH	0	0	0	0	1	0	1	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA203.SAS
GENERATED: 17NOV2005 13:50:18 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL WBC COUNT	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	137	0	137	0	138	1	137	0	154	1	153	0
	HIGH	1	0	1	0	0	0	0	0	0	0	0	0
NEUTROPHILS (10**9/L) AGRAN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	136	0	135	1	136	0	136	0	154	0	154	0
	HIGH	2	0	2	0	2	0	0	2	0	0	0	0
NEUTROPHILS (10**9/L)	LOW	1	0	1	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	135	2	132	1	136	0	136	0	154	1	153	0
	HIGH	2	0	2	0	2	0	0	2	0	0	0	0
EOSINOPHILS (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	138	0	138	0	137	1	154	0	154	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA203.SAS
GENERATED: 17NOV2005 13:50:18 iceadmn3

Table 11.3.7.1.1.3.3 Hematology Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
BASOPHILS (10**9/L)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	138	0	138	0	138	0	154	0	154	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LYMPHOCYTES (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	138	0	138	0	138	0	154	0	154	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
MONOCYTES (10**9/L)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	138	0	138	0	138	0	138	0	154	0	154	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA203.SAS
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Table 11.3.7.1.1.3.4 Potentially Clinically Important Hematology Findings
Categorical Shifts from Baseline to Final

LAB PARAMETER	SHIFT TO LOW: QUETIAPINE 300mg n/N (%)	SHIFT TO LOW: QUETIAPINE 600mg n/N (%)	SHIFT TO LOW: PLACEBO n/N (%)	SHIFT TO HIGH: QUETIAPINE 300mg n/N (%)	SHIFT TO HIGH: QUETIAPINE 600mg n/N (%)	SHIFT TO HIGH: PLACEBO n/N (%)
Hematocrit	2/137 (1.5%)	0/137 (0.0%)	0/153 (0.0%)	0/135 (0.0%)	0/137 (0.0%)	0/152 (0.0%)
Hemoglobin	2/137 (1.5%)	2/137 (1.5%)	0/153 (0.0%)	1/136 (0.7%)	0/138 (0.0%)	0/153 (0.0%)
RBC	1/138 (0.7%)	0/138 (0.0%)	0/154 (0.0%)	0/137 (0.0%)	0/136 (0.0%)	0/151 (0.0%)
Platelets	0/137 (0.0%)	0/137 (0.0%)	0/154 (0.0%)	0/137 (0.0%)	0/136 (0.0%)	0/154 (0.0%)
WBC	0/138 (0.0%)	1/138 (0.7%)	1/154 (0.6%)	0/137 (0.0%)	0/138 (0.0%)	0/154 (0.0%)
Total Abs. Neutrophil Count(Agran)	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)	1/136 (0.7%)	0/136 (0.0%)	0/154 (0.0%)
Total Abs. Neutrophil Count	2/137 (1.5%)	0/138 (0.0%)	1/154 (0.6%)	1/136 (0.7%)	0/136 (0.0%)	0/154 (0.0%)
Eosinophils	NA	NA	NA	0/138 (0.0%)	1/138 (0.7%)	0/154 (0.0%)
Basophils	NA	NA	NA	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)
Lymphocytes	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)
Monocytes	NA	NA	NA	0/138 (0.0%)	0/138 (0.0%)	0/154 (0.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA204.SAS
GENERATED: 17NOV2005 13:50:21 iceadmn3

FIGURE 11.3.7.1.1.4 1 SHIFT PLOT: ERYTHROCYTES - RBC (X10**12/L)

(SAFETY POPULATION)

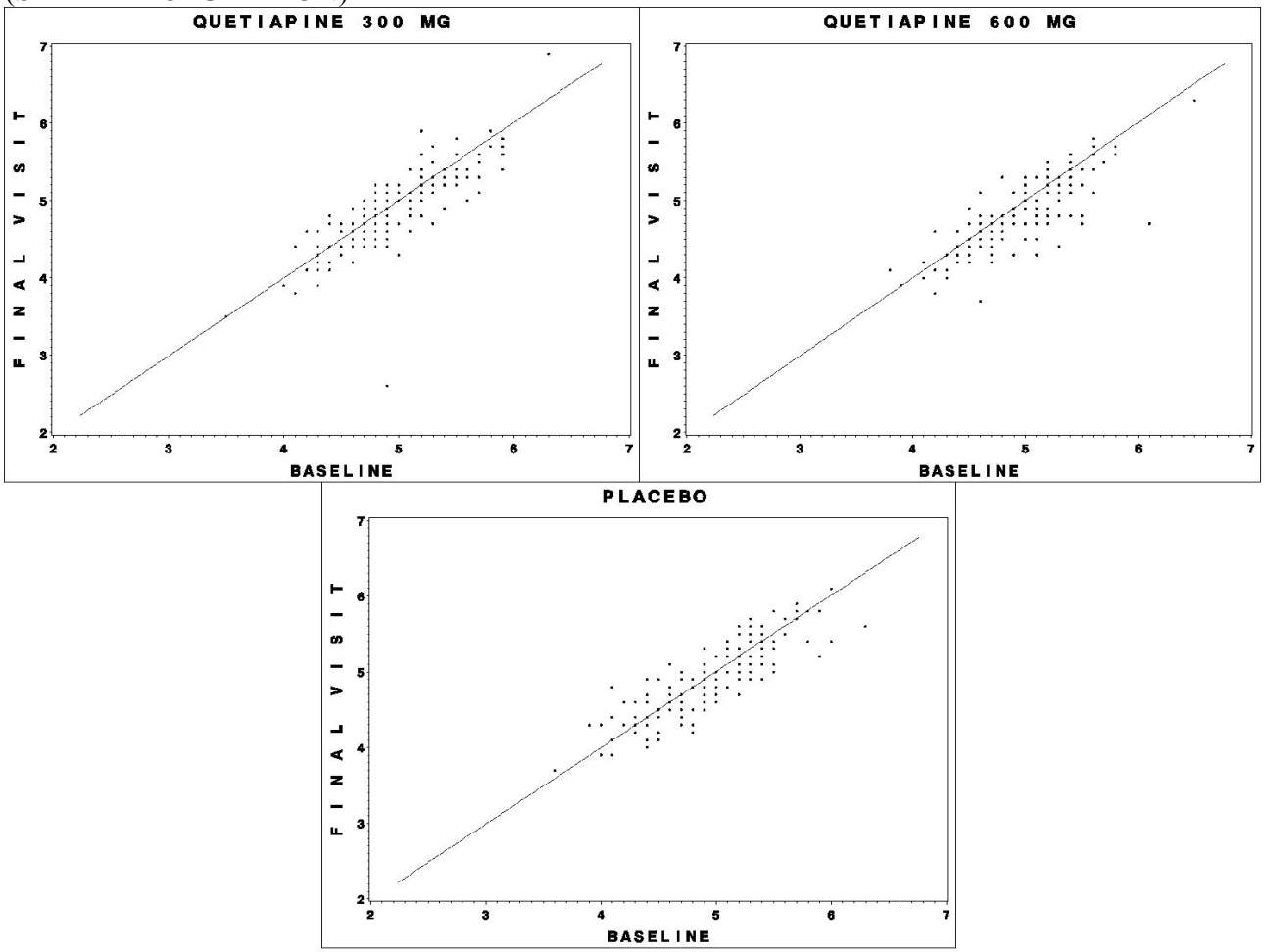

FIGURE 11.3.7.1.1.4.2 SHIFT PLOT: HEMATOCRIT - PCV (VOL FRACTION)

(SAFETY POPULATION)

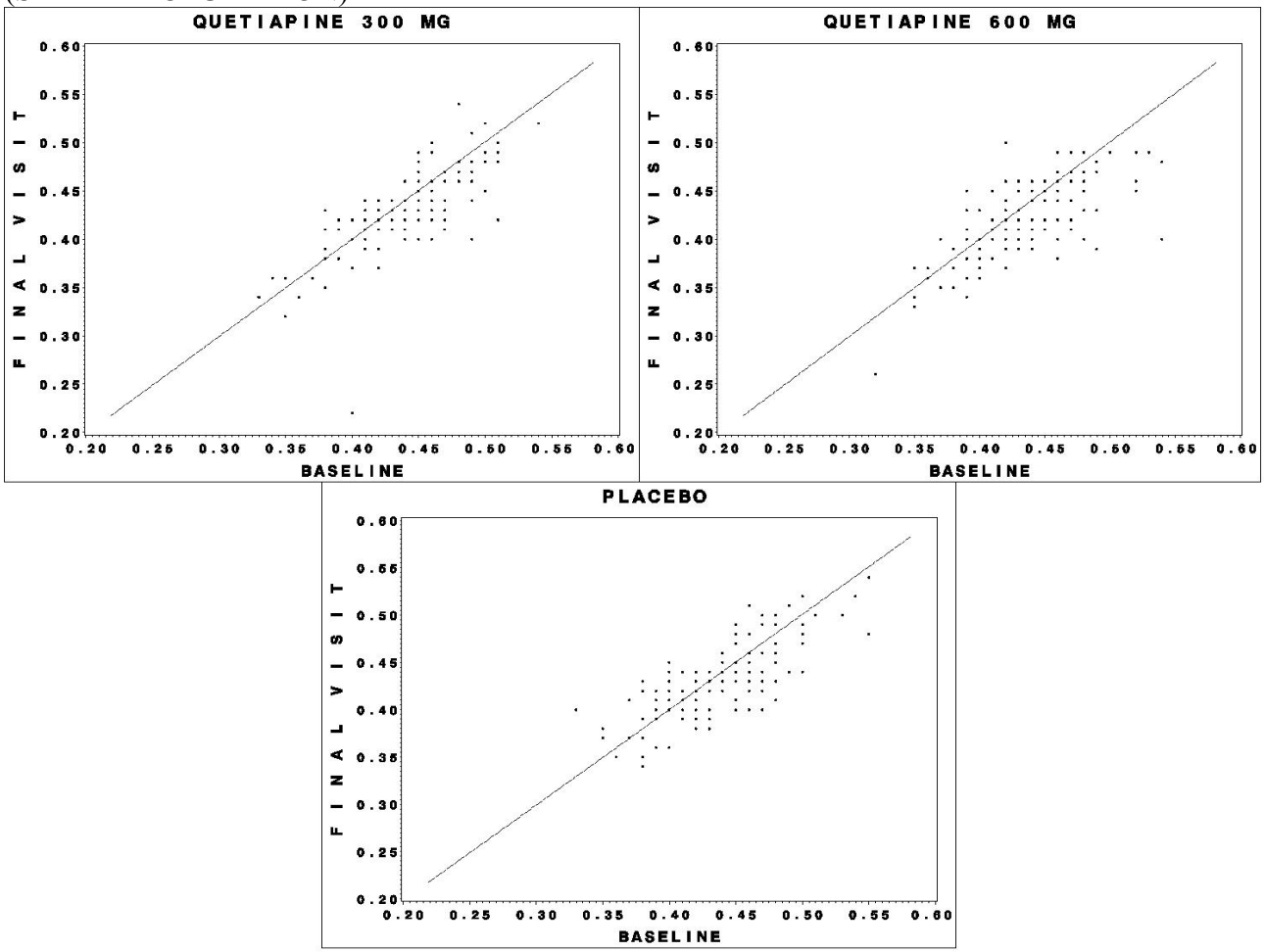

FIGURE 11.3.7.1.1.4.3 SHIFT PLOT: HEMOGLOBIN (G/DL)

(SAFETY POPULATION)

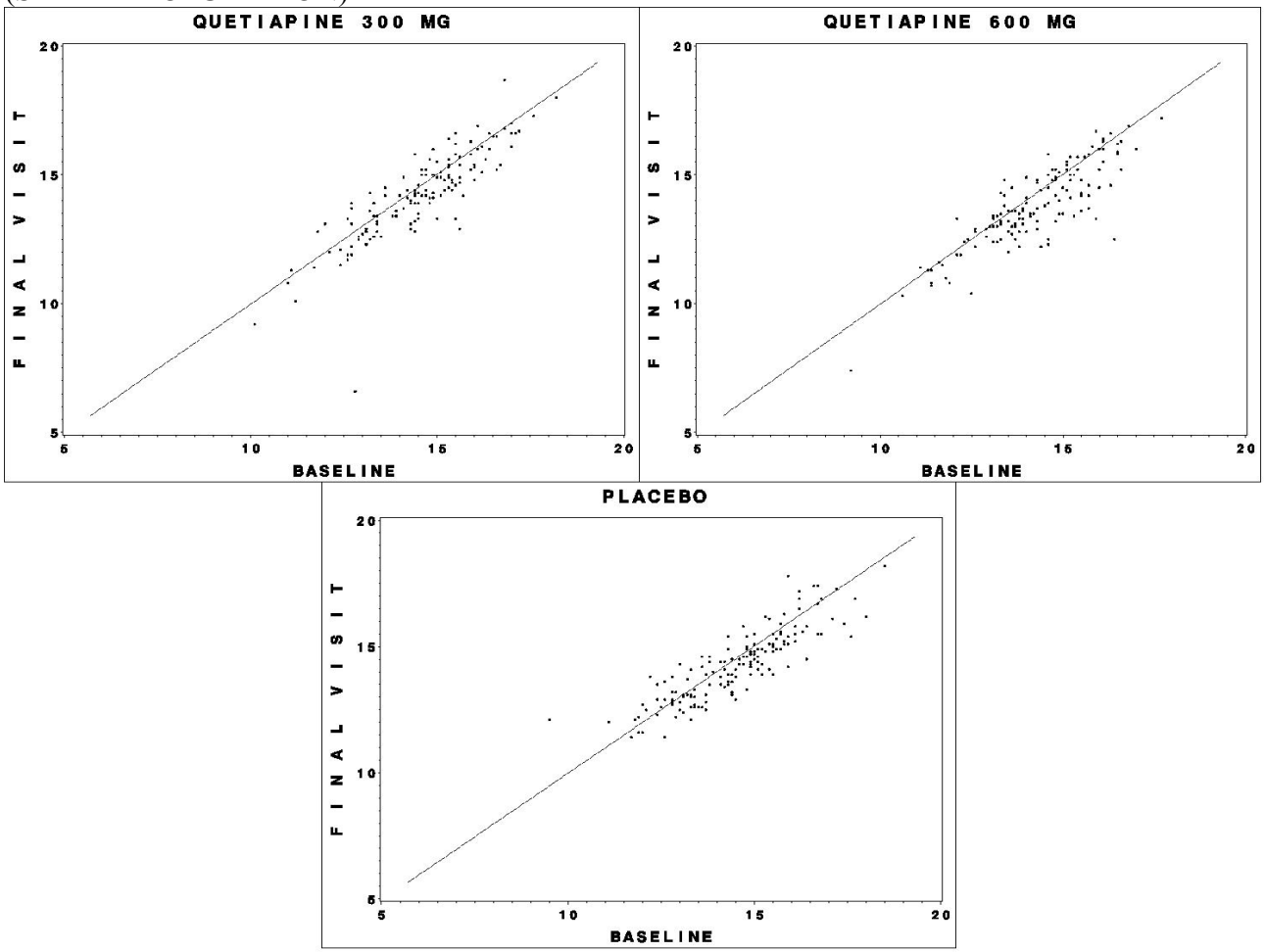

FIGURE 11.3.7.1.1.4.4 SHIFT PLOT: PLATELETS (X10**9/L)

(SAFETY POPULATION)

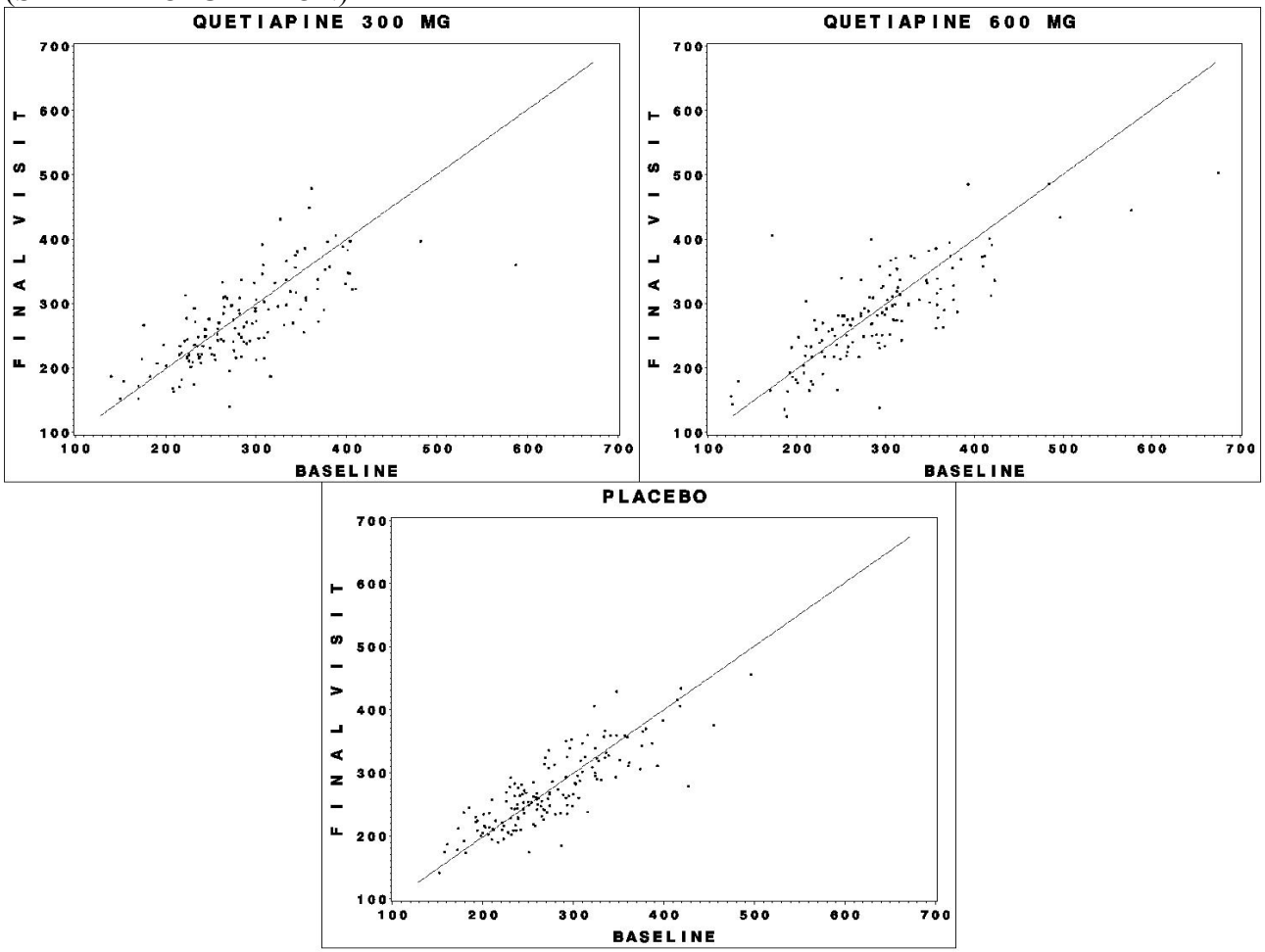

FIGURE 11.3.7.1.1.4.5 SHIFT PLOT: TOTAL WBC (X10**9/L)

(SAFETY POPULATION)

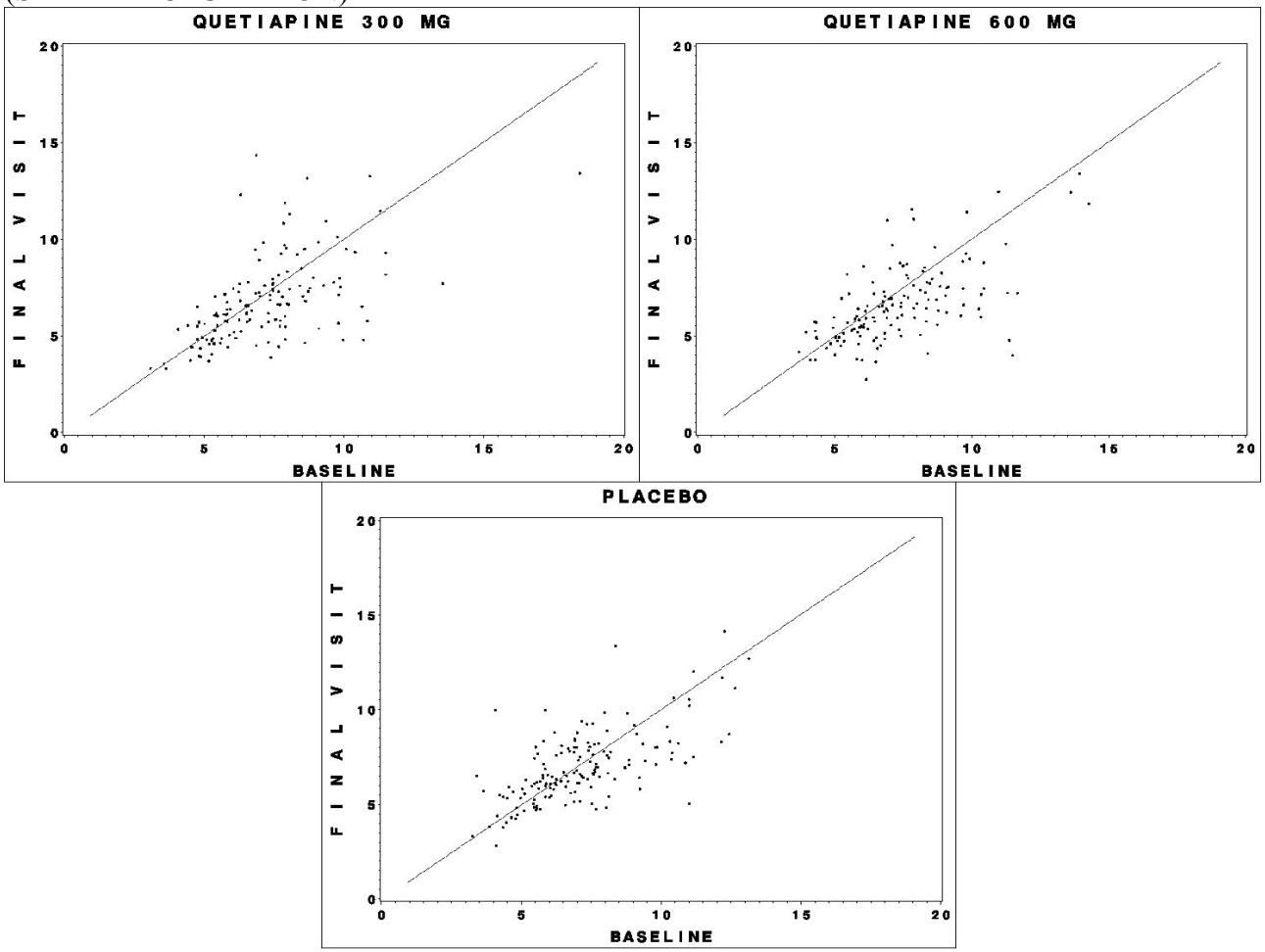

FIGURE 11.3.7.1.1.4.6 SHIFT PLOT: LYMPHOCYTES (%)

(SAFETY POPULATION)

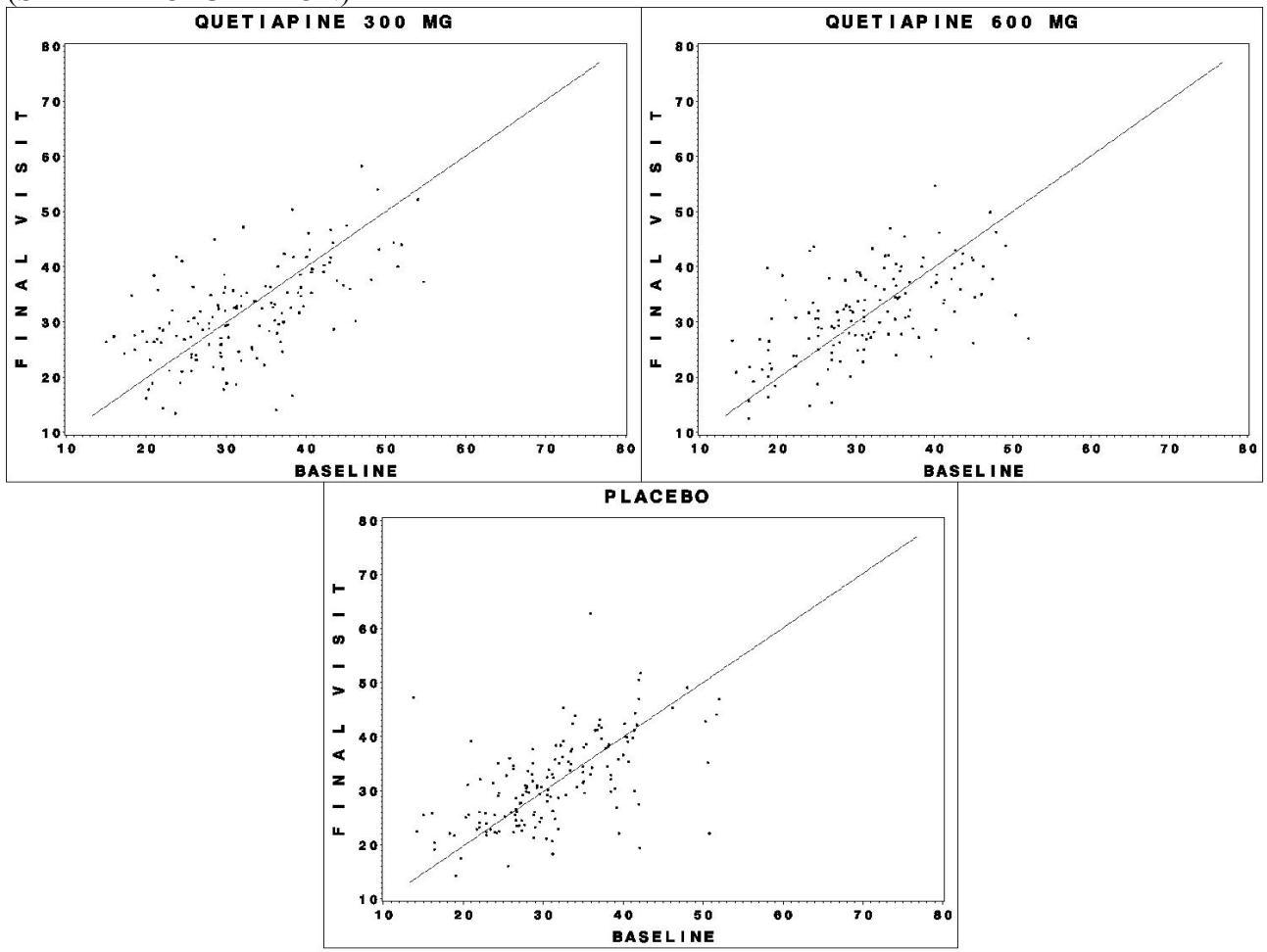

FIGURE 11.3.7.1.1.4.7 SHIFT PLOT: EOSINOPHILS (%)

(SAFETY POPULATION)

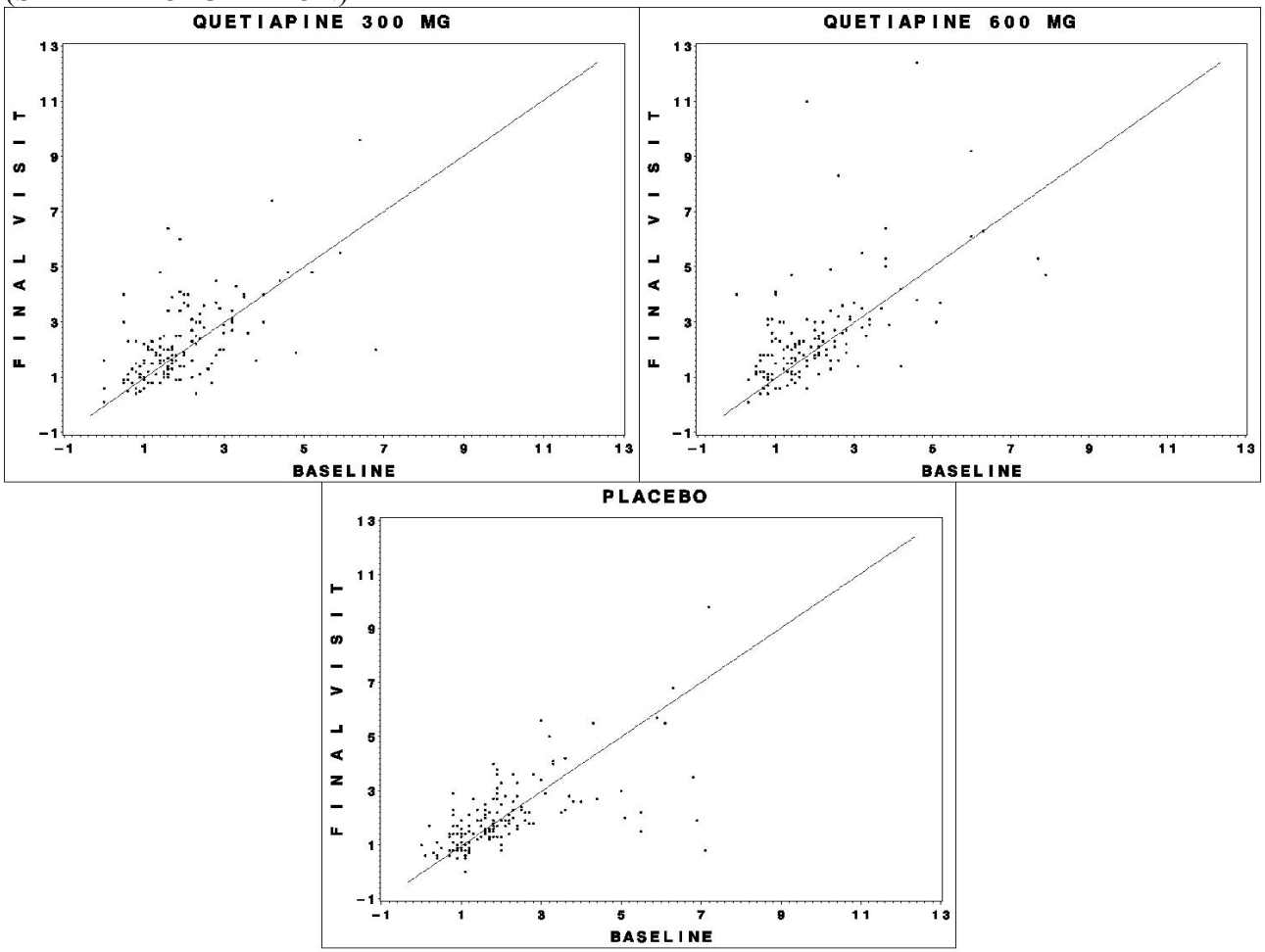

FIGURE 11.3.7.1.1.4.8 SHIFT PLOT: BASOPHILS (%)

(SAFETY POPULATION)

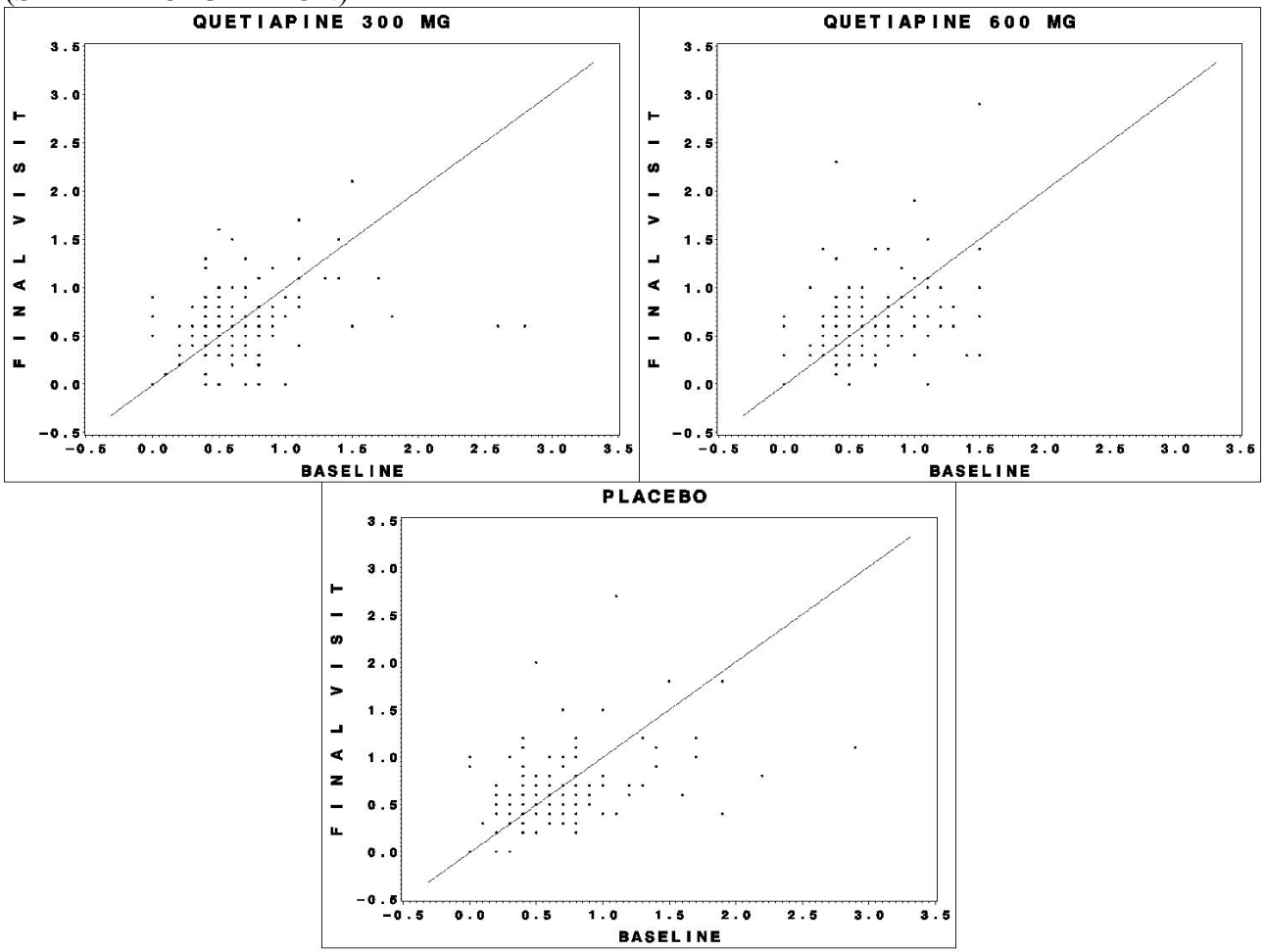

FIGURE 11.3.7.1.1.4.9 SHIFT PLOT: MONOCYTES (%)

(SAFETY POPULATION)

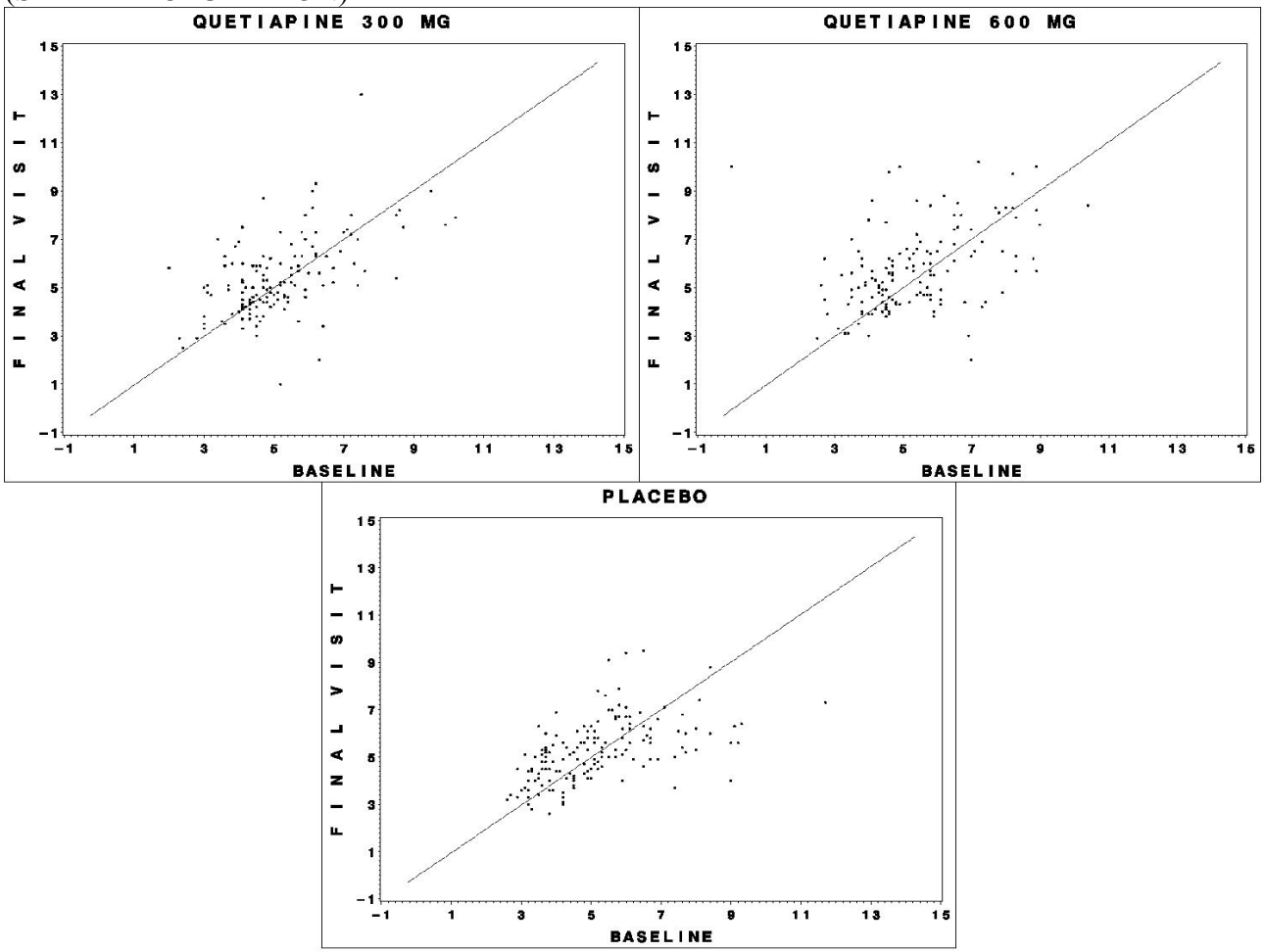

FIGURE 11.3.7.1.1.4.10 SHIFT PLOT: NEUTROPHILS (%)

(SAFETY POPULATION)

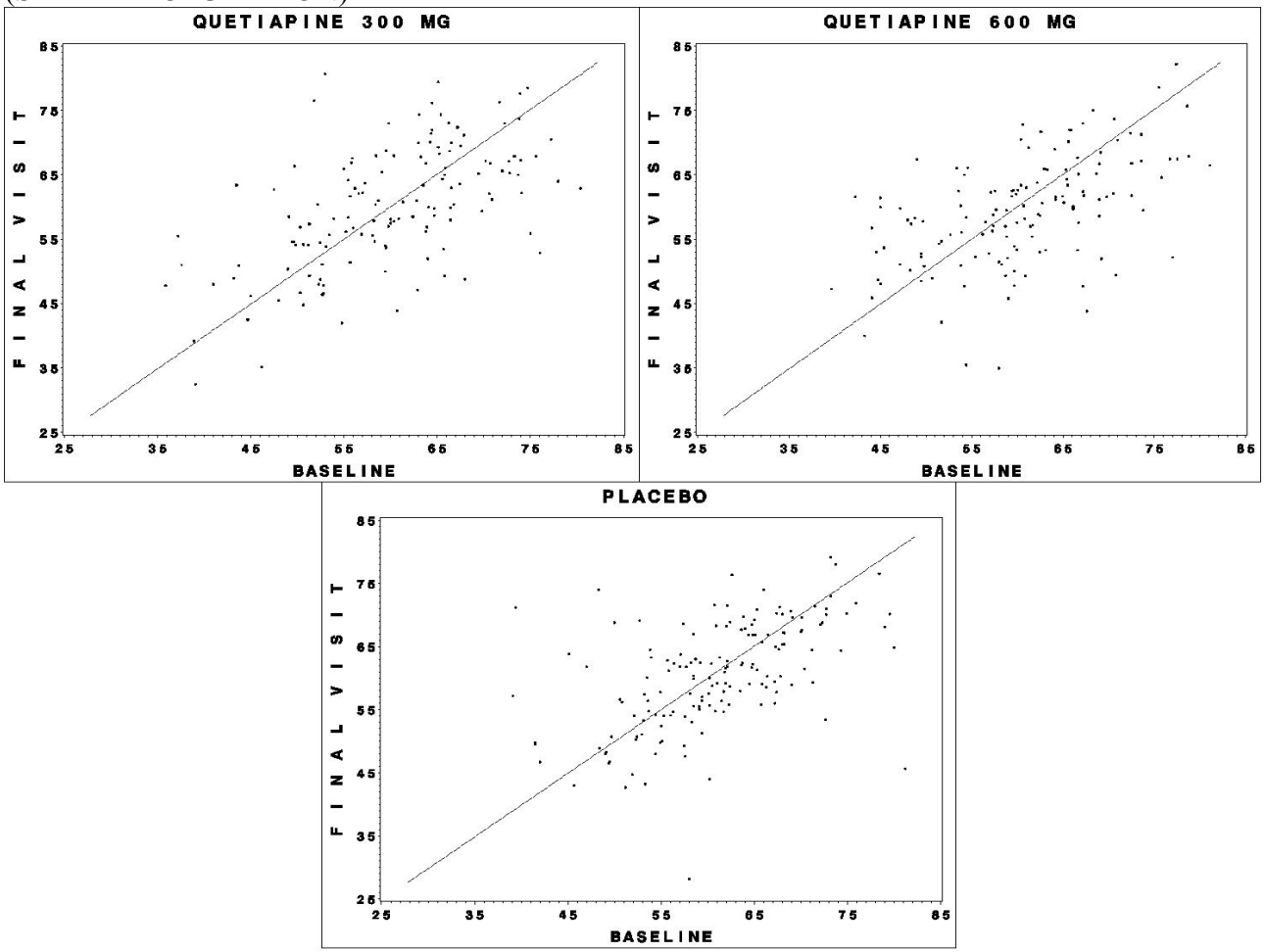

Table 11.3.7.1.2.1 Chemistry Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
RANDOM GLUCOSE	BOTH	18-58	mg/dL	70	115	1	MG/DL	70	115
	BOTH	59-65	mg/dL	70	120	1	MG/DL	70	120
AST (SGOT)	FEMALE	18-65	U/L	9	34	1	U/L	9	34
	MALE	18-63	U/L	11	36	1	U/L	11	36
ALT (SGPT)	FEMALE	18-65	U/L	6	34	1	U/L	6	34
	MALE	18-63	U/L	6	43	1	U/L	6	43
Alkaline Phosphatase	FEMALE	18-49	U/L	31	106	1	U/L	31	106
	MALE	18-49	U/L	31	129	1	U/L	31	129
	FEMALE	50-65	U/L	35	123	1	U/L	35	123
	MALE	60-63	U/L	35	125	1	U/L	35	125
	MALE	50-59	U/L	35	131	1	U/L	35	131
Total Bilirubin	BOTH	18-65	mg/dL	0.2	1.2	1	MG/DL	0.2	1.2
Creatinine (Rate Blanked)	FEMALE	18-65	mg/dL	0.4	1.1	1	MG/DL	0.4	1.1
	MALE	18-49	mg/dL	0.5	1.2	1	MG/DL	0.5	1.2
	MALE	50-63	mg/dL	0.5	1.3	1	MG/DL	0.5	1.3
Glucose, NaFl Pl, Fasting	BOTH	18-58	mg/dL	70	115	1	MG/DL	70	115
	BOTH	59-65	mg/dL	70	120	1	MG/DL	70	120
Ultrasens, Insulin Fasting	BOTH	18-65	uIU/mL	1.90	23.00	6.945	PMOL/L	13.196	159.74
Serum Sodium	BOTH	18-58	mEq/L	132	147	1	MMOL/L	132	147
	BOTH	59-65	mEq/L	135	145	1	MMOL/L	135	145
Serum Potassium	BOTH	18-65	mEq/L	3.4	5.4	1	MMOL/L	3.4	5.4
Serum Chloride	BOTH	18-65	mEq/L	94	112	1	MMOL/L	94	112
Serum Bicarbonate	BOTH	18-65	mEq/L	17.0	30.6	1	MMOL/L	17	30.6
Triglycerides (GPO)	FEMALE	20-29	mg/dL	36	144	1	MG/DL	36	144
	MALE	18-19	mg/dL	37	148	1	MG/DL	37	148

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM200.SAS
GENERATED: 17NOV2005 13:46:23 iceadmn3

Table 11.3.7.1.2.1 Chemistry Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
Triglycerides (GPO)	FEMALE	18-19	mg/dL	39	124	1	MG/DL	39	124
	FEMALE	30-39	mg/dL	39	176	1	MG/DL	39	176
	MALE	20-29	mg/dL	44	249	1	MG/DL	44	249
	FEMALE	40-49	mg/dL	45	214	1	MG/DL	45	214
	MALE	30-40	mg/dL	50	321	1	MG/DL	50	321
	FEMALE	50-59	mg/dL	52	262	1	MG/DL	52	262
	MALE	40-49	mg/dL	55	327	1	MG/DL	55	327
	FEMALE	60-65	mg/dL	56	240	1	MG/DL	56	240
	MALE	60-63	mg/dL	58	260	1	MG/DL	58	260
	MALE	50-59	mg/dL	58	320	1	MG/DL	58	320
Cholesterol (High Performance)	MALE	18-19	mg/dL	114	198	1	MG/DL	114	198
	FEMALE	18-19	mg/dL	125	212	1	MG/DL	125	212
	FEMALE	20-29	mg/dL	128	218	1	MG/DL	128	218
	MALE	20-29	mg/dL	128	236	1	MG/DL	128	236
	FEMALE	30-39	mg/dL	141	240	1	MG/DL	141	240
	MALE	30-40	mg/dL	150	264	1	MG/DL	150	264
	FEMALE	40-49	mg/dL	155	265	1	MG/DL	155	265
	MALE	40-49	mg/dL	162	280	1	MG/DL	162	280
	MALE	50-59	mg/dL	170	291	1	MG/DL	170	291
	FEMALE	50-59	mg/dL	171	291	1	MG/DL	171	291
	MALE	60-63	mg/dL	175	298	1	MG/DL	175	298
	FEMALE	60-65	mg/dL	188	320	1	MG/DL	188	320
HDL Cholesterol Dex Sul-Mg	MALE	39-43	mg/dL	27	67	1	MG/DL	27	67
	MALE	29-53	mg/dL	28	63	1	MG/DL	28	63
	MALE	54-58	mg/dL	28	71	1	MG/DL	28	71
	MALE	34-38	mg/dL	29	62	1	MG/DL	29	62
	MALE	18-23	mg/dL	30	63	1	MG/DL	30	63
	MALE	44-48	mg/dL	30	64	1	MG/DL	30	64
	MALE	59-63	mg/dL	30	74	1	MG/DL	30	74
	MALE	24-28	mg/dL	31	63	1	MG/DL	31	63
	FEMALE	19-23	mg/dL	33	79	1	MG/DL	33	79
	FEMALE	34-38	mg/dL	34	82	1	MG/DL	34	82
	FEMALE	44-48	mg/dL	34	87	1	MG/DL	34	87
	FEMALE	39-43	mg/dL	34	88	1	MG/DL	34	88
	FEMALE	18-18	mg/dL	35	74	1	MG/DL	35	74
	FEMALE	64-65	mg/dL	35	98	1	MG/DL	35	98

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM200.SAS
GENERATED: 17NOV2005 13:46:23 iceadmn3

Table 11.3.7.1.2.1 Chemistry Conversion Factors

LAB TEST	SEX	AGE RANGE	ORIGINAL UNITS	ORIGINAL LOWER RANGE	ORIGINAL UPPER RANGE	REPORTED UNIT CONVERSION FACTOR	REPORTED UNITS	REPORTED LOWER RANGE	REPORTED UPPER RANGE
HDL Cholesterol Dex Sul-Mg	FEMALE	29-33	mg/dL	36	77	1	MG/DL	36	77
	FEMALE	24-28	mg/dL	37	83	1	MG/DL	37	83
	FEMALE	54-58	mg/dL	37	91	1	MG/DL	37	91
	FEMALE	49-53	mg/dL	37	92	1	MG/DL	37	92
	FEMALE	59-62	mg/dL	38	92	1	MG/DL	38	92
LDL Cholesterol-Friedwald	FEMALE	20-24	mg/dL	57	159	1	MG/DL	57	159
	FEMALE	18-19	mg/dL	59	137	1	MG/DL	59	137
	MALE	18-19	mg/dL	62	130	1	MG/DL	62	130
	MALE	20-24	mg/dL	66	147	1	MG/DL	66	147
	FEMALE	30-34	mg/dL	70	156	1	MG/DL	70	156
	MALE	25-29	mg/dL	70	165	1	MG/DL	70	165
	FEMALE	25-29	mg/dL	71	164	1	MG/DL	71	164
	FEMALE	40-44	mg/dL	74	174	1	MG/DL	74	174
	FEMALE	35-39	mg/dL	75	172	1	MG/DL	75	172
	MALE	30-34	mg/dL	78	185	1	MG/DL	78	185
	FEMALE	45-49	mg/dL	79	186	1	MG/DL	79	186
	MALE	35-40	mg/dL	81	189	1	MG/DL	81	189
	MALE	60-63	mg/dL	83	210	1	MG/DL	83	210
	MALE	40-44	mg/dL	87	186	1	MG/DL	87	186
	FEMALE	50-54	mg/dL	88	201	1	MG/DL	88	201
	MALE	55-59	mg/dL	88	203	1	MG/DL	88	203
	MALE	50-54	mg/dL	89	197	1	MG/DL	89	197
	FEMALE	55-59	mg/dL	89	210	1	MG/DL	89	210
	FEMALE	65-65	mg/dL	92	221	1	MG/DL	92	221
	MALE	45-49	mg/dL	97	202	1	MG/DL	97	202
	FEMALE	60-64	mg/dL	100	224	1	MG/DL	100	224
Thyroid Stim. Hormone	BOTH	18-65	uIU/mL	0.32	5.00	1	MIU/L	0.32	5
Free T4	BOTH	18-65	ng/dL	0.7	1.9	12.87	PMOL/L	9.009	24.453
T3-Uptake	BOTH	21-65	%	27	44	1	%	27	44
	FEMALE	18-20	%	27	49	1	%	27	49

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM200.SAS
GENERATED: 17NOV2005 13:46:23 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
AST (U/L)	BSLN	125	23.66	8.94	22.0	9.0	54.0	128	23.02	8.04	21.0	9.0	52.0	139	23.60	9.08	21.0	11.0	70.0
	VISIT 10	125	25.28	13.45	22.0	11.0	112.0	128	26.09	14.14	23.0	11.0	127.0	139	23.69	12.72	20.0	10.0	99.0
	FINAL	125	25.28	13.45	22.0	11.0	112.0	128	26.09	14.14	23.0	11.0	127.0	139	23.69	12.72	20.0	10.0	99.0
	CHG FRM BSLN	125	1.62	13.00	1.0	-34.0	87.0	128	3.07	11.98	1.5	-19.0	85.0	139	0.09	9.70	-1.0	-24.0	75.0
ALT (U/L)	BSLN	127	26.98	16.09	22.0	7.0	110.0	129	26.73	16.95	22.0	8.0	95.0	142	27.74	19.44	21.0	8.0	108.0
	VISIT 10	127	26.72	15.64	22.0	6.0	84.0	129	31.61	26.04	24.0	6.0	180.0	142	27.77	23.39	20.0	5.0	146.0
	FINAL	127	26.72	15.64	22.0	6.0	84.0	129	31.61	26.04	24.0	6.0	180.0	142	27.77	23.39	20.0	5.0	146.0
	CHG FRM BSLN	127	-0.26	14.60	-1.0	-88.0	62.0	129	4.88	21.10	2.0	-33.0	135.0	142	0.03	15.89	-1.0	-68.0	95.0
ALKALINE PHOSPHATASE (U/L)	BSLN	127	75.58	19.07	73.0	34.0	141.0	129	78.54	21.18	75.0	33.0	153.0	142	78.23	20.48	75.0	38.0	150.0
	VISIT 10	127	76.90	19.17	76.0	32.0	134.0	129	85.90	31.95	81.0	38.0	301.0	142	76.28	20.21	74.0	39.0	155.0
	FINAL	127	76.90	19.17	76.0	32.0	134.0	129	85.90	31.95	81.0	38.0	301.0	142	76.28	20.21	74.0	39.0	155.0
	CHG FRM BSLN	127	1.31	9.65	0.0	-22.0	28.0	129	7.36	21.99	6.0	-27.0	197.0	142	-1.95	10.19	-1.0	-41.0	34.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
TOTAL BILIRUBIN (MG/DL)	BSLN	114	0.47	0.18	0.4	0.2	1.1	112	0.50	0.36	0.4	0.2	2.9	132	0.52	0.27	0.4	0.2	1.9
	VISIT 10	114	0.48	0.25	0.4	0.2	1.8	112	0.43	0.26	0.4	0.2	2.2	132	0.48	0.23	0.4	0.2	1.6
	FINAL	114	0.48	0.25	0.4	0.2	1.8	112	0.43	0.26	0.4	0.2	2.2	132	0.48	0.23	0.4	0.2	1.6
	CHG FRM BSLN	114	0.01	0.24	0.0	-0.4	1.1	112	-0.07	0.23	0.0	-0.8	0.6	132	-0.04	0.19	0.0	-0.8	0.5
CREATININE (MG/DL)	BSLN	127	0.84	0.18	0.8	0.5	1.4	129	0.81	0.16	0.8	0.4	1.2	142	0.84	0.19	0.8	0.3	1.5
	VISIT 10	127	0.85	0.19	0.8	0.5	1.4	129	0.81	0.16	0.8	0.5	1.2	142	0.83	0.17	0.8	0.5	1.3
	FINAL	127	0.85	0.19	0.8	0.5	1.4	129	0.81	0.16	0.8	0.5	1.2	142	0.83	0.17	0.8	0.5	1.3
	CHG FRM BSLN	127	0.01	0.13	0.0	-0.3	0.3	129	0.01	0.11	0.0	-0.2	0.5	142	-0.00	0.13	0.0	-0.7	0.3
FASTING GLUCOSE (MG/DL)	BSLN	139	90.75	15.40	88.0	65.0	207.0	137	89.23	11.86	88.0	38.0	131.0	154	91.29	14.03	90.0	68.0	183.0
	VISIT 6	136	97.15	22.99	91.5	56.0	235.0	135	95.16	25.15	92.0	60.0	283.0	150	95.55	20.57	91.0	69.0	236.0
	VISIT 10	103	95.39	30.38	91.0	47.0	341.0	97	97.49	29.75	91.0	62.0	257.0	114	91.18	14.14	89.0	51.0	164.0
	FINAL	139	96.77	29.97	91.0	47.0	341.0	137	96.61	27.28	91.0	62.0	257.0	154	94.18	20.69	90.0	51.0	236.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST ----- FASTING GLUCOSE (MG/DL)	WINDOWED VISIT ----- CHG FRM BSLN	139	6.02	22.35	3.0	-35.0	186.0	137	7.38	24.96	3.0	-29.0	173.0	154	2.90	15.95	1.0	-55.0	87.0
INSULIN (PMOL/L)	BSLN	136	50.71	34.15	38.6	10.5	228.5	136	56.64	55.41	40.8	8.3	526.4	153	61.63	73.17	44.2	9.7	733.9
	VISIT 6	133	80.25	108.64	48.8	7.7	1058.6	133	85.88	108.50	52.2	9.1	818.2	147	71.76	95.95	46.8	8.8	713.9
	VISIT 10	100	73.96	80.70	51.7	9.4	587.1	96	79.46	97.12	47.9	9.7	607.5	113	61.55	46.93	49.1	9.0	252.3
	FINAL	136	81.77	116.53	50.2	9.4	1058.6	136	82.90	95.32	51.1	9.1	607.5	153	64.24	50.89	49.1	9.0	265.6
	CHG FRM BSLN	136	31.05	112.96	4.1	-132.9	953.5	136	26.27	86.26	5.3	-131.7	500.4	153	2.61	72.44	5.6	-620.3	239.2
INSULIN (uIU/mL)	BSLN	136	7.30	4.92	5.6	1.5	32.9	136	8.16	7.98	5.9	1.2	75.8	153	8.87	10.54	6.4	1.4	105.7
	VISIT 6	133	11.55	15.64	7.0	1.1	152.4	133	12.37	15.62	7.5	1.3	117.8	147	10.33	13.82	6.7	1.3	102.8
	VISIT 10	100	10.65	11.62	7.5	1.4	84.5	96	11.44	13.98	6.9	1.4	87.5	113	8.86	6.76	7.1	1.3	36.3
	FINAL	136	11.77	16.78	7.2	1.4	152.4	136	11.94	13.73	7.4	1.3	87.5	153	9.25	7.33	7.1	1.3	38.2

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
INSULIN (uIU/mL)	CHG FRM BSLN	136	4.47	16.27	0.6	-19.1	137.3	136	3.78	12.42	0.8	-19.0	72.1	153	0.38	10.43	0.8	-89.3	34.4
FASTING HGBA1C (%)	BSLN	126	5.32	0.46	5.3	4.1	7.3	127	5.30	0.44	5.3	4.1	7.0	141	5.22	0.46	5.2	4.0	7.6
	VISIT 10	126	5.34	0.72	5.3	4.2	11.8	127	5.37	0.46	5.4	4.3	7.5	141	5.25	0.50	5.2	4.2	8.0
	FINAL	126	5.34	0.72	5.3	4.2	11.8	127	5.37	0.46	5.4	4.3	7.5	141	5.25	0.50	5.2	4.2	8.0
	CHG FRM BSLN	126	0.03	0.48	0.0	-1.4	4.5	127	0.07	0.27	0.1	-0.6	1.3	141	0.03	0.27	0.0	-0.9	1.1
SODIUM (MEQ/L)	BSLN	127	140.89	2.24	141.0	135.0	146.0	129	140.64	2.21	140.0	135.0	149.0	142	141.04	2.43	141.0	136.0	150.0
	VISIT 10	127	140.17	2.37	140.0	133.0	148.0	129	140.43	2.30	141.0	134.0	147.0	142	140.12	2.13	140.0	135.0	146.0
	FINAL	127	140.17	2.37	140.0	133.0	148.0	129	140.43	2.30	141.0	134.0	147.0	142	140.12	2.13	140.0	135.0	146.0
	CHG FRM BSLN	127	-0.72	2.74	-1.0	-9.0	6.0	129	-0.22	2.78	0.0	-12.0	7.0	142	-0.92	2.68	-1.0	-8.0	7.0
POTASSIUM (MEQ/L)	BSLN	127	4.29	0.35	4.3	3.5	5.4	128	4.35	0.43	4.3	3.0	5.8	142	4.40	0.43	4.4	3.3	5.5
	VISIT 10	127	4.21	0.39	4.1	3.5	5.7	128	4.29	0.40	4.2	3.4	5.4	142	4.37	0.45	4.3	3.3	6.2
	FINAL	127	4.21	0.39	4.1	3.5	5.7	128	4.29	0.40	4.2	3.4	5.4	142	4.37	0.45	4.3	3.3	6.2

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
POTASSIUM (MEQ/L)	CHG FRM BSLN	127	-0.08	0.37	0.0	-1.0	0.9	128	-0.05	0.47	0.0	-1.5	1.1	142	-0.03	0.49	-0.1	-1.2	1.7
CHLORIDE (MEQ/L)	BSLN	127	103.60	2.66	104.0	96.0	111.0	129	103.25	2.74	103.0	95.0	109.0	142	103.42	2.27	103.0	98.0	110.0
	VISIT 10	127	103.54	2.35	104.0	96.0	108.0	129	103.75	2.23	104.0	98.0	109.0	142	103.26	2.38	103.0	95.0	109.0
	FINAL	127	103.54	2.35	104.0	96.0	108.0	129	103.75	2.23	104.0	98.0	109.0	142	103.26	2.38	103.0	95.0	109.0
	CHG FRM BSLN	127	-0.06	2.70	0.0	-9.0	8.0	129	0.50	3.08	1.0	-7.0	10.0	142	-0.15	2.67	0.0	-6.0	6.0
BICARBONATE (MEQ/L)	BSLN	127	24.39	3.26	23.9	15.2	31.5	129	24.14	3.01	24.0	16.3	30.4	142	24.18	3.21	24.3	17.3	31.0
	VISIT 10	127	24.56	2.61	24.7	18.3	30.9	129	24.59	2.68	24.7	16.3	30.6	142	25.00	2.87	25.2	18.0	30.9
	FINAL	127	24.56	2.61	24.7	18.3	30.9	129	24.59	2.68	24.7	16.3	30.6	142	25.00	2.87	25.2	18.0	30.9
	CHG FRM BSLN	127	0.17	3.40	0.4	-8.1	7.8	129	0.46	2.96	0.7	-6.9	7.6	142	0.81	3.15	0.6	-6.4	9.9
TRIGLYCERIDE (MG/DL)	BSLN	127	158.42	126.56	125.0	44.0	901.0	129	154.56	108.30	123.0	32.0	684.0	142	147.63	104.00	114.5	40.0	914.0
	VISIT 10	127	198.50	195.41	148.0	52.0	1387.0	129	161.30	113.91	130.0	36.0	558.0	142	149.39	144.24	116.5	38.0	1529.0
	FINAL	127	198.50	195.41	148.0	52.0	1387.0	129	161.30	113.91	130.0	36.0	558.0	142	149.39	144.24	116.5	38.0	1529.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST ----- TRIG-LYCE-RIDE (MG/-DL)	WINDO-WED VISIT ------ CHG FRM BSLN	127	40.08	128.08	15.0	-187.0	758.0	129	6.74	96.75	7.0	-512.0	405.0	142	1.76	85.89	-4.0	-256.0	615.0
TOTAL CHOL-ESTE-ROL (MG/-DL)	BSLN	127	206.20	39.89	201.0	122.0	332.0	129	203.68	48.47	201.0	101.0	365.0	142	204.12	46.68	200.0	111.0	324.0
	------ VISIT 10	127	207.63	45.27	205.0	125.0	458.0	129	201.85	45.37	197.0	109.0	331.0	142	197.96	41.86	194.0	96.0	296.0
	FINAL	127	207.63	45.27	205.0	125.0	458.0	129	201.85	45.37	197.0	109.0	331.0	142	197.96	41.86	194.0	96.0	296.0
	------ CHG FRM BSLN	127	1.43	32.99	-2.0	-55.0	171.0	129	-1.83	31.74	4.0	-109.0	109.0	142	-6.15	25.93	-5.0	-86.0	65.0
DIRE-CT HDL (MG/-DL)	BSLN	123	48.84	14.62	46.0	24.0	98.0	129	49.20	11.91	48.0	29.0	85.0	141	50.88	15.97	49.0	26.0	130.0
	------ VISIT 10	123	48.13	14.17	48.0	22.0	98.0	129	48.78	12.39	47.0	25.0	98.0	141	50.19	17.06	46.0	26.0	147.0
	FINAL	123	48.13	14.17	48.0	22.0	98.0	129	48.78	12.39	47.0	25.0	98.0	141	50.19	17.06	46.0	26.0	147.0
	------ CHG FRM BSLN	123	-0.71	7.42	-2.0	-22.0	21.0	129	-0.43	8.39	0.0	-19.0	23.0	141	-0.69	7.58	-1.0	-18.0	31.0

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
LDL CALCULATED (MG/DL)	BSLN	116	126.72	35.64	124.0	48.0	254.0	120	123.07	39.10	115.0	50.0	273.0	140	124.77	37.94	121.0	40.0	242.0
	VISIT 10	116	122.27	33.82	121.0	40.0	221.0	120	123.23	38.29	115.5	47.0	247.0	140	119.52	35.07	117.0	35.0	221.0
	FINAL	116	122.27	33.82	121.0	40.0	221.0	120	123.23	38.29	115.5	47.0	247.0	140	119.52	35.07	117.0	35.0	221.0
	CHG FRM BSLN	116	-4.46	22.69	-3.0	-66.0	56.0	120	0.17	26.37	2.0	-95.0	84.0	140	-5.25	22.19	-4.0	-79.0	64.0
TSH (MIU/L)	BSLN	127	1.45	1.03	1.1	0.1	5.5	129	1.46	0.95	1.2	0.3	5.0	140	1.48	0.89	1.3	0.3	5.3
	VISIT 10	127	1.64	1.43	1.3	0.2	11.5	129	1.83	2.10	1.5	0.3	20.9	140	1.48	1.02	1.3	0.2	7.2
	FINAL	127	1.64	1.43	1.3	0.2	11.5	129	1.83	2.10	1.5	0.3	20.9	140	1.48	1.02	1.3	0.2	7.2
	CHG FRM BSLN	127	0.20	1.54	0.0	-4.9	11.1	129	0.37	1.78	0.1	-1.8	17.2	140	0.00	0.86	-0.0	-4.5	3.4
FREE T4 (PMOL/L)	BSLN	127	12.61	2.13	12.9	7.7	19.3	129	12.07	1.82	11.6	7.7	18.0	142	12.53	2.15	12.9	7.7	24.5
	VISIT 10	127	11.68	2.16	11.6	6.4	19.3	129	10.95	2.26	10.3	5.1	18.0	142	12.74	2.09	12.9	9.0	23.2
	FINAL	127	11.68	2.16	11.6	6.4	19.3	129	10.95	2.26	10.3	5.1	18.0	142	12.74	2.09	12.9	9.0	23.2
	CHG FRM BSLN	127	-0.92	2.40	-1.3	-10.3	6.4	129	-1.12	2.28	-1.3	-5.1	5.1	142	0.21	1.83	0.0	-5.1	6.4

(Continued)

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.1 Chemistry Descriptive Statistics
Safety Population

		QUETIAPINE 300 MG					QUETIAPINE 600 MG					PLACEBO				
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST ----- T3-UPTAKE (%)	WINDOWED VISIT ----- BSLN	127	34.23	4.12	34.0	24.0	58.0	129	33.32	3.94	33.0	26.0	56.0	142	33.73	5.29	33.0	22.0	67.0
	VISIT 10	127	34.85	4.21	35.0	24.0	54.0	129	34.52	3.93	34.0	25.0	54.0	142	33.86	5.26	34.0	22.0	67.0
	FINAL	127	34.85	4.21	35.0	24.0	54.0	129	34.52	3.93	34.0	25.0	54.0	142	33.86	5.26	34.0	22.0	67.0
	CHG FRM BSLN	127	0.62	2.34	1.0	-9.0	6.0	129	1.20	2.51	1.0	-5.0	12.0	142	0.13	2.63	0.0	-8.0	8.0

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM201.SAS
GENERATED: 17NOV2005 13:46:26 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
AST (U/L)	BSLN	104	23.57	8.72	22.0	12.0	54.0	95	22.22	7.43	20.0	9.0	46.0	113	23.57	9.08	21.0	11.0	70.0
	VISIT 10	104	24.84	13.36	22.0	12.0	112.0	95	25.31	14.01	22.0	11.0	127.0	113	23.89	13.46	20.0	10.0	99.0
	FINAL	104	24.84	13.36	22.0	12.0	112.0	95	25.31	14.01	22.0	11.0	127.0	113	23.89	13.46	20.0	10.0	99.0
	CHG FRM BSLN	104	1.27	13.78	0.5	-34.0	87.0	95	3.08	12.90	2.0	-19.0	85.0	113	0.33	10.22	-1.0	-24.0	75.0
ALT (U/L)	BSLN	104	26.91	16.10	22.0	9.0	110.0	96	25.67	16.23	21.5	8.0	95.0	117	27.72	18.74	22.0	8.0	101.0
	VISIT 10	104	25.88	14.84	22.0	7.0	84.0	96	30.21	24.90	23.0	8.0	180.0	117	27.16	21.54	20.0	5.0	141.0
	FINAL	104	25.88	14.84	22.0	7.0	84.0	96	30.21	24.90	23.0	8.0	180.0	117	27.16	21.54	20.0	5.0	141.0
	CHG FRM BSLN	104	-1.03	15.33	-1.0	-88.0	62.0	96	4.54	22.00	2.0	-33.0	135.0	117	-0.56	14.50	-2.0	-68.0	63.0
ALKALINE PHOSPHATASE (U/L)	BSLN	104	76.34	19.92	73.5	34.0	141.0	96	77.64	21.50	74.5	33.0	153.0	117	77.56	19.93	74.0	39.0	150.0
	VISIT 10	104	76.87	19.65	76.5	32.0	134.0	96	83.41	25.41	80.0	38.0	187.0	117	75.38	18.46	74.0	43.0	128.0
	FINAL	104	76.87	19.65	76.5	32.0	134.0	96	83.41	25.41	80.0	38.0	187.0	117	75.38	18.46	74.0	43.0	128.0
	CHG FRM BSLN	104	0.53	9.77	-1.0	-22.0	28.0	96	5.77	13.74	6.0	-27.0	67.0	117	-2.18	8.38	-1.0	-27.0	20.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
TOTAL BILIRUBIN (MG/DL)	BSLN	94	0.47	0.19	0.4	0.2	1.1	85	0.50	0.31	0.4	0.2	1.8	111	0.53	0.29	0.4	0.3	1.9
	VISIT 10	94	0.49	0.26	0.4	0.2	1.8	85	0.43	0.22	0.4	0.2	1.1	111	0.49	0.24	0.4	0.2	1.6
	FINAL	94	0.49	0.26	0.4	0.2	1.8	85	0.43	0.22	0.4	0.2	1.1	111	0.49	0.24	0.4	0.2	1.6
	CHG FRM BSLN	94	0.02	0.23	0.0	-0.4	1.1	85	-0.07	0.25	0.0	-0.8	0.6	111	-0.04	0.19	0.0	-0.8	0.5
CREATININE (MG/DL)	BSLN	104	0.83	0.18	0.8	0.5	1.4	96	0.81	0.15	0.8	0.4	1.2	117	0.83	0.19	0.8	0.3	1.3
	VISIT 10	104	0.85	0.18	0.8	0.5	1.4	96	0.81	0.16	0.8	0.5	1.2	117	0.83	0.16	0.8	0.5	1.2
	FINAL	104	0.85	0.18	0.8	0.5	1.4	96	0.81	0.16	0.8	0.5	1.2	117	0.83	0.16	0.8	0.5	1.2
	CHG FRM BSLN	104	0.01	0.13	0.0	-0.3	0.3	96	0.00	0.11	0.0	-0.2	0.2	117	0.00	0.11	0.0	-0.3	0.3
FASTING GLUCOSE (MG/DL)	BSLN	115	90.54	12.14	88.0	71.0	155.0	106	89.30	10.72	88.0	62.0	131.0	128	90.74	13.64	89.0	68.0	183.0
	VISIT 6	105	96.44	20.36	92.0	56.0	212.0	101	94.83	26.26	92.0	60.0	283.0	117	95.11	21.03	91.0	69.0	236.0
	VISIT 10	88	94.61	31.22	90.0	47.0	341.0	80	98.36	32.32	91.0	62.0	257.0	103	91.50	14.49	89.0	51.0	164.0
	FINAL	115	95.57	28.88	90.0	47.0	341.0	106	96.96	28.66	91.0	62.0	257.0	128	93.60	20.82	89.5	51.0	236.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST ----- FASTING GLUCOSE (MG/DL)	WINDOWED VISIT ------ CHG FRM BSLN	115	5.03	23.03	3.0	-35.0	186.0	106	7.66	25.97	3.0	-19.0	173.0	128	2.86	16.51	1.0	-55.0	87.0
INSULIN (PMOL/L)	BSLN	114	50.76	34.86	39.0	10.5	228.5	105	51.39	39.37	38.5	8.3	214.5	127	59.50	74.82	42.3	9.7	733.9
	VISIT 6	104	68.96	67.98	45.3	7.7	436.1	99	81.23	114.55	51.3	11.0	818.2	115	70.12	94.03	41.9	8.8	713.9
	VISIT 10	87	71.00	82.73	48.1	9.4	587.1	80	75.68	85.53	46.0	9.7	509.1	103	59.97	45.51	44.1	9.0	252.3
	FINAL	114	71.33	84.07	47.5	9.4	587.1	105	75.55	82.83	47.6	9.7	509.1	127	63.22	51.59	44.1	9.0	265.6
	CHG FRM BSLN	114	20.57	82.16	1.4	-132.9	457.1	105	24.15	75.76	5.6	-131.7	476.6	127	3.72	72.63	5.0	-620.3	239.2
INSULIN (uIU/mL)	BSLN	114	7.31	5.02	5.6	1.5	32.9	105	7.40	5.67	5.5	1.2	30.9	127	8.57	10.77	6.1	1.4	105.7
	VISIT 6	104	9.93	9.79	6.5	1.1	62.8	99	11.70	16.49	7.4	1.6	117.8	115	10.10	13.54	6.0	1.3	102.8
	VISIT 10	87	10.22	11.91	6.9	1.4	84.5	80	10.90	12.32	6.6	1.4	73.3	103	8.64	6.55	6.4	1.3	36.3
	FINAL	114	10.27	12.11	6.8	1.4	84.5	105	10.88	11.93	6.9	1.4	73.3	127	9.10	7.43	6.4	1.3	38.2

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
INSULIN (uIU/mL)	CHG FRM BSLN	114	2.96	11.83	0.2	-19.1	65.8	105	3.48	10.91	0.8	-19.0	68.6	127	0.54	10.46	0.7	-89.3	34.4
FASTING HGBA1C (%)	BSLN	103	5.34	0.47	5.3	4.3	7.3	94	5.27	0.44	5.3	4.1	7.0	116	5.21	0.48	5.2	4.0	7.6
	VISIT 10	103	5.37	0.77	5.3	4.4	11.8	94	5.34	0.47	5.4	4.3	7.5	116	5.26	0.52	5.2	4.2	8.0
	FINAL	103	5.37	0.77	5.3	4.4	11.8	94	5.34	0.47	5.4	4.3	7.5	116	5.26	0.52	5.2	4.2	8.0
	CHG FRM BSLN	103	0.03	0.52	0.0	-1.4	4.5	94	0.08	0.28	0.1	-0.6	1.3	116	0.04	0.26	0.0	-0.5	1.1
SODIUM (MEQ/L)	BSLN	104	140.88	2.25	141.0	135.0	146.0	96	140.61	2.23	140.0	135.0	149.0	117	141.14	2.47	141.0	136.0	150.0
	VISIT 10	104	140.11	2.41	140.0	133.0	148.0	96	140.32	2.31	140.0	134.0	147.0	117	140.13	2.20	140.0	135.0	146.0
	FINAL	104	140.11	2.41	140.0	133.0	148.0	96	140.32	2.31	140.0	134.0	147.0	117	140.13	2.20	140.0	135.0	146.0
	CHG FRM BSLN	104	-0.77	2.77	-1.0	-9.0	6.0	96	-0.29	2.97	0.0	-12.0	7.0	117	-1.01	2.72	-1.0	-8.0	7.0
POTASSIUM (MEQ/L)	BSLN	104	4.30	0.36	4.3	3.5	5.4	95	4.34	0.41	4.3	3.0	5.6	117	4.42	0.44	4.4	3.3	5.5
	VISIT 10	104	4.21	0.41	4.1	3.5	5.7	95	4.30	0.41	4.3	3.4	5.4	117	4.40	0.44	4.3	3.6	6.2
	FINAL	104	4.21	0.41	4.1	3.5	5.7	95	4.30	0.41	4.3	3.4	5.4	117	4.40	0.44	4.3	3.6	6.2

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*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
POTASSIUM (MEQ/L)	CHG FRM BSLN	104	-0.08	0.38	-0.0	-1.0	0.9	95	-0.04	0.47	0.0	-1.5	1.1	117	-0.02	0.48	-0.1	-1.2	1.5
CHLORIDE (MEQ/L)	BSLN	104	103.66	2.68	104.0	96.0	111.0	96	103.20	2.79	104.0	95.0	109.0	117	103.53	2.25	103.0	98.0	110.0
	VISIT 10	104	103.60	2.33	104.0	96.0	108.0	96	103.76	2.01	104.0	99.0	109.0	117	103.19	2.46	103.0	95.0	109.0
	FINAL	104	103.60	2.33	104.0	96.0	108.0	96	103.76	2.01	104.0	99.0	109.0	117	103.19	2.46	103.0	95.0	109.0
	CHG FRM BSLN	104	-0.07	2.79	0.0	-9.0	8.0	96	0.56	2.79	1.0	-7.0	7.0	117	-0.34	2.66	0.0	-6.0	6.0
BICARBONATE (MEQ/L)	BSLN	104	24.33	3.34	23.9	15.2	31.5	96	24.24	3.07	24.1	16.3	30.4	117	24.34	3.21	24.7	17.3	31.0
	VISIT 10	104	24.54	2.61	24.6	18.3	30.9	96	24.70	2.83	24.7	16.3	30.6	117	25.07	2.84	25.2	18.0	30.9
	FINAL	104	24.54	2.61	24.6	18.3	30.9	96	24.70	2.83	24.7	16.3	30.6	117	25.07	2.84	25.2	18.0	30.9
	CHG FRM BSLN	104	0.22	3.32	0.6	-8.1	7.8	96	0.45	2.97	0.8	-6.9	7.6	117	0.74	3.20	0.5	-6.4	9.9
TRIGLYCERIDE (MG/DL)	BSLN	104	149.84	101.29	121.5	44.0	604.0	96	146.35	96.79	119.0	32.0	563.0	117	139.40	81.01	112.0	40.0	373.0
	VISIT 10	104	182.85	167.64	137.0	52.0	1054.0	96	155.13	115.94	123.5	36.0	558.0	117	133.53	82.60	114.0	38.0	395.0
	FINAL	104	182.85	167.64	137.0	52.0	1054.0	96	155.13	115.94	123.5	36.0	558.0	117	133.53	82.60	114.0	38.0	395.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
TRIGLYCERIDE (MG/DL)	CHG FRM BSLN	104	33.01	120.71	12.0	-187.0	758.0	96	8.77	87.02	1.0	-297.0	405.0	117	-5.87	59.07	-4.0	-163.0	182.0
TOTAL CHOLESTEROL (MG/DL)	BSLN	104	204.77	38.82	199.0	122.0	332.0	96	200.66	47.68	193.0	101.0	365.0	117	204.87	47.18	201.0	111.0	324.0
	VISIT 10	104	206.17	41.50	206.5	125.0	359.0	96	197.09	42.63	194.5	109.0	320.0	117	199.21	43.00	195.0	96.0	296.0
	FINAL	104	206.17	41.50	206.5	125.0	359.0	96	197.09	42.63	194.5	109.0	320.0	117	199.21	43.00	195.0	96.0	296.0
	CHG FRM BSLN	104	1.40	30.41	-2.5	-55.0	171.0	96	-3.56	30.86	4.0	-109.0	71.0	117	-5.67	26.46	-5.0	-86.0	65.0
DIRECT HDL (MG/DL)	BSLN	102	49.75	15.10	46.5	24.0	98.0	96	49.07	11.40	47.0	30.0	85.0	117	50.91	16.37	48.0	26.0	130.0
	VISIT 10	102	49.10	14.79	48.0	22.0	98.0	96	48.98	12.19	47.5	25.0	98.0	117	50.65	17.85	46.0	26.0	147.0
	FINAL	102	49.10	14.79	48.0	22.0	98.0	96	48.98	12.19	47.5	25.0	98.0	117	50.65	17.85	46.0	26.0	147.0
	CHG FRM BSLN	102	-0.65	7.61	-2.0	-22.0	21.0	96	-0.09	7.98	0.0	-18.0	23.0	117	-0.26	7.50	-1.0	-17.0	31.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST	WINDOWED VISIT																		
LDL CALCULATED (MG/DL)	BSLN	95	124.92	33.96	123.0	61.0	241.0	90	121.21	36.36	114.5	50.0	244.0	117	126.09	38.48	124.0	40.0	242.0
	VISIT 10	95	122.48	33.97	122.0	57.0	221.0	90	119.83	35.18	114.0	47.0	207.0	117	121.85	35.81	122.0	35.0	221.0
	FINAL	95	122.48	33.97	122.0	57.0	221.0	90	119.83	35.18	114.0	47.0	207.0	117	121.85	35.81	122.0	35.0	221.0
	CHG FRM BSLN	95	-2.43	21.84	-2.0	-56.0	56.0	90	-1.38	23.87	1.0	-78.0	58.0	117	-4.23	21.16	-1.0	-79.0	64.0
TSH (MIU/L)	BSLN	104	1.40	0.94	1.1	0.1	4.9	95	1.49	0.93	1.3	0.3	5.0	115	1.48	0.93	1.2	0.3	5.3
	VISIT 10	104	1.73	1.52	1.3	0.4	11.5	95	1.88	2.32	1.6	0.3	20.9	115	1.50	1.08	1.3	0.2	7.2
	FINAL	104	1.73	1.52	1.3	0.4	11.5	95	1.88	2.32	1.6	0.3	20.9	115	1.50	1.08	1.3	0.2	7.2
	CHG FRM BSLN	104	0.33	1.60	0.1	-3.0	11.1	95	0.40	2.01	0.1	-1.8	17.2	115	0.02	0.93	0.0	-4.5	3.4
FREE T4 (PMOL/L)	BSLN	104	12.60	2.18	12.9	7.7	19.3	95	12.23	1.92	11.6	7.7	18.0	116	12.59	2.17	12.9	7.7	24.5
	VISIT 10	104	11.72	2.28	11.6	6.4	19.3	95	10.96	2.42	10.3	5.1	18.0	116	12.86	2.14	12.9	9.0	23.2
	FINAL	104	11.72	2.28	11.6	6.4	19.3	95	10.96	2.42	10.3	5.1	18.0	116	12.86	2.14	12.9	9.0	23.2
	CHG FRM BSLN	104	-0.88	2.49	-1.3	-10.3	6.4	95	-1.27	2.39	-1.3	-5.1	5.1	116	0.27	1.79	0.0	-3.9	6.4

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.2.2 Chemistry Descriptive Statistics (Fasting Confirmed*)
Safety Population

		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
LAB TEST ----- T3-UPTAKE (%)	WINDOWED VISIT ------ BSLN	104	34.13	4.15	34.0	24.0	58.0	95	33.15	3.89	33.0	26.0	56.0	116	33.69	5.58	33.0	22.0	67.0
	VISIT 10	104	34.83	4.18	35.0	24.0	54.0	95	34.52	3.71	34.0	25.0	54.0	116	34.08	5.52	34.0	22.0	67.0
	FINAL	104	34.83	4.18	35.0	24.0	54.0	95	34.52	3.71	34.0	25.0	54.0	116	34.08	5.52	34.0	22.0	67.0
	CHG FRM BSLN	104	0.70	2.25	1.0	-6.0	6.0	95	1.37	2.67	1.0	-5.0	12.0	116	0.39	2.41	0.0	-7.0	8.0

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM215.SAS
GENERATED: 17NOV2005 13:47:11 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
AST	BASELINE												
	LOW	1	0	1	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	113	0	104	9	119	0	103	16	128	0	120	8
	HIGH	11	0	6	5	9	0	5	4	11	0	7	4
ALT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	106	0	95	11	106	0	92	14	116	1	108	7
	HIGH	21	0	10	11	23	0	5	18	26	0	10	16
ALKALINE PHOSPHATASE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	121	0	119	2	123	0	116	7	136	0	134	2
	HIGH	6	0	2	4	6	0	1	5	6	0	1	5
TOTAL BILIRUBIN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	114	0	112	2	107	0	107	0	128	0	127	1
	HIGH	0	0	0	0	5	0	4	1	4	0	4	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM202.SAS
GENERATED: 17NOV2005 13:46:33 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
CREATININE	BASELINE												
	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	124	0	122	2	129	0	129	0	139	0	139	0
	HIGH	3	0	2	1	0	0	0	0	2	0	2	0
FASTING GLUCOSE	LOW	1	0	0	1	3	0	3	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	132	4	121	7	131	2	122	7	147	2	141	4
	HIGH	6	0	1	5	3	0	0	3	6	0	2	4
INSULIN	LOW	7	1	5	1	6	1	4	1	5	1	4	0
	NOT CLINICALLY IMPORTANT	128	2	116	10	126	3	107	16	142	3	133	6
	HIGH	1	0	1	0	4	0	1	3	6	0	4	2
SODIUM	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	126	1	128	0	128	0	141	0	141	0
	HIGH	0	0	0	0	1	0	1	0	1	0	1	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM202.SAS
GENERATED: 17NOV2005 13:46:33 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
POTASSIUM	BASELINE												
	LOW	0	0	0	0	1	0	1	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	127	0	126	1	124	0	124	0	140	1	136	3
	HIGH	0	0	0	0	3	0	3	0	1	0	1	0
CHLORIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	129	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
BICARBONATE	LOW	1	0	1	0	1	0	1	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	121	0	120	1	128	1	127	0	140	0	139	1
	HIGH	5	0	5	0	0	0	0	0	2	0	2	0
TRIGLYCERIDE	LOW	1	0	1	0	6	3	3	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	105	0	95	10	99	2	88	9	118	5	107	6
	HIGH	21	0	4	17	24	0	8	16	23	0	11	12

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM202.SAS
GENERATED: 17NOV2005 13:46:33 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL CHOLESTEROL	BASELINE												
	LOW	7	2	5	0	17	8	9	0	10	8	2	0
	NOT CLINICALLY IMPORTANT	105	3	98	4	98	5	87	6	114	2	109	3
	HIGH	15	0	6	9	14	0	5	9	18	0	13	5
DIRECT HDL	LOW	9	4	5	0	4	2	2	0	9	6	3	0
	NOT CLINICALLY IMPORTANT	106	9	92	5	119	5	113	1	123	4	116	3
	HIGH	8	0	3	5	6	0	3	3	9	0	3	6
LDL CALCULATED	LOW	7	5	2	0	7	4	3	0	9	8	1	0
	NOT CLINICALLY IMPORTANT	100	3	94	3	104	7	88	9	119	5	111	3
	HIGH	9	0	5	4	9	0	3	6	12	0	10	2
TSH	LOW	1	0	0	1	3	1	2	0	1	1	0	0
	NOT CLINICALLY IMPORTANT	124	1	121	2	126	1	120	5	138	2	133	3
	HIGH	2	0	2	0	0	0	0	0	1	0	1	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM202.SAS
GENERATED: 17NOV2005 13:46:33 iceadmn3

Table 11.3.7.1.2.3.1 Chemistry Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH
FREE T4	BASELINE												
	LOW	2	0	2	0	2	0	2	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	125	3	122	0	127	14	113	0	141	0	141	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
T3-UPTAKE	LOW	3	1	2	0	4	2	2	0	11	5	6	0
	NOT CLINICALLY IMPORTANT	123	3	120	0	124	0	124	0	128	4	123	1
	HIGH	1	0	0	1	1	0	0	1	3	0	1	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM202.SAS
GENERATED: 17NOV2005 13:46:33 iceadmn3

Table 11.3.7.1.2.3.2 Chemistry Findings Exceeding Laboratory Norms
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
AST (SGOT)	0/124 (0.0%)	0/128 (0.0%)	0/139 (0.0%)	9/114 (7.9%)	16/119 (13.4%)	8/128 (6.3%)
ALT (SGPT)	0/127 (0.0%)	0/129 (0.0%)	1/142 (0.7%)	11/106 (10.4%)	14/106 (13.2%)	7/116 (6.0%)
Alkaline Phosphatase	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)	2/121 (1.7%)	7/123 (5.7%)	2/136 (1.5%)
Total Bilirubin	0/114 (0.0%)	0/112 (0.0%)	0/132 (0.0%)	2/114 (1.8%)	0/107 (0.0%)	1/128 (0.8%)
Creatinine (Rate Blanked)	0/127 (0.0%)	0/129 (0.0%)	0/141 (0.0%)	2/124 (1.6%)	0/129 (0.0%)	0/140 (0.0%)
Glucose, NaFl Pl, Fasting	4/138 (2.9%)	2/134 (1.5%)	2/153 (1.3%)	8/133 (6.0%)	7/134 (5.2%)	4/148 (2.7%)
Ultrasens, Insulin Fasting	2/129 (1.6%)	3/130 (2.3%)	3/148 (2.0%)	11/135 (8.1%)	17/132 (12.9%)	6/147 (4.1%)
Serum Sodium	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)	1/127 (0.8%)	0/128 (0.0%)	0/141 (0.0%)
Serum Potassium	0/127 (0.0%)	0/127 (0.0%)	1/141 (0.7%)	1/127 (0.8%)	0/125 (0.0%)	3/141 (2.1%)
Serum Chloride	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
Serum Bicarbonate	0/126 (0.0%)	1/128 (0.8%)	0/142 (0.0%)	1/122 (0.8%)	0/129 (0.0%)	1/140 (0.7%)
Triglycerides (GPO)	0/126 (0.0%)	2/123 (1.6%)	5/141 (3.5%)	10/106 (9.4%)	9/105 (8.6%)	6/119 (5.0%)
Cholesterol (High Performance)	3/120 (2.5%)	5/112 (4.5%)	2/132 (1.5%)	4/112 (3.6%)	6/115 (5.2%)	3/124 (2.4%)
HDL Cholesterol Dex Sul-Mg	9/114 (7.9%)	5/125 (4.0%)	4/132 (3.0%)	5/115 (4.3%)	1/123 (0.8%)	3/132 (2.3%)
LDL Cholesterol-Friedwald	3/109 (2.8%)	7/113 (6.2%)	5/131 (3.8%)	3/107 (2.8%)	9/111 (8.1%)	3/128 (2.3%)
Thyroid Stim. Hormone	1/126 (0.8%)	1/126 (0.8%)	2/139 (1.4%)	3/125 (2.4%)	5/129 (3.9%)	3/139 (2.2%)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM205.SAS
GENERATED: 17NOV2005 13:46:44 iceadmn3

Table 11.3.7.1.2.3.2 Chemistry Findings Exceeding Laboratory Norms
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
Free T4	3/125 (2.4%)	14/127 (11.0%)	0/141 (0.0%)	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
T-Uptake	3/124 (2.4%)	0/125 (0.0%)	4/131 (3.1%)	0/126 (0.0%)	0/128 (0.0%)	1/139 (0.7%)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM205.SAS
GENERATED: 17NOV2005 13:46:44 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
AST	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	125	0	124	1	128	0	127	1	139	0	139	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
ALT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	127	2	142	0	140	2
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	129	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL BILIRUBIN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	114	0	113	1	110	0	110	0	131	0	131	0
	HIGH	0	0	0	0	2	0	1	1	1	0	1	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM203.SAS
GENERATED: 17NOV2005 13:46:37 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
CREATININE	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	129	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
FASTING GLUCOSE	LOW	0	0	0	0	1	0	1	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	135	0	130	5	134	0	129	5	151	0	148	3
	HIGH	4	0	0	4	2	0	0	2	3	0	0	3
FASTING HGBA1C	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	126	0	125	1	127	0	127	0	140	0	139	1
	HIGH	0	0	0	0	0	0	0	0	1	0	0	1
SODIUM	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	129	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM203.SAS
GENERATED: 17NOV2005 13:46:37 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
POTASSIUM	BASELINE												
	LOW	0	0	0	0	1	0	1	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	126	1	124	0	124	0	141	0	138	3
	HIGH	0	0	0	0	3	0	3	0	1	0	1	0
CHLORIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	129	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
BICARBONATE	LOW	3	0	3	0	2	0	2	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	117	0	115	2	125	1	122	2	136	1	132	3
	HIGH	7	0	7	0	2	0	2	0	5	0	4	1
TRIGLYCERIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	101	0	85	16	97	0	89	8	111	0	100	11
	HIGH	26	0	3	23	32	0	12	20	31	0	16	15

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM203.SAS
GENERATED: 17NOV2005 13:46:37 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL CHOLESTEROL	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	92	12	101	0	93	8	119	0	112	7
	HIGH	23	0	13	10	28	0	12	16	23	0	4	19
DIRECT HDL	LOW	39	30	9	0	32	23	9	0	32	25	7	0
	NOT CLINICALLY IMPORTANT	84	10	74	0	97	13	84	0	109	15	94	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LDL CALCULATED	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	101	0	95	6	97	0	90	7	120	0	114	6
	HIGH	15	0	7	8	23	0	10	13	20	0	10	10
TSH	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	125	0	122	3	129	0	124	5	139	0	136	3
	HIGH	2	0	2	0	0	0	0	0	1	0	1	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM203.SAS
GENERATED: 17NOV2005 13:46:37 iceadmn3

Table 11.3.7.1.2.3.3 Chemistry Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH	TOTAL	LOW	NOT CLINI-CALLY IMPOR-TANT	HIGH
FREE T4	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	2	125	0	129	3	126	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
T3-UPTAKE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	127	0	127	0	129	0	129	0	142	0	142	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM203.SAS
GENERATED: 17NOV2005 13:46:37 iceadmn3

Table 11.3.7.1.2.3.4 Potentially Clinically Important Chemistry Findings
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
AST (SGOT)	NA	NA	NA	1/125 (0.8%)	1/128 (0.8%)	0/139 (0.0%)
ALT (SGPT)	NA	NA	NA	0/127 (0.0%)	2/129 (1.6%)	2/142 (1.4%)
Alkaline Phosphatase	NA	NA	NA	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
Total Bilirubin	NA	NA	NA	1/114 (0.9%)	0/110 (0.0%)	0/131 (0.0%)
Creatinine (Rate Blanked)	NA	NA	NA	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
Glucose, NaFl Pl, Fasting	0/139 (0.0%)	0/136 (0.0%)	0/154 (0.0%)	5/135 (3.7%)	5/135 (3.7%)	3/151 (2.0%)
FastHgbA1c-HPLCVariant(-70)-QT	NA	NA	NA	1/126 (0.8%)	0/127 (0.0%)	1/140 (0.7%)
Serum Sodium	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
Serum Potassium	0/127 (0.0%)	0/127 (0.0%)	0/142 (0.0%)	1/127 (0.8%)	0/125 (0.0%)	3/141 (2.1%)
Serum Chloride	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
Serum Bicarbonate	0/124 (0.0%)	1/127 (0.8%)	1/141 (0.7%)	2/120 (1.7%)	2/127 (1.6%)	3/137 (2.2%)
Triglycerides (GPO)	NA	NA	NA	16/101 (15.8%)	8/ 97 (8.2%)	11/111 (9.9%)
Cholesterol (High Performance)	NA	NA	NA	12/104 (11.5%)	8/101 (7.9%)	7/119 (5.9%)
HDL Cholesterol Dex Sul-Mg	10/ 84 (11.9%)	13/ 97 (13.4%)	15/109 (13.8%)	0/123 (0.0%)	0/129 (0.0%)	0/141 (0.0%)
LDL Cholesterol-Friedwald	NA	NA	NA	6/101 (5.9%)	7/ 97 (7.2%)	6/120 (5.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM204.SAS
GENERATED: 17NOV2005 13:46:40 iceadmn3

Table 11.3.7.1.2.3.4 Potentially Clinically Important Chemistry Findings
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
Thyroid Stim. Hormone	NA	NA	NA	3/125 (2.4%)	5/129 (3.9%)	3/139 (2.2%)
Free T4	2/127 (1.6%)	3/129 (2.3%)	0/142 (0.0%)	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)
T-Uptake	NA	NA	NA	0/127 (0.0%)	0/129 (0.0%)	0/142 (0.0%)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM204.SAS
GENERATED: 17NOV2005 13:46:40 iceadmn3

Table 11.3.7.1.2.3.5 Chemistry Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
AST	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	96	0	89	7	90	0	78	12	106	0	99	7
	HIGH	8	0	6	2	5	0	4	1	7	0	4	3
ALT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	86	0	78	8	84	0	72	12	96	1	88	7
	HIGH	18	0	10	8	12	0	4	8	21	0	10	11
ALKALINE PHOSPHATASE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	98	0	96	2	92	0	88	4	113	0	112	1
	HIGH	6	0	2	4	4	0	1	3	4	0	0	4
TOTAL BILIRUBIN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	94	0	92	2	81	0	81	0	107	0	106	1

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM216.SAS
GENERATED: 17NOV2005 13:47:19 iceadmn3

Table 11.3.7.1.2.3.5 Chemistry Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL BILIRUBIN	BASELINE												
	HIGH	0	0	0	0	4	0	4	0	4	0	4	0
CREATININE	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	102	0	101	1	96	0	96	0	115	0	115	0
	HIGH	2	0	1	1	0	0	0	0	1	0	1	0
FASTING GLUCOSE	LOW	0	0	0	0	1	0	1	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	111	3	102	6	103	2	96	5	123	2	117	4
	HIGH	4	0	1	3	2	0	0	2	4	0	1	3
INSULIN	LOW	7	1	5	1	6	1	4	1	4	1	3	0
	NOT CLINICALLY IMPORTANT	106	2	96	8	96	1	85	10	119	3	111	5
	HIGH	1	0	1	0	3	0	1	2	4	0	2	2
SODIUM	LOW	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM216.SAS
GENERATED: 17NOV2005 13:47:19 iceadmn3

Table 11.3.7.1.2.3.5 Chemistry Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
SODIUM	BASELINE												
	NOT CLINICALLY IMPORTANT	104	0	103	1	95	0	95	0	116	0	116	0
	HIGH	0	0	0	0	1	0	1	0	1	0	1	0
POTASSIUM	LOW	0	0	0	0	1	0	1	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	104	0	103	1	93	0	93	0	115	0	113	2
	HIGH	0	0	0	0	1	0	1	0	1	0	1	0
CHLORIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	104	0	96	0	96	0	117	0	117	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
BICARBONATE	LOW	1	0	1	0	1	0	1	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	98	0	97	1	95	1	94	0	115	0	114	1
	HIGH	5	0	5	0	0	0	0	0	2	0	2	0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM216.SAS
GENERATED: 17NOV2005 13:47:19 iceadmn3

Table 11.3.7.1.2.3.5 Chemistry Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TRIGLYCERIDE	BASELINE												
	LOW	1	0	1	0	4	3	1	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	86	0	80	6	75	2	66	7	100	5	92	3
	HIGH	17	0	4	13	17	0	6	11	16	0	8	8
TOTAL CHOLESTEROL	LOW	7	2	5	0	13	6	7	0	8	6	2	0
	NOT CLINICALLY IMPORTANT	85	3	79	3	75	5	65	5	94	2	89	3
	HIGH	12	0	5	7	8	0	4	4	15	0	10	5
DIRECT HDL	LOW	7	4	3	0	1	1	0	0	6	4	2	0
	NOT CLINICALLY IMPORTANT	87	6	76	5	91	4	86	1	103	4	96	3
	HIGH	8	0	3	5	4	0	1	3	8	0	2	6
LDL CALCULATED	LOW	6	4	2	0	4	4	0	0	8	7	1	0
	NOT CLINICALLY IMPORTANT	82	3	76	3	79	5	68	6	99	3	93	3

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM216.SAS
GENERATED: 17NOV2005 13:47:19 iceadmn3

Table 11.3.7.1.2.3.5 Chemistry Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
LDL CALCULATED	BASELINE												
	HIGH	7	0	4	3	7	0	3	4	10	0	8	2
TSH	LOW	1	0	0	1	3	1	2	0	1	1	0	0
	NOT CLINICALLY IMPORTANT	103	0	101	2	92	0	89	3	113	1	109	3
	HIGH	0	0	0	0	0	0	0	0	1	0	1	0
FREE T4	LOW	2	0	2	0	2	0	2	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	102	3	99	0	93	13	80	0	115	0	115	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
T3-UPTAKE	LOW	2	0	2	0	3	1	2	0	10	5	5	0
	NOT CLINICALLY IMPORTANT	101	3	98	0	91	0	91	0	103	1	101	1
	HIGH	1	0	0	1	1	0	0	1	3	0	1	2

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM216.SAS
GENERATED: 17NOV2005 13:47:19 iceadmn3

Table 11.3.7.1.2.3.6 Chemistry Findings Exceeding Laboratory Norms (Fasting Confirmed*)
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
AST (SGOT)	0/104 (0.0%)	0/ 95 (0.0%)	0/113 (0.0%)	7/ 96 (7.3%)	12/ 90 (13.3%)	7/106 (6.6%)
ALT (SGPT)	0/104 (0.0%)	0/ 96 (0.0%)	1/117 (0.9%)	8/ 86 (9.3%)	12/ 84 (14.3%)	7/ 96 (7.3%)
Alkaline Phosphatase	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)	2/ 98 (2.0%)	4/ 92 (4.3%)	1/113 (0.9%)
Total Bilirubin	0/ 94 (0.0%)	0/ 85 (0.0%)	0/111 (0.0%)	2/ 94 (2.1%)	0/ 81 (0.0%)	1/107 (0.9%)
Creatinine (Rate Blanked)	0/104 (0.0%)	0/ 96 (0.0%)	0/116 (0.0%)	1/102 (1.0%)	0/ 96 (0.0%)	0/116 (0.0%)
Glucose, NaFl Pl, Fasting	3/115 (2.6%)	2/105 (1.9%)	2/127 (1.6%)	6/111 (5.4%)	5/104 (4.8%)	4/124 (3.2%)
Ultrasens, Insulin Fasting	2/107 (1.9%)	1/ 99 (1.0%)	3/123 (2.4%)	9/113 (8.0%)	11/102 (10.8%)	5/123 (4.1%)
Serum Sodium	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)	1/104 (1.0%)	0/ 95 (0.0%)	0/116 (0.0%)
Serum Potassium	0/104 (0.0%)	0/ 94 (0.0%)	0/116 (0.0%)	1/104 (1.0%)	0/ 94 (0.0%)	2/116 (1.7%)
Serum Chloride	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)
Serum Bicarbonate	0/103 (0.0%)	1/ 95 (1.1%)	0/117 (0.0%)	1/ 99 (1.0%)	0/ 96 (0.0%)	1/115 (0.9%)
Triglycerides (GPO)	0/103 (0.0%)	2/ 92 (2.2%)	5/116 (4.3%)	6/ 87 (6.9%)	7/ 79 (8.9%)	3/101 (3.0%)
Cholesterol (High Performance)	3/ 97 (3.1%)	5/ 83 (6.0%)	2/109 (1.8%)	3/ 92 (3.3%)	5/ 88 (5.7%)	3/102 (2.9%)
HDL Cholesterol Dex Sul-Mg	6/ 95 (6.3%)	4/ 95 (4.2%)	4/111 (3.6%)	5/ 94 (5.3%)	1/ 92 (1.1%)	3/109 (2.8%)
LDL Cholesterol-Friedwald	3/ 89 (3.4%)	5/ 86 (5.8%)	3/109 (2.8%)	3/ 88 (3.4%)	6/ 83 (7.2%)	3/107 (2.8%)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM217.SAS
GENERATED: 17NOV2005 13:47:23 iceadmn3

Table 11.3.7.1.2.3.6 Chemistry Findings Exceeding Laboratory Norms (Fasting Confirmed*)
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
Thyroid Stim. Hormone	0/103 (0.0%)	0/ 92 (0.0%)	1/114 (0.9%)	3/104 (2.9%)	3/ 95 (3.2%)	3/114 (2.6%)
Free T4	3/102 (2.9%)	13/ 93 (14.0%)	0/115 (0.0%)	0/104 (0.0%)	0/ 95 (0.0%)	0/116 (0.0%)
T-Uptake	3/102 (2.9%)	0/ 92 (0.0%)	1/106 (0.9%)	0/103 (0.0%)	0/ 94 (0.0%)	1/113 (0.9%)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM217.SAS
GENERATED: 17NOV2005 13:47:23 iceadmn3

Table 11.3.7.1.2.3.7 Chemistry Potentially Clinically Important Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
AST	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	103	1	95	0	94	1	113	0	113	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
ALT	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	104	0	96	0	95	1	117	0	116	1
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	104	0	96	0	96	0	117	0	117	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL BILIRUBIN	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	94	0	93	1	84	0	84	0	110	0	110	0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM218.SAS
GENERATED: 17NOV2005 13:47:26 iceadmn3

Table 11.3.7.1.2.3.7 Chemistry Potentially Clinically Important Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TOTAL BILIRUBIN	BASELINE												
	HIGH	0	0	0	0	1	0	1	0	1	0	1	0
CREATININE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	104	0	96	0	96	0	117	0	117	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
FASTING GLUCOSE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	112	0	110	2	104	0	100	4	126	0	123	3
	HIGH	3	0	0	3	2	0	0	2	2	0	0	2
FASTING HGBA1C	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	103	0	102	1	94	0	94	0	115	0	114	1
	HIGH	0	0	0	0	0	0	0	0	1	0	0	1
SODIUM	LOW	0	0	0	0	0	0	0	0	0	0	0	0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM218.SAS
GENERATED: 17NOV2005 13:47:26 iceadmn3

Table 11.3.7.1.2.3.7 Chemistry Potentially Clinically Important Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
SODIUM	BASELINE												
	NOT CLINICALLY IMPORTANT	104	0	104	0	96	0	96	0	117	0	117	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
POTASSIUM	LOW	0	0	0	0	1	0	1	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	103	1	93	0	93	0	116	0	114	2
	HIGH	0	0	0	0	1	0	1	0	1	0	1	0
CHLORIDE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	104	0	96	0	96	0	117	0	117	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
BICARBONATE	LOW	3	0	3	0	2	0	2	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	94	0	93	1	92	1	89	2	111	1	107	3
	HIGH	7	0	7	0	2	0	2	0	5	0	4	1

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM218.SAS
GENERATED: 17NOV2005 13:47:26 iceadmn3

Table 11.3.7.1.2.3.7 Chemistry Potentially Clinically Important Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
TRIGLYCERIDE	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	83	0	73	10	75	0	69	6	93	0	85	8
	HIGH	21	0	3	18	21	0	6	15	24	0	12	12
TOTAL CHOLESTEROL	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	87	0	76	11	78	0	73	5	98	0	92	6
	HIGH	17	0	10	7	18	0	9	9	19	0	3	16
DIRECT HDL	LOW	31	25	6	0	23	14	9	0	26	20	6	0
	NOT CLINICALLY IMPORTANT	71	8	63	0	73	10	63	0	91	13	78	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
LDL CALCULATED	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	83	0	77	6	75	0	70	5	99	0	93	6

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM218.SAS
GENERATED: 17NOV2005 13:47:26 iceadmn3

Table 11.3.7.1.2.3.7 Chemistry Potentially Clinically Important Shift to Final (Fasting Confirmed*)
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
LDL CALCULATED	BASELINE												
	HIGH	12	0	6	6	15	0	7	8	18	0	9	9
TSH	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	101	3	95	0	92	3	114	0	111	3
	HIGH	0	0	0	0	0	0	0	0	1	0	1	0
FREE T4	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	2	102	0	95	3	92	0	116	0	116	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
T3-UPTAKE	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	104	0	104	0	95	0	95	0	116	0	116	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM218.SAS
GENERATED: 17NOV2005 13:47:26 iceadmn3

Table 11.3.7.1.2.3.8 Potentially Clinically Important Chemistry Findings (Fasting Confirmed*)
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
AST (SGOT)	NA	NA	NA	1/104 (1.0%)	1/ 95 (1.1%)	0/113 (0.0%)
ALT (SGPT)	NA	NA	NA	0/104 (0.0%)	1/ 96 (1.0%)	1/117 (0.9%)
Alkaline Phosphatase	NA	NA	NA	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)
Total Bilirubin	NA	NA	NA	1/ 94 (1.1%)	0/ 84 (0.0%)	0/110 (0.0%)
Creatinine (Rate Blanked)	NA	NA	NA	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)
Glucose, NaFl Pl, Fasting	0/115 (0.0%)	0/106 (0.0%)	0/128 (0.0%)	2/112 (1.8%)	4/104 (3.8%)	3/126 (2.4%)
FastHgbA1c-HPLCVariant(-70)-QT	NA	NA	NA	1/103 (1.0%)	0/ 94 (0.0%)	1/115 (0.9%)
Serum Sodium	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)
Serum Potassium	0/104 (0.0%)	0/ 94 (0.0%)	0/117 (0.0%)	1/104 (1.0%)	0/ 94 (0.0%)	2/116 (1.7%)
Serum Chloride	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)	0/104 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)
Serum Bicarbonate	0/101 (0.0%)	1/ 94 (1.1%)	1/116 (0.9%)	1/ 97 (1.0%)	2/ 94 (2.1%)	3/112 (2.7%)
Triglycerides (GPO)	NA	NA	NA	10/ 83 (12.0%)	6/ 75 (8.0%)	8/ 93 (8.6%)
Cholesterol (High Performance)	NA	NA	NA	11/ 87 (12.6%)	5/ 78 (6.4%)	6/ 98 (6.1%)
HDL Cholesterol Dex Sul-Mg	8/ 71 (11.3%)	10/ 73 (13.7%)	13/ 91 (14.3%)	0/102 (0.0%)	0/ 96 (0.0%)	0/117 (0.0%)
LDL Cholesterol-Friedwald	NA	NA	NA	6/ 83 (7.2%)	5/ 75 (6.7%)	6/ 99 (6.1%)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM219.SAS
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Table 11.3.7.1.2.3.8 Potentially Clinically Important Chemistry Findings (Fasting Confirmed*)
Categorical Shifts from Baseline to Final

	SHIFT TO LOW			SHIFT TO HIGH		
LAB PARAMETER	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)	QUETIAPINE 300MG n/N (%)	QUETIAPINE 600MG n/N (%)	PLACEBO n/N (%)
Thyroid Stim. Hormone	NA	NA	NA	3/104 (2.9%)	3/ 95 (3.2%)	3/114 (2.6%)
Free T4	2/104 (1.9%)	3/ 95 (3.2%)	0/116 (0.0%)	0/104 (0.0%)	0/ 95 (0.0%)	0/116 (0.0%)
T3-Uptake	NA	NA	NA	0/104 (0.0%)	0/ 95 (0.0%)	0/116 (0.0%)

*Confirmed by last meal date and time >8 hours before lab draw.

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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	139	90.75	15.40	88.0	65.0	207.0	137	89.23	11.86	88.0	38.0	131.0
		VISIT 6	136	97.15	22.99	91.5	56.0	235.0	135	95.16	25.15	92.0	60.0	283.0
		VISIT 10	103	95.39	30.38	91.0	47.0	341.0	97	97.49	29.75	91.0	62.0	257.0
		FINAL	139	96.77	29.97	91.0	47.0	341.0	137	96.61	27.28	91.0	62.0	257.0
		CHG FRM BSLN	139	6.02	22.35	3.0	-35.0	186.0	137	7.38	24.96	3.0	-29.0	173.0
	INSULIN (uIU/mL)	BSLN	136	7.30	4.92	5.6	1.5	32.9	136	8.16	7.98	5.9	1.2	75.8
		VISIT 6	133	11.55	15.64	7.0	1.1	152.4	133	12.37	15.62	7.5	1.3	117.8
		VISIT 10	100	10.65	11.62	7.5	1.4	84.5	96	11.44	13.98	6.9	1.4	87.5
		FINAL	136	11.77	16.78	7.2	1.4	152.4	136	11.94	13.73	7.4	1.3	87.5
		CHG FRM BSLN	136	4.47	16.27	0.6	-19.1	137.3	136	3.78	12.42	0.8	-19.0	72.1
	FASTING HGBA1C (%)	BSLN	126	5.32	0.46	5.3	4.1	7.3	127	5.30	0.44	5.3	4.1	7.0
		VISIT 10	126	5.34	0.72	5.3	4.2	11.8	127	5.37	0.46	5.4	4.3	7.5
		FINAL	126	5.34	0.72	5.3	4.2	11.8	127	5.37	0.46	5.4	4.3	7.5
		CHG FRM BSLN	126	0.03	0.48	0.0	-1.4	4.5	127	0.07	0.27	0.1	-0.6	1.3
	HOMA-R	BSLN	128	1.59	1.19	1.2	0.3	8.0	131	1.88	2.27	1.3	0.3	22.6

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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	VISIT 6	122	2.80	3.83	1.5	0.3	32.0	125	3.49	6.56	1.6	0.3	56.2
		VISIT 10	90	2.65	3.30	1.6	0.3	21.8	90	3.01	4.43	1.7	0.3	25.9
		FINAL	128	2.81	4.08	1.6	0.3	32.0	131	3.14	4.57	1.7	0.3	29.3
		CHG FRM BSLN	128	1.21	3.90	0.2	-4.9	28.7	131	1.26	3.75	0.3	-4.4	25.0
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	9	117.78	44.01	91.0	79.0	207.0	5	103.60	23.33	90.0	84.0	131.0
		VISIT 6	9	134.00	59.21	110.0	71.0	235.0	5	131.60	84.70	95.0	88.0	283.0
		VISIT 10	6	153.00	99.48	117.0	82.0	341.0	5	127.00	59.05	93.0	70.0	200.0
		FINAL	9	150.67	87.75	110.0	82.0	341.0	5	127.00	59.05	93.0	70.0	200.0
		CHG FRM BSLN	9	32.89	58.76	8.0	0.0	186.0	5	23.40	35.95	5.0	-14.0	69.0
	INSULIN (uIU/mL)	BSLN	8	9.53	5.32	7.8	4.8	20.0	5	8.76	6.91	7.6	1.7	16.6
		VISIT 6	8	16.47	9.43	13.0	7.0	32.8	5	13.18	14.78	8.6	3.5	39.2
		VISIT 10	6	15.70	9.33	12.3	7.1	28.8	5	18.13	10.84	20.1	4.0	29.5
		FINAL	8	13.94	8.58	11.2	7.0	28.8	5	18.13	10.84	20.1	4.0	29.5
		CHG FRM BSLN	8	4.41	4.06	2.7	0.9	12.0	5	9.37	10.84	4.9	1.3	27.8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	FASTING HGBA1C (%)	BSLN	7	5.91	0.84	6.1	4.8	7.3	5	5.34	1.07	5.1	4.1	7.0
		VISIT 10	7	6.74	2.34	6.3	5.0	11.8	5	5.78	1.26	5.8	4.3	7.5
		FINAL	7	6.74	2.34	6.3	5.0	11.8	5	5.78	1.26	5.8	4.3	7.5
		CHG FRM BSLN	7	0.83	1.64	0.3	-0.3	4.5	5	0.44	0.51	0.2	0.0	1.3
	HOMA-R	BSLN	8	2.76	2.16	1.8	1.0	6.7	5	2.37	2.00	2.5	0.4	5.2
		VISIT 6	8	5.31	4.46	3.2	1.6	13.0	5	6.72	11.57	2.0	0.8	27.4
		VISIT 10	6	7.19	7.87	4.1	1.5	21.8	5	5.51	4.00	5.0	0.9	12.0
		FINAL	8	5.95	7.05	2.8	1.5	21.8	5	5.51	4.00	5.0	0.9	12.0
		CHG FRM BSLN	8	3.19	5.50	1.1	0.2	16.5	5	3.14	2.62	2.6	0.3	6.8
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	38	94.37	11.32	96.5	72.0	117.0	43	94.81	14.13	96.0	38.0	121.0
		VISIT 6	37	94.05	8.56	93.0	80.0	116.0	42	100.33	30.01	94.5	60.0	236.0
		VISIT 10	30	93.40	15.28	91.5	66.0	160.0	28	110.32	43.84	98.0	82.0	257.0
		FINAL	38	93.11	14.14	91.0	66.0	160.0	43	107.49	39.35	97.0	70.0	257.0
		CHG FRM BSLN	38	-1.26	13.00	-4.0	-25.0	43.0	43	12.67	39.75	2.0	-29.0	173.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	INSULIN (uIU/mL)	BSLN	37	9.24	4.28	10.1	2.6	18.7	43	12.03	11.94	7.9	2.7	75.8
		VISIT 6	35	10.74	7.91	8.0	2.6	39.6	41	17.01	17.96	11.6	1.5	96.6
		VISIT 10	29	12.24	14.50	10.1	2.4	84.5	28	17.12	22.34	8.2	2.4	87.5
		FINAL	37	10.92	13.10	8.5	2.4	84.5	43	18.21	20.32	9.0	1.5	87.5
		CHG FRM BSLN	37	1.67	11.54	-0.4	-8.0	65.8	43	6.18	18.97	0.8	-16.7	72.1
	FASTING HGBA1C (%)	BSLN	35	5.37	0.40	5.3	4.7	6.5	39	5.42	0.41	5.4	4.6	6.7
		VISIT 10	35	5.35	0.43	5.3	4.7	6.5	39	5.50	0.42	5.5	4.7	6.8
		FINAL	35	5.35	0.43	5.3	4.7	6.5	39	5.50	0.42	5.5	4.7	6.8
		CHG FRM BSLN	35	-0.02	0.32	0.0	-1.4	0.7	39	0.08	0.19	0.1	-0.3	0.6
	HOMA-R	BSLN	35	2.03	0.91	2.2	0.7	3.9	42	2.95	3.51	1.9	0.5	22.6
		VISIT 6	31	2.38	1.80	1.8	0.5	8.1	40	5.33	9.57	2.8	0.3	56.2
		VISIT 10	27	2.17	1.01	2.0	0.5	4.1	28	4.97	6.97	2.1	0.5	25.9
		FINAL	35	1.99	0.99	1.8	0.5	4.1	42	5.36	7.00	2.6	0.3	29.3
		CHG FRM BSLN	35	-0.04	1.03	-0.2	-2.4	2.9	42	2.41	5.88	0.7	-4.2	25.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	92	86.61	6.50	87.0	65.0	98.0	89	85.72	7.61	86.0	62.0	106.0
		VISIT 6	90	94.73	17.61	91.0	56.0	172.0	88	90.63	10.47	91.0	67.0	126.0
		VISIT 10	67	91.12	15.88	89.0	47.0	144.0	64	89.58	9.89	88.5	62.0	121.0
		FINAL	92	93.01	17.23	90.0	47.0	172.0	89	89.64	9.66	89.0	62.0	121.0
		CHG FRM BSLN	92	6.40	17.07	4.0	-35.0	88.0	89	3.92	10.45	3.0	-14.0	41.0
	INSULIN (uIU/mL)	BSLN	91	6.32	4.88	4.8	1.5	32.9	88	6.23	4.07	5.2	1.2	27.4
		VISIT 6	90	11.44	18.15	5.8	1.1	152.4	87	10.13	14.11	6.7	1.3	117.8
		VISIT 10	65	9.47	10.25	6.0	1.4	54.7	63	8.39	6.85	6.0	1.4	31.2
		FINAL	91	11.93	18.63	6.4	1.4	152.4	88	8.52	7.36	6.1	1.3	33.7
		CHG FRM BSLN	91	5.62	18.38	1.2	-19.1	137.3	88	2.29	7.31	0.7	-19.0	26.2
	FASTING HGBA1C (%)	BSLN	84	5.24	0.40	5.3	4.1	6.0	83	5.24	0.40	5.3	4.3	6.1
		VISIT 10	84	5.22	0.37	5.2	4.2	6.1	83	5.28	0.37	5.3	4.4	6.2
		FINAL	84	5.22	0.37	5.2	4.2	6.1	83	5.28	0.37	5.3	4.4	6.2
		CHG FRM BSLN	84	-0.02	0.24	0.0	-0.7	0.9	83	0.04	0.26	0.0	-0.6	0.7
	HOMA-R	BSLN	85	1.30	1.06	1.1	0.3	8.0	84	1.32	0.92	1.1	0.3	6.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=139						N=137					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
NON DIABETIC	HOMA-R	VISIT 6	83	2.72	4.26	1.3	0.3	32.0	80	2.38	3.46	1.5	0.3	26.4
		VISIT 10	57	2.40	2.99	1.3	0.3	13.6	57	1.82	1.67	1.3	0.3	9.3
		FINAL	85	2.85	4.40	1.3	0.3	32.0	84	1.89	1.83	1.4	0.3	9.3
		CHG FRM BSLN	85	1.55	4.35	0.3	-4.9	28.7	84	0.57	1.81	0.1	-4.4	7.5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	154	91.29	14.03	90.0	68.0	183.0
		VISIT 6	150	95.55	20.57	91.0	69.0	236.0
		VISIT 10	114	91.18	14.14	89.0	51.0	164.0
		FINAL	154	94.18	20.69	90.0	51.0	236.0
		CHG FRM BSLN	154	2.90	15.95	1.0	-55.0	87.0
	INSULIN (uIU/mL)	BSLN	153	8.87	10.54	6.4	1.4	105.7
		VISIT 6	147	10.33	13.82	6.7	1.3	102.8
		VISIT 10	113	8.86	6.76	7.1	1.3	36.3
		FINAL	153	9.25	7.33	7.1	1.3	38.2
		CHG FRM BSLN	153	0.38	10.43	0.8	-89.3	34.4
	FASTING HGBA1C (%)	BSLN	141	5.22	0.46	5.2	4.0	7.6
		VISIT 10	141	5.25	0.50	5.2	4.2	8.0
		FINAL	141	5.25	0.50	5.2	4.2	8.0
		CHG FRM BSLN	141	0.03	0.27	0.0	-0.9	1.1
	HOMA-R	BSLN	152	2.03	2.28	1.4	0.3	15.7

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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	VISIT 6	143	2.71	4.30	1.4	0.3	29.0
		VISIT 10	112	2.06	1.84	1.5	0.3	11.0
		FINAL	152	2.46	3.15	1.5	0.3	25.2
		CHG FRM BSLN	152	0.42	2.50	0.2	-9.3	15.5
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	9	117.89	36.26	100.0	79.0	183.0
		VISIT 6	9	139.56	59.57	102.0	80.0	236.0
		VISIT 10	4	106.75	38.74	90.5	82.0	164.0
		FINAL	9	135.22	59.30	97.0	80.0	236.0
		CHG FRM BSLN	9	17.33	37.24	1.0	-19.0	87.0
	INSULIN (uIU/mL)	BSLN	9	18.13	14.01	10.1	4.9	42.8
		VISIT 6	9	16.43	12.27	8.7	4.6	37.8
		VISIT 10	4	13.38	7.57	10.5	8.2	24.3
		FINAL	9	15.15	11.62	8.3	4.6	37.8
		CHG FRM BSLN	9	-2.98	16.11	-1.7	-27.0	29.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
DIABETIC	FASTING HGBA1C (%)	BSLN	8	5.73	1.05	5.3	4.8	7.6
		VISIT 10	8	5.71	1.44	4.9	4.6	8.0
		FINAL	8	5.71	1.44	4.9	4.6	8.0
		CHG FRM BSLN	8	-0.01	0.56	-0.1	-0.9	1.1
	HOMA-R	BSLN	9	5.89	5.51	2.5	1.1	15.7
		VISIT 6	9	9.20	9.07	3.9	1.1	25.2
		VISIT 10	4	4.02	3.89	2.3	1.7	9.8
		FINAL	9	8.58	9.04	2.6	1.1	25.2
		CHG FRM BSLN	9	2.69	6.50	0.1	-3.6	15.5
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	43	94.86	11.93	92.0	76.0	121.0
		VISIT 6	42	96.95	14.02	96.0	77.0	137.0
		VISIT 10	33	94.64	17.83	90.0	51.0	156.0
		FINAL	43	96.35	16.65	93.0	51.0	156.0
		CHG FRM BSLN	43	1.49	19.41	0.0	-55.0	44.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	INSULIN (uIU/mL)	BSLN	43	13.12	16.47	8.8	3.0	105.7
		VISIT 6	42	14.61	19.81	9.0	2.3	102.8
		VISIT 10	32	12.98	8.32	10.1	2.7	36.3
		FINAL	43	12.86	8.85	9.8	2.7	38.2
		CHG FRM BSLN	43	-0.25	16.59	0.5	-89.3	34.4
	FASTING HGBA1C (%)	BSLN	37	5.21	0.48	5.2	4.0	6.2
		VISIT 10	37	5.25	0.47	5.3	4.2	6.4
		FINAL	37	5.25	0.47	5.3	4.2	6.4
		CHG FRM BSLN	37	0.05	0.28	0.0	-0.6	0.8
	HOMA-R	BSLN	42	2.82	2.48	2.0	0.8	11.6
		VISIT 6	41	3.21	4.63	2.1	0.5	29.0
		VISIT 10	31	3.10	2.28	2.1	0.6	11.0
		FINAL	42	3.15	2.56	2.1	0.6	12.1
		CHG FRM BSLN	42	0.33	3.11	0.3	-9.3	11.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	102	87.43	7.16	88.0	68.0	99.0
		VISIT 6	99	90.95	8.45	90.0	69.0	113.0
		VISIT 10	77	88.90	9.00	89.0	67.0	114.0
		FINAL	102	89.65	9.04	89.0	67.0	114.0
		CHG FRM BSLN	102	2.22	9.96	1.0	-21.0	36.0
	INSULIN (uIU/mL)	BSLN	101	6.24	4.08	4.8	1.4	19.8
		VISIT 6	96	7.89	9.68	5.4	1.3	87.4
		VISIT 10	77	6.92	4.97	4.8	1.3	27.4
		FINAL	101	7.19	4.99	5.4	1.3	27.4
		CHG FRM BSLN	101	0.94	5.25	0.9	-13.6	23.3
	FASTING HGBA1C (%)	BSLN	96	5.18	0.36	5.2	4.4	6.1
		VISIT 10	96	5.21	0.33	5.2	4.5	6.0
		FINAL	96	5.21	0.33	5.2	4.5	6.0
		CHG FRM BSLN	96	0.03	0.23	0.0	-0.5	0.8
	HOMA-R	BSLN	101	1.36	0.92	1.0	0.3	4.3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	HOMA-R	VISIT 6	93	1.86	2.67	1.2	0.3	24.1
		VISIT 10	77	1.54	1.17	1.1	0.3	5.4
		FINAL	101	1.62	1.21	1.1	0.3	5.5
		CHG FRM BSLN	101	0.26	1.27	0.2	-3.1	5.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	128	0.3733	0.0412	0.3723	0.2850	0.4778	131	0.3694	0.0427	0.3663	0.2524	0.4963
		VISIT 6	122	0.3559	0.0454	0.3592	0.2432	0.4654	125	0.3540	0.0501	0.3543	0.2295	0.4963
		VISIT 10	90	0.3572	0.0473	0.3555	0.2534	0.4950	90	0.3562	0.0482	0.3536	0.2487	0.4818
		FINAL	128	0.3568	0.0470	0.3557	0.2432	0.4950	131	0.3551	0.0502	0.3530	0.2454	0.4963
		CHG FRM BSLN	128	-0.0164	0.0486	-0.0089	-0.2105	0.0885	131	-0.0143	0.0452	-0.0161	-0.1619	0.1103
DIABETIC	QUICKI	BSLN	8	0.3438	0.0364	0.3524	0.2914	0.3820	5	0.3677	0.0702	0.3336	0.3009	0.4635
		VISIT 6	8	0.3144	0.0321	0.3213	0.2688	0.3553	5	0.3408	0.0581	0.3426	0.2472	0.3975
		VISIT 10	6	0.3123	0.0432	0.3140	0.2534	0.3594	5	0.3141	0.0441	0.3020	0.2713	0.3889
		FINAL	8	0.3196	0.0396	0.3280	0.2534	0.3594	5	0.3141	0.0441	0.3020	0.2713	0.3889
		CHG FRM BSLN	8	-0.0242	0.0164	-0.0192	-0.0514	-0.0080	5	-0.0536	0.0610	-0.0306	-0.1619	-0.0143
DIABETIC RISK	QUICKI	BSLN	35	0.3511	0.0285	0.3400	0.3122	0.4126	42	0.3454	0.0381	0.3471	0.2524	0.4275
		VISIT 6	31	0.3508	0.0370	0.3490	0.2844	0.4281	40	0.3357	0.0525	0.3278	0.2295	0.4837
		VISIT 10	27	0.3483	0.0309	0.3427	0.3110	0.4397	28	0.3355	0.0462	0.3405	0.2487	0.4363
		FINAL	35	0.3539	0.0326	0.3492	0.3110	0.4397	42	0.3311	0.0496	0.3301	0.2454	0.4837
		CHG FRM BSLN	35	0.0028	0.0300	0.0049	-0.0873	0.0789	42	-0.0143	0.0495	-0.0128	-0.1433	0.0893

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			QUETIAPINE 300 MG N=139						QUETIAPINE 600 MG N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	QUICKI	BSLN	85	0.3852	0.0411	0.3799	0.2850	0.4778	84	0.3815	0.0382	0.3796	0.2944	0.4963
		VISIT 6	83	0.3617	0.0474	0.3675	0.2432	0.4654	80	0.3639	0.0461	0.3610	0.2481	0.4963
		VISIT 10	57	0.3662	0.0510	0.3667	0.2673	0.4950	57	0.3700	0.0442	0.3689	0.2796	0.4818
		FINAL	85	0.3615	0.0512	0.3662	0.2432	0.4950	84	0.3695	0.0451	0.3647	0.2796	0.4963
		CHG FRM BSLN	85	-0.0236	0.0545	-0.0161	-0.2105	0.0885	84	-0.0119	0.0414	-0.0173	-0.1109	0.1103

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO					
			N=154					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	QUICKI	BSLN	152	0.3669	0.0440	0.3624	0.2629	0.4822
		VISIT 6	143	0.3610	0.0473	0.3615	0.2457	0.4952
		VISIT 10	112	0.3641	0.0450	0.3585	0.2740	0.4838
		FINAL	152	0.3598	0.0447	0.3585	0.2494	0.4838
		CHG FRM BSLN	152	-0.0072	0.0412	-0.0076	-0.1830	0.0803
DIABETIC	QUICKI	BSLN	9	0.3189	0.0435	0.3327	0.2629	0.3796
		VISIT 6	9	0.3099	0.0513	0.3130	0.2494	0.3773
		VISIT 10	4	0.3264	0.0335	0.3380	0.2778	0.3516
		FINAL	9	0.3140	0.0514	0.3313	0.2494	0.3773
		CHG FRM BSLN	9	-0.0049	0.0340	-0.0031	-0.0738	0.0396
DIABETIC RISK	QUICKI	BSLN	42	0.3431	0.0342	0.3440	0.2724	0.4014
		VISIT 6	41	0.3450	0.0396	0.3410	0.2457	0.4325
		VISIT 10	31	0.3375	0.0356	0.3402	0.2740	0.4181
		FINAL	42	0.3385	0.0364	0.3404	0.2710	0.4181
		CHG FRM BSLN	42	-0.0046	0.0383	-0.0058	-0.1229	0.0782

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM206.SAS
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Table 11.3.7.1.2.3.9 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose)
Safety Population

			PLACEBO N=154					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	QUICKI	BSLN	101	0.3811	0.0406	0.3830	0.3086	0.4822
		VISIT 6	93	0.3730	0.0450	0.3713	0.2506	0.4952
		VISIT 10	77	0.3768	0.0435	0.3801	0.2992	0.4838
		FINAL	101	0.3727	0.0415	0.3750	0.2989	0.4838
		CHG FRM BSLN	101	-0.0085	0.0432	-0.0108	-0.1830	0.0803

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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=101						QUETIAPINE 600 MG N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	101	90.02	13.00	87.0	65.0	155.0	89	89.37	10.55	87.0	66.0	131.0
		VISIT 6	99	95.70	20.35	92.0	56.0	212.0	88	94.99	27.85	91.0	60.0	283.0
		VISIT 10	100	95.83	30.69	91.0	47.0	341.0	88	97.68	31.17	91.0	62.0	257.0
		FINAL	101	95.80	30.53	91.0	47.0	341.0	89	97.49	31.04	91.0	62.0	257.0
		CHG FRM BSLN	101	5.78	23.52	3.0	-35.0	186.0	89	8.12	27.81	3.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	99	7.53	5.31	5.6	1.5	32.9	88	7.61	5.21	6.0	1.2	27.4
		VISIT 6	97	10.19	8.66	7.0	1.1	46.7	86	11.60	16.74	6.9	1.6	117.8
		VISIT 10	97	10.84	11.75	7.8	1.4	84.5	87	10.74	12.96	6.2	1.4	87.5
		FINAL	99	10.85	11.68	7.8	1.4	84.5	88	10.66	12.91	6.1	1.4	87.5
		CHG FRM BSLN	99	3.32	11.50	0.5	-19.1	65.8	88	3.05	12.59	0.3	-19.0	72.1
	FASTING HGBA1C (%)	BSLN	97	5.30	0.46	5.3	4.3	7.3	87	5.27	0.46	5.3	4.1	7.0
		VISIT 10	97	5.34	0.79	5.3	4.4	11.8	87	5.35	0.49	5.3	4.3	7.5
		FINAL	97	5.34	0.79	5.3	4.4	11.8	87	5.35	0.49	5.3	4.3	7.5
		CHG FRM BSLN	97	0.04	0.54	0.0	-1.4	4.5	87	0.08	0.29	0.1	-0.6	1.3
	HOMA-R	BSLN	92	1.64	1.30	1.2	0.3	8.0	85	1.73	1.31	1.4	0.3	6.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=101						QUETIAPINE 600 MG N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	VISIT 6	87	2.54	2.63	1.5	0.3	13.0	80	3.38	7.36	1.5	0.3	56.2
		VISIT 10	87	2.71	3.34	1.6	0.3	21.8	82	2.85	4.33	1.5	0.3	25.9
		FINAL	92	2.67	3.27	1.6	0.3	21.8	85	2.79	4.26	1.5	0.3	25.9
		CHG FRM BSLN	92	1.04	3.07	0.1	-4.9	16.5	85	1.05	4.06	0.1	-4.4	25.0
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	6	112.67	33.63	110.0	79.0	155.0	4	108.00	24.43	108.5	84.0	131.0
		VISIT 6	6	128.00	55.45	117.5	71.0	212.0	4	140.25	95.22	95.0	88.0	283.0
		VISIT 10	6	153.00	99.48	117.0	82.0	341.0	4	136.00	64.10	137.0	70.0	200.0
		FINAL	6	153.00	99.48	117.0	82.0	341.0	4	136.00	64.10	137.0	70.0	200.0
		CHG FRM BSLN	6	40.33	72.67	7.5	0.0	186.0	4	28.00	39.77	28.5	-14.0	69.0
	INSULIN (uIU/mL)	BSLN	6	10.96	5.44	10.2	5.3	20.0	4	7.14	6.80	5.1	1.7	16.6
		VISIT 6	6	19.08	9.53	19.5	8.9	32.8	4	14.34	16.81	7.3	3.5	39.2
		VISIT 10	6	15.70	9.33	12.3	7.1	28.8	4	17.64	12.45	18.5	4.0	29.5
		FINAL	6	15.70	9.33	12.3	7.1	28.8	4	17.64	12.45	18.5	4.0	29.5
		CHG FRM BSLN	6	4.74	4.57	2.7	0.9	12.0	4	10.49	12.18	6.4	1.3	27.8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=101						QUETIAPINE 600 MG N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	FASTING HGBA1C (%)	BSLN	6	5.88	0.92	5.8	4.8	7.3	4	5.45	1.21	5.4	4.1	7.0
		VISIT 10	6	6.82	2.56	6.2	5.0	11.8	4	6.00	1.33	6.1	4.3	7.5
		FINAL	6	6.82	2.56	6.2	5.0	11.8	4	6.00	1.33	6.1	4.3	7.5
		CHG FRM BSLN	6	0.93	1.77	0.4	-0.3	4.5	4	0.55	0.52	0.4	0.2	1.3
	HOMA-R	BSLN	6	3.30	2.26	2.7	1.0	6.7	4	2.15	2.24	1.5	0.4	5.2
		VISIT 6	6	6.35	4.75	4.5	1.8	13.0	4	7.89	13.01	1.7	0.8	27.4
		VISIT 10	6	7.19	7.87	4.1	1.5	21.8	4	5.76	4.58	5.1	0.9	12.0
		FINAL	6	7.19	7.87	4.1	1.5	21.8	4	5.76	4.58	5.1	0.9	12.0
		CHG FRM BSLN	6	3.89	6.30	1.4	0.2	16.5	4	3.61	2.78	3.7	0.3	6.8
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	30	93.33	11.26	94.5	72.0	117.0	26	94.42	9.90	93.0	76.0	112.0
		VISIT 6	30	94.57	8.29	94.0	80.0	116.0	26	100.15	30.86	94.5	60.0	236.0
		VISIT 10	29	93.48	15.55	92.0	66.0	160.0	26	111.46	45.34	98.5	82.0	257.0
		FINAL	30	93.47	15.28	92.5	66.0	160.0	26	111.46	45.34	98.5	82.0	257.0
		CHG FRM BSLN	30	0.13	13.38	-2.0	-25.0	43.0	26	17.04	46.13	3.0	-19.0	173.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=101						QUETIAPINE 600 MG N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	INSULIN (uIU/mL)	BSLN	29	9.51	4.46	10.2	2.6	18.7	26	10.45	5.90	7.6	2.7	22.1
		VISIT 6	28	11.80	8.43	9.8	2.9	39.6	25	14.76	19.15	9.3	2.3	96.6
		VISIT 10	28	12.49	14.70	10.2	2.4	84.5	26	15.44	20.17	8.2	2.4	87.5
		FINAL	29	12.18	14.54	10.1	2.4	84.5	26	15.44	20.17	8.2	2.4	87.5
		CHG FRM BSLN	29	2.67	12.80	-0.2	-6.6	65.8	26	4.99	20.13	-0.5	-11.1	72.1
	FASTING HGBA1C (%)	BSLN	29	5.29	0.35	5.3	4.7	6.1	26	5.38	0.43	5.3	4.6	6.7
		VISIT 10	29	5.27	0.39	5.3	4.7	6.5	26	5.48	0.47	5.4	4.7	6.8
		FINAL	29	5.27	0.39	5.3	4.7	6.5	26	5.48	0.47	5.4	4.7	6.8
		CHG FRM BSLN	29	-0.02	0.35	0.0	-1.4	0.7	26	0.10	0.17	0.1	-0.3	0.5
	HOMA-R	BSLN	27	2.04	0.91	2.2	0.7	3.9	26	2.47	1.48	1.6	0.6	5.4
		VISIT 6	24	2.65	1.95	2.0	0.6	8.1	25	4.90	10.94	2.0	0.4	56.2
		VISIT 10	26	2.21	1.01	2.0	0.5	4.1	26	4.62	6.72	2.1	0.5	25.9
		FINAL	27	2.16	1.02	2.0	0.5	4.1	26	4.62	6.72	2.1	0.5	25.9
		CHG FRM BSLN	27	0.12	1.00	-0.0	-1.3	2.9	26	2.15	6.72	-0.0	-3.3	25.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG N=101						QUETIAPINE 600 MG N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	65	86.40	7.21	86.0	65.0	98.0	59	85.88	6.92	86.0	66.0	98.0
		VISIT 6	63	93.16	16.32	91.0	56.0	161.0	58	89.55	10.13	90.5	67.0	111.0
		VISIT 10	65	91.60	15.83	90.0	47.0	144.0	58	88.86	9.81	88.0	62.0	121.0
		FINAL	65	91.60	15.83	90.0	47.0	144.0	59	88.73	9.78	88.0	62.0	121.0
		CHG FRM BSLN	65	5.20	15.61	4.0	-35.0	61.0	59	2.85	9.12	2.0	-14.0	31.0
	INSULIN (uIU/mL)	BSLN	64	6.32	5.32	4.8	1.5	32.9	58	6.37	4.30	5.4	1.2	27.4
		VISIT 6	63	8.62	8.16	5.7	1.1	46.7	57	10.02	15.67	6.3	1.6	117.8
		VISIT 10	63	9.65	10.37	6.4	1.4	54.7	57	8.12	6.88	5.2	1.4	31.2
		FINAL	64	9.79	10.35	6.5	1.4	54.7	58	8.04	6.84	5.2	1.4	31.2
		CHG FRM BSLN	64	3.48	11.44	0.5	-19.1	50.8	58	1.66	6.98	0.3	-19.0	25.7
	FASTING HGBA1C (%)	BSLN	62	5.25	0.41	5.3	4.3	6.0	57	5.21	0.38	5.2	4.5	6.1
		VISIT 10	62	5.23	0.38	5.2	4.4	6.1	57	5.25	0.35	5.3	4.4	5.8
		FINAL	62	5.23	0.38	5.2	4.4	6.1	57	5.25	0.35	5.3	4.4	5.8
		CHG FRM BSLN	62	-0.02	0.26	0.0	-0.7	0.9	57	0.04	0.29	0.0	-0.6	0.6
	HOMA-R	BSLN	59	1.28	1.17	1.0	0.3	8.0	55	1.36	0.98	1.2	0.3	6.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=101						N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	HOMA-R	VISIT 6	57	2.09	2.30	1.2	0.3	11.2	51	2.29	3.75	1.3	0.3	26.4
		VISIT 10	55	2.46	3.02	1.3	0.3	13.6	52	1.74	1.68	1.1	0.3	9.3
		FINAL	59	2.45	2.94	1.3	0.3	13.6	55	1.70	1.64	1.1	0.3	9.3
		CHG FRM BSLN	59	1.16	3.11	0.0	-4.9	13.3	55	0.35	1.64	0.1	-4.4	7.4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO					
			N=110					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	110	89.87	13.08	88.5	68.0	183.0
		VISIT 6	108	93.03	14.03	90.5	69.0	187.0
		VISIT 10	107	91.30	14.49	89.0	51.0	164.0
		FINAL	110	91.31	14.32	89.0	51.0	164.0
		CHG FRM BSLN	110	1.44	14.17	1.0	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	109	9.00	11.48	6.4	1.4	105.7
		VISIT 6	106	10.54	15.42	6.8	1.3	102.8
		VISIT 10	106	8.99	6.92	7.2	1.3	36.3
		FINAL	109	9.08	6.96	7.3	1.3	36.3
		CHG FRM BSLN	109	0.08	10.72	0.7	-89.3	23.3
	FASTING HGBA1C (%)	BSLN	107	5.19	0.46	5.2	4.0	7.6
		VISIT 10	107	5.23	0.45	5.2	4.2	7.9
		FINAL	107	5.23	0.45	5.2	4.2	7.9
		CHG FRM BSLN	107	0.04	0.24	0.0	-0.5	0.8
	HOMA-R	BSLN	108	1.96	2.00	1.4	0.3	11.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO N=110					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	VISIT 6	102	2.44	3.90	1.5	0.3	29.0
		VISIT 10	105	2.10	1.89	1.5	0.3	11.0
		FINAL	108	2.12	1.90	1.5	0.3	11.0
		CHG FRM BSLN	108	0.16	1.90	0.2	-9.3	5.1
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	4	111.75	48.01	92.5	79.0	183.0
		VISIT 6	4	116.50	47.51	97.0	85.0	187.0
		VISIT 10	4	106.75	38.74	90.5	82.0	164.0
		FINAL	4	106.75	38.74	90.5	82.0	164.0
		CHG FRM BSLN	4	-5.00	10.58	-3.0	-19.0	5.0
	INSULIN (uIU/mL)	BSLN	4	15.89	10.25	15.0	5.3	28.3
		VISIT 6	4	16.26	10.31	13.6	7.9	30.0
		VISIT 10	4	13.38	7.57	10.5	8.2	24.3
		FINAL	4	13.38	7.57	10.5	8.2	24.3
		CHG FRM BSLN	4	-2.51	9.09	0.6	-15.6	4.4

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
GENERATED: 17NOV2005 13:46:53 iceadmn3

Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO					
			N=110					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	FASTING HGBA1C (%)	BSLN	4	5.60	1.34	5.0	4.8	7.6
		VISIT 10	4	5.58	1.55	4.9	4.7	7.9
		FINAL	4	5.58	1.55	4.9	4.7	7.9
		CHG FRM BSLN	4	-0.02	0.24	-0.1	-0.2	0.3
	HOMA-R	BSLN	4	4.60	3.64	4.1	1.3	9.0
		VISIT 6	4	5.42	5.68	2.9	2.0	13.8
		VISIT 10	4	4.02	3.89	2.3	1.7	9.8
		FINAL	4	4.02	3.89	2.3	1.7	9.8
		CHG FRM BSLN	4	-0.58	2.10	0.2	-3.6	0.9
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	34	94.12	11.88	92.0	76.0	121.0
		VISIT 6	33	95.00	14.40	92.0	77.0	137.0
		VISIT 10	32	94.34	18.04	89.5	51.0	156.0
		FINAL	34	94.32	17.53	89.5	51.0	156.0
		CHG FRM BSLN	34	0.21	20.51	-1.5	-55.0	44.0

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers
Safety Population

			PLACEBO					
			N=110					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	INSULIN (uIU/mL)	BSLN	34	14.70	18.15	9.6	3.4	105.7
		VISIT 6	33	15.40	21.62	9.2	2.3	102.8
		VISIT 10	31	13.21	8.35	10.4	2.7	36.3
		FINAL	34	13.12	8.30	10.1	2.7	36.3
		CHG FRM BSLN	34	-1.58	17.58	0.4	-89.3	15.6
	FASTING HGBA1C (%)	BSLN	33	5.20	0.49	5.2	4.0	6.2
		VISIT 10	33	5.28	0.47	5.3	4.2	6.4
		FINAL	33	5.28	0.47	5.3	4.2	6.4
		CHG FRM BSLN	33	0.07	0.27	0.1	-0.4	0.8
	HOMA-R	BSLN	33	3.12	2.68	2.2	0.8	11.6
		VISIT 6	32	3.21	4.93	2.2	0.5	29.0
		VISIT 10	30	3.16	2.30	2.4	0.6	11.0
		FINAL	33	3.13	2.28	2.1	0.6	11.0
		CHG FRM BSLN	33	0.01	2.90	0.3	-9.3	4.8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers
Safety Population

			PLACEBO					
			N=110					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	72	86.65	7.31	87.0	68.0	98.0
		VISIT 6	71	90.79	8.42	90.0	69.0	113.0
		VISIT 10	71	89.06	9.30	89.0	67.0	114.0
		FINAL	72	89.03	9.24	89.0	67.0	114.0
		CHG FRM BSLN	72	2.38	10.21	1.5	-21.0	36.0
	INSULIN (uIU/mL)	BSLN	71	5.88	3.88	4.3	1.4	19.8
		VISIT 6	69	7.89	11.04	5.3	1.3	87.4
		VISIT 10	71	6.89	5.10	4.8	1.3	27.4
		FINAL	71	6.89	5.10	4.8	1.3	27.4
		CHG FRM BSLN	71	1.02	5.04	0.8	-13.6	23.3
	FASTING HGBA1C (%)	BSLN	70	5.17	0.36	5.2	4.4	6.1
		VISIT 10	70	5.19	0.31	5.2	4.6	6.0
		FINAL	70	5.19	0.31	5.2	4.6	6.0
		CHG FRM BSLN	70	0.03	0.23	0.0	-0.5	0.6
	HOMA-R	BSLN	71	1.27	0.87	1.0	0.3	4.3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO					
			N=110					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	HOMA-R	VISIT 6	66	1.88	3.07	1.1	0.3	24.1
		VISIT 10	71	1.54	1.21	1.1	0.3	5.4
		FINAL	71	1.54	1.21	1.1	0.3	5.4
		CHG FRM BSLN	71	0.27	1.20	0.2	-3.1	5.1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=101						N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	92	0.3736	0.0431	0.3727	0.2850	0.4778	85	0.3696	0.0424	0.3639	0.2944	0.4963
		VISIT 6	87	0.3569	0.0448	0.3601	0.2688	0.4654	80	0.3578	0.0477	0.3592	0.2295	0.4698
		VISIT 10	87	0.3559	0.0472	0.3546	0.2534	0.4950	82	0.3591	0.0483	0.3594	0.2487	0.4818
		FINAL	92	0.3566	0.0475	0.3547	0.2534	0.4950	85	0.3598	0.0478	0.3595	0.2487	0.4818
		CHG FRM BSLN	92	-0.0170	0.0477	-0.0051	-0.2105	0.0885	85	-0.0098	0.0409	-0.0059	-0.1619	0.0792
DIABETIC	QUICKI	BSLN	6	0.3332	0.0362	0.3292	0.2914	0.3820	4	0.3794	0.0752	0.3765	0.3009	0.4635
		VISIT 6	6	0.3055	0.0313	0.3078	0.2688	0.3482	4	0.3403	0.0671	0.3583	0.2472	0.3975
		VISIT 10	6	0.3123	0.0432	0.3140	0.2534	0.3594	4	0.3160	0.0507	0.3018	0.2713	0.3889
		FINAL	6	0.3123	0.0432	0.3140	0.2534	0.3594	4	0.3160	0.0507	0.3018	0.2713	0.3889
		CHG FRM BSLN	6	-0.0209	0.0144	-0.0181	-0.0466	-0.0080	4	-0.0634	0.0657	-0.0311	-0.1619	-0.0296
DIABETIC RISK	QUICKI	BSLN	27	0.3511	0.0288	0.3380	0.3122	0.4126	26	0.3453	0.0329	0.3558	0.2997	0.4218
		VISIT 6	24	0.3455	0.0368	0.3443	0.2844	0.4153	25	0.3446	0.0501	0.3437	0.2295	0.4441
		VISIT 10	26	0.3473	0.0312	0.3427	0.3110	0.4397	26	0.3371	0.0449	0.3405	0.2487	0.4363
		FINAL	27	0.3493	0.0321	0.3427	0.3110	0.4397	26	0.3371	0.0449	0.3405	0.2487	0.4363
		CHG FRM BSLN	27	-0.0018	0.0279	0.0013	-0.0873	0.0479	26	-0.0082	0.0441	0.0014	-0.1433	0.0457

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=101						N=89					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	QUICKI	BSLN	59	0.3880	0.0426	0.3842	0.2850	0.4778	55	0.3804	0.0396	0.3732	0.2944	0.4963
		VISIT 6	57	0.3671	0.0447	0.3709	0.2736	0.4654	51	0.3657	0.0441	0.3678	0.2481	0.4698
		VISIT 10	55	0.3646	0.0510	0.3662	0.2673	0.4950	52	0.3735	0.0443	0.3769	0.2796	0.4818
		FINAL	59	0.3645	0.0513	0.3662	0.2673	0.4950	55	0.3738	0.0434	0.3770	0.2796	0.4818
		CHG FRM BSLN	59	-0.0235	0.0553	-0.0050	-0.2105	0.0885	55	-0.0067	0.0352	-0.0059	-0.0673	0.0792

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
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Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers Safety Population

			PLACEBO N=110					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	QUICKI	BSLN	108	0.3687	0.0456	0.3646	0.2724	0.4822
		VISIT 6	102	0.3653	0.0490	0.3589	0.2457	0.4952
		VISIT 10	105	0.3641	0.0461	0.3585	0.2740	0.4838
		FINAL	108	0.3635	0.0460	0.3576	0.2740	0.4838
		CHG FRM BSLN	108	-0.0053	0.0418	-0.0062	-0.1830	0.0803
DIABETIC	QUICKI	BSLN	4	0.3222	0.0417	0.3194	0.2808	0.3691
		VISIT 6	4	0.3170	0.0365	0.3285	0.2668	0.3442
		VISIT 10	4	0.3264	0.0335	0.3380	0.2778	0.3516
		FINAL	4	0.3264	0.0335	0.3380	0.2778	0.3516
		CHG FRM BSLN	4	0.0041	0.0257	0.0019	-0.0244	0.0373
DIABETIC RISK	QUICKI	BSLN	33	0.3381	0.0335	0.3400	0.2724	0.3960
		VISIT 6	32	0.3449	0.0396	0.3397	0.2457	0.4325
		VISIT 10	30	0.3368	0.0359	0.3359	0.2740	0.4181
		FINAL	33	0.3373	0.0357	0.3402	0.2740	0.4181
		CHG FRM BSLN	33	-0.0008	0.0362	-0.0078	-0.0642	0.0782

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
GENERATED: 17NOV2005 13:46:53 iceadmn3

Table 11.3.7.1.2.3.10 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose) for Completers
Safety Population

			PLACEBO N=110					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	QUICKI	BSLN	71	0.3856	0.0417	0.3867	0.3086	0.4822
		VISIT 6	66	0.3781	0.0491	0.3756	0.2506	0.4952
		VISIT 10	71	0.3777	0.0446	0.3801	0.2992	0.4838
		FINAL	71	0.3777	0.0446	0.3801	0.2992	0.4838
		CHG FRM BSLN	71	-0.0078	0.0450	-0.0072	-0.1830	0.0803

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM207.SAS
GENERATED: 17NOV2005 13:46:53 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG N=129						QUETIAPINE 600 MG N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	122	90.27	12.04	88.0	65.0	155.0	109	89.34	10.64	88.0	62.0	131.0
		VISIT 6	112	96.16	19.79	92.0	56.0	212.0	104	94.85	25.89	92.0	60.0	283.0
		VISIT 10	88	94.61	31.22	90.0	47.0	341.0	80	98.36	32.32	91.0	62.0	257.0
		FINAL	122	95.37	28.08	90.0	47.0	341.0	109	96.92	28.26	91.0	62.0	257.0
		CHG FRM BSLN	122	5.10	22.60	3.0	-35.0	186.0	109	7.58	25.64	3.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	121	7.21	4.95	5.6	1.5	32.9	108	7.39	5.59	5.6	1.2	30.9
		VISIT 6	111	9.91	9.61	6.5	1.1	62.8	102	11.57	16.27	7.1	1.6	117.8
		VISIT 10	87	10.22	11.91	6.9	1.4	84.5	80	10.90	12.32	6.6	1.4	73.3
		FINAL	121	10.23	11.85	6.8	1.4	84.5	108	10.78	11.78	6.8	1.4	73.3
		CHG FRM BSLN	121	3.02	11.54	0.3	-19.1	65.8	108	3.39	10.77	0.8	-19.0	68.6
	FASTING HGBA1C (%)	BSLN	103	5.34	0.47	5.3	4.3	7.3	94	5.27	0.44	5.3	4.1	7.0
		VISIT 10	103	5.37	0.77	5.3	4.4	11.8	94	5.34	0.47	5.4	4.3	7.5
		FINAL	103	5.37	0.77	5.3	4.4	11.8	94	5.34	0.47	5.4	4.3	7.5
		CHG FRM BSLN	103	0.03	0.52	0.0	-1.4	4.5	94	0.08	0.28	0.1	-0.6	1.3

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*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
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Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG N=129						QUETIAPINE 600 MG N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	BSLN	114	1.57	1.21	1.2	0.3	8.0	104	1.68	1.34	1.3	0.3	7.0
		VISIT 6	101	2.38	2.71	1.4	0.3	16.6	96	3.28	6.85	1.5	0.3	56.2
		VISIT 10	79	2.51	3.30	1.5	0.3	21.8	75	2.88	4.01	1.7	0.3	25.9
		FINAL	114	2.45	3.15	1.5	0.3	21.8	104	2.75	3.64	1.7	0.3	25.9
		CHG FRM BSLN	114	0.87	2.97	0.1	-4.9	16.5	104	1.07	3.32	0.3	-4.4	25.0
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	7	110.57	30.74	91.0	84.0	155.0	5	103.60	23.33	90.0	84.0	131.0
		VISIT 6	7	128.57	47.73	110.0	83.0	212.0	5	131.60	84.70	95.0	88.0	283.0
		VISIT 10	4	186.25	109.81	159.5	85.0	341.0	5	127.00	59.05	93.0	70.0	200.0
		FINAL	7	148.57	90.95	110.0	85.0	341.0	5	127.00	59.05	93.0	70.0	200.0
		CHG FRM BSLN	7	38.00	66.42	8.0	0.0	186.0	5	23.40	35.95	5.0	-14.0	69.0
	INSULIN (uIU/mL)	BSLN	7	10.14	5.43	9.5	4.8	20.0	5	8.76	6.91	7.6	1.7	16.6
		VISIT 6	7	16.57	10.19	10.3	7.0	32.8	5	13.18	14.78	8.6	3.5	39.2
		VISIT 10	4	18.57	10.44	19.2	7.1	28.8	5	18.13	10.84	20.1	4.0	29.5
		FINAL	7	16.39	9.28	12.4	7.0	28.8	5	18.13	10.84	20.1	4.0	29.5

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG N=129						QUETIAPINE 600 MG N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (uIU/mL)	CHG FRM BSLN	7	6.26	4.81	5.5	0.9	12.2	5	9.37	10.84	4.9	1.3	27.8
	FASTING HGBA1C (%)	BSLN	5	6.16	0.89	6.3	4.8	7.3	5	5.34	1.07	5.1	4.1	7.0
		VISIT 10	5	7.30	2.61	6.6	5.0	11.8	5	5.78	1.26	5.8	4.3	7.5
		FINAL	5	7.30	2.61	6.6	5.0	11.8	5	5.78	1.26	5.8	4.3	7.5
		CHG FRM BSLN	5	1.14	1.88	0.3	0.2	4.5	5	0.44	0.51	0.2	0.0	1.3
	HOMA-R	BSLN	7	3.01	2.21	2.3	1.1	6.7	5	2.37	2.00	2.5	0.4	5.2
		VISIT 6	7	5.67	4.69	3.7	1.6	13.0	5	6.72	11.57	2.0	0.8	27.4
		VISIT 10	4	9.71	8.80	7.8	1.5	21.8	5	5.51	4.00	5.0	0.9	12.0
		FINAL	7	6.93	7.21	5.3	1.5	21.8	5	5.51	4.00	5.0	0.9	12.0
		CHG FRM BSLN	7	3.93	5.68	2.2	0.2	16.5	5	3.14	2.62	2.6	0.3	6.8
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	35	94.51	10.52	97.0	72.0	117.0	31	94.87	9.78	93.0	76.0	113.0
		VISIT 6	33	94.39	8.81	93.0	80.0	116.0	29	99.10	29.23	95.0	60.0	236.0
		VISIT 10	25	92.52	7.28	92.0	79.0	105.0	20	115.90	50.79	100.0	82.0	257.0
		FINAL	35	92.20	7.48	91.0	79.0	109.0	31	109.94	41.64	99.0	82.0	257.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=129						N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	CHG FRM BSLN	35	-2.31	10.64	-4.0	-25.0	19.0	31	15.06	42.35	3.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	35	9.48	4.27	10.1	2.6	18.7	30	10.38	7.04	7.5	2.7	30.9
		VISIT 6	32	9.54	5.83	7.9	2.6	28.0	27	16.72	19.11	10.5	2.3	96.6
		VISIT 10	25	12.31	15.60	9.3	2.4	84.5	20	17.57	20.00	11.5	2.4	73.3
		FINAL	35	10.52	13.48	8.0	2.4	84.5	30	17.81	17.93	11.5	2.4	73.3
		CHG FRM BSLN	35	1.04	11.70	-0.8	-8.0	65.8	30	7.43	17.00	1.9	-9.2	68.6
	FASTING HGBA1C (%)	BSLN	31	5.42	0.39	5.4	4.8	6.5	23	5.35	0.35	5.4	4.6	6.1
		VISIT 10	31	5.39	0.44	5.4	4.7	6.5	23	5.43	0.38	5.4	4.7	6.4
		FINAL	31	5.39	0.44	5.4	4.7	6.5	23	5.43	0.38	5.4	4.7	6.4
		CHG FRM BSLN	31	-0.03	0.33	0.0	-1.4	0.7	23	0.08	0.16	0.1	-0.3	0.3
	HOMA-R	BSLN	33	2.10	0.90	2.2	0.7	3.9	30	2.41	1.61	1.7	0.6	7.0
		VISIT 6	28	2.09	1.37	1.8	0.5	6.7	27	5.15	10.50	2.7	0.4	56.2
		VISIT 10	23	2.13	1.03	2.0	0.5	4.1	20	5.23	6.54	3.0	0.5	25.9
		FINAL	33	1.90	0.98	1.6	0.5	4.1	30	4.97	5.60	3.0	0.5	25.9

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
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Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=129						N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	HOMA-R	CHG FRM BSLN	33	-0.20	0.88	-0.2	-2.4	1.8	30	2.56	5.45	0.7	-1.9	25.0
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	80	86.64	6.70	87.0	65.0	98.0	73	86.01	7.82	87.0	62.0	106.0
		VISIT 6	72	93.82	16.56	91.0	56.0	172.0	70	90.46	10.61	91.0	67.0	126.0
		VISIT 10	59	89.29	14.37	88.0	47.0	143.0	55	89.38	9.50	89.0	62.0	110.0
		FINAL	80	92.10	17.01	89.0	47.0	172.0	73	89.33	9.38	89.0	62.0	110.0
		CHG FRM BSLN	80	5.46	16.67	4.0	-35.0	88.0	73	3.32	10.34	2.0	-14.0	41.0
	INSULIN (uIU/mL)	BSLN	79	5.94	4.78	4.7	1.5	32.9	73	6.07	4.27	5.0	1.2	27.4
		VISIT 6	72	9.42	10.72	5.5	1.1	62.8	70	9.47	14.91	6.1	1.6	117.8
		VISIT 10	58	8.75	9.84	5.7	1.4	54.7	55	7.81	6.43	5.3	1.4	30.7
		FINAL	79	9.56	11.24	5.8	1.4	62.8	73	7.39	5.86	5.3	1.4	30.7
		CHG FRM BSLN	79	3.61	11.85	0.5	-19.1	55.5	73	1.32	5.99	0.5	-19.0	25.7
	FASTING HGBA1C (%)	BSLN	67	5.24	0.40	5.3	4.3	6.0	66	5.23	0.40	5.3	4.3	6.1
		VISIT 10	67	5.21	0.34	5.2	4.4	5.9	66	5.28	0.39	5.3	4.4	6.2
		FINAL	67	5.21	0.34	5.2	4.4	5.9	66	5.28	0.39	5.3	4.4	6.2

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
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Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG N=129						QUETIAPINE 600 MG N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING HGBA1C (%)	CHG FRM BSLN	67	-0.03	0.24	0.0	-0.7	0.6	66	0.05	0.27	0.0	-0.6	0.7
	HOMA-R	BSLN	74	1.21	1.03	1.0	0.3	8.0	69	1.31	0.99	1.0	0.3	6.2
		VISIT 6	66	2.16	2.69	1.2	0.3	16.6	64	2.23	3.63	1.3	0.3	26.4
		VISIT 10	52	2.12	2.70	1.3	0.3	13.6	50	1.67	1.39	1.2	0.3	7.4
		FINAL	74	2.27	2.93	1.3	0.3	16.6	69	1.59	1.27	1.1	0.3	7.4
		CHG FRM BSLN	74	1.06	3.03	0.2	-4.9	15.3	69	0.28	1.30	0.1	-4.4	5.1

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	132	90.67	13.48	89.0	68.0	183.0
		VISIT 6	121	94.79	20.75	91.0	69.0	236.0
		VISIT 10	103	91.50	14.49	89.0	51.0	164.0
		FINAL	132	93.36	20.55	89.0	51.0	236.0
		CHG FRM BSLN	132	2.69	16.32	1.0	-55.0	87.0
	INSULIN (uIU/mL)	BSLN	130	8.51	10.65	6.1	1.4	105.7
		VISIT 6	118	10.03	13.37	6.1	1.3	102.8
		VISIT 10	103	8.64	6.55	6.4	1.3	36.3
		FINAL	130	9.07	7.35	6.5	1.3	38.2
		CHG FRM BSLN	130	0.56	10.34	0.7	-89.3	34.4
	FASTING HGBA1C (%)	BSLN	116	5.21	0.48	5.2	4.0	7.6
		VISIT 10	116	5.26	0.52	5.2	4.2	8.0
		FINAL	116	5.26	0.52	5.2	4.2	8.0
		CHG FRM BSLN	116	0.04	0.26	0.0	-0.5	1.1

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	BSLN	129	1.83	1.89	1.3	0.3	15.7
		VISIT 6	115	2.43	3.45	1.4	0.3	24.1
		VISIT 10	102	2.03	1.86	1.5	0.3	11.0
		FINAL	129	2.29	2.68	1.5	0.3	18.0
		CHG FRM BSLN	129	0.46	2.11	0.2	-3.6	15.5
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	7	115.43	38.56	96.0	79.0	183.0
		VISIT 6	7	139.29	64.04	102.0	80.0	236.0
		VISIT 10	4	106.75	38.74	90.5	82.0	164.0
		FINAL	7	133.71	63.60	97.0	80.0	236.0
		CHG FRM BSLN	7	18.29	41.81	1.0	-19.0	87.0
	INSULIN (uIU/mL)	BSLN	7	17.05	14.19	10.1	4.9	42.8
		VISIT 6	7	19.38	12.43	18.4	6.1	37.8
		VISIT 10	4	13.38	7.57	10.5	8.2	24.3
		FINAL	7	17.73	12.01	12.7	6.1	37.8

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
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Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (uIU/mL)	CHG FRM BSLN	7	0.68	15.28	1.2	-16.0	29.6
	FASTING HGBA1C (%)	BSLN	6	5.70	1.22	5.0	4.8	7.6
		VISIT 10	6	5.87	1.62	4.9	4.7	8.0
		FINAL	6	5.87	1.62	4.9	4.7	8.0
		CHG FRM BSLN	6	0.17	0.49	0.0	-0.2	1.1
	HOMA-R	BSLN	7	5.38	5.42	2.5	1.1	15.7
		VISIT 6	7	8.06	7.38	3.9	1.2	18.0
		VISIT 10	4	4.02	3.89	2.3	1.7	9.8
		FINAL	7	7.26	7.17	2.6	1.2	18.0
		CHG FRM BSLN	7	1.88	6.18	0.1	-3.6	15.5
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	37	94.00	11.43	92.0	76.0	121.0
		VISIT 6	34	96.74	13.14	96.0	77.0	137.0
		VISIT 10	29	95.69	18.52	91.0	51.0	156.0
		FINAL	37	96.86	17.33	93.0	51.0	156.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	CHG FRM BSLN	37	2.86	20.27	2.0	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	37	12.90	17.02	8.8	3.0	105.7
		VISIT 6	34	13.78	17.62	9.2	2.3	102.8
		VISIT 10	29	12.54	7.64	9.8	2.7	36.3
		FINAL	37	12.82	8.66	9.8	2.7	38.2
		CHG FRM BSLN	37	-0.08	17.01	0.3	-89.3	34.4
	FASTING HGBA1C (%)	BSLN	31	5.20	0.48	5.2	4.0	6.2
		VISIT 10	31	5.26	0.48	5.3	4.2	6.4
		FINAL	31	5.26	0.48	5.3	4.2	6.4
		CHG FRM BSLN	31	0.06	0.23	0.0	-0.3	0.5
	HOMA-R	BSLN	36	2.41	1.63	2.0	0.8	8.7
		VISIT 6	33	2.72	2.28	2.2	0.5	12.1
		VISIT 10	28	3.06	2.29	2.1	0.6	11.0
		FINAL	36	3.21	2.66	2.1	0.6	12.1

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	HOMA-R	CHG FRM BSLN	36	0.79	2.43	0.2	-3.1	11.2
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	88	87.30	7.17	88.0	68.0	99.0
		VISIT 6	80	90.08	8.44	89.5	69.0	113.0
		VISIT 10	70	88.89	8.84	89.0	67.0	114.0
		FINAL	88	88.67	8.60	88.5	67.0	114.0
		CHG FRM BSLN	88	1.38	9.45	1.0	-21.0	36.0
	INSULIN (uIU/mL)	BSLN	86	5.93	3.76	4.5	1.4	19.8
		VISIT 6	77	7.53	10.38	5.3	1.3	87.4
		VISIT 10	70	6.75	5.10	4.5	1.3	27.4
		FINAL	86	6.75	4.72	5.2	1.3	27.4
		CHG FRM BSLN	86	0.82	4.80	0.8	-13.6	23.3
	FASTING HGBA1C (%)	BSLN	79	5.18	0.36	5.2	4.4	6.1
		VISIT 10	79	5.21	0.33	5.2	4.6	6.0
		FINAL	79	5.21	0.33	5.2	4.6	6.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING HGBA1C (%)	CHG FRM BSLN	79	0.03	0.25	0.0	-0.5	0.8
	HOMA-R	BSLN	86	1.29	0.86	1.0	0.3	4.3
		VISIT 6	75	1.77	2.87	1.1	0.3	24.1
		VISIT 10	70	1.50	1.20	0.9	0.3	5.4
		FINAL	86	1.50	1.11	1.1	0.3	5.4
		CHG FRM BSLN	86	0.21	1.13	0.2	-3.1	5.1

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG N=129						QUETIAPINE 600 MG N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	114	0.3744	0.0416	0.3728	0.2850	0.4778	104	0.3727	0.0431	0.3671	0.2896	0.4963
		VISIT 6	101	0.3602	0.0434	0.3635	0.2613	0.4654	96	0.3572	0.0473	0.3581	0.2295	0.4698
		VISIT 10	79	0.3612	0.0480	0.3575	0.2534	0.4950	75	0.3573	0.0493	0.3536	0.2487	0.4818
		FINAL	114	0.3609	0.0457	0.3602	0.2534	0.4950	104	0.3576	0.0476	0.3536	0.2487	0.4818
		CHG FRM BSLN	114	-0.0134	0.0461	-0.0045	-0.2105	0.0885	104	-0.0150	0.0408	-0.0186	-0.1619	0.0792
DIABETIC	QUICKI	BSLN	7	0.3383	0.0356	0.3375	0.2914	0.3789	5	0.3677	0.0702	0.3336	0.3009	0.4635
		VISIT 6	7	0.3125	0.0342	0.3152	0.2688	0.3553	5	0.3408	0.0581	0.3426	0.2472	0.3975
		VISIT 10	4	0.2972	0.0455	0.2880	0.2534	0.3594	5	0.3141	0.0441	0.3020	0.2713	0.3889
		FINAL	7	0.3103	0.0394	0.3004	0.2534	0.3594	5	0.3141	0.0441	0.3020	0.2713	0.3889
		CHG FRM BSLN	7	-0.0280	0.0169	-0.0215	-0.0514	-0.0080	5	-0.0536	0.0610	-0.0306	-0.1619	-0.0143
DIABETIC RISK	QUICKI	BSLN	33	0.3489	0.0276	0.3380	0.3122	0.4126	30	0.3473	0.0330	0.3537	0.2896	0.4218
		VISIT 6	28	0.3548	0.0351	0.3497	0.2912	0.4281	27	0.3366	0.0480	0.3298	0.2295	0.4441
		VISIT 10	23	0.3500	0.0325	0.3449	0.3110	0.4397	20	0.3278	0.0448	0.3251	0.2487	0.4363
		FINAL	33	0.3568	0.0328	0.3544	0.3110	0.4397	30	0.3261	0.0419	0.3248	0.2487	0.4363

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			QUETIAPINE 300 MG N=129						QUETIAPINE 600 MG N=122					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	QUICKI	CHG FRM BSLN	33	0.0078	0.0246	0.0135	-0.0317	0.0789	30	-0.0212	0.0400	-0.0167	-0.1433	0.0406
NON DIABETIC	QUICKI	BSLN	74	0.3891	0.0400	0.3855	0.2850	0.4778	69	0.3840	0.0406	0.3824	0.2944	0.4963
		VISIT 6	66	0.3676	0.0443	0.3717	0.2613	0.4654	64	0.3672	0.0436	0.3684	0.2481	0.4698
		VISIT 10	52	0.3710	0.0496	0.3692	0.2673	0.4950	50	0.3733	0.0439	0.3723	0.2876	0.4818
		FINAL	74	0.3676	0.0484	0.3688	0.2613	0.4950	69	0.3745	0.0413	0.3770	0.2876	0.4818
		CHG FRM BSLN	74	-0.0215	0.0521	-0.0108	-0.2105	0.0885	69	-0.0096	0.0383	-0.0148	-0.1109	0.0792

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO					
			N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	129	0.3693	0.0418	0.3675	0.2629	0.4822
		VISIT 6	115	0.3645	0.0481	0.3640	0.2506	0.4952
		VISIT 10	102	0.3658	0.0456	0.3607	0.2740	0.4838
		FINAL	129	0.3625	0.0449	0.3610	0.2589	0.4838
		CHG FRM BSLN	129	-0.0068	0.0392	-0.0052	-0.1830	0.0803
DIABETIC	QUICKI	BSLN	7	0.3234	0.0450	0.3327	0.2629	0.3796
		VISIT 6	7	0.3089	0.0463	0.3130	0.2589	0.3722
		VISIT 10	4	0.3264	0.0335	0.3380	0.2778	0.3516
		FINAL	7	0.3142	0.0465	0.3313	0.2589	0.3722
		CHG FRM BSLN	7	-0.0092	0.0340	-0.0031	-0.0738	0.0373
DIABETIC RISK	QUICKI	BSLN	36	0.3456	0.0296	0.3442	0.2818	0.4014
		VISIT 6	33	0.3460	0.0392	0.3384	0.2710	0.4325
		VISIT 10	28	0.3385	0.0361	0.3404	0.2740	0.4181
		FINAL	36	0.3388	0.0380	0.3404	0.2710	0.4181

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.11 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*)
Safety Population

			PLACEBO N=137					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	QUICKI	CHG FRM BSLN	36	-0.0068	0.0367	-0.0039	-0.1229	0.0521
NON DIABETIC	QUICKI	BSLN	86	0.3830	0.0391	0.3833	0.3086	0.4822
		VISIT 6	75	0.3779	0.0458	0.3751	0.2506	0.4952
		VISIT 10	70	0.3789	0.0437	0.3868	0.2992	0.4838
		FINAL	86	0.3764	0.0409	0.3762	0.2992	0.4838
		CHG FRM BSLN	86	-0.0067	0.0409	-0.0062	-0.1830	0.0803

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM211.SAS
GENERATED: 17NOV2005 13:46:56 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=99						N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	93	90.19	13.00	88.0	65.0	155.0	76	89.79	10.29	89.0	71.0	131.0
		VISIT 6	84	95.15	19.70	92.0	56.0	212.0	72	95.00	30.15	91.0	60.0	283.0
		VISIT 10	85	95.11	31.61	90.0	47.0	341.0	72	98.61	34.00	91.0	62.0	257.0
		FINAL	93	94.85	30.26	90.0	47.0	341.0	76	98.25	33.16	91.0	62.0	257.0
		CHG FRM BSLN	93	4.66	23.03	3.0	-35.0	186.0	76	8.46	29.53	2.5	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	92	7.60	5.37	5.7	1.5	32.9	76	7.20	5.16	5.7	1.2	27.4
		VISIT 6	83	9.48	8.05	6.8	1.1	46.7	71	11.22	17.86	6.6	1.6	117.8
		VISIT 10	84	10.43	12.07	7.0	1.4	84.5	72	9.91	10.47	6.0	1.4	73.3
		FINAL	92	10.29	11.69	6.9	1.4	84.5	76	9.72	10.24	6.0	1.4	73.3
		CHG FRM BSLN	92	2.69	11.25	0.2	-19.1	65.8	76	2.52	10.39	0.4	-19.0	68.6
	FASTING HGBA1C (%)	BSLN	83	5.32	0.48	5.3	4.3	7.3	70	5.27	0.45	5.3	4.1	7.0
		VISIT 10	83	5.35	0.84	5.3	4.4	11.8	70	5.35	0.49	5.4	4.3	7.5
		FINAL	83	5.35	0.84	5.3	4.4	11.8	70	5.35	0.49	5.4	4.3	7.5
		CHG FRM BSLN	83	0.03	0.57	0.0	-1.4	4.5	70	0.08	0.30	0.1	-0.6	1.3

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	BSLN	86	1.65	1.32	1.2	0.3	8.0	74	1.65	1.28	1.4	0.3	6.2
		VISIT 6	74	2.30	2.41	1.4	0.3	13.0	66	3.41	8.01	1.4	0.3	56.2
		VISIT 10	76	2.57	3.34	1.6	0.3	21.8	68	2.65	3.77	1.4	0.3	25.9
		FINAL	86	2.52	3.18	1.6	0.3	21.8	74	2.55	3.64	1.4	0.3	25.9
		CHG FRM BSLN	86	0.87	2.90	0.0	-4.9	16.5	74	0.90	3.44	0.1	-4.4	25.0
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	5	119.40	32.76	135.0	84.0	155.0	4	108.00	24.43	108.5	84.0	131.0
		VISIT 6	5	139.40	53.56	143.0	83.0	212.0	4	140.25	95.22	95.0	88.0	283.0
		VISIT 10	4	186.25	109.81	159.5	85.0	341.0	4	136.00	64.10	137.0	70.0	200.0
		FINAL	5	167.40	104.02	143.0	85.0	341.0	4	136.00	64.10	137.0	70.0	200.0
		CHG FRM BSLN	5	48.00	78.50	8.0	0.0	186.0	4	28.00	39.77	28.5	-14.0	69.0
	INSULIN (uIU/mL)	BSLN	5	12.10	5.22	10.9	6.2	20.0	4	7.14	6.80	5.1	1.7	16.6
		VISIT 6	5	19.73	10.51	23.2	8.9	32.8	4	14.34	16.81	7.3	3.5	39.2
		VISIT 10	4	18.57	10.44	19.2	7.1	28.8	4	17.64	12.45	18.5	4.0	29.5
		FINAL	5	19.49	9.27	23.2	7.1	28.8	4	17.64	12.45	18.5	4.0	29.5

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (uIU/mL)	CHG FRM BSLN	5	7.39	5.20	8.8	0.9	12.2	4	10.49	12.18	6.4	1.3	27.8
	FASTING HGBA1C (%)	BSLN	4	6.18	1.03	6.3	4.8	7.3	4	5.45	1.21	5.4	4.1	7.0
		VISIT 10	4	7.55	2.95	6.7	5.0	11.8	4	6.00	1.33	6.1	4.3	7.5
		FINAL	4	7.55	2.95	6.7	5.0	11.8	4	6.00	1.33	6.1	4.3	7.5
		CHG FRM BSLN	4	1.38	2.09	0.4	0.2	4.5	4	0.55	0.52	0.4	0.2	1.3
	HOMA-R	BSLN	5	3.75	2.20	3.2	1.3	6.7	4	2.15	2.24	1.5	0.4	5.2
		VISIT 6	5	7.06	4.93	5.3	1.8	13.0	4	7.89	13.01	1.7	0.8	27.4
		VISIT 10	4	9.71	8.80	7.8	1.5	21.8	4	5.76	4.58	5.1	0.9	12.0
		FINAL	5	8.82	7.88	5.4	1.5	21.8	4	5.76	4.58	5.1	0.9	12.0
		CHG FRM BSLN	5	5.07	6.51	3.0	0.2	16.5	4	3.61	2.78	3.7	0.3	6.8
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	27	93.41	10.19	96.0	72.0	115.0	21	93.71	9.55	93.0	76.0	108.0
		VISIT 6	26	95.08	8.53	94.0	80.0	116.0	19	99.63	35.37	94.0	60.0	236.0
		VISIT 10	24	92.58	7.42	93.0	79.0	105.0	19	116.79	52.03	101.0	82.0	257.0
		FINAL	27	92.33	7.05	92.0	79.0	105.0	21	114.52	49.88	96.0	82.0	257.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	CHG FRM BSLN	27	-1.07	10.54	-2.0	-25.0	19.0	21	20.81	50.16	3.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	27	9.83	4.43	10.3	2.6	18.7	21	9.77	5.90	7.3	2.7	22.1
		VISIT 6	25	10.39	6.20	9.3	2.9	28.0	18	14.14	21.47	8.8	2.3	96.6
		VISIT 10	24	12.60	15.86	9.7	2.4	84.5	19	14.67	15.64	10.5	2.4	73.3
		FINAL	27	11.76	15.12	9.1	2.4	84.5	21	13.78	15.11	8.1	2.4	73.3
		CHG FRM BSLN	27	1.92	13.15	-0.4	-6.6	65.8	21	4.01	15.87	-0.2	-9.2	68.6
	FASTING HGBA1C (%)	BSLN	25	5.34	0.34	5.3	4.8	6.1	18	5.34	0.38	5.4	4.6	6.1
		VISIT 10	25	5.31	0.41	5.3	4.7	6.5	18	5.43	0.42	5.4	4.7	6.4
		FINAL	25	5.31	0.41	5.3	4.7	6.5	18	5.43	0.42	5.4	4.7	6.4
		CHG FRM BSLN	25	-0.04	0.36	0.0	-1.4	0.7	18	0.09	0.18	0.1	-0.3	0.3
	HOMA-R	BSLN	25	2.12	0.89	2.3	0.7	3.9	21	2.27	1.42	1.6	0.6	5.3
		VISIT 6	21	2.30	1.49	1.8	0.6	6.7	18	5.13	12.83	2.0	0.4	56.2
		VISIT 10	22	2.18	1.04	2.0	0.5	4.1	19	4.58	6.00	2.6	0.5	25.9
		FINAL	25	2.05	1.04	1.8	0.5	4.1	21	4.25	5.78	2.6	0.5	25.9

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	HOMA-R	CHG FRM BSLN	25	-0.07	0.84	-0.1	-1.3	1.8	21	1.98	5.81	0.4	-1.9	25.0
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	61	86.38	7.23	86.0	65.0	98.0	51	86.75	6.64	87.0	71.0	98.0
		VISIT 6	53	91.02	12.56	91.0	56.0	127.0	49	89.51	9.96	91.0	67.0	109.0
		VISIT 10	57	89.77	14.33	88.0	47.0	143.0	49	88.51	9.32	88.0	62.0	110.0
		FINAL	61	90.02	14.01	88.0	47.0	143.0	51	88.59	9.33	88.0	62.0	110.0
		CHG FRM BSLN	61	3.64	13.50	3.0	-35.0	61.0	51	1.84	8.20	2.0	-14.0	21.0
	INSULIN (uIU/mL)	BSLN	60	6.22	5.30	4.8	1.5	32.9	51	6.15	4.41	5.0	1.2	27.4
		VISIT 6	53	8.08	7.97	5.5	1.1	46.7	49	9.90	16.68	6.3	1.6	117.8
		VISIT 10	56	8.92	9.98	5.9	1.4	54.7	49	7.43	6.37	5.0	1.4	30.7
		FINAL	60	8.86	9.70	5.9	1.4	54.7	51	7.44	6.29	5.0	1.4	30.7
		CHG FRM BSLN	60	2.64	10.72	0.2	-19.1	50.8	51	1.28	6.68	0.2	-19.0	25.7
	FASTING HGBA1C (%)	BSLN	54	5.25	0.42	5.3	4.3	6.0	48	5.24	0.38	5.3	4.5	6.1
		VISIT 10	54	5.21	0.36	5.3	4.4	5.9	48	5.27	0.36	5.3	4.4	5.8
		FINAL	54	5.21	0.36	5.3	4.4	5.9	48	5.27	0.36	5.3	4.4	5.8

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING HGBA1C (%)	CHG FRM BSLN	54	-0.04	0.24	0.0	-0.7	0.6	48	0.04	0.29	0.0	-0.6	0.6
	HOMA-R	BSLN	56	1.25	1.15	1.0	0.3	8.0	49	1.35	1.03	1.1	0.3	6.2
		VISIT 6	48	1.81	1.82	1.2	0.3	10.6	44	2.30	3.98	1.3	0.3	26.4
		VISIT 10	50	2.18	2.74	1.3	0.3	13.6	45	1.56	1.35	1.0	0.3	7.4
		FINAL	56	2.16	2.61	1.3	0.3	13.6	49	1.56	1.32	1.1	0.3	7.4
		CHG FRM BSLN	56	0.91	2.75	0.0	-4.9	13.3	49	0.21	1.37	0.1	-4.4	5.1

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			PLACEBO N=106					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	FASTING GLUCOSE (MG/DL)	BSLN	103	89.86	13.02	89.0	68.0	183.0
		VISIT 6	95	93.07	14.04	91.0	69.0	187.0
		VISIT 10	99	91.44	14.72	89.0	51.0	164.0
		FINAL	103	91.41	14.46	89.0	51.0	164.0
		CHG FRM BSLN	103	1.54	14.13	1.0	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	102	8.70	11.34	6.3	1.4	105.7
		VISIT 6	93	9.95	14.21	6.0	1.3	102.8
		VISIT 10	99	8.80	6.63	7.1	1.3	36.3
		FINAL	102	8.89	6.69	7.1	1.3	36.3
		CHG FRM BSLN	102	0.18	10.47	0.7	-89.3	23.3
	FASTING HGBA1C (%)	BSLN	98	5.20	0.47	5.2	4.0	7.6
		VISIT 10	98	5.24	0.46	5.2	4.2	7.9
		FINAL	98	5.24	0.46	5.2	4.2	7.9
		CHG FRM BSLN	98	0.04	0.23	0.0	-0.5	0.6

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers
Safety Population

			PLACEBO					
			N=106					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	HOMA-R	BSLN	101	1.78	1.54	1.3	0.3	9.0
		VISIT 6	90	2.20	3.02	1.4	0.3	24.1
		VISIT 10	98	2.07	1.89	1.5	0.3	11.0
		FINAL	101	2.09	1.90	1.5	0.3	11.0
		CHG FRM BSLN	101	0.31	1.40	0.2	-3.6	5.1
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	4	111.75	48.01	92.5	79.0	183.0
		VISIT 6	4	116.50	47.51	97.0	85.0	187.0
		VISIT 10	4	106.75	38.74	90.5	82.0	164.0
		FINAL	4	106.75	38.74	90.5	82.0	164.0
		CHG FRM BSLN	4	-5.00	10.58	-3.0	-19.0	5.0
	INSULIN (uIU/mL)	BSLN	4	15.89	10.25	15.0	5.3	28.3
		VISIT 6	4	16.26	10.31	13.6	7.9	30.0
		VISIT 10	4	13.38	7.57	10.5	8.2	24.3
		FINAL	4	13.38	7.57	10.5	8.2	24.3

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers
Safety Population

			PLACEBO					
			N=106					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC	INSULIN (uIU/mL)	CHG FRM BSLN	4	-2.51	9.09	0.6	-15.6	4.4
	FASTING HGBA1C (%)	BSLN	4	5.60	1.34	5.0	4.8	7.6
		VISIT 10	4	5.58	1.55	4.9	4.7	7.9
		FINAL	4	5.58	1.55	4.9	4.7	7.9
		CHG FRM BSLN	4	-0.02	0.24	-0.1	-0.2	0.3
	HOMA-R	BSLN	4	4.60	3.64	4.1	1.3	9.0
		VISIT 6	4	5.42	5.68	2.9	2.0	13.8
		VISIT 10	4	4.02	3.89	2.3	1.7	9.8
		FINAL	4	4.02	3.89	2.3	1.7	9.8
		CHG FRM BSLN	4	-0.58	2.10	0.2	-3.6	0.9
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	30	93.77	11.35	92.0	76.0	121.0
		VISIT 6	28	95.29	12.95	94.0	77.0	137.0
		VISIT 10	28	95.39	18.79	90.5	51.0	156.0
		FINAL	30	95.30	18.18	90.5	51.0	156.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			PLACEBO N=106					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	CHG FRM BSLN	30	1.53	21.21	1.0	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	30	14.25	18.63	9.6	3.4	105.7
		VISIT 6	28	13.78	18.60	9.2	2.3	102.8
		VISIT 10	28	12.78	7.66	11.6	2.7	36.3
		FINAL	30	12.86	7.76	11.6	2.7	36.3
		CHG FRM BSLN	30	-1.39	17.71	0.4	-89.3	14.6
	FASTING HGBA1C (%)	BSLN	28	5.21	0.49	5.2	4.0	6.2
		VISIT 10	28	5.28	0.49	5.3	4.2	6.4
		FINAL	28	5.28	0.49	5.3	4.2	6.4
		CHG FRM BSLN	28	0.07	0.24	0.1	-0.3	0.5
	HOMA-R	BSLN	29	2.59	1.72	2.0	0.8	8.7
		VISIT 6	27	2.47	1.56	2.2	0.5	6.5
		VISIT 10	27	3.12	2.31	2.1	0.6	11.0
		FINAL	29	3.14	2.31	2.1	0.6	11.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers
Safety Population

			PLACEBO					
			N=106					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	HOMA-R	CHG FRM BSLN	29	0.55	1.78	0.3	-3.1	4.8
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	69	86.90	7.34	88.0	68.0	98.0
		VISIT 6	63	90.60	8.53	90.0	69.0	113.0
		VISIT 10	67	88.88	9.04	89.0	67.0	114.0
		FINAL	69	88.83	8.91	89.0	67.0	114.0
		CHG FRM BSLN	69	1.93	10.00	1.0	-21.0	36.0
	INSULIN (uIU/mL)	BSLN	68	5.84	3.71	4.4	1.4	19.8
		VISIT 6	61	7.78	11.59	4.8	1.3	87.4
		VISIT 10	67	6.87	5.18	4.6	1.3	27.4
		FINAL	68	6.87	5.14	4.7	1.3	27.4
		CHG FRM BSLN	68	1.04	4.86	0.8	-13.6	23.3
	FASTING HGBA1C (%)	BSLN	66	5.17	0.37	5.2	4.4	6.1
		VISIT 10	66	5.20	0.31	5.2	4.6	6.0
		FINAL	66	5.20	0.31	5.2	4.6	6.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			PLACEBO N=106					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING HGBA1C (%)	CHG FRM BSLN	66	0.03	0.23	0.0	-0.5	0.6
	HOMA-R	BSLN	68	1.27	0.84	1.0	0.3	4.3
		VISIT 6	59	1.86	3.22	1.1	0.3	24.1
		VISIT 10	67	1.53	1.22	1.0	0.3	5.4
		FINAL	68	1.53	1.21	1.0	0.3	5.4
		CHG FRM BSLN	68	0.26	1.16	0.2	-3.1	5.1

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	86	0.3734	0.0434	0.3727	0.2850	0.4778	74	0.3727	0.0432	0.3646	0.2944	0.4963
		VISIT 6	74	0.3602	0.0431	0.3621	0.2688	0.4654	66	0.3607	0.0478	0.3617	0.2295	0.4698
		VISIT 10	76	0.3598	0.0480	0.3565	0.2534	0.4950	68	0.3611	0.0492	0.3619	0.2487	0.4818
		FINAL	86	0.3595	0.0469	0.3572	0.2534	0.4950	74	0.3618	0.0478	0.3621	0.2487	0.4818
		CHG FRM BSLN	86	-0.0138	0.0455	-0.0040	-0.2105	0.0885	74	-0.0110	0.0407	-0.0108	-0.1619	0.0792
DIABETIC	QUICKI	BSLN	5	0.3234	0.0305	0.3209	0.2914	0.3674	4	0.3794	0.0752	0.3765	0.3009	0.4635
		VISIT 6	5	0.3010	0.0327	0.3004	0.2688	0.3482	4	0.3403	0.0671	0.3583	0.2472	0.3975
		VISIT 10	4	0.2972	0.0455	0.2880	0.2534	0.3594	4	0.3160	0.0507	0.3018	0.2713	0.3889
		FINAL	5	0.2978	0.0394	0.2994	0.2534	0.3594	4	0.3160	0.0507	0.3018	0.2713	0.3889
		CHG FRM BSLN	5	-0.0256	0.0159	-0.0215	-0.0466	-0.0080	4	-0.0634	0.0657	-0.0311	-0.1619	-0.0296
DIABETIC RISK	QUICKI	BSLN	25	0.3482	0.0276	0.3374	0.3122	0.4126	21	0.3494	0.0327	0.3572	0.3004	0.4218
		VISIT 6	21	0.3500	0.0351	0.3482	0.2912	0.4153	18	0.3503	0.0510	0.3448	0.2295	0.4441
		VISIT 10	22	0.3489	0.0329	0.3438	0.3110	0.4397	19	0.3315	0.0430	0.3304	0.2487	0.4363
		FINAL	25	0.3526	0.0329	0.3492	0.3110	0.4397	21	0.3355	0.0430	0.3310	0.2487	0.4363

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			QUETIAPINE 300 MG N=99						QUETIAPINE 600 MG N=88					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	QUICKI	CHG FRM BSLN	25	0.0044	0.0208	0.0028	-0.0271	0.0479	21	-0.0139	0.0425	-0.0044	-0.1433	0.0406
NON DIABETIC	QUICKI	BSLN	56	0.3890	0.0418	0.3855	0.2850	0.4778	49	0.3822	0.0413	0.3793	0.2944	0.4963
		VISIT 6	48	0.3708	0.0417	0.3717	0.2753	0.4654	44	0.3668	0.0447	0.3684	0.2481	0.4698
		VISIT 10	50	0.3695	0.0497	0.3679	0.2673	0.4950	45	0.3777	0.0437	0.3808	0.2876	0.4818
		FINAL	56	0.3681	0.0487	0.3664	0.2673	0.4950	49	0.3767	0.0429	0.3789	0.2876	0.4818
		CHG FRM BSLN	56	-0.0209	0.0527	-0.0045	-0.2105	0.0885	49	-0.0054	0.0352	-0.0059	-0.0646	0.0792

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			PLACEBO N=106					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	101	0.3699	0.0429	0.3672	0.2808	0.4822
		VISIT 6	90	0.3679	0.0495	0.3637	0.2506	0.4952
		VISIT 10	98	0.3651	0.0463	0.3585	0.2740	0.4838
		FINAL	101	0.3644	0.0461	0.3585	0.2740	0.4838
		CHG FRM BSLN	101	-0.0054	0.0392	-0.0052	-0.1830	0.0803
DIABETIC	QUICKI	BSLN	4	0.3222	0.0417	0.3194	0.2808	0.3691
		VISIT 6	4	0.3170	0.0365	0.3285	0.2668	0.3442
		VISIT 10	4	0.3264	0.0335	0.3380	0.2778	0.3516
		FINAL	4	0.3264	0.0335	0.3380	0.2778	0.3516
		CHG FRM BSLN	4	0.0041	0.0257	0.0019	-0.0244	0.0373
DIABETIC RISK	QUICKI	BSLN	29	0.3416	0.0287	0.3438	0.2818	0.3960
		VISIT 6	27	0.3472	0.0376	0.3384	0.2925	0.4325
		VISIT 10	27	0.3376	0.0366	0.3402	0.2740	0.4181
		FINAL	29	0.3376	0.0368	0.3402	0.2740	0.4181

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.12 Glucose and Insulin Descriptive Statistics by Diabetic Status (Fasting Glucose - Confirmed*) for Completers Safety Population

			PLACEBO N=106					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	QUICKI	CHG FRM BSLN	29	-0.0040	0.0330	-0.0078	-0.0642	0.0521
NON DIABETIC	QUICKI	BSLN	68	0.3847	0.0403	0.3856	0.3086	0.4822
		VISIT 6	59	0.3808	0.0500	0.3784	0.2506	0.4952
		VISIT 10	67	0.3784	0.0446	0.3813	0.2992	0.4838
		FINAL	68	0.3781	0.0444	0.3807	0.2992	0.4838
		CHG FRM BSLN	68	-0.0066	0.0425	-0.0062	-0.1830	0.0803

*Confirmed by last meal date and time >8 hours before lab draw.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM213.SAS
GENERATED: 17NOV2005 13:47:04 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	56	91.13	13.12	88.0	71.0	138.0	47	88.98	10.13	89.0	62.0	113.0
		VISIT 6	46	97.54	18.64	94.5	62.0	167.0	40	94.25	24.84	91.5	67.0	236.0
		VISIT 10	37	92.24	19.37	89.0	65.0	176.0	31	96.10	32.35	88.0	70.0	257.0
		FINAL	56	92.70	17.48	89.5	65.0	176.0	47	95.21	26.85	91.0	67.0	257.0
		CHG FRM BSLN	56	1.57	11.40	2.0	-25.0	38.0	47	6.23	28.46	1.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	55	7.62	4.44	6.2	1.6	20.0	46	6.63	4.07	5.6	1.7	19.7
		VISIT 6	46	9.21	6.68	7.6	2.3	32.8	40	11.10	15.09	7.7	2.1	96.6
		VISIT 10	36	11.69	15.86	6.9	1.6	84.5	31	10.88	13.11	7.2	1.9	73.3
		FINAL	55	9.85	13.16	6.5	1.6	84.5	46	10.73	11.42	7.8	1.9	73.3
		CHG FRM BSLN	55	2.24	12.22	-0.3	-15.8	65.8	46	4.10	12.11	1.2	-14.4	68.6
	FASTING HGBA1C (%)	BSLN	45	5.40	0.45	5.4	4.3	6.5	36	5.17	0.47	5.2	4.1	6.1
		VISIT 10	45	5.43	0.49	5.3	4.4	6.8	36	5.21	0.46	5.2	4.3	6.4
		FINAL	45	5.43	0.49	5.3	4.4	6.8	36	5.21	0.46	5.2	4.3	6.4
		CHG FRM BSLN	45	0.03	0.26	0.0	-0.6	0.7	36	0.04	0.22	0.1	-0.6	0.6

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	BSLN	50	1.64	1.06	1.3	0.3	6.7	43	1.50	0.98	1.3	0.3	4.4
		VISIT 6	43	2.34	2.20	1.7	0.4	11.6	37	3.54	9.03	1.7	0.5	56.2
		VISIT 10	31	2.43	2.65	1.6	0.3	11.9	28	2.94	4.68	1.8	0.4	25.9
		FINAL	50	2.13	2.22	1.4	0.3	11.9	43	2.77	3.91	1.8	0.4	25.9
		CHG FRM BSLN	50	0.49	1.97	-0.1	-2.4	11.1	43	1.27	4.04	0.4	-2.7	25.0
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	4	112.25	28.14	113.0	85.0	138.0	2	87.00	4.24	87.0	84.0	90.0
		VISIT 6	4	125.75	36.85	126.5	83.0	167.0	2	91.50	4.95	91.5	88.0	95.0
		VISIT 10	3	134.67	46.07	143.0	85.0	176.0	2	81.50	16.26	81.5	70.0	93.0
		FINAL	4	128.50	39.59	126.5	85.0	176.0	2	81.50	16.26	81.5	70.0	93.0
		CHG FRM BSLN	4	16.25	16.46	13.5	0.0	38.0	2	-5.50	12.02	-5.5	-14.0	3.0
	INSULIN (uIU/mL)	BSLN	4	10.12	6.88	7.8	4.8	20.0	2	2.20	0.69	2.2	1.7	2.7
		VISIT 6	4	15.25	11.74	9.6	8.9	32.8	2	4.18	1.03	4.2	3.5	4.9
		VISIT 10	3	16.12	11.29	12.4	7.1	28.8	2	16.76	18.02	16.8	4.0	29.5
		FINAL	4	14.66	9.67	11.4	7.1	28.8	2	16.76	18.02	16.8	4.0	29.5

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
DIABETIC	INSULIN (uIU/mL)	CHG FRM BSLN	4	4.54	3.39	4.2	0.9	8.8	2	14.56	18.72	14.6	1.3	27.8
	FASTING HGBA1C (%)	BSLN	4	5.88	0.72	6.2	4.8	6.3	2	4.85	1.06	4.9	4.1	5.6
		VISIT 10	4	6.18	0.81	6.5	5.0	6.8	2	5.05	1.06	5.1	4.3	5.8
		FINAL	4	6.18	0.81	6.5	5.0	6.8	2	5.05	1.06	5.1	4.3	5.8
		CHG FRM BSLN	4	0.30	0.14	0.3	0.2	0.5	2	0.20	0.00	0.2	0.2	0.2
	HOMA-R	BSLN	4	3.07	2.59	2.3	1.1	6.7	2	0.48	0.17	0.5	0.4	0.6
		VISIT 6	4	4.97	4.47	3.2	1.8	11.6	2	0.94	0.18	0.9	0.8	1.1
		VISIT 10	3	5.68	4.34	5.4	1.5	10.2	2	3.01	2.95	3.0	0.9	5.1
		FINAL	4	4.96	3.83	4.1	1.5	10.2	2	3.01	2.95	3.0	0.9	5.1
		CHG FRM BSLN	4	1.89	1.36	1.9	0.2	3.5	2	2.53	3.12	2.5	0.3	4.7
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	19	95.26	12.11	99.0	72.0	117.0	14	95.00	10.51	93.0	76.0	113.0
		VISIT 6	15	97.67	8.89	95.0	85.0	110.0	11	110.82	42.14	101.0	87.0	236.0
		VISIT 10	13	93.38	8.49	92.0	79.0	105.0	8	122.00	57.55	102.0	84.0	257.0
		FINAL	19	93.58	8.61	91.0	79.0	109.0	14	112.79	43.83	101.5	84.0	257.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	CHG FRM BSLN	19	-1.68	11.09	1.0	-25.0	17.0	14	17.79	48.94	1.5	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	20	9.30	4.32	9.5	2.6	18.7	14	8.02	4.48	7.1	3.5	19.7
		VISIT 6	16	9.12	4.86	7.8	3.1	17.8	11	20.45	26.33	11.6	3.2	96.6
		VISIT 10	14	14.35	20.68	9.7	2.4	84.5	8	17.38	22.97	9.2	5.0	73.3
		FINAL	20	11.80	17.59	6.8	2.4	84.5	14	16.17	17.90	9.4	3.2	73.3
		CHG FRM BSLN	20	2.50	15.37	-0.4	-8.0	65.8	14	8.15	19.28	2.4	-9.2	68.6
	FASTING HGBA1C (%)	BSLN	17	5.49	0.41	5.5	4.9	6.5	10	5.19	0.43	5.2	4.6	6.1
		VISIT 10	17	5.53	0.46	5.5	4.7	6.5	10	5.30	0.48	5.2	4.7	6.4
		FINAL	17	5.53	0.46	5.5	4.7	6.5	10	5.30	0.48	5.2	4.7	6.4
		CHG FRM BSLN	17	0.04	0.26	0.0	-0.3	0.7	10	0.11	0.16	0.2	-0.2	0.3
	HOMA-R	BSLN	17	1.94	0.81	2.1	0.7	3.2	14	1.86	0.98	1.6	0.8	4.3
		VISIT 6	14	2.10	1.10	2.0	0.7	3.9	11	7.93	16.13	2.8	0.8	56.2
		VISIT 10	12	2.06	1.13	1.8	0.5	4.0	8	5.53	8.31	2.6	1.1	25.9
		FINAL	17	1.85	1.03	1.6	0.5	4.0	14	4.70	6.35	2.6	0.8	25.9

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	HOMA-R	CHG FRM BSLN	17	-0.09	1.00	-0.2	-2.4	1.8	14	2.84	6.67	1.1	-1.7	25.0
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	33	86.18	6.93	87.0	71.0	98.0	31	86.39	9.20	87.0	62.0	106.0
		VISIT 6	27	93.30	16.16	92.0	62.0	125.0	27	87.70	8.98	88.0	67.0	105.0
		VISIT 10	21	85.48	10.06	86.0	65.0	105.0	21	87.62	5.70	86.0	79.0	103.0
		FINAL	33	87.85	12.31	86.0	65.0	125.0	31	88.16	7.49	87.0	67.0	105.0
		CHG FRM BSLN	33	1.67	9.77	2.0	-18.0	30.0	31	1.77	10.35	1.0	-12.0	41.0
	INSULIN (uIU/mL)	BSLN	31	6.21	3.75	5.3	1.6	19.8	30	6.28	3.78	5.4	1.7	18.4
		VISIT 6	26	8.33	6.55	5.5	2.3	31.6	27	7.81	4.80	6.7	2.1	26.0
		VISIT 10	19	9.04	12.25	4.9	1.6	54.7	21	7.85	5.19	6.0	1.9	18.6
		FINAL	31	7.98	9.87	5.0	1.6	54.7	30	7.79	4.66	7.3	1.9	18.6
		CHG FRM BSLN	31	1.77	10.81	-0.4	-15.8	50.8	30	1.51	5.16	0.7	-14.4	12.4
	FASTING HGBA1C (%)	BSLN	24	5.27	0.38	5.3	4.3	6.0	24	5.19	0.46	5.2	4.3	6.1
		VISIT 10	24	5.24	0.30	5.3	4.4	5.8	24	5.19	0.42	5.3	4.4	6.2
		FINAL	24	5.24	0.30	5.3	4.4	5.8	24	5.19	0.42	5.3	4.4	6.2

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
NON DIABETIC	FASTING HGBA1C (%)	CHG FRM BSLN	24	-0.03	0.26	0.0	-0.6	0.6	24	0.00	0.25	0.0	-0.6	0.6
	HOMA-R	BSLN	29	1.27	0.63	1.1	0.3	3.1	27	1.38	0.96	1.1	0.3	4.4
		VISIT 6	25	2.06	2.01	1.4	0.4	9.7	24	1.75	1.15	1.4	0.5	5.6
		VISIT 10	16	2.10	2.88	1.0	0.3	11.9	18	1.78	1.15	1.5	0.4	3.8
		FINAL	29	1.90	2.28	1.0	0.3	11.9	27	1.75	1.06	1.7	0.4	3.8
		CHG FRM BSLN	29	0.63	2.35	-0.1	-2.3	11.1	27	0.37	1.18	0.2	-2.7	2.4

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO					
			N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	FASTING GLUCOSE (MG/DL)	BSLN	55	93.56	17.17	90.0	68.0	183.0
		VISIT 6	42	99.07	28.66	91.0	69.0	236.0
		VISIT 10	46	93.11	15.63	91.0	51.0	156.0
		FINAL	55	97.67	27.03	91.0	51.0	236.0
		CHG FRM BSLN	55	4.11	18.28	1.0	-55.0	87.0
	INSULIN (uIU/mL)	BSLN	55	8.10	7.73	5.5	1.4	42.8
		VISIT 6	40	9.22	7.21	5.8	1.5	30.0
		VISIT 10	46	8.85	6.62	7.4	2.1	36.3
		FINAL	55	9.27	7.42	7.1	2.1	36.3
		CHG FRM BSLN	55	1.17	5.31	1.1	-16.0	23.3
	FASTING HGBA1C (%)	BSLN	47	5.17	0.41	5.1	4.5	6.2
		VISIT 10	47	5.22	0.36	5.2	4.6	6.4
		FINAL	47	5.22	0.36	5.2	4.6	6.4
		CHG FRM BSLN	47	0.05	0.24	0.0	-0.3	0.6

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO					
			N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	HOMA-R	BSLN	55	2.04	2.55	1.3	0.3	15.7
		VISIT 6	40	2.57	3.17	1.3	0.3	15.6
		VISIT 10	46	2.11	1.86	1.6	0.5	11.0
		FINAL	55	2.50	2.99	1.5	0.5	15.6
		CHG FRM BSLN	55	0.46	1.24	0.3	-1.2	4.9
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	2	166.00	24.04	166.0	149.0	183.0
		VISIT 6	2	211.50	34.65	211.5	187.0	236.0
		FINAL	2	211.50	34.65	211.5	187.0	236.0
		CHG FRM BSLN	2	45.50	58.69	45.5	4.0	87.0
	INSULIN (uIU/mL)	BSLN	2	31.32	16.18	31.3	19.9	42.8
		VISIT 6	2	28.38	2.26	28.4	26.8	30.0
		FINAL	2	28.38	2.26	28.4	26.8	30.0
		CHG FRM BSLN	2	-2.95	18.43	-2.9	-16.0	10.1
	HOMA-R	BSLN	2	12.35	4.77	12.3	9.0	15.7

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO					
			N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
DIABETIC	HOMA-R	VISIT 6	2	14.71	1.25	14.7	13.8	15.6
		FINAL	2	14.71	1.25	14.7	13.8	15.6
		CHG FRM BSLN	2	2.36	3.52	2.4	-0.1	4.9
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	15	98.80	10.92	102.0	76.0	114.0
		VISIT 6	11	100.64	15.47	99.0	77.0	137.0
		VISIT 10	11	101.64	25.65	100.0	51.0	156.0
		FINAL	15	100.93	21.96	100.0	51.0	156.0
		CHG FRM BSLN	15	2.13	23.88	-1.0	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	15	11.56	9.12	8.0	3.0	38.1
		VISIT 6	11	10.61	5.94	9.2	2.9	20.3
		VISIT 10	11	12.76	8.96	13.4	2.7	36.3
		FINAL	15	11.43	8.73	9.8	2.7	36.3
		CHG FRM BSLN	15	-0.12	3.89	-1.1	-7.3	6.7

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO					
			N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
DIABETIC RISK	FASTING HGBA1C (%)	BSLN	12	5.36	0.46	5.4	4.6	6.2
		VISIT 10	12	5.33	0.51	5.3	4.7	6.4
		FINAL	12	5.33	0.51	5.3	4.7	6.4
		CHG FRM BSLN	12	-0.02	0.23	-0.0	-0.3	0.5
	HOMA-R	BSLN	15	2.78	2.16	2.0	0.8	8.7
		VISIT 6	11	2.62	1.48	2.5	0.7	5.0
		VISIT 10	11	3.39	2.91	3.3	0.6	11.0
		FINAL	15	3.00	2.72	2.1	0.6	11.0
		CHG FRM BSLN	15	0.22	1.14	-0.1	-0.9	2.6
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	38	87.68	6.28	88.0	68.0	98.0
		VISIT 6	29	90.72	9.91	90.0	69.0	113.0
		VISIT 10	35	90.43	9.94	90.0	67.0	114.0
		FINAL	38	90.39	9.61	90.0	67.0	114.0
		CHG FRM BSLN	38	2.71	9.09	1.0	-12.0	28.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO					
			N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	INSULIN (uIU/mL)	BSLN	38	5.51	2.78	4.7	1.4	13.2
		VISIT 6	27	7.23	5.58	5.3	1.5	24.1
		VISIT 10	35	7.62	5.28	6.3	2.1	27.4
		FINAL	38	7.41	5.12	5.4	2.1	27.4
		CHG FRM BSLN	38	1.89	4.91	1.2	-5.2	23.3
	FASTING HGBA1C (%)	BSLN	35	5.11	0.38	5.1	4.5	6.1
		VISIT 10	35	5.18	0.30	5.2	4.6	5.9
		FINAL	35	5.18	0.30	5.2	4.6	5.9
		CHG FRM BSLN	35	0.07	0.24	0.1	-0.3	0.6
	HOMA-R	BSLN	38	1.20	0.63	1.0	0.3	3.0
		VISIT 6	27	1.65	1.39	1.2	0.3	6.6
		VISIT 10	35	1.71	1.19	1.5	0.5	5.3
		FINAL	38	1.66	1.16	1.3	0.5	5.3
		CHG FRM BSLN	38	0.46	1.10	0.4	-1.2	4.4

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=98						N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	QUICKI	BSLN	50	0.3668	0.0351	0.3675	0.2914	0.4746	43	0.3748	0.0402	0.3653	0.3076	0.4740
		VISIT 6	43	0.3550	0.0391	0.3518	0.2724	0.4433	37	0.3534	0.0413	0.3537	0.2295	0.4368
		VISIT 10	31	0.3617	0.0495	0.3548	0.2716	0.4789	28	0.3533	0.0442	0.3488	0.2487	0.4455
		FINAL	50	0.3637	0.0434	0.3628	0.2716	0.4789	43	0.3519	0.0415	0.3497	0.2487	0.4455
		CHG FRM BSLN	50	-0.0031	0.0404	0.0023	-0.1278	0.0789	43	-0.0228	0.0457	-0.0267	-0.1619	0.0461
DIABETIC	QUICKI	BSLN	4	0.3396	0.0408	0.3442	0.2914	0.3789	2	0.4415	0.0312	0.4415	0.4195	0.4635
		VISIT 6	4	0.3158	0.0320	0.3213	0.2724	0.3482	2	0.3885	0.0127	0.3885	0.3796	0.3975
		VISIT 10	3	0.3118	0.0427	0.2994	0.2767	0.3594	2	0.3453	0.0617	0.3453	0.3017	0.3889
		FINAL	4	0.3157	0.0358	0.3134	0.2767	0.3594	2	0.3453	0.0617	0.3453	0.3017	0.3889
		CHG FRM BSLN	4	-0.0239	0.0191	-0.0181	-0.0514	-0.0080	2	-0.0962	0.0928	-0.0962	-0.1619	-0.0306
DIABETIC RISK	QUICKI	BSLN	17	0.3528	0.0288	0.3415	0.3215	0.4126	14	0.3553	0.0262	0.3570	0.3087	0.4007
		VISIT 6	14	0.3511	0.0311	0.3447	0.3126	0.4034	11	0.3253	0.0453	0.3279	0.2295	0.3983
		VISIT 10	12	0.3549	0.0394	0.3496	0.3111	0.4397	8	0.3267	0.0400	0.3307	0.2487	0.3802
		FINAL	17	0.3593	0.0352	0.3546	0.3111	0.4397	14	0.3285	0.0390	0.3307	0.2487	0.3983

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			QUETIAPINE 300 MG N=98						QUETIAPINE 600 MG N=87					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	QUICKI	CHG FRM BSLN	17	0.0065	0.0304	0.0049	-0.0317	0.0789	14	-0.0268	0.0491	-0.0274	-0.1433	0.0296
NON DIABETIC	QUICKI	BSLN	29	0.3787	0.0336	0.3774	0.3231	0.4746	27	0.3799	0.0408	0.3790	0.3076	0.4740
		VISIT 6	25	0.3635	0.0411	0.3651	0.2781	0.4433	24	0.3634	0.0344	0.3616	0.2982	0.4368
		VISIT 10	16	0.3761	0.0525	0.3842	0.2716	0.4789	18	0.3660	0.0413	0.3616	0.3133	0.4455
		FINAL	29	0.3729	0.0450	0.3810	0.2716	0.4789	27	0.3646	0.0376	0.3537	0.3133	0.4455
		CHG FRM BSLN	29	-0.0058	0.0465	0.0039	-0.1278	0.0781	27	-0.0153	0.0368	-0.0198	-0.0967	0.0461

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	QUICKI	BSLN	55	0.3683	0.0436	0.3687	0.2629	0.4769
		VISIT 6	40	0.3575	0.0433	0.3675	0.2631	0.4681
		VISIT 10	46	0.3593	0.0385	0.3565	0.2740	0.4389
		FINAL	55	0.3576	0.0414	0.3604	0.2631	0.4389
		CHG FRM BSLN	55	-0.0107	0.0321	-0.0108	-0.0916	0.0602
DIABETIC	QUICKI	BSLN	2	0.2718	0.0127	0.2718	0.2629	0.2808
		VISIT 6	2	0.2649	0.0026	0.2649	0.2631	0.2668
		FINAL	2	0.2649	0.0026	0.2649	0.2631	0.2668
		CHG FRM BSLN	2	-0.0069	0.0101	-0.0069	-0.0141	0.0002
DIABETIC RISK	QUICKI	BSLN	15	0.3425	0.0351	0.3438	0.2818	0.4014
		VISIT 6	11	0.3420	0.0348	0.3333	0.3021	0.4041
		VISIT 10	11	0.3365	0.0407	0.3197	0.2740	0.4181
		FINAL	15	0.3452	0.0431	0.3406	0.2740	0.4181
		CHG FRM BSLN	15	0.0027	0.0219	0.0031	-0.0486	0.0398

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.13 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

			PLACEBO N=103					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	QUICKI	BSLN	38	0.3836	0.0359	0.3831	0.3243	0.4769
		VISIT 6	27	0.3707	0.0374	0.3713	0.2918	0.4681
		VISIT 10	35	0.3664	0.0355	0.3610	0.3003	0.4389
		FINAL	38	0.3674	0.0343	0.3689	0.3003	0.4389
		CHG FRM BSLN	38	-0.0162	0.0349	-0.0196	-0.0916	0.0602

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM212.SAS
GENERATED: 17NOV2005 13:47:01 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	FASTING GLUCOSE (MG/DL)	BSLN	43	90.63	13.99	87.0	71.0	138.0	35	87.86	8.60	87.0	73.0	108.0
		VISIT 6	34	96.35	19.68	94.5	62.0	167.0	29	93.48	28.86	89.0	67.0	236.0
		VISIT 10	35	92.94	19.52	89.0	65.0	176.0	29	96.21	33.41	88.0	70.0	257.0
		FINAL	43	91.74	18.10	89.0	65.0	176.0	35	94.97	30.83	89.0	67.0	257.0
		CHG FRM BSLN	43	1.12	10.81	2.0	-25.0	38.0	35	7.11	32.02	1.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	42	7.90	4.89	6.3	1.6	20.0	34	6.65	4.32	5.8	1.7	19.7
		VISIT 6	34	9.37	6.27	8.0	2.3	32.8	29	10.79	17.20	6.7	2.1	96.6
		VISIT 10	34	12.14	16.22	7.0	1.6	84.5	29	11.07	13.55	6.9	1.9	73.3
		FINAL	42	10.96	14.80	6.6	1.6	84.5	34	10.35	12.63	7.1	1.9	73.3
		CHG FRM BSLN	42	3.06	13.66	-0.0	-15.8	65.8	34	3.70	13.38	0.6	-14.4	68.6
	FASTING HGBA1C (%)	BSLN	34	5.38	0.43	5.5	4.3	6.3	28	5.13	0.46	5.2	4.1	6.1
		VISIT 10	34	5.42	0.49	5.4	4.4	6.8	28	5.18	0.45	5.2	4.3	6.4
		FINAL	34	5.42	0.49	5.4	4.4	6.8	28	5.18	0.45	5.2	4.3	6.4
		CHG FRM BSLN	34	0.04	0.28	0.0	-0.6	0.7	28	0.04	0.25	0.0	-0.6	0.6

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
ALL	HOMA-R	BSLN	37	1.67	1.18	1.3	0.3	6.7	32	1.48	1.02	1.4	0.3	4.4
		VISIT 6	31	2.33	2.07	1.8	0.4	11.6	26	3.82	10.75	1.3	0.5	56.2
		VISIT 10	29	2.54	2.71	1.6	0.3	11.9	27	2.97	4.77	1.8	0.4	25.9
		FINAL	37	2.32	2.47	1.5	0.3	11.9	32	2.70	4.42	1.7	0.4	25.9
		CHG FRM BSLN	37	0.65	2.11	0.2	-2.3	11.1	32	1.23	4.56	0.3	-2.7	25.0
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	3	119.33	29.77	135.0	85.0	138.0	2	87.00	4.24	87.0	84.0	90.0
		VISIT 6	3	131.00	43.27	143.0	83.0	167.0	2	91.50	4.95	91.5	88.0	95.0
		VISIT 10	3	134.67	46.07	143.0	85.0	176.0	2	81.50	16.26	81.5	70.0	93.0
		FINAL	3	134.67	46.07	143.0	85.0	176.0	2	81.50	16.26	81.5	70.0	93.0
		CHG FRM BSLN	3	15.33	20.03	8.0	0.0	38.0	2	-5.50	12.02	-5.5	-14.0	3.0
	INSULIN (uIU/mL)	BSLN	3	11.89	7.22	9.5	6.2	20.0	2	2.20	0.69	2.2	1.7	2.7
		VISIT 6	3	16.91	13.79	9.0	8.9	32.8	2	4.18	1.03	4.2	3.5	4.9
		VISIT 10	3	16.12	11.29	12.4	7.1	28.8	2	16.76	18.02	16.8	4.0	29.5
		FINAL	3	16.12	11.29	12.4	7.1	28.8	2	16.76	18.02	16.8	4.0	29.5

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
DIABETIC	INSULIN (uIU/mL)	CHG FRM BSLN	3	4.23	4.07	3.0	0.9	8.8	2	14.56	18.72	14.6	1.3	27.8
	FASTING HGBA1C (%)	BSLN	3	5.80	0.87	6.3	4.8	6.3	2	4.85	1.06	4.9	4.1	5.6
		VISIT 10	3	6.13	0.99	6.6	5.0	6.8	2	5.05	1.06	5.1	4.3	5.8
		FINAL	3	6.13	0.99	6.6	5.0	6.8	2	5.05	1.06	5.1	4.3	5.8
		CHG FRM BSLN	3	0.33	0.15	0.3	0.2	0.5	2	0.20	0.00	0.2	0.2	0.2
	HOMA-R	BSLN	3	3.73	2.72	3.2	1.3	6.7	2	0.48	0.17	0.5	0.4	0.6
		VISIT 6	3	5.70	5.18	3.7	1.8	11.6	2	0.94	0.18	0.9	0.8	1.1
		VISIT 10	3	5.68	4.34	5.4	1.5	10.2	2	3.01	2.95	3.0	0.9	5.1
		FINAL	3	5.68	4.34	5.4	1.5	10.2	2	3.01	2.95	3.0	0.9	5.1
		CHG FRM BSLN	3	1.95	1.66	2.2	0.2	3.5	2	2.53	3.12	2.5	0.3	4.7
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	14	94.29	11.68	95.0	72.0	115.0	10	92.60	10.24	92.5	76.0	108.0
		VISIT 6	11	98.00	8.54	95.0	86.0	110.0	7	115.86	53.42	97.0	87.0	236.0
		VISIT 10	12	93.58	8.84	93.5	79.0	105.0	8	122.00	57.55	102.0	84.0	257.0
		FINAL	14	92.86	8.36	91.0	79.0	105.0	10	117.10	51.82	101.0	84.0	257.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	CHG FRM BSLN	14	-1.43	11.82	1.0	-25.0	17.0	10	24.50	56.86	2.0	-19.0	173.0
	INSULIN (uIU/mL)	BSLN	15	9.85	4.71	10.3	2.6	18.7	10	8.88	4.91	7.1	4.7	19.7
		VISIT 6	12	10.17	5.11	9.8	3.2	17.8	7	21.29	33.46	9.3	3.2	96.6
		VISIT 10	13	15.05	21.35	10.1	2.4	84.5	8	17.38	22.97	9.2	5.0	73.3
		FINAL	15	13.79	20.05	9.3	2.4	84.5	10	15.05	20.87	8.0	3.2	73.3
		CHG FRM BSLN	15	3.94	17.52	-0.4	-6.6	65.8	10	6.18	22.51	-0.4	-9.2	68.6
	FASTING HGBA1C (%)	BSLN	13	5.37	0.32	5.4	4.9	5.9	8	5.16	0.47	5.1	4.6	6.1
		VISIT 10	13	5.44	0.45	5.5	4.7	6.5	8	5.29	0.54	5.2	4.7	6.4
		FINAL	13	5.44	0.45	5.5	4.7	6.5	8	5.29	0.54	5.2	4.7	6.4
		CHG FRM BSLN	13	0.07	0.28	0.0	-0.3	0.7	8	0.13	0.18	0.2	-0.2	0.3
	HOMA-R	BSLN	12	1.96	0.83	2.2	0.7	2.9	10	2.01	1.06	1.6	0.9	4.3
		VISIT 6	10	2.38	1.16	2.6	0.7	3.9	7	9.76	20.51	2.0	0.8	56.2
		VISIT 10	11	2.14	1.15	2.0	0.5	4.0	8	5.53	8.31	2.6	1.1	25.9
		FINAL	12	2.05	1.14	1.8	0.5	4.0	10	4.70	7.54	2.3	0.8	25.9

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	HOMA-R	CHG FRM BSLN	12	0.09	0.89	-0.1	-1.3	1.8	10	2.69	7.96	0.1	-1.7	25.0
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	26	85.35	7.18	85.0	71.0	98.0	23	85.87	7.49	86.0	73.0	98.0
		VISIT 6	20	90.25	14.39	89.5	62.0	119.0	20	85.85	8.88	87.5	67.0	100.0
		VISIT 10	20	86.30	9.57	86.0	65.0	105.0	19	86.89	4.71	86.0	79.0	97.0
		FINAL	26	86.19	9.52	86.0	65.0	105.0	23	86.52	6.67	86.0	67.0	97.0
		CHG FRM BSLN	26	0.85	7.98	2.0	-15.0	22.0	23	0.65	7.74	1.0	-12.0	15.0
	INSULIN (uIU/mL)	BSLN	24	6.18	4.12	5.1	1.6	19.8	22	6.04	3.78	5.1	1.7	18.4
		VISIT 6	19	7.67	4.70	5.7	2.3	19.0	20	7.78	5.25	6.5	2.1	26.0
		VISIT 10	18	9.38	12.51	5.0	1.6	54.7	19	7.82	5.46	5.2	1.9	18.6
		FINAL	24	8.55	10.96	5.1	1.6	54.7	22	7.63	5.14	5.6	1.9	18.6
		CHG FRM BSLN	24	2.37	11.96	-0.1	-15.8	50.8	22	1.59	5.34	0.6	-14.4	12.4
	FASTING HGBA1C (%)	BSLN	18	5.32	0.41	5.5	4.3	6.0	18	5.15	0.41	5.2	4.5	6.1
		VISIT 10	18	5.29	0.33	5.4	4.4	5.8	18	5.14	0.36	5.2	4.4	5.7
		FINAL	18	5.29	0.33	5.4	4.4	5.8	18	5.14	0.36	5.2	4.4	5.7

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
NON DIABETIC	FASTING HGBA1C (%)	CHG FRM BSLN	18	-0.03	0.26	0.0	-0.6	0.6	18	-0.01	0.28	-0.1	-0.6	0.6
	HOMA-R	BSLN	22	1.23	0.67	1.1	0.3	3.1	20	1.31	0.94	1.0	0.3	4.4
		VISIT 6	18	1.74	1.16	1.3	0.4	4.2	17	1.71	1.24	1.3	0.5	5.6
		VISIT 10	15	2.21	2.95	1.0	0.3	11.9	17	1.75	1.18	1.3	0.4	3.8
		FINAL	22	2.01	2.49	1.0	0.3	11.9	20	1.67	1.11	1.3	0.4	3.8
		CHG FRM BSLN	22	0.78	2.55	0.1	-2.3	11.1	20	0.36	1.12	0.2	-2.7	2.3

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	FASTING GLUCOSE (MG/DL)	BSLN	48	91.65	15.99	88.5	68.0	183.0
		VISIT 6	36	95.75	20.12	91.0	69.0	187.0
		VISIT 10	45	92.87	15.72	91.0	51.0	156.0
		FINAL	48	94.88	20.41	91.0	51.0	187.0
		CHG FRM BSLN	48	3.23	15.14	1.0	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	48	7.57	6.38	5.4	1.4	38.1
		VISIT 6	34	8.97	6.77	6.5	1.5	30.0
		VISIT 10	45	8.92	6.68	7.5	2.1	36.3
		FINAL	48	9.17	7.21	7.4	2.1	36.3
		CHG FRM BSLN	48	1.59	4.99	1.2	-7.3	23.3
	FASTING HGBA1C (%)	BSLN	44	5.16	0.41	5.1	4.5	6.2
		VISIT 10	44	5.22	0.36	5.2	4.6	6.4
		FINAL	44	5.22	0.36	5.2	4.6	6.4
		CHG FRM BSLN	44	0.05	0.24	0.0	-0.3	0.6

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	HOMA-R	BSLN	48	1.80	1.81	1.2	0.3	9.0
		VISIT 6	34	2.30	2.48	1.5	0.3	13.8
		VISIT 10	45	2.13	1.88	1.6	0.5	11.0
		FINAL	48	2.32	2.50	1.6	0.5	13.8
		CHG FRM BSLN	48	0.52	1.30	0.3	-1.2	4.9
DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	1	183.00	.	183.0	183.0	183.0
		VISIT 6	1	187.00	.	187.0	187.0	187.0
		FINAL	1	187.00	.	187.0	187.0	187.0
		CHG FRM BSLN	1	4.00	.	4.0	4.0	4.0
	INSULIN (uIU/mL)	BSLN	1	19.88	.	19.9	19.9	19.9
		VISIT 6	1	29.97	.	30.0	30.0	30.0
		FINAL	1	29.97	.	30.0	30.0	30.0
		CHG FRM BSLN	1	10.09	.	10.1	10.1	10.1
	HOMA-R	BSLN	1	8.98	.	9.0	9.0	9.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
DIABETIC	HOMA-R	VISIT 6	1	13.83	.	13.8	13.8	13.8
		FINAL	1	13.83	.	13.8	13.8	13.8
		CHG FRM BSLN	1	4.85	.	4.9	4.9	4.9
DIABETIC RISK	FASTING GLUCOSE (MG/DL)	BSLN	12	96.67	10.99	100.5	76.0	112.0
		VISIT 6	9	99.89	17.20	97.0	77.0	137.0
		VISIT 10	10	101.40	27.03	98.5	51.0	156.0
		FINAL	12	100.17	24.71	98.0	51.0	156.0
		CHG FRM BSLN	12	3.50	26.64	-1.5	-55.0	44.0
	INSULIN (uIU/mL)	BSLN	12	12.45	9.80	9.0	3.4	38.1
		VISIT 6	9	10.46	5.14	9.2	3.6	20.3
		VISIT 10	10	13.46	9.12	13.4	2.7	36.3
		FINAL	12	11.94	8.99	11.6	2.7	36.3
		CHG FRM BSLN	12	-0.51	3.96	-1.4	-7.3	6.7

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
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Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
DIABETIC RISK	FASTING HGBA1C (%)	BSLN	10	5.37	0.47	5.4	4.6	6.2
		VISIT 10	10	5.35	0.51	5.3	4.7	6.4
		FINAL	10	5.35	0.51	5.3	4.7	6.4
		CHG FRM BSLN	10	-0.02	0.25	-0.0	-0.3	0.5
	HOMA-R	BSLN	12	2.95	2.33	2.0	0.8	8.7
		VISIT 6	9	2.56	1.25	2.5	0.9	4.5
		VISIT 10	10	3.58	2.99	3.4	0.6	11.0
		FINAL	12	3.15	2.89	2.7	0.6	11.0
		CHG FRM BSLN	12	0.19	1.21	-0.2	-0.9	2.6
NON DIABETIC	FASTING GLUCOSE (MG/DL)	BSLN	35	87.31	6.38	87.0	68.0	98.0
		VISIT 6	26	90.81	10.37	90.0	69.0	113.0
		VISIT 10	35	90.43	9.94	90.0	67.0	114.0
		FINAL	35	90.43	9.94	90.0	67.0	114.0
		CHG FRM BSLN	35	3.11	9.34	1.0	-12.0	28.0

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
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Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	INSULIN (uIU/mL)	BSLN	35	5.55	2.85	4.6	1.4	13.2
		VISIT 6	24	7.53	5.86	5.3	1.5	24.1
		VISIT 10	35	7.62	5.28	6.3	2.1	27.4
		FINAL	35	7.62	5.28	6.3	2.1	27.4
		CHG FRM BSLN	35	2.07	5.05	1.2	-5.2	23.3
	FASTING HGBA1C (%)	BSLN	34	5.10	0.38	5.1	4.5	6.1
		VISIT 10	34	5.18	0.31	5.2	4.6	5.9
		FINAL	34	5.18	0.31	5.2	4.6	5.9
		CHG FRM BSLN	34	0.08	0.24	0.1	-0.3	0.6
	HOMA-R	BSLN	35	1.20	0.65	1.0	0.3	3.0
		VISIT 6	24	1.72	1.46	1.2	0.3	6.6
		VISIT 10	35	1.71	1.19	1.5	0.5	5.3
		FINAL	35	1.71	1.19	1.5	0.5	5.3
		CHG FRM BSLN	35	0.51	1.13	0.4	-1.2	4.4

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
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Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG N=81						QUETIAPINE 600 MG N=67					
			N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT												
ALL	QUICKI	BSLN	37	0.3683	0.0387	0.3674	0.2914	0.4746	32	0.3772	0.0430	0.3636	0.3076	0.4740
		VISIT 6	31	0.3540	0.0394	0.3482	0.2724	0.4433	26	0.3593	0.0428	0.3676	0.2295	0.4368
		VISIT 10	29	0.3587	0.0490	0.3546	0.2716	0.4789	27	0.3538	0.0449	0.3497	0.2487	0.4455
		FINAL	37	0.3612	0.0459	0.3594	0.2716	0.4789	32	0.3570	0.0429	0.3536	0.2487	0.4455
		CHG FRM BSLN	37	-0.0071	0.0386	-0.0080	-0.1278	0.0781	32	-0.0202	0.0472	-0.0154	-0.1619	0.0461
DIABETIC	QUICKI	BSLN	3	0.3266	0.0383	0.3209	0.2914	0.3674	2	0.4415	0.0312	0.4415	0.4195	0.4635
		VISIT 6	3	0.3119	0.0380	0.3152	0.2724	0.3482	2	0.3885	0.0127	0.3885	0.3796	0.3975
		VISIT 10	3	0.3118	0.0427	0.2994	0.2767	0.3594	2	0.3453	0.0617	0.3453	0.3017	0.3889
		FINAL	3	0.3118	0.0427	0.2994	0.2767	0.3594	2	0.3453	0.0617	0.3453	0.3017	0.3889
		CHG FRM BSLN	3	-0.0148	0.0068	-0.0148	-0.0215	-0.0080	2	-0.0962	0.0928	-0.0962	-0.1619	-0.0306
DIABETIC RISK	QUICKI	BSLN	12	0.3530	0.0304	0.3390	0.3257	0.4126	10	0.3508	0.0245	0.3570	0.3087	0.3920
		VISIT 6	10	0.3446	0.0321	0.3323	0.3126	0.4034	7	0.3337	0.0534	0.3437	0.2295	0.3983
		VISIT 10	11	0.3533	0.0409	0.3449	0.3111	0.4397	8	0.3267	0.0400	0.3307	0.2487	0.3802
		FINAL	12	0.3555	0.0398	0.3496	0.3111	0.4397	10	0.3357	0.0420	0.3385	0.2487	0.3983

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
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Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			QUETIAPINE 300 MG						QUETIAPINE 600 MG					
			N=81						N=67					
DIABETES	LAB TEST	WINDOWED VISIT	N	MEAN	SD	MED	MIN	MAX	N	MEAN	SD	MED	MIN	MAX
DIABETIC RISK	QUICKI	CHG FRM BSLN	12	0.0026	0.0247	0.0031	-0.0263	0.0479	10	-0.0151	0.0530	-0.0043	-0.1433	0.0296
NON DIABETIC	QUICKI	BSLN	22	0.3823	0.0368	0.3775	0.3231	0.4746	20	0.3840	0.0428	0.3807	0.3076	0.4740
		VISIT 6	18	0.3663	0.0386	0.3663	0.3094	0.4433	17	0.3664	0.0366	0.3678	0.2982	0.4368
		VISIT 10	15	0.3721	0.0517	0.3810	0.2716	0.4789	17	0.3676	0.0419	0.3695	0.3133	0.4455
		FINAL	22	0.3710	0.0462	0.3806	0.2716	0.4789	20	0.3689	0.0396	0.3685	0.3133	0.4455
		CHG FRM BSLN	22	-0.0113	0.0464	-0.0047	-0.1278	0.0781	20	-0.0151	0.0348	-0.0129	-0.0967	0.0461

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
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Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
ALL	QUICKI	BSLN	48	0.3707	0.0423	0.3722	0.2808	0.4769
		VISIT 6	34	0.3586	0.0417	0.3611	0.2668	0.4681
		VISIT 10	45	0.3592	0.0390	0.3545	0.2740	0.4389
		FINAL	48	0.3584	0.0404	0.3565	0.2668	0.4389
		CHG FRM BSLN	48	-0.0123	0.0332	-0.0151	-0.0916	0.0602
DIABETIC	QUICKI	BSLN	1	0.2808	.	0.2808	0.2808	0.2808
		VISIT 6	1	0.2668	.	0.2668	0.2668	0.2668
		FINAL	1	0.2668	.	0.2668	0.2668	0.2668
		CHG FRM BSLN	1	-0.0141	.	-0.0141	-0.0141	-0.0141
DIABETIC RISK	QUICKI	BSLN	12	0.3396	0.0344	0.3440	0.2818	0.3960
		VISIT 6	9	0.3396	0.0287	0.3333	0.3068	0.3928
		VISIT 10	10	0.3341	0.0421	0.3187	0.2740	0.4181
		FINAL	12	0.3426	0.0430	0.3302	0.2740	0.4181
		CHG FRM BSLN	12	0.0029	0.0237	0.0035	-0.0486	0.0398

(Continued)

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

Table 11.3.7.1.2.3.14 Glucose and Insulin Descriptive Statistics by Diabetic Status
(Fasting Glucose - Confirmed with Morning Lab Draw*) for Completers
Safety Population

			PLACEBO					
			N=85					
			N	MEAN	SD	MED	MIN	MAX
DIABETES	LAB TEST	WINDOWED VISIT						
NON DIABETIC	QUICKI	BSLN	35	0.3839	0.0366	0.3833	0.3243	0.4769
		VISIT 6	24	0.3696	0.0396	0.3708	0.2918	0.4681
		VISIT 10	35	0.3664	0.0355	0.3610	0.3003	0.4389
		FINAL	35	0.3664	0.0355	0.3610	0.3003	0.4389
		CHG FRM BSLN	35	-0.0174	0.0352	-0.0206	-0.0916	0.0602

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM214.SAS
GENERATED: 17NOV2005 13:47:08 iceadmn3

FIGURE 11.3.7.1.2.4.1 SHIFT PLOT: AST (U/L)

(SAFETY POPULATION)

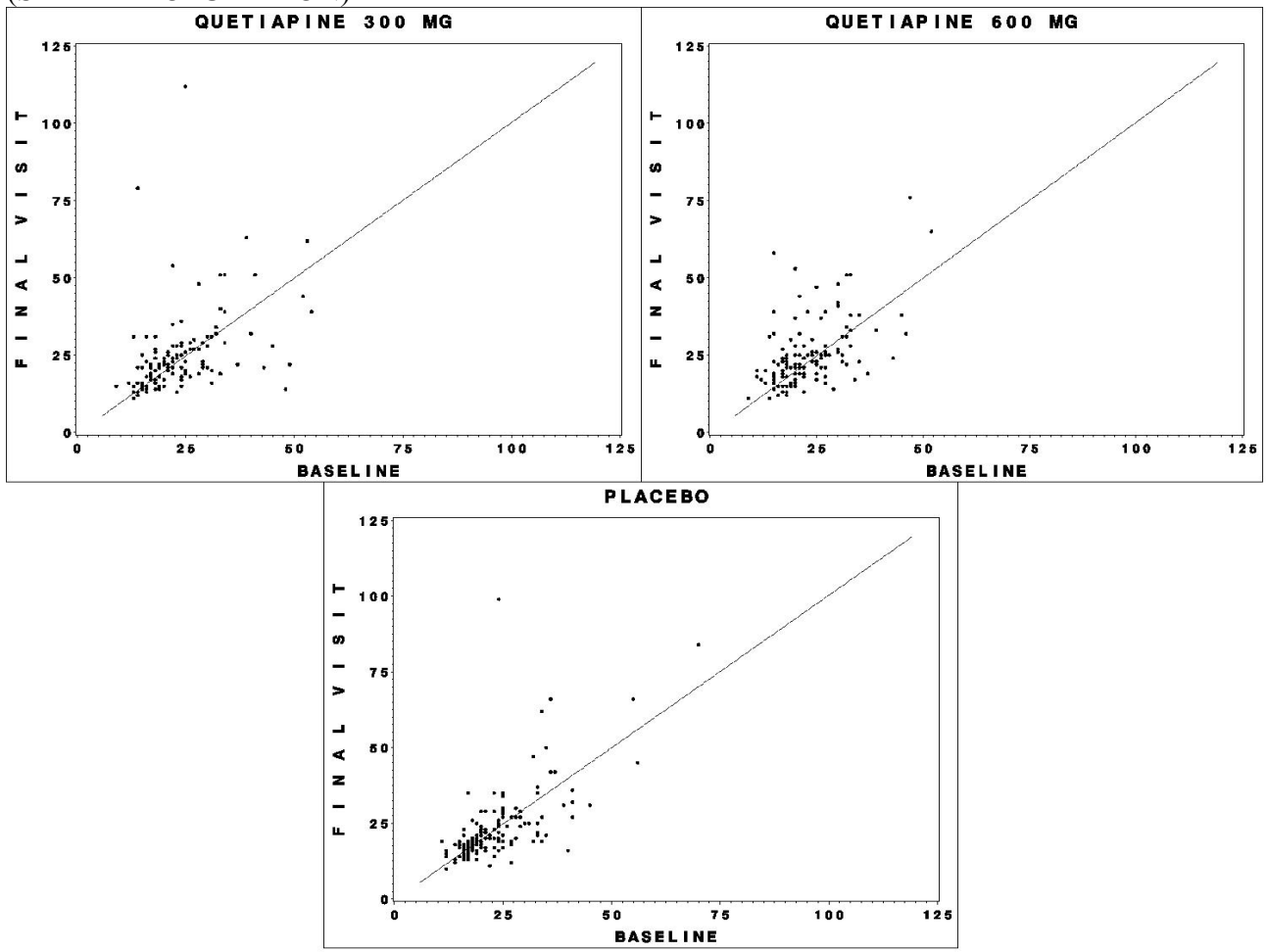

FIGURE 11.3.7.1.2.4.2 SHIFT PLOT: ALT (U/L)

(SAFETY POPULATION)

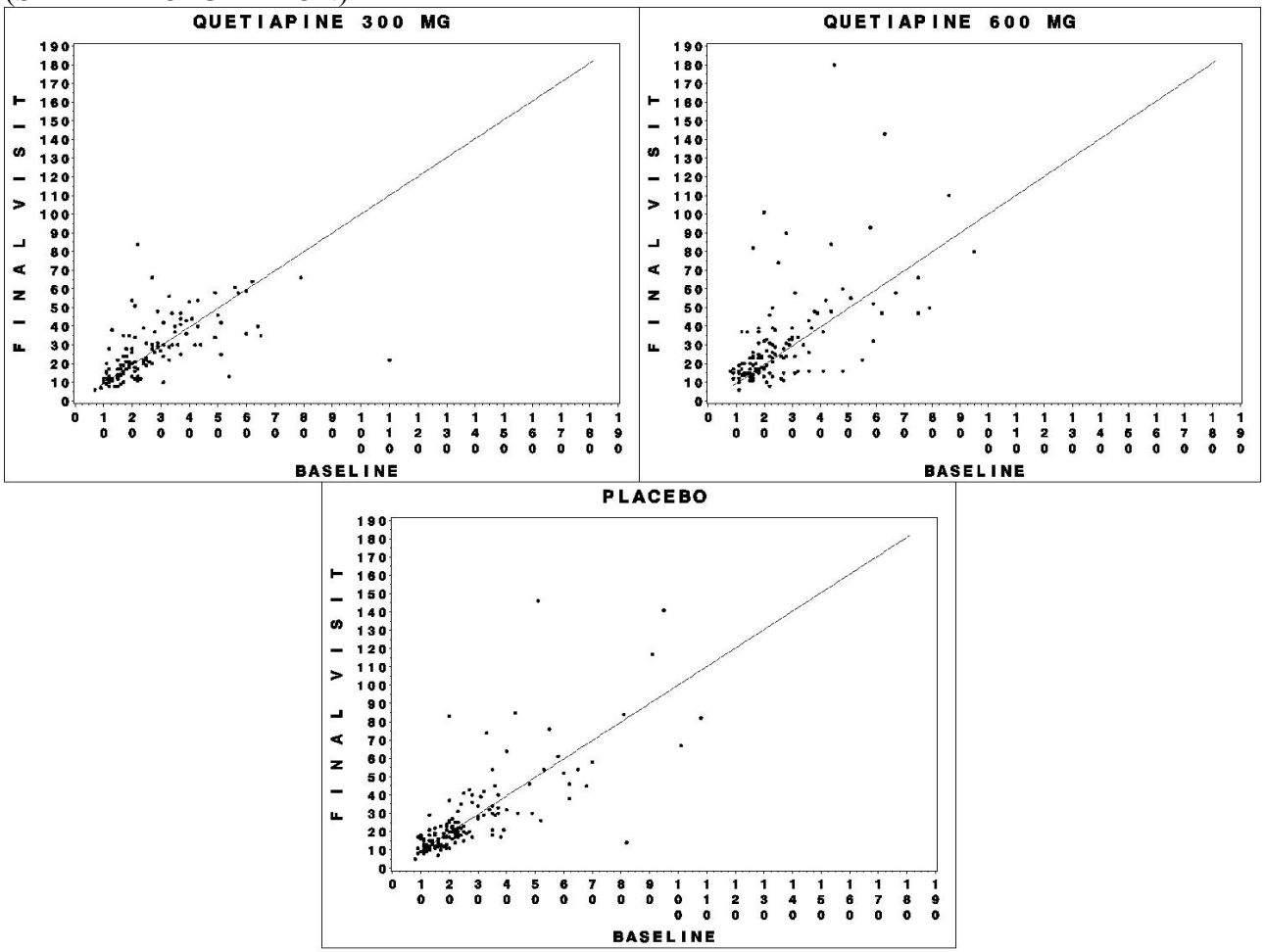

FIGURE 11.3.7.1.2.4.3 SHIFT PLOT: CREATININE (MG/DL)

(SAFETY POPULATION)

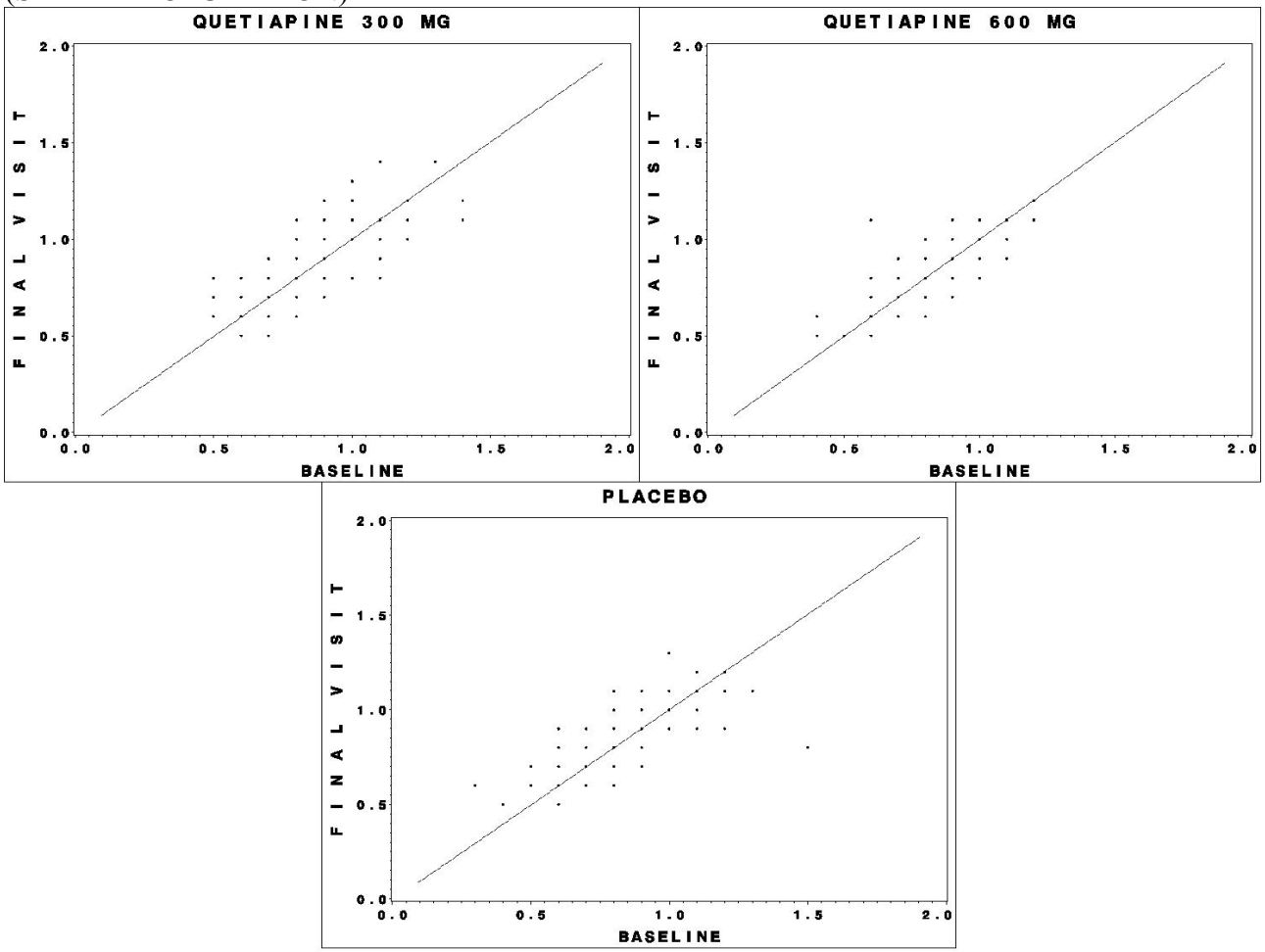

FIGURE 11.3.7.1.2.4.4 SHIFT PLOT: GLUCOSE (MG/DL)

(SAFETY POPULATION)

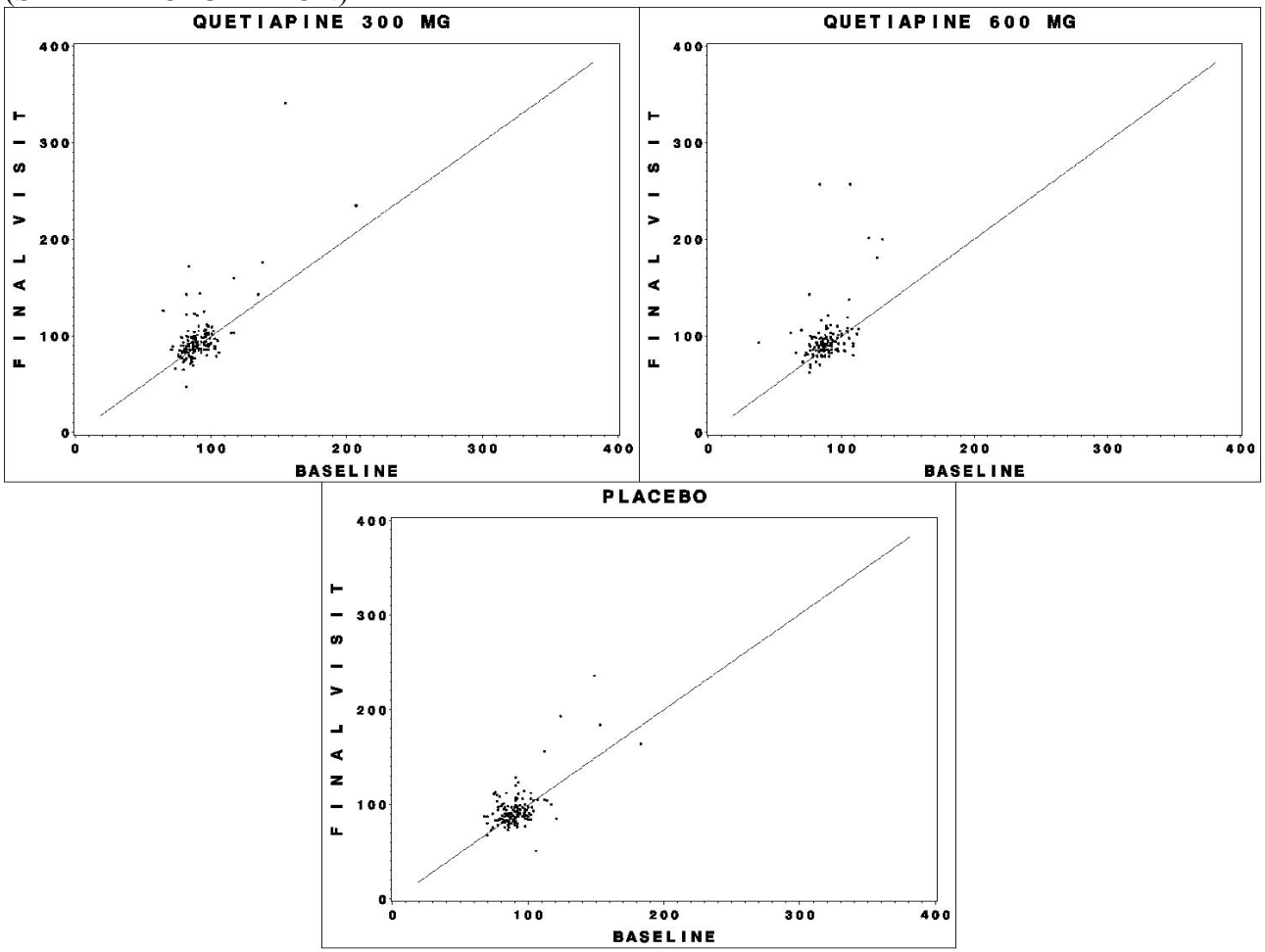

FIGURE 11.3.7.1.2.4.5 SHIFT PLOT: TSH (MIU/L)

(SAFETY POPULATION)

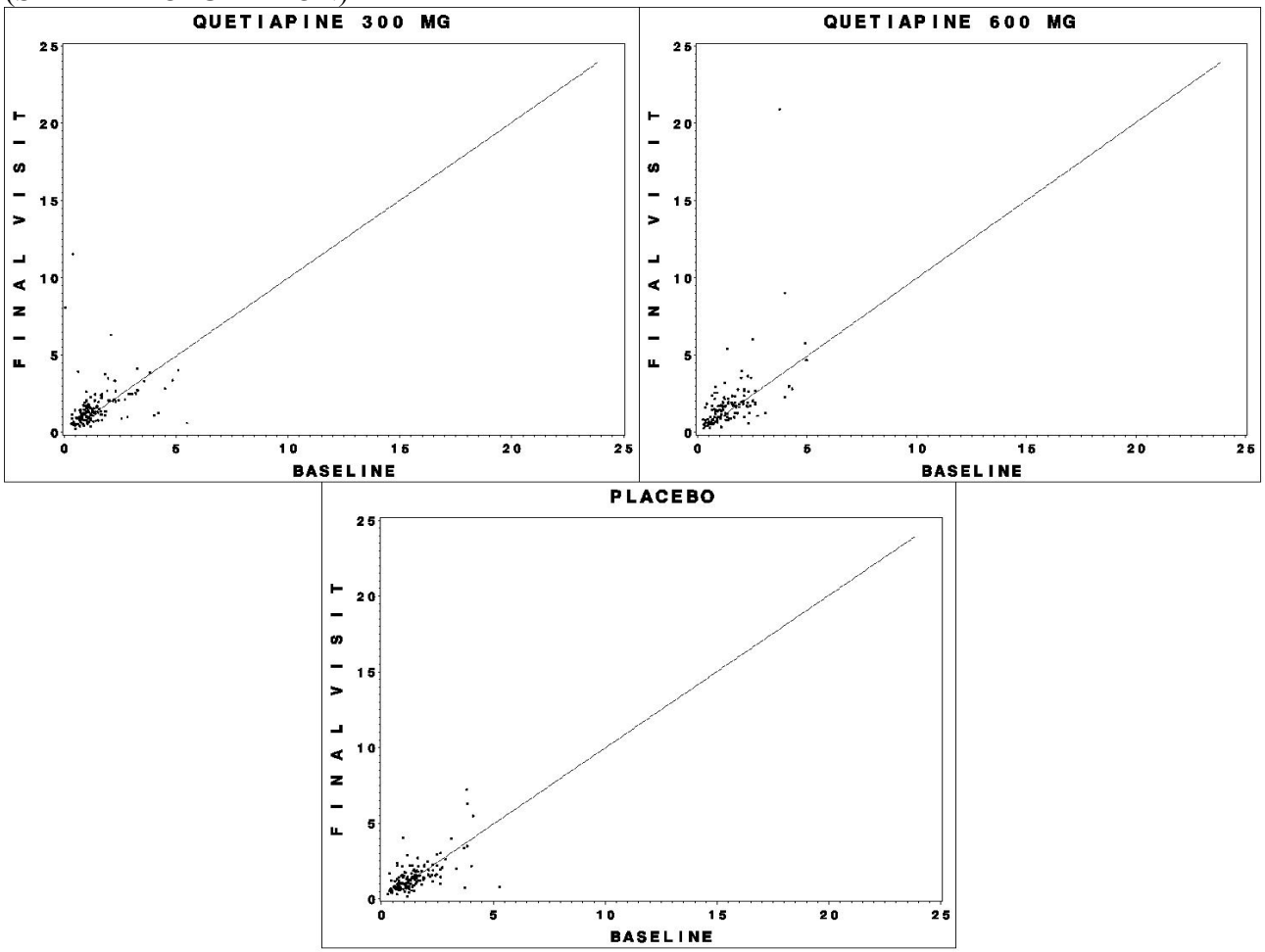

FIGURE 11.3.7.1.2.4.6 SHIFT PLOT: THYROXINE - T4 (NMOL/L)

(SAFETY POPULATION)

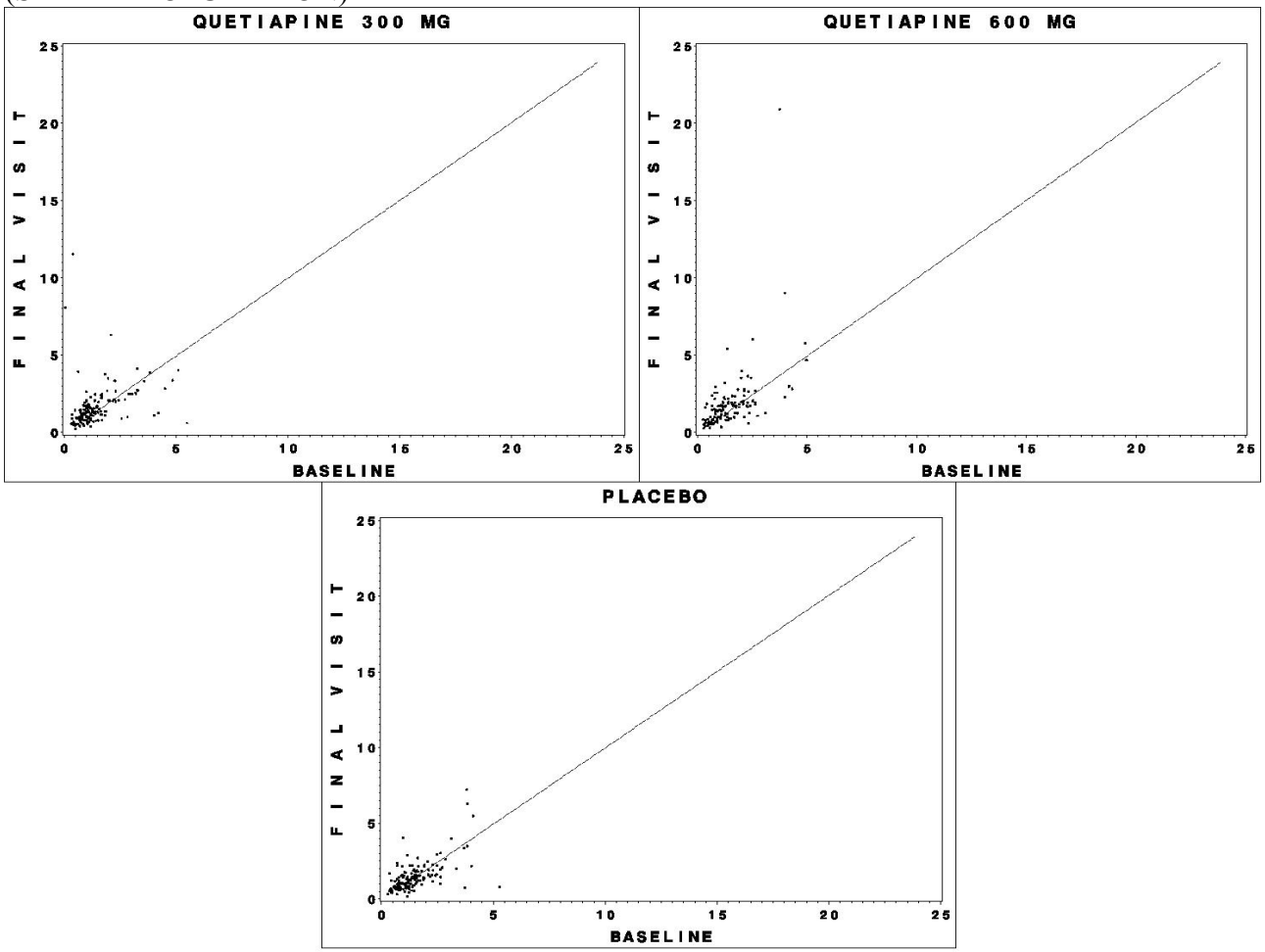

FIGURE 11.3.7.1.2.4.7 SHIFT PLOT: SODIUM (MEQ/L)

(SAFETY POPULATION)

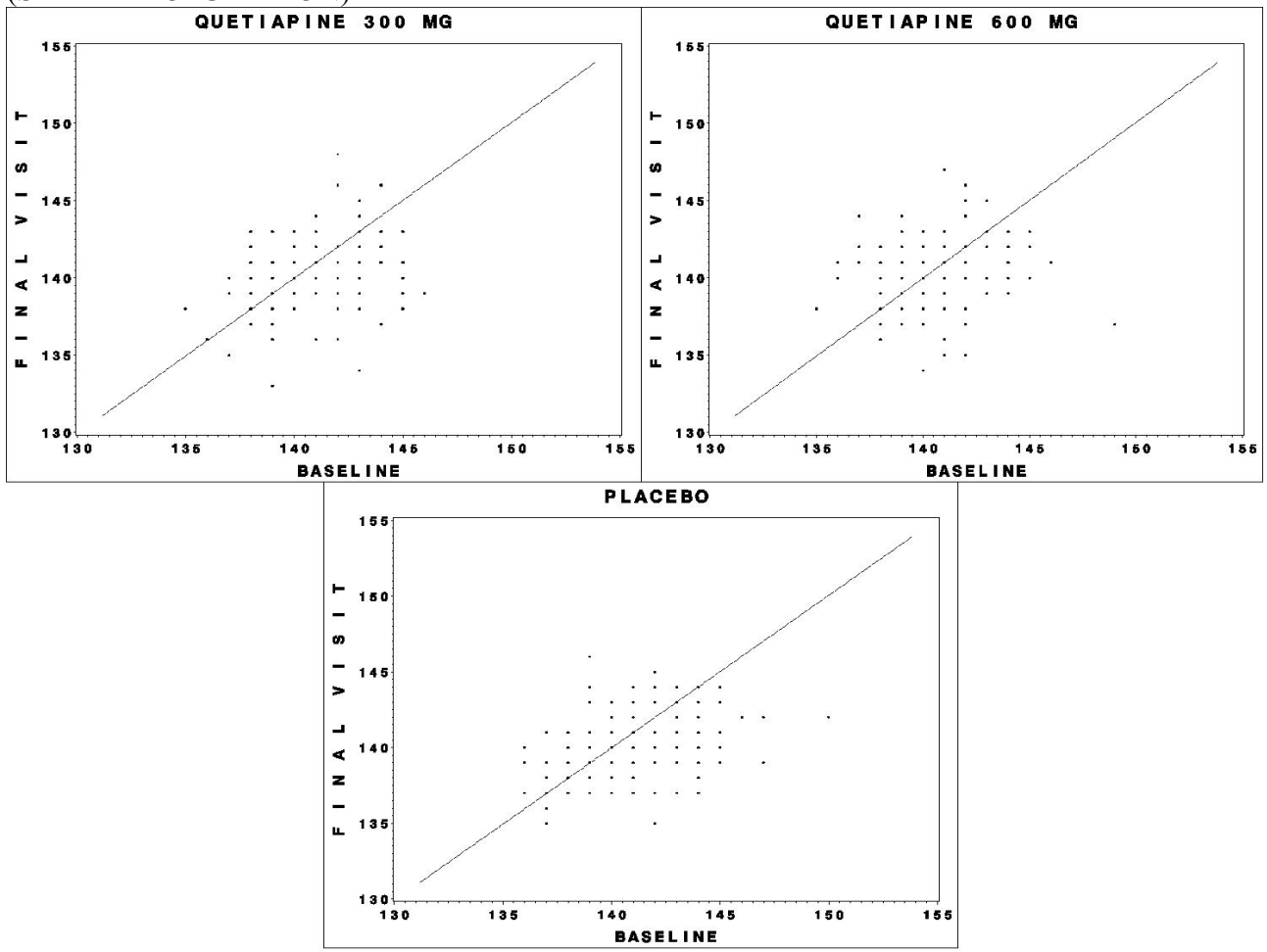

FIGURE 11.3.7.1.2.4.8 SHIFT PLOT: POTASSIUM (MEQ/L)

(SAFETY POPULATION)

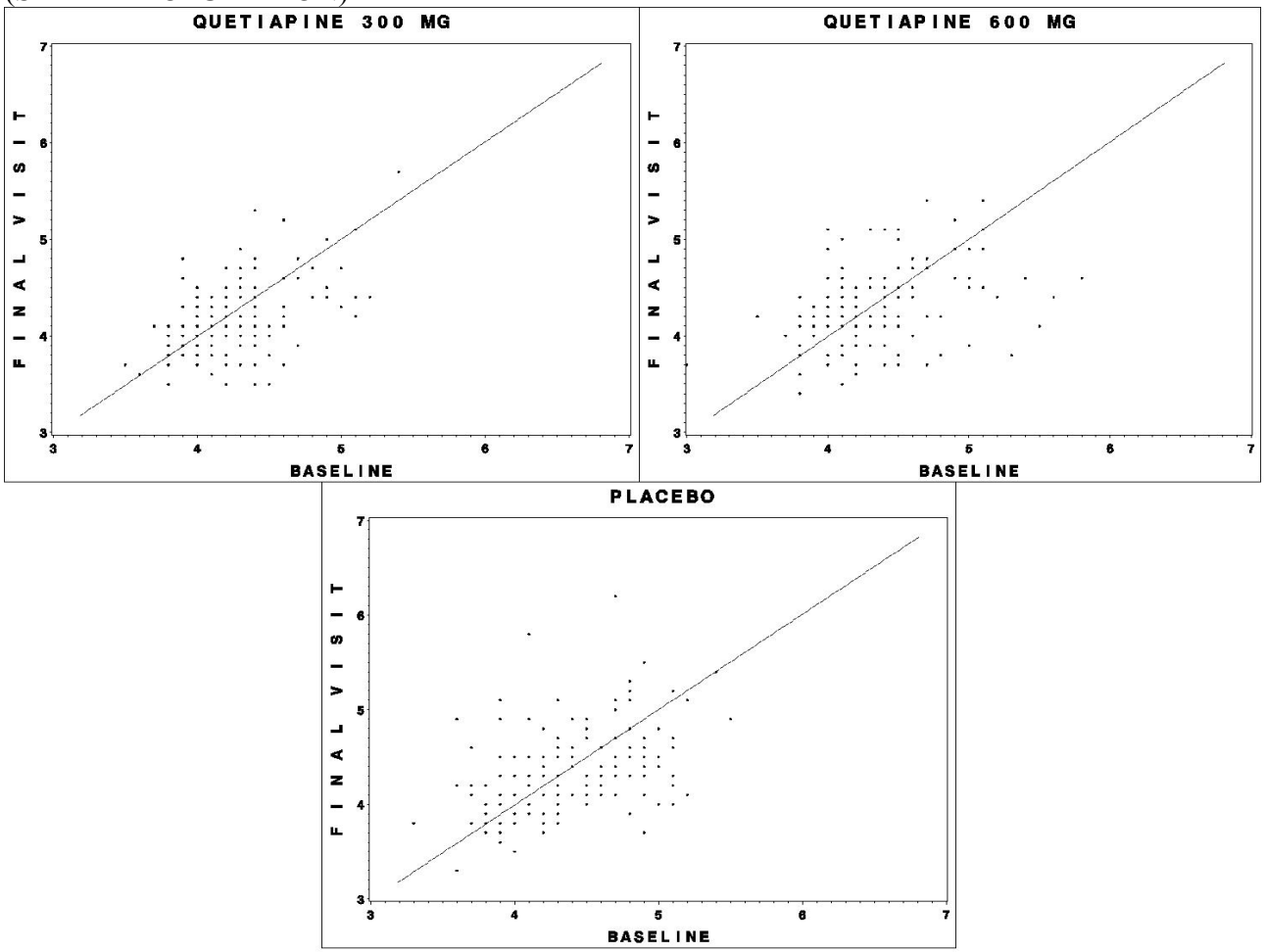

FIGURE 11.3.7.1.2.4.9 SHIFT PLOT: CHLORIDE (MEQ/L)

(SAFETY POPULATION)

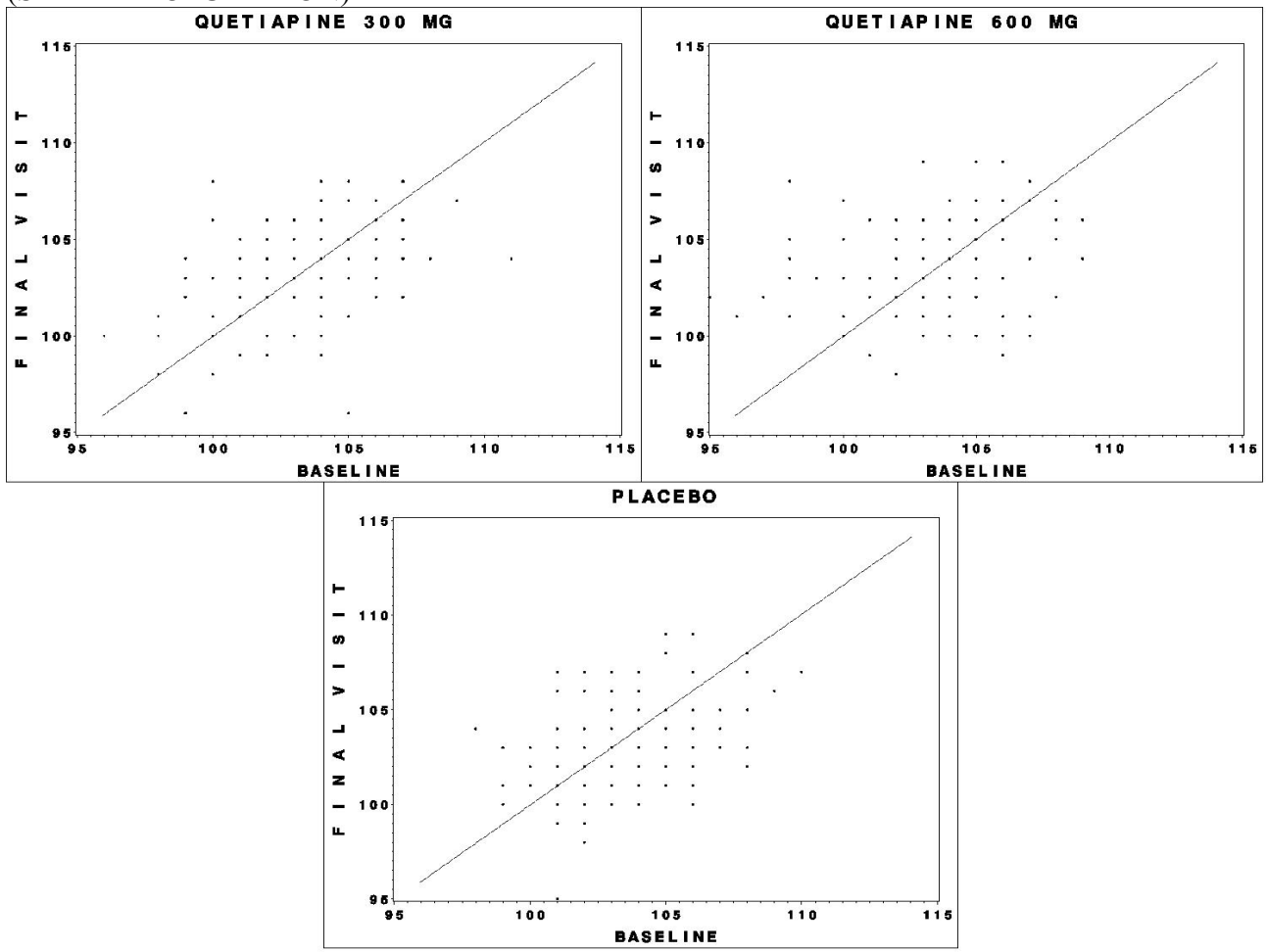

FIGURE 11.3.7.1.2.4.10 SHIFT PLOT: BICARBONATE (MEQ/L)

(SAFETY POPULATION)

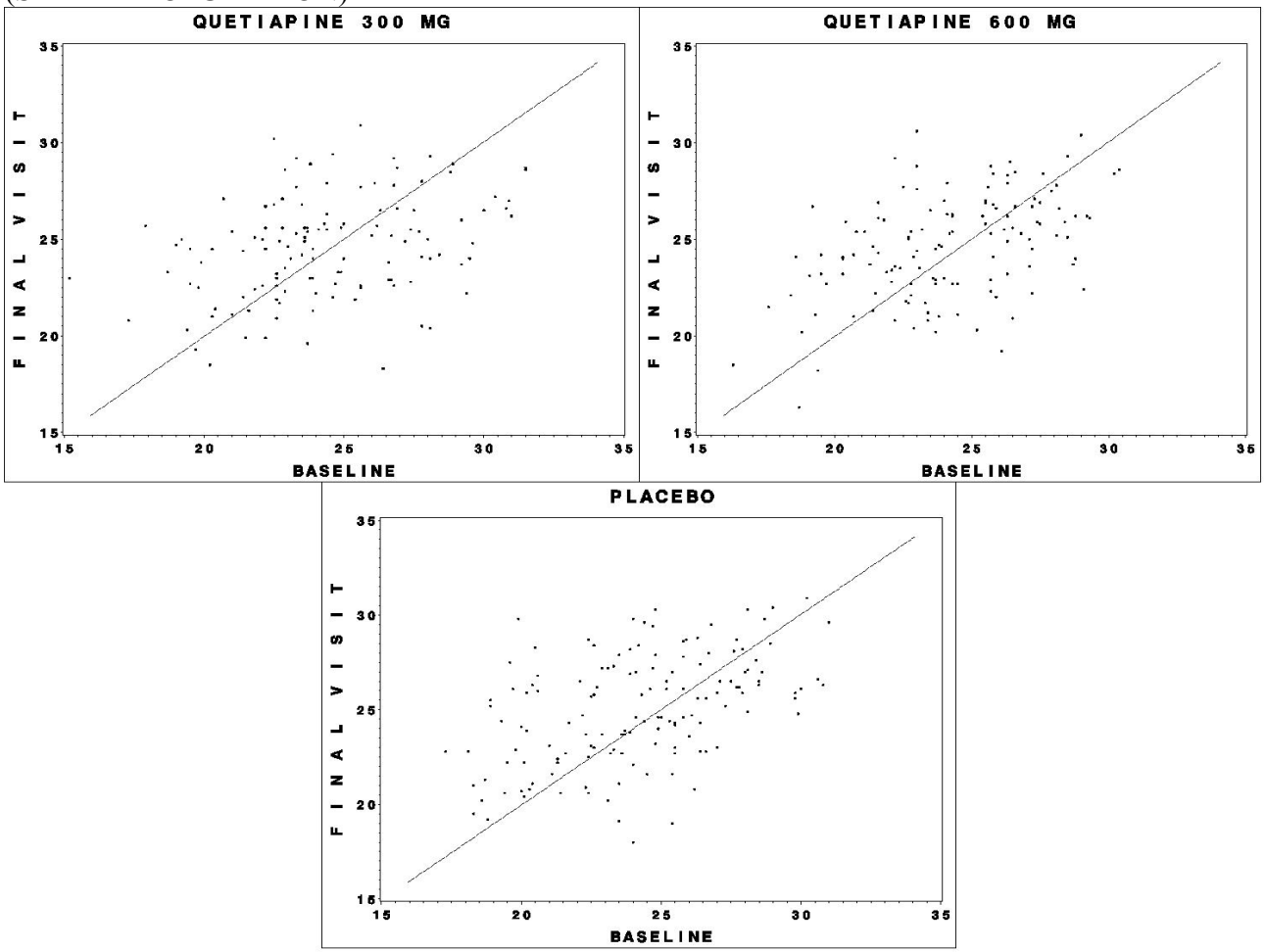

FIGURE 11.3.7.1.2.4.11 CUMULATIVE PERCENTAGE OF PATIENTS BY TIME OF BLOOD SAMPLING FOR CLINICAL LABS (BASELINE)

(SAFETY POPULATION)

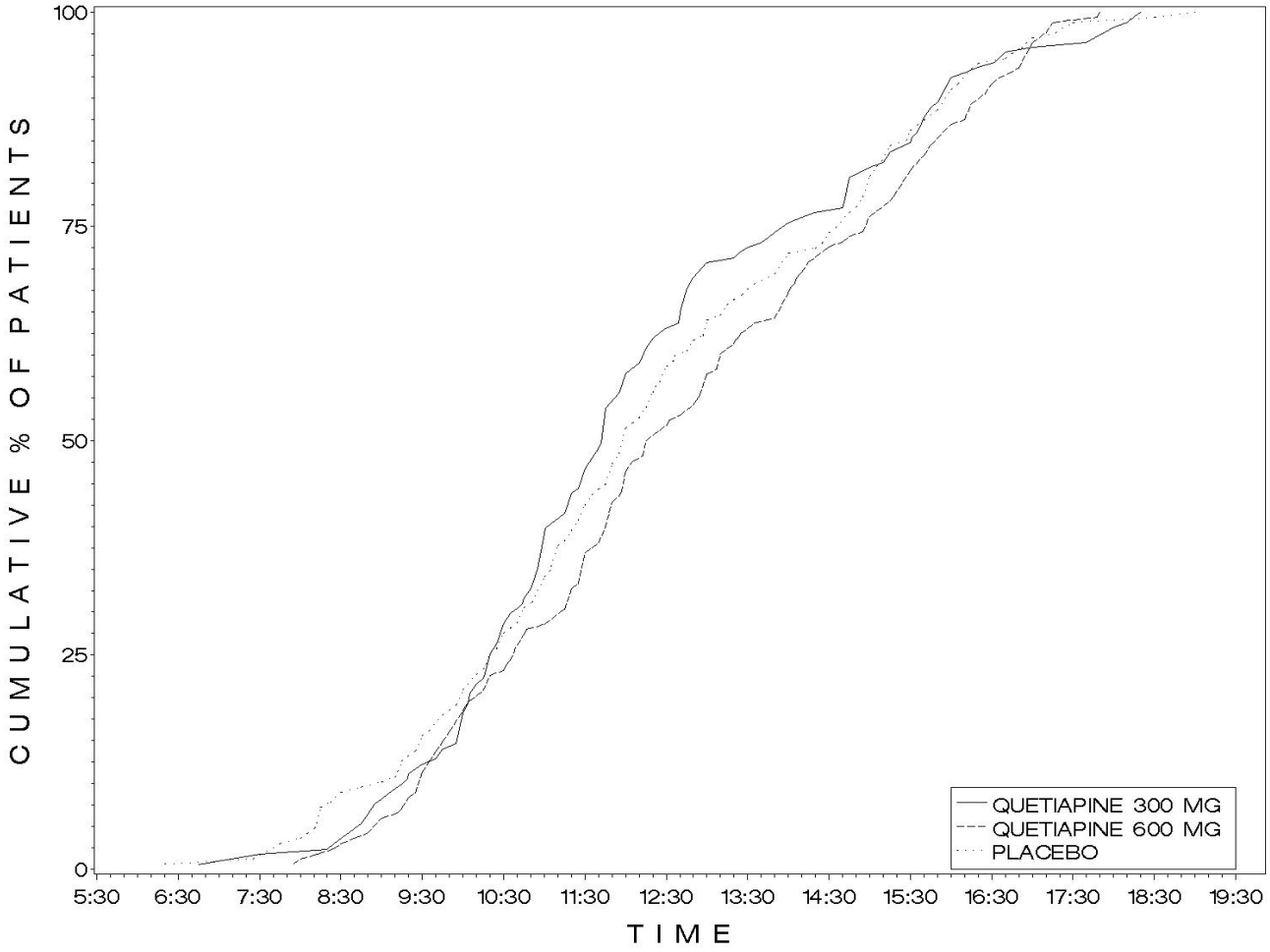

FIGURE 11.3.7.1.2.4.12 CUMULATIVE PERCENTAGE OF PATIENTS BY TIME OF BLOOD SAMPLING FOR CLINICAL LABS (FINAL)

(SAFETY POPULATION)

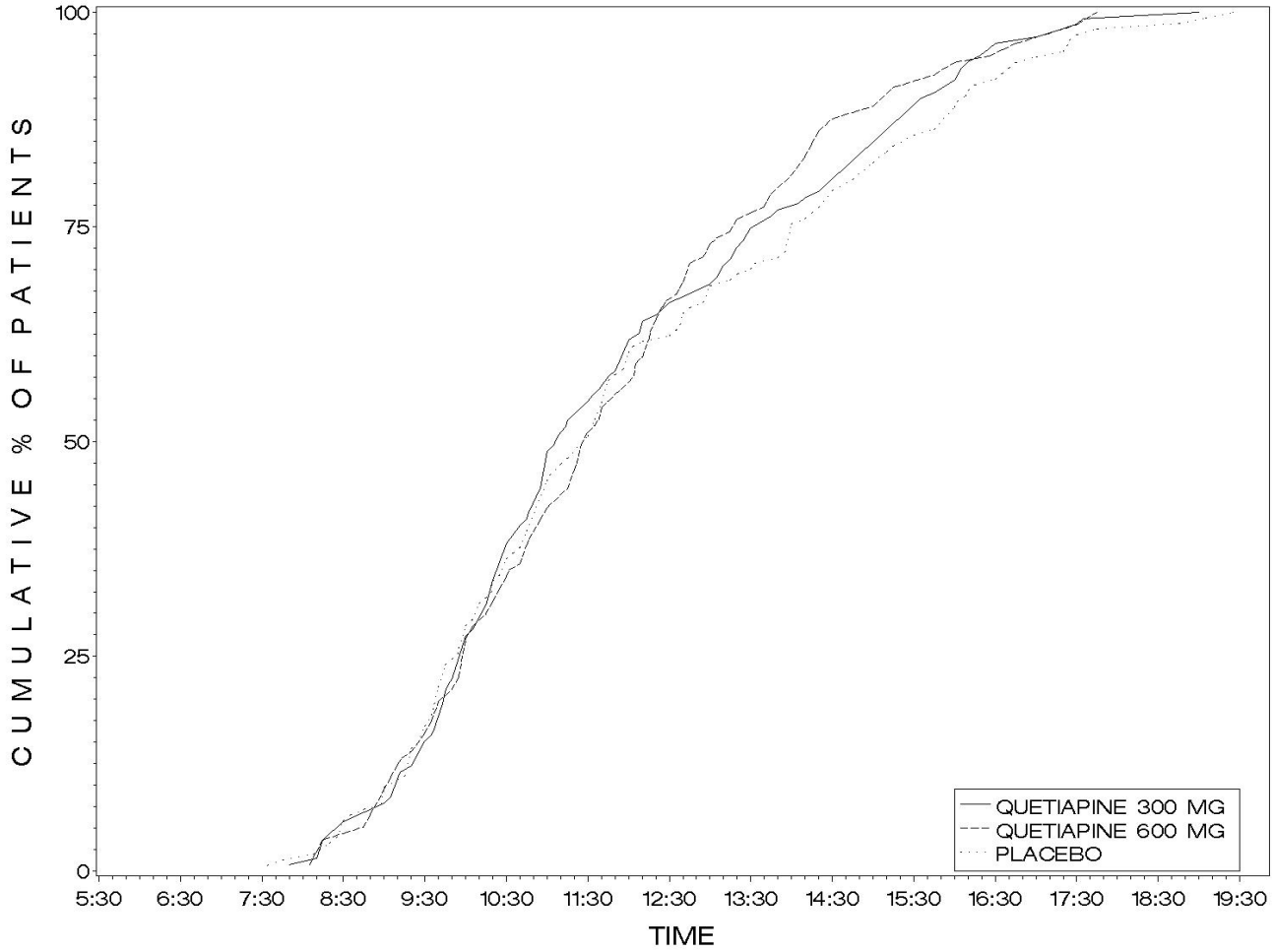

Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0006001	BSLN		28JUL2004	11:20	-7	0.500	H#	16.5	H#	5.7	H	410	H
		VISIT 10	*	02SEP2004	9:10	30	0.490	H	16.0		5.4		290	
		VISIT 10		30SEP2004	15:20	58	0.480		16.5	H#	5.5		323	
	E0015022	BSLN		11MAY2005	12:20	-6	0.500		16.3		5.7		353	
		VISIT 10	*	14JUN2005	13:10	29	0.260	L#	8.5	L#	2.9	L#		
		VISIT 10		21JUN2005	11:50	36	0.480		15.6		5.3		255	
		VISIT 10	*	08JUL2005	14:20	53	0.470		15.9		5.3		319	
		VISIT 10	*	18JUL2005	15:20	63	0.500		15.6		5.4		275	
	E0021024	BSLN		27JAN2005	12:30	-7	0.400		12.8		4.9		359	
		VISIT 10		17FEB2005	12:30	15	0.220	L#	6.6	L#	2.6	L#	449	H
	E0032002	BSLN		30NOV2004	11:45	-8	0.510	H#	17.2	H#	5.9	H	258	
		VISIT 10	*	22DEC2004	11:30	15	0.470		16.4		5.6		246	
		VISIT 10	*	06JAN2005	9:55	30	0.490	H	17.2	H#	5.9	H	198	
		VISIT 10		02FEB2005	10:15	57	0.500	H#	16.7	H#	5.8	H	243	
	E0033001	BSLN		23JUN2004	11:42	-7	0.350	L#	10.1	L#	4.9		261	
		VISIT 10	*	28JUL2004	11:08	29	0.360	L#	9.7	L#	4.9		255	
		VISIT 10		23AUG2004	10:46	55	0.320	L#	9.2	L#	4.4		244	
	E0039009	BSLN		30SEP2004	13:00	-7	0.480		16.8		6.3	#	258	
		VISIT 10		09NOV2004	10:00	34	0.540		18.7	H#	6.9	H#	261	
	E0040018	BSLN	*	20MAY2005	12:00	-19			16.3		6.1	#		
		BSLN		31MAY2005	10:00	-8	0.470		15.4		5.6		236	
		VISIT 10	*	06JUL2005	16:00	29	0.440		14.8		5.4			
		VISIT 10		03AUG2005	15:30	57	0.440		14.8		5.4		248	
QUETIAPINE 300 MG (BIPOLAR II)	E0010005	BSLN		13OCT2004	12:15	-13	0.470		16.6	H#	5.5		256	
	E0011001	BSLN		09JUL2004	13:00	-7	0.510	H#	15.3		5.3		354	
		VISIT 10	*	13AUG2004	10:45	29	0.440		14.4		5.0		412	H

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA102.SAS
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Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0011001	VISIT 10	10SEP2004	11:14	57	0.420		14.5		4.7		386	
	E0020020	BSLN	09NOV2004	10:04	-7	0.350		11.2	L	4.3		268	
		VISIT 10 *	14DEC2004	8:15	29	0.330	L	10.5	L#	4.1		243	
		VISIT 10 *	20DEC2004	16:30	35	0.310	L#	10.1	L#	3.9	L	254	
		VISIT 10	12JAN2005	8:30	58	0.320	L#	10.1	L#	3.9	L	308	
	E0025029	BSLN	16NOV2004	12:55	-14	0.420		13.9		4.7		316	
		VISIT 10 *	04JAN2005	10:29	36	0.360	L#	12.1	L	4.2	L	182	
		VISIT 10	25JAN2005	11:00	57	0.420		13.4		4.5		187	
QUETIAPINE 600 MG (BIPOLAR I)	E0012004	BSLN	23JUL2004	15:00	-7	0.320	L#	9.2	L#	4.6		484	H
		VISIT 10 *	27AUG2004	13:15	29	0.260	L#	7.5	L#	3.7	L	439	H
		VISIT 10	03SEP2004	11:00	36	0.260	L#	7.4	L#	3.7	L	486	H
	E0014023	BSLN	16JUN2005	14:00	-7	0.460		15.1		4.9		214	
		VISIT 10 *	22JUL2005	15:38	30	0.510	H#	16.3		5.3		158	
		VISIT 10	03AUG2005	15:15	42	0.470		14.4		4.7		165	
	E0025024	BSLN	05OCT2004	15:00	-13	0.440		13.7		4.1	L	675	H#
		VISIT 10 *	15NOV2004	11:00	29	0.440		13.8		4.1	L	513	H
		VISIT 10	13DEC2004	10:45	57	0.440		13.6		4.0	L	503	H
	E0026011	BSLN	19OCT2004	11:20	-20	0.390		11.8		4.6		419	H
		VISIT 10 *	08DEC2004	9:20	31	0.380		10.9	L	4.6		368	
		VISIT 10 *	22DEC2004	10:15	45	0.370		11.0	L	4.5		346	
		VISIT 10	11JAN2005	10:55	65	0.360		11.0	L	4.5		312	
		VISIT 10 *	26JAN2005	9:20	80	0.360		10.5	L#	4.5		315	
	E0039002	BSLN	10AUG2004	11:30	-21	0.350		10.6	L	4.1		257	
		VISIT 10 *	28SEP2004	9:30	29	0.300	L#	9.7	L#	3.7	L	264	
		VISIT 10 *	05OCT2004	10:15	36	0.300	L#	9.9	L#	3.8	L	276	
		VISIT 10	28OCT2004	9:30	59	0.330	L	10.3	L#	4.0	L	275	

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Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019005	BSLN		10NOV2004	11:50	-19	0.390		12.5		4.2		308	
		VISIT 10	*	27DEC2004	10:40	29	0.390		12.6		4.3		329	
		VISIT 10		24JAN2005	11:40	57	0.340		10.4	L#	3.8	L	311	
	E0022005	BSLN		22SEP2004	14:15	-14	0.540	H#	16.4	H	6.1	H#	172	
		VISIT 10		15NOV2004	14:30	41	0.400		12.5		4.7		406	H
	E0029007	BSLN		22OCT2004	8:49	-7	0.520		17.9		6.0	#	184	
	E0030002	BSLN		15JUL2004	9:45	-6	0.350	L#	11.8	L	3.9	L	157	
	E0035009	BSLN		13AUG2004	8:30	-7	0.590	H#	19.2	H#	6.2	#	281	
	E0036003	BSLN		24JAN2005	9:30	-2	0.470		14.6		6.5	H#	338	
		VISIT 10	*	23FEB2005	9:35	29	0.450		14.4		6.1	#	325	
		VISIT 10		24MAR2005	14:45	58	0.460		15.0		6.3	#	306	
PLACEBO (BIPOLAR I)	E0021030	BSLN		05APR2005	13:30	-8	0.370	L#	13.3		4.4	L	235	
		VISIT 10	*	09MAY2005	9:40	27	0.360	L#	13.6		4.5		278	
		VISIT 10		08JUN2005	10:10	57	0.410		14.1		4.9		283	
		VISIT 10	*	23AUG2005	11:45	133	0.360	L#	12.6	L	4.5		187	
	E0027021	BSLN		23MAY2005	12:00	-8	0.540		18.0		6.3	#	234	
		VISIT 10	*	29JUN2005	15:15	30	0.460		15.2		5.3		243	
		VISIT 10		27JUL2005	15:02	58	0.520		16.2		5.6		209	
	E0029011	BSLN		08FEB2005	8:11	-3	0.550	H#	17.4		6.0	#	172	
		VISIT 10	*	11MAR2005	16:00	29	0.470		15.8		5.4		182	
		VISIT 10		08APR2005	16:00	57	0.480		15.9		5.4		178	
	E0030034	BSLN		03MAY2005	12:50	-7	0.500		16.2		6.0	#	194	
		VISIT 10	*	08JUN2005	13:00	30	0.500		16.4		6.0	#	247	
		VISIT 10		06JUL2005	13:20	58	0.520		17.2		6.1	#	209	

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Table 11.3.7.2.1.1 Hematology Data for Red Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	HEMATOCRIT (VOL. FRAC.)		HEMOGLOBIN (G/DL)		TOTAL RBC COUNT (X10**12/L)		PLATELET COUNT (X10**9/L)
PLACEBO (BIPOLAR I)	E0033011	BSLN		11JAN2005	9:19	-7	0.550	H#	18.5	H#	5.9		295
		VISIT 10	*	14FEB2005	10:36	28	0.540		17.8		6.0	#	308
		VISIT 10		14MAR2005	10:19	56	0.540		18.2	H	5.8		263
PLACEBO (BIPOLAR II)	E0037025	BSLN	*	11MAR2005	11:50	-17	0.350		9.8	L#	4.3		385
		BSLN		17MAR2005	16:30	-11	0.330	L	9.5	L#	4.1		316
		VISIT 10	*	25APR2005	16:05	29	0.360		10.1	L#	4.4		237
		VISIT 10		24MAY2005	16:35	58	0.400		12.1		4.8		238

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	NEUTROPHILS (%)	NEUTROPHILS,AGRAN (X10**9/L)	NEUTROPHILS,COUNT (X10**9/L)	EOSINOPHILS (%)	EOSINOPHILS (X10**9/L)	BASOPHILS (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0004029	BSLN	14APR2005	12:45	-14	5.2	46.2	2.39	2.39	1.2	0.06	2.6H
		VISIT 6	26MAY2005	15:30	29	3.8L	33.9L	1.27L	1.27L#	2.2	0.08	0.4
		VISIT 10	23JUN2005	15:45	57	3.7L	35.2L	1.30L	1.30L#	2.3	0.09	0.6
	E0012011	BSLN	13SEP2004	10:30	-11	3.6L	49.8	1.77L	1.77L	3.2	0.11	0.6
		VISIT 6	22OCT2004	13:45	29	2.8L#	43.0	1.19L	1.19L#	4.0	0.11	0.0
		VISIT 10	19NOV2004	12:00	57	3.6L	54.1	1.93L	1.93L	3.4	0.12	0.4
	E0015003	BSLN	*20AUG2004	9:20	-5	16.7H#	84.5H	14.10H#	14.10H#	0.6	0.10	0.2
		BSLN	25AUG2004	10:20	1	7.0	72.5	5.08	5.08	1.1	0.08	0.5
	E0015015	BSLN	15FEB2005	16:20	-8	8.0	58.4	4.65	4.65	1.9	0.15	0.8
		VISIT 6	24MAR2005	13:35	30	9.9	60.9	6.02	6.02	11.2H	1.11H#	0.6
		VISIT 10	19APR2005	9:37	56	6.7	60.4	4.03	4.03	4.1	0.27	0.6
	E0015022	BSLN	11MAY2005	12:20	-6	6.9	65.1	4.47	4.47	2.7	0.19	1.1
		VISIT 6	14JUN2005	13:10	29	1.4L#	78.2H	1.12L	1.12L#	2.5	0.04	0.4
		VISIT 6	*21JUN2005	11:50	36	7.9	71.0	5.60	5.60	1.4	0.11	0.4
		VISIT 10	08JUL2005	14:20	53	14.4H	79.4H	11.39H#	11.39H#	0.8	0.12	0.4
		VISIT 10	*18JUL2005	15:20	63	7.8	61.0	4.76	4.76	1.6	0.13	0.6
	E0033018	BSLN	13MAY2005	10:51	-6	13.5H	78.0H	10.56H#	10.56H#	1.5	0.21	0.9
		VISIT 6	22JUN2005	10:49	35	8.7	63.0	5.45	5.45	1.5	0.13	1.2
		VISIT 10	13JUL2005	12:10	56	7.7	64.0	4.94	4.94	1.1	0.08	1.2
	E0041008	BSLN	*02NOV2004	10:44	-15	11.0H	61.1	6.71	6.71	2.5	0.27	0.3
		BSLN	*15NOV2004	14:45	-2	17.0H#	68.0	11.53H#	11.53H#	11.0H	1.87H#	0.0
		BSLN	17NOV2004	11:45	1	12.3H	64.3	7.89H	7.89H	2.1	0.26	0.5

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	BASO-PHILS (X10**9/L)	LYMPHO-CYTES (%)	LYMPHO-CYTES (X10**9/L)	MONO-CYTES (%)	MONO-CYTES (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR I)	E0004029	BSLN	14APR2005	12:45	-14	5.2	0.1	47.0	2.4	3.0	0.2
		VISIT 6	26MAY2005	15:30	29	3.8L	0.0	59.7H	2.3	3.8	0.1
		VISIT 10	23JUN2005	15:45	57	3.7L	0.0	58.3H	2.2	3.5	0.1
	E0012011	BSLN	13SEP2004	10:30	-11	3.6L	0.0	39.4	1.4	7.1	0.3
		VISIT 6	22OCT2004	13:45	29	2.8L#	0.0	46.0	1.3	7.0	0.2
		VISIT 10	19NOV2004	12:00	57	3.6L	0.0	34.7	1.2	7.4	0.3
	E0015003	BSLN	*20AUG2004	9:20	-5	16.7H#	0.0	12.5L	2.1	2.4L	0.4
		BSLN	25AUG2004	10:20	1	7.0	0.0	21.0	1.5	4.7	0.3
	E0015015	BSLN	15FEB2005	16:20	-8	8.0	0.1	34.2	2.7	4.7	0.4
		VISIT 6	24MAR2005	13:35	30	9.9	0.1	23.9	2.4	3.4	0.3
		VISIT 10	19APR2005	9:37	56	6.7	0.0	29.3	2.0	5.5	0.4
	E0015022	BSLN	11MAY2005	12:20	-6	6.9	0.1	23.7	1.6	7.3	0.5
		VISIT 6	14JUN2005	13:10	29	1.4L#	0.0	12.8L	0.2L#	6.2	0.1 L
		VISIT 6	*21JUN2005	11:50	36	7.9	0.0	19.9	1.6	7.3	0.6
		VISIT 10	08JUL2005	14:20	53	14.4H	0.1	13.4L	1.9	6.0	0.9
		VISIT 10	*18JUL2005	15:20	63	7.8	0.1	27.9	2.2	8.8	0.7
	E0033018	BSLN	13MAY2005	10:51	-6	13.5H	0.1	16.0	2.2	3.6	0.5
		VISIT 6	22JUN2005	10:49	35	8.7	0.1	28.4	2.5	5.9	0.5
		VISIT 10	13JUL2005	12:10	56	7.7	0.1	27.4	2.1	6.3	0.5
	E0041008	BSLN	*02NOV2004	10:44	-15	11.0H	0.0	28.8	3.2	7.3	0.8
		BSLN	*15NOV2004	14:45	-2	17.0H#	0.0	19.0	3.2	2.0L	0.3
		BSLN	17NOV2004	11:45	1	12.3H	0.1	24.9	3.1	8.2	1.0 H

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	WBC COUNT (X10 DAY**9/L)	NEUTRO-PHILS (%)	NEUTRO-PHILS,AGRAN (X10 **9/L)	NEUTRO-PHILS,COUNT (X10 **9/L)	EOSIN-OPHILS (%)	EOSIN-OPHILS (X10 **9/L)	BASO-PHILS (%)
QUETIAPINE 300 MG (BIPOLAR II)	E0004004	BSLN	14JUL2004	11:40	-7	18.4H#	63.0	11.62H#	11.62H#	1.6	0.30	0.8
		VISIT 6	*29JUL2004	11:55	9	13.8H	73.0	10.06H#	10.06H#	0.0	0.00	0.0
		VISIT 6	18AUG2004	9:45	29	13.9H	64.1	8.89H	8.89H	1.4	0.19	0.5
		VISIT 10	15SEP2004	10:55	57	13.4H	70.0	9.40H	9.40H	1.0	0.13	0.0
	E0004025	BSLN	07FEB2005	14:45	-21	5.5	51.2	2.79	2.79	2.3	0.12	0.4
		VISIT 6	28MAR2005	9:00	29	13.5H	81.6H	11.02H#	11.02H#	0.3	0.04	0.2
		VISIT 10	25APR2005	10:55	57	6.2	54.1	3.34	3.34	0.4	0.02	0.8
	E0020020	BSLN	09NOV2004	10:04	-7	4.6	39.1L	1.79L	1.79L	5.2	0.24	0.8
		VISIT 6	14DEC2004	8:15	29	4.0	35.2L	1.41L	1.41L#	7.7H	0.31	0.4
		VISIT 6	*20DEC2004	16:30	35	5.0	32.5L	1.61L	1.61L	6.9H	0.34	0.5
		VISIT 10	12JAN2005	8:30	58	4.4	32.5L	1.43L	1.43L#	4.8	0.21	0.8
	E0025018	BSLN	07SEP2004	14:00	-6	7.6	59.5	4.50	4.50	0.5	0.04	0.7
		VISIT 6	11OCT2004	9:00	29	19.4H#	77.1H	14.97H#	14.97H#	0.6	0.12	0.5
		VISIT 10	08NOV2004	13:00	57	5.8	53.7	3.14	3.14	0.8	0.04	1.3
	E0036002	BSLN	11JAN2005	8:40	-1	3.1L	35.9L	1.11L	1.11L#	5.9	0.18	1.4
		VISIT 6	04FEB2005	10:00	24	3.3L	47.8	1.59L	1.59L	5.5	0.18	1.5

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	BASO-PHILS (X10**9/L)	LYMPHO-CYTES (%)	LYMPHO-CYTES (X10**9/L)	MONO-CYTES (%)	MONO-CYTES (X10**9/L)
QUETIAPINE 300 MG (BIPOLAR II)	E0004004	BSLN	14JUL2004	11:40	-7	18.4H#	0.1	29.4	5.4H	5.2	1.0 H
		VISIT 6	*29JUL2004	11:55	9	13.8H	0.0	20.0	2.8	5.0	0.7
		VISIT 6	18AUG2004	9:45	29	13.9H	0.1	30.1	4.2	3.9	0.5
		VISIT 10	15SEP2004	10:55	57	13.4H	0.0	26.0	3.5	1.0L	0.1
	E0004025	BSLN	07FEB2005	14:45	-21	5.5	0.0	40.8	2.2	5.3	0.3
		VISIT 6	28MAR2005	9:00	29	13.5H	0.0	14.4L	1.9	3.5	0.5
		VISIT 10	25APR2005	10:55	57	6.2	0.1	39.6	2.5	5.2	0.3
	E0020020	BSLN	09NOV2004	10:04	-7	4.6	0.0	49.0H	2.2	5.9	0.3
		VISIT 6	14DEC2004	8:15	29	4.0	0.0	50.2H	2.0	6.4	0.3
		VISIT 6	*20DEC2004	16:30	35	5.0	0.0	54.0H	2.7	6.1	0.3
		VISIT 10	12JAN2005	8:30	58	4.4	0.0	54.0H	2.4	8.0	0.4
	E0025018	BSLN	07SEP2004	14:00	-6	7.6	0.1	29.7	2.3	9.5	0.7
		VISIT 6	11OCT2004	9:00	29	19.4H#	0.1	15.5	3.0	6.3	1.2 H
		VISIT 10	08NOV2004	13:00	57	5.8	0.1	35.3	2.1	9.0	0.5
	E0036002	BSLN	11JAN2005	8:40	-1	3.1L	0.0	48.2	1.5	8.7	0.3
		VISIT 6	04FEB2005	10:00	24	3.3L	0.1	37.7	1.3	7.5	0.3

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Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	WBC COUNT (X10**9/L) DAY	NEUTROPHILS (%)	NEUTROPHILS,AGRAN (X10**9/L)	NEUTROPHILS,COUNT (X10**9/L)	EOSINOPHILS (%)	EOSINOPHILS (X10**9/L)	BASOPHILS (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0001002	BSLN	28JUL2004	15:18	-14 3.7L	44.8	1.66L	1.66L	1.2	0.04	0.3
		VISIT 6	08SEP2004	12:00	29 3.3L	42.5	1.38L	1.38L#	0.9	0.03	0.4
		VISIT 10	24SEP2004	13:45	45 4.2	48.7	2.03	2.03	1.3	0.05	0.6
	E0011023	BSLN	02MAR2005	12:52	-6 11.3H	73.6	8.28H	8.28H	0.5	0.06	0.8
		VISIT 6	05APR2005	13:04	29 12.6H	79.7H	10.08H#	10.08H#	0.6	0.07	0.7
		VISIT 10	03MAY2005	10:32	57 9.8	71.3	6.95	6.95	1.1	0.11	0.5
	E0015005	BSLN	20SEP2004	12:40	-7 14.0H	75.5H	10.54H#	10.54H#	0.7	0.09	0.5
		VISIT 6	11OCT2004	12:20	15 13.4H	78.6H	10.54H#	10.54H#	0.6	0.08	0.7
	E0027001	BSLN	09JUL2004	11:00	-21 13.6H	77.4H	10.53H#	10.53H#	1.5	0.20	0.8
		VISIT 6	06AUG2004	10:00	8 12.4H	82.2H	10.22H#	10.22H#	0.8	0.10	0.6
	E0042023	BSLN	27APR2005	14:45	-19 6.2	73.8	4.55	4.55	0.9	0.05	0.4
		VISIT 6	13JUN2005	9:25	29 4.6	63.8	2.91	2.91	2.2	0.10	0.6
		VISIT 10	13JUL2005	9:10	59 2.7L#	59.5	1.63L	1.63L	2.6	0.07	0.9
	E0045003	BSLN	10FEB2005	9:15	-15 11.0H	73.6	8.09H	8.09H	4.6	0.51	0.6
		VISIT 6	14MAR2005	8:45	18 12.5H	67.1	8.36H	8.36H	12.4H	1.54H#	0.5

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L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA103.SAS
GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	BASO-PHILS (X10**9/L)	LYMPHO-CYTES (%)	LYMPHO-CYTES (X10**9/L)	MONO-CYTES (%)	MONO-CYTES (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR I)	E0001002	BSLN	28JUL2004	15:18	-14	3.7L	0.0	49.1H	1.8	4.7	0.2
		VISIT 6	08SEP2004	12:00	29	3.3L	0.0	49.9H	1.6	6.3	0.2
		VISIT 10	24SEP2004	13:45	45	4.2	0.0	43.8	1.8	5.6	0.2
	E0011023	BSLN	02MAR2005	12:52	-6	11.3H	0.1	22.0	2.5	3.1	0.4
		VISIT 6	05APR2005	13:04	29	12.6H	0.1	16.2	2.1	2.8	0.4
		VISIT 10	03MAY2005	10:32	57	9.8	0.1	23.9	2.3	3.3	0.3
	E0015005	BSLN	20SEP2004	12:40	-7	14.0H	0.1	18.8	2.6	4.5	0.6
		VISIT 6	11OCT2004	12:20	15	13.4H	0.1	16.4	2.2	3.8	0.5
	E0027001	BSLN	09JUL2004	11:00	-21	13.6H	0.1	16.3	2.2	4.0	0.6
		VISIT 6	06AUG2004	10:00	8	12.4H	0.1	12.6L	1.6	3.9	0.5
	E0042023	BSLN	27APR2005	14:45	-19	6.2	0.0	22.3	1.4	2.7	0.2
		VISIT 6	13JUN2005	9:25	29	4.6	0.0	29.1	1.3	4.3	0.2
		VISIT 10	13JUL2005	9:10	59	2.7L#	0.0	30.8	0.9L	6.2	0.2
	E0045003	BSLN	10FEB2005	9:15	-15	11.0H	0.1	16.3	1.8	4.8	0.5
		VISIT 6	14MAR2005	8:45	18	12.5H	0.1	15.7	2.0	4.3	0.5

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA103.SAS
GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	NEUTROPHILS (%)	NEUTROPHILS,AGRAN (X10**9/L)	NEUTROPHILS,COUNT (X10**9/L)	EOSINOPHILS (%)	EOSINOPHILS (X10**9/L)	BASOPHILS (%)
QUETIAPINE 600 MG (BIPOLAR II)	E0046001	BSLN	04NOV2004	17:48	-6	11.5H	58.0	6.68	6.68	2.2	0.25	0.5
		VISIT 6	08DEC2004	9:10	29	4.0	19.0L	0.76L	0.76L#	9.0H	0.36	0.0
		VISIT 6 *	13DEC2004	11:30	34	9.2	49.2	4.52	4.52	3.7	0.34	0.7
		VISIT 10	05JAN2005	10:40	57	4.0	35.0L	1.60L	1.60L	3.0	0.12	0.0

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GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	BASO-PHILS (X10**9/L)	LYMPHO-CYTES (%)	LYMPHO-CYTES (X10**9/L)	MONO-CYTES (%)	MONO-CYTES (X10**9/L)
QUETIAPINE 600 MG (BIPOLAR II)	E0046001	BSLN	04NOV2004	17:48	-6	11.5H	0.1	34.4	4.0	4.9	0.6
		VISIT 6	08DEC2004	9:10	29	4.0	0.0	70.0H	2.8	2.0L	0.1 L
		VISIT 6 *	13DEC2004	11:30	34	9.2	0.1	41.6	3.8	4.8	0.5
		VISIT 10	05JAN2005	10:40	57	4.0	0.0	47.0	1.9	10.0	0.4

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GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	NEUTROPHILS (%)	NEUTROPHILS,AGRAN (X10**9/L)	NEUTROPHILS,COUNT (X10**9/L)	EOSINOPHILS (%)	EOSINOPHILS (X10**9/L)	BASOPHILS (%)
PLACEBO (BIPOLAR I)	E0001013	BSLN	28APR2005	12:30	-7	4.1	58.0	2.38	2.38	0.4	0.02	0.5
		VISIT 6	02JUN2005	11:00	29	2.8L#	28.2L	0.80L	0.80L#	0.6	0.02	0.5
		VISIT 6	*06JUN2005	10:22	33	3.3L	40.0L			1.0		1.0
	E0008011	BSLN	26JAN2005	11:10	-7	6.2	74.3	4.62	4.62	0.8	0.05	0.1
		VISIT 6	*09FEB2005	12:40	8	3.2L	47.1	1.50L	1.50L#	0.7	0.02	0.5
		VISIT 6	*02MAR2005	11:55	29	4.1	53.6	2.19	2.19	1.5	0.06	0.1
		VISIT 6	15MAR2005	13:00	42	6.1	64.4	3.94	3.94	0.8	0.05	0.3

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA103.SAS
GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	BASO-PHILS (X10**9/L)	LYMPHO-CYTES (%)	LYMPHO-CYTES (X10**9/L)	MONO-CYTES (%)	MONO-CYTES (X10**9/L)
PLACEBO (BIPOLAR I)	E0001013	BSLN	28APR2005	12:30	-7	4.1	0.0	35.9	1.5	5.2	0.2
		VISIT 6	02JUN2005	11:00	29	2.8L#	0.0	62.8H	1.8	7.8	0.2
		VISIT 6	*06JUN2005	10:22	33	3.3L		51.0H		7.0	
	E0008011	BSLN	26JAN2005	11:10	-7	6.2	0.0	20.6	1.3	4.2	0.3
		VISIT 6	*09FEB2005	12:40	8	3.2L	0.0	43.3	1.4	8.5	0.3
		VISIT 6	*02MAR2005	11:55	29	4.1	0.0	39.9	1.6	4.8	0.2
		VISIT 6	15MAR2005	13:00	42	6.1	0.0	31.1	1.9	3.5	0.2

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GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	NEUTROPHILS (%)	NEUTROPHILS,AGRAN (X10**9/L)	NEUTROPHILS,COUNT (X10**9/L)	EOSINOPHILS (%)	EOSINOPHILS (X10**9/L)	BASOPHILS (%)
PLACEBO (BIPOLAR II)	E0037003	BSLN	*07SEP2004	17:45	-14	18.4H#	72.8	13.36H#	13.36H#	0.8	0.15	0.2
		BSLN	16SEP2004	12:55	-5	12.3H	67.3	8.26H	8.26H	1.1	0.14	0.3
		VISIT 6	19OCT2004	17:20	29	13.7H	53.0	7.23	7.23	1.0	0.14	1.0
		VISIT 10	16NOV2004	17:20	57	14.2H	65.0	9.20H	9.20H	0.0	0.00	0.0

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GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.1.2 Hematology Data for White Cells - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	WBC COUNT (X10**9/L)	BASO-PHILS (X10**9/L)	LYMPHO-CYTES (%)	LYMPHO-CYTES (X10**9/L)	MONO-CYTES (%)	MONO-CYTES (X10**9/L)
PLACEBO (BIPOLAR II)	E0037003	BSLN	*07SEP2004	17:45	-14	18.4H#	0.0	22.9	4.2	3.3	0.6
		BSLN	16SEP2004	12:55	-5	12.3H	0.0	27.8	3.4	3.4	0.4
		VISIT 6	19OCT2004	17:20	29	13.7H	0.1	43.0	5.9H	2.0L	0.3
		VISIT 10	16NOV2004	17:20	57	14.2H	0.0	31.0	4.4H	4.0	0.6

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/HEMA103.SAS
GENERATED: 17NOV2005 13:50:01 iceadmn3

Table 11.3.7.2.2.1 Chemistry Data for Liver Function Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)		TOTAL BILIRUBIN (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0014003	BSLN	*	23JUL2004	15:35	-14	157H#	85H	89.0		0.6	
		BSLN		29JUL2004	13:50	-8	25	51H	79.0		0.7	
		VISIT 10		28SEP2004	12:20	54	19	25	88.0		0.7	
	E0021009	BSLN		22SEP2004	11:00	-8	29	14	73.0		0.7	
		VISIT 10		02DEC2004	13:24	64	22	8	78.0		1.8	H#
	E0034014	BSLN	*	31MAY2005	11:15	-24	60H	146H#	62.0		0.3	
		BSLN		13JUN2005	11:08	-11	24	32	67.0		0.6	
QUETIAPINE 300 MG (BIPOLAR II)	E0011016	BSLN		07DEC2004	12:40	-9	25	27	104.0		0.2	
		VISIT 10		11FEB2005	11:38	58	112H#	66H	100.0			
QUETIAPINE 600 MG (BIPOLAR I)	E0021033	BSLN		25APR2005	12:25	-8	22	18	81.0		1.8	H#
		VISIT 10		29JUN2005	13:42	58	21	25	92.0		1.0	
	E0025056	BSLN	*	26APR2005	16:30	-16	16	10	64.0		2.8	H#
		BSLN		02MAY2005	14:35	-10	18	13	64.0		2.9	H#
		VISIT 10		07JUN2005	13:05	27	22	15	71.0		2.2	H#
QUETIAPINE 600 MG (BIPOLAR II)	E0022005	BSLN		22SEP2004	14:15	-14	47H	63H	104.0			
		VISIT 10		15NOV2004	14:30	41	76H	143H#	301.0	H	0.3	
	E0037020	BSLN		08MAR2005	14:05	-7	42H	45H	77.0		0.6	
		VISIT 10		10MAY2005	12:40	57	127H#	180H#	86.0		0.5	
		VISIT 10	*	18MAY2005	12:30	65	46H	66H	90.0		0.7	
PLACEBO (BIPOLAR I)	E0006019	BSLN		18NOV2004	7:45	-6	55H	95H	77.0		0.5	
		VISIT 10		19JAN2005	11:35	57	66H	141H#	68.0		0.8	
	E0037010	BSLN		01NOV2004	11:25	-7	45H	51H	89.0		0.3	

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM106.SAS
GENERATED: 17NOV2005 13:46:02 iceadmn3

Table 11.3.7.2.2.1 Chemistry Data for Liver Function Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	AST (U/L)	ALT (U/L)	ALKALINE PHOSPHATASE (U/L)	TOTAL BILIRUBIN (MG/DL)	
PLACEBO (BIPOLAR I)	E0037010	VISIT 10		13DEC2004	17:45	36	31	146H#	96.0		
	E0041004	BSLN		30AUG2004	11:04	-23	21	23	67.0	1.9	H#
		VISIT 10		17NOV2004	8:58	57	22	20	67.0	1.1	
PLACEBO (BIPOLAR II)	E0027015	BSLN	*	23SEP2004	11:20	-20	171H#	240H#	81.0	0.2	
		BSLN		01OCT2004	9:30	-12	33	82H	96.0	0.3	
		VISIT 10		08DEC2004	15:00	57	22	14	77.0	0.3	

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM106.SAS
GENERATED: 17NOV2005 13:46:02 iceadmn3

Table 11.3.7.2.2.2 Chemistry Data for Renal Tests - Potentially Clinically Important

NOTE: THERE WERE NO POTENTIALLY CLINICALLY IMPORTANT 'RENAL' DATA.

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM107.SAS
GENERATED: 17NOV2005 13:46:05 iceadmn3

Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)	HgbA1C (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	BSLN		02NOV2004	6:45	-6	26.0	92.0	28.8	4	4.7
		VISIT 6		06DEC2004	16:40	29	26.0	98.0	70.1	10	
		VISIT 10		05JAN2005	15:35	59	26.0	144.0 H#	93.5	13	4.6
	E0021008	BSLN		20SEP2004	13:40	-7	31.7	98.0	38.5	6	5.2
		VISIT 6		25OCT2004	12:15	29	31.7	161.0 H#	195.2 H	28 H	
		VISIT 6	*	01NOV2004	11:30	36	31.7	104.0			
		VISIT 10		22NOV2004	11:33	57	31.7	103.0	31.5	5	5.4
	E0024003	BSLN		12OCT2004	10:15	-7	37.6		130.0	19	5.2
		BSLN		15OCT2004	9:00	-4	37.6	117.0 H			
		VISIT 6		18NOV2004	9:22	31	37.6	98.0	123.9	18	
		VISIT 10		15DEC2004	9:43	58	37.6	160.0 H#	587.1 H	85 H	5.6
	E0025020	BSLN		10SEP2004	13:30	-6	24.1	155.0 H#	96.5	14	7.3
		VISIT 6		13OCT2004	10:00	28	24.1	212.0 H#	172.2 H	25 H	
		VISIT 10		09NOV2004	13:00	55	24.1	341.0 H#	180.0 H	26 H	11.8 #
	E0025028	BSLN		11NOV2004	15:00	-12	16.7	207.0 H#	55.0	8	8.2 #
		VISIT 6		21DEC2004	14:40	29	16.7	235.0 H#			
	E0026021		*	15FEB2005	9:35	7	48.7	150.0 H#			
		BSLN		03FEB2005	10:25	-6	48.7	135.0 H#	139.0	20	6.3
		VISIT 6		10MAR2005	10:50	30	48.7	143.0 H#	228.0 H	33 H	
		VISIT 10		08APR2005	10:40	59	48.7	143.0 H#	199.9 H	29 H	6.6
	E0040002	BSLN		28JUL2004	14:10	-9	32.4	84.0	43.1	6	6.3
		VISIT 6		03SEP2004	12:10	29	32.4	172.0 H#	271.3 H	39 H	
	E0040017	BSLN		18MAY2005	14:45	-7	21.1	82.0	10.5 L	2 L	5.7
		VISIT 6		24JUN2005	14:30	31	21.1	100.0	87.2	13	
		VISIT 10		22JUL2005	11:00	59	21.1	143.0 H#	267.3 H	38 H	5.3
	E0040018	BSLN		20MAY2005	12:00	-19	28.0	65.0 L	37.8	5	5.7
		VISIT 6		06JUL2005	16:00	29	28.0	102.0	95.3	14	

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM108.SAS
GENERATED: 17NOV2005 13:46:08 iceadmn3

Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)	HgbA1C (%)
QUETIAPINE 300 MG (BIPOLAR I)	E0040018	VISIT 10		03AUG2005	15:30	57	28.0	126.0 H#	284.0 H	41 H	6.1
QUETIAPINE 300 MG (BIPOLAR II)	E0004025	BSLN		07FEB2005	14:45	-21	21.9	91.0	12.4 L	2 L	5.4
		VISIT 6		28MAR2005	9:00	29	21.9	127.0 H#	31.5	5	
		VISIT 10		25APR2005	10:55	57	21.9	105.0	26.6	4	5.3
	E0011016	BSLN		07DEC2004	12:40	-9	31.6	96.0	15.4	2	4.9
		VISIT 6		13JAN2005	15:40	29	31.6	149.0 H#	161.7 H	23 H	
		VISIT 10		11FEB2005	11:38	58	31.6	106.0	99.8	14	4.9
	E0011025	BSLN		08MAR2005	12:15	-7	27.8	130.0 H#	29.9	4	6.8
	E0035007	BSLN	*	09AUG2004	11:12	-10	36.7	144.0 H#	74.9	11	6.3
		BSLN		12AUG2004	10:00	-7	36.7	138.0 H#	65.8	9	6.3
		VISIT 6		16SEP2004	8:50	29	36.7	167.0 H#	61.9	9	
		VISIT 10		13OCT2004	8:30	56	36.7	176.0 H#	86.4	12	6.8
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	BSLN	*	21DEC2004	15:15	-10	29.7				6.9
		BSLN		21DEC2004	15:15	-10	29.7	106.0	39.7	6	
		BSLN		27DEC2004	8:25	-4	29.7				6.7
		VISIT 6		28JAN2005	13:00	29	29.7	120.0 H	33.4	5	
		VISIT 10		03MAR2005	10:00	63	29.7	138.0 H#	44.3	6	6.8
	E0013008	BSLN		27OCT2004	11:50	-15	43.0	107.0	138.3	20	5.6
		VISIT 6		08DEC2004	16:40	28	43.0	95.0	91.5	13	
		VISIT 10		03JAN2005	15:00	54	43.0	257.0 H#	160.2 H	23 H	5.7
		VISIT 10	*	19JAN2005	15:00	70	43.0	95.0	78.3	11	
	E0025060	BSLN		04MAY2005	17:15	-15	51.6	127.0 H#	115.1	17	5.1
		VISIT 6		15JUN2005	17:00	28	51.6	95.0	67.9	10	
		VISIT 10		15JUL2005	10:25	58	51.6	181.0 H#	186.1 H	27 H	6.4
	E0028013	BSLN		15FEB2005	12:00	-6	20.2	70.0	25.5	4	5.5

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM108.SAS
GENERATED: 17NOV2005 13:46:08 iceadmn3

Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)	HgbA1C (%)
QUETIAPINE 600 MG (BIPOLAR I)	E0028013	VISIT 6		21MAR2005	16:10	29	20.2	126.0 H#	91.7	13	
		VISIT 10		20APR2005	14:10	59	20.2	106.0	43.8	6	5.5
	E0034001	BSLN		03SEP2004	11:20	-13	36.0	76.0	32.5	5	5.2
		VISIT 6		14OCT2004	9:00	29	36.0	236.0 H#	670.8 H	97 H	
		VISIT 10		11NOV2004	9:00	57	36.0	143.0 H#	509.1 H	73 H	5.5
	E0042023	BSLN		27APR2005	14:45	-19	34.2	131.0 H#	52.7	8	7.0
		VISIT 6		13JUN2005	9:25	29	34.2	283.0 H#	272.4 H	39 H	
		VISIT 6	*	20JUN2005	9:30	36	34.2	235.0 H#	132.3	19	
		VISIT 10		13JUL2005	9:10	59	34.2	200.0 H#	71.0	10	7.5
	E0046004	BSLN		29NOV2004	11:45	-3	44.1	84.0	51.3	7	4.6
		VISIT 6		29DEC2004	14:09	28	44.1	97.0	73.1	11	
		VISIT 10		24JAN2005	8:50	54	44.1	257.0 H#	47.6	7	4.8
		VISIT 10	*	09FEB2005	9:55	70	44.1	95.0			
QUETIAPINE 600 MG (BIPOLAR II)	E0022005	BSLN		22SEP2004	14:15	-14	29.5	121.0 H	526.4 H	76 H	6.4
		VISIT 6		15NOV2004	14:30	41	29.5	201.0 H#	410.7 H	59 H	
		VISIT 10		15NOV2004	14:30	41	29.5				6.2
	E0025002	BSLN	*	14JUL2004	15:30	-34	32.0	109.0	150.4	22	4.8
		BSLN		09AUG2004	14:00	-8	32.0	38.0 L#	39.9	6	5.0
		VISIT 6		24AUG2004	16:00	8	32.0	93.0	207.4 H	30 H	
		VISIT 10		24AUG2004	16:00	8	32.0				4.9
PLACEBO (BIPOLAR I)	E0025007	BSLN		27JUL2004	14:00	-22	34.7	153.0 H#	240.6 H	35 H	5.5
		VISIT 6		26AUG2004	11:00	9	34.7		52.9	8	
		VISIT 6	*	15SEP2004	14:00	29	34.7		386.1 H	56 H	
		VISIT 6		15SEP2004	14:00	29	34.7	184.0 H#			
		VISIT 10		15SEP2004	14:00	29	34.7				4.6
	E0026015	BSLN		02NOV2004	10:30	-14	42.7	112.0	144.0	21	6.2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM108.SAS
GENERATED: 17NOV2005 13:46:08 iceadmn3

Table 11.3.7.2.2.3 Chemistry Data for Diabetic Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	BASELINE BMI	FASTING GLUCOSE (MG/DL)	INSULIN (PMOL/L)	INSULIN (UIU/ML)	HgbA1C (%)
PLACEBO (BIPOLAR I)	E0026015	VISIT 6	15DEC2004	10:35	30	42.7	137.0 H#	92.0	13	
		VISIT 10 *	04JAN2005	7:30	50	42.7	155.0 H#			
		VISIT 10	13JAN2005	7:34	59	42.7	156.0 H#	93.5	13	6.4
		VISIT 10 *	21JAN2005	7:38	67	42.7	129.0 H#			
	E0027012	BSLN	19AUG2004	12:30	-11	22.8	124.0 H	56.7	8	6.2
		VISIT 6	29SEP2004	10:15	31	22.8	193.0 H#	262.2 H	38 H	
	E0033014	BSLN	22FEB2005	8:30	-6	47.0	183.0 H#	138.1	20	7.6 #
		VISIT 6	28MAR2005	10:13	29	47.0	187.0 H#	208.1 H	30 H	
		VISIT 10	25APR2005	13:33	57	47.0	164.0 H#	168.7 H	24 H	7.9 #
PLACEBO (BIPOLAR II)	E0011015	BSLN	03DEC2004	12:35	-6	43.0	91.0	26.4	4	5.1
		VISIT 6	07JAN2005	11:35	30	43.0	128.0 H#	265.6 H	38 H	
	E0013011	BSLN	08NOV2004	17:17	-7	43.0	76.0	30.9	4	5.0
		VISIT 6	13DEC2004	15:00	29	43.0	133.0 H#	614.1 H	88 H	
		VISIT 10	10JAN2005	15:00	57	43.0	83.0	47.9	7	5.2
	E0026002	BSLN	29JUL2004	14:30	-11	34.6				6.9
		BSLN	04AUG2004	11:10	-5	34.6	149.0 H#	297.0 H	43 H	
		VISIT 6	09SEP2004	9:20	32	34.6	236.0 H#	186.0 H	27 H	
		VISIT 10	09SEP2004	9:20	32	34.6				8.0 #

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Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR I)	E0004016	BSLN	12OCT2004	11:10	-6	139	5.0	101.0	31.5	H#
	E0012025	BSLN	07JUN2005	15:00	-6	138	4.0	102.0	16.8	L#
	E0015019	BSLN	15APR2005	12:40	-20	144	3.9	107.0	17.9	#
		VISIT 10	05JUL2005	11:07	62	143	3.9	104.0	25.7	
	E0020002	BSLN	19JUL2004	8:50	-7	140	4.6	98.0	31.5	H#
		VISIT 10	23SEP2004	11:45	60	140	4.6	101.0	28.6	
	E0021008	BSLN	20SEP2004	13:40	-7	142	4.6	105.0	30.9	H#
		VISIT 10	22NOV2004	11:33	57	141	4.6	105.0	27.0	
	E0028012	BSLN	11FEB2005	9:15	-5	141	4.9	103.0	30.0	#
		VISIT 10	13APR2005	9:30	57	140	4.5	104.0	26.5	
	E0030009	BSLN	18AUG2004	10:55	-6	138	4.6	101.0	30.4	#
		VISIT 10	21OCT2004	12:00	59	140	3.7	102.0	27.2	
	E0030029	BSLN	24FEB2005	10:10	-7	141	5.5 H#	104.0	31.6	H#
	E0033004	BSLN	08SEP2004	18:15	-16	142	3.8	101.0	31.0	H#
		VISIT 10	19NOV2004	9:43	57	139	3.7	99.0	26.2	
	E0040017	BSLN	18MAY2005	14:45	-7	140	4.1	105.0	15.2	L#
		VISIT 10	22JUL2005	11:00	59	140	3.6	105.0	23.0	
	E0046008	BSLN	13JAN2005	18:20	-6	142	5.4	104.0	25.6	
		VISIT 10	14MAR2005	9:10	55	142	5.7 H#	107.0	22.5	
QUETIAPINE 300 MG (BIPOLAR II)	E0011021	BSLN	10FEB2005	11:01	-7	143	4.3	107.0	17.3	#
		VISIT 10	12APR2005	10:16	55	140	4.1	104.0	20.8	
	E0013014	BSLN	07FEB2005	12:10	-7	143	4.3	101.0	30.8	H#

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GENERATED: 17NOV2005 13:46:11 iceadmn3

Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 300 MG (BIPOLAR II)	E0013014	VISIT 10	11APR2005	9:00	57	142	4.5	103.0	26.6	
	E0014005	BSLN	16AUG2004	11:00	-14	144	5.2	104.0	31.5	H#
		VISIT 10	15SEP2004	9:35	17	142	4.4	99.0	28.7	
	E0014007	BSLN	15SEP2004	10:55	-7	140	5.7 H#	105.0	28.0	
	E0025018	BSLN	07SEP2004	14:00	-6	143	5.1	98.0	22.5	
		VISIT 10	08NOV2004	13:00	57	139	4.2	100.0	30.2	#
	E0036002	BSLN	11JAN2005	8:40	-1	139	4.2	102.0	25.6	
		VISIT 10	04FEB2005	10:00	24	138	4.5	99.0	30.9	H#
QUETIAPINE 600 MG (BIPOLAR I)	E0001009	BSLN	03DEC2004	14:10	-4	138	4.1	103.0	18.0	#
	E0004012	BSLN	13SEP2004	13:25	-7	143	3.0 L#	104.0	30.4	#
		VISIT 10	17NOV2004	10:00	59	145	3.7	107.0	28.6	
	E0014011	BSLN	09FEB2005	15:15	-8	143	5.6 H#	102.0	17.6	#
		VISIT 10	13APR2005	11:45	56	143	4.4	103.0	21.5	
		VISIT 10 *	20APR2005	14:30	63	144	4.7	105.0	25.3	
	E0015006	BSLN	28SEP2004	11:05	-6	145	5.5 H#	108.0	20.8	
		VISIT 10	25OCT2004	13:30	22	140	4.1	102.0	25.4	
	E0025024	BSLN	05OCT2004	15:00	-13	142	5.8 H#	98.0	27.1	
		VISIT 10	13DEC2004	10:45	57	146	4.6	108.0	23.6	
	E0027009	BSLN	23AUG2004	9:30	-3	140	3.8	101.0	23.0	
		VISIT 10	22OCT2004	11:30	58	140	4.1	102.0	30.6	#
	E0042021	BSLN	30MAR2005	13:35	-14	149H	5.6 H#	107.0	24.6	

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GENERATED: 17NOV2005 13:46:11 iceadmn3

Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
QUETIAPINE 600 MG (BIPOLAR II)	E0019005	BSLN	10NOV2004	11:50	-19	144	3.8	106.0	16.3	L#
		VISIT 10	24JAN2005	11:40	57	140	4.2	103.0	18.5	
	E0020021	BSLN	10NOV2004	7:55	-13	139	4.1	100.0	30.2	#
		VISIT 10	18JAN2005	14:15	57	144	4.6	103.0	28.4	
	E0025017	BSLN	02SEP2004	17:00	-12	141	4.5	98.0	18.7	
		VISIT 10	09NOV2004	14:25	57	147	4.4	104.0	16.3	L#
	E0025021	*	28SEP2004	16:30		141	4.4	102.0	15.9	L#
	E0030002	BSLN	15JUL2004	9:45	-6	143	5.6 H#	109.0	22.2	
	E0030024	BSLN	07DEC2004	13:22	-7	140	4.9	101.0	29.0	
		VISIT 10	25JAN2005	9:20	43	141	4.9	102.0	30.4	#
PLACEBO (BIPOLAR I)	E0004007	BSLN	27JUL2004	16:52	-7	142	4.1	102.0	30.2	#
		VISIT 10	29SEP2004	11:40	58	144	4.2	102.0	30.9	H#
	E0021004	BSLN	04AUG2004	16:05	-14	142	5.4	105.0	30.4	#
	E0025055	BSLN	18APR2005	14:45	-10	145	3.3 L	107.0	17.3	#
		VISIT 10	23JUN2005	14:00	57	139	3.8	105.0	22.8	
	E0026024	BSLN	31MAR2005	9:25	-11	139	4.9	102.0	24.0	
		VISIT 10	31MAY2005	9:20	51	140	4.4	104.0	18.0	#
	E0028006	BSLN	20JUL2004	15:40	-8	141	4.5	103.0	30.8	H#
		VISIT 10	22SEP2004	9:35	57	141	4.3	105.0	26.3	
	E0028014	BSLN	18FEB2005	12:15	-7	139	4.7	101.0	22.5	
		VISIT 10	21APR2005	10:20	56	141	6.2 H#	106.0	25.7	
	E0030021	BSLN	18NOV2004	10:15	-5	143	4.7	105.0	29.0	

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GENERATED: 17NOV2005 13:46:11 iceadmn3

Table 11.3.7.2.2.4 Chemistry Data for Electrolytes - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	SODIUM (MEQ/L)	POTASSIUM (MEQ/L)	CHLORIDE (MEQ/L)	BICARBONATE (MEQ/L)	
PLACEBO (BIPOLAR I)	E0030021	VISIT 10	19JAN2005	9:20	58	141	4.7	101.0	30.4	#
	E0030031	BSLN	01MAR2005	10:35	-7	145	5.5 H#	105.0	26.3	
		VISIT 10	03MAY2005	9:30	57	143	4.9	103.0	28.8	
	E0032006	BSLN	09FEB2005	13:00	-14	142	4.2	104.0	17.3	#
	E0033014	BSLN	22FEB2005	8:30	-6	137	4.8	99.0	30.6	#
		VISIT 10	25APR2005	13:33	57	141	4.5	100.0	26.6	
PLACEBO (BIPOLAR II)	E0014016	BSLN	09MAR2005	16:20	-8	141	5.1	104.0	24.8	
		VISIT 10	11MAY2005	11:15	56	138	4.3	102.0	30.3	#
	E0020019	BSLN	03NOV2004	8:05	-13	145	4.8	105.0	28.1	
		VISIT 10	11JAN2005	11:30	57	144	5.2	104.0	30.3	#
	E0020029	BSLN	15DEC2004	9:50	-6	144	4.9	103.0	25.8	
		VISIT 10	15FEB2005	9:45	57	144	5.5 H#	103.0	28.6	
	E0020035	BSLN	20JAN2005	12:36	-7	141	4.3	99.0	31.0	H#
		VISIT 10 *	01MAR2005	15:50	34	140	4.7	98.0	29.4	
		VISIT 10	24MAR2005	15:30	57	143	5.1	101.0	29.6	
	E0025008	BSLN	28JUL2004	17:30	-7	145	4.1	102.0	19.4	
		VISIT 10	28SEP2004	14:30	56	140	5.8 H#	99.0	20.6	
	E0028007	BSLN	26JUL2004	11:00	-7	139	4.9	102.0	30.0	#
		VISIT 10	27SEP2004	9:50	57	141	4.7	104.0	26.1	

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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM109.SAS
GENERATED: 17NOV2005 13:46:11 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0001005	BSLN		15SEP2004	16:32	-5	189		277	H#	41		198	H#
	E0003010	BSLN		09DEC2004	11:00	-7	211	#	325	H#	29	#	254	H#
		VISIT 10		11JAN2005	11:45	27	356	H#	284	H#	25	L#	188	H#
	E0003012	BSLN		15MAR2005	10:00	-24	115		247	#	73		151	
		VISIT 10		07JUN2005	9:20	61	112		226		70		134	
	E0007004	BSLN		08NOV2004	9:30	-7	237	H#	301	H#	56		198	H#
	E0008010	BSLN		24JAN2005	11:45	-7	68		141		39	#	88	
		VISIT 10		07FEB2005	13:10	8	68		125	L	34	L#	77	
	E0010002	BSLN		26JUL2004	15:30	-7	284	H#	193		37	#	99	
		VISIT 10		28SEP2004	10:30	58	239	H#	149		36	L#	65	L
	E0010017	BSLN		06MAY2005	11:30	-7	145		184		47		108	
		VISIT 10		10JUN2005	10:30	29	471	H#	224		61			
	E0011014		*	30NOV2004	11:20		97		242	#	74		149	
	E0012010	BSLN		01SEP2004	18:00	-7	135		174		45		102	
		VISIT 10		14SEP2004	16:00	7	103		182		39	#	122	
	E0012020	BSLN	*	22DEC2004	11:10	-19	73		197		73	H	109	
		BSLN		04JAN2005	11:30	-6	50	L	219		85	H	124	
		VISIT 10		08MAR2005	13:20	58	236	#	198		63		88	
	E0012025	BSLN		07JUN2005	15:00	-6	162	H	250	H#	44		174	H#
	E0013006	BSLN	*	22SEP2004	18:00	-14					53			
		BSLN		29SEP2004	16:40	-7	150		231		54		147	
		VISIT 10		11OCT2004	17:35	6	200	H#	244	H#	57		147	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	BSLN	02NOV2004	6:45	-6	151		205		33	#	142	
		VISIT 10	05JAN2005	15:35	59	113		202		39	#	140	
	E0014003	BSLN	23JUL2004	15:35	-14	177		225		36	#	154	H
		VISIT 10	28SEP2004	12:20	54	163		213		34	#	146	
	E0014010	BSLN	14DEC2004	14:45	-20	245	#	245	#	37	#	159	
		VISIT 10	09FEB2005	17:15	38	267	#	200		46		101	
	E0014018	BSLN	20APR2005	15:15	-6	152		167		27	L#	110	
		VISIT 10	22JUN2005	12:08	58	178		162		28	L#	98	
	E0015015	BSLN	15FEB2005	16:20	-8	190		207		43		126	
		VISIT 10	19APR2005	9:37	56	948	H#	273	#	33	#		
		VISIT 10 *	27APR2005	9:45	64	182		214		45			
		VISIT 10	27APR2005	9:45	64							133	
	E0015016	BSLN	16FEB2005	16:00	-8	77		227	H	38	#	174	H#
		VISIT 10	22APR2005	10:15	58	102		216		56		140	
	E0015022	BSLN	11MAY2005	12:20	-6	114		123	L	36	#	64	L
		VISIT 10	08JUL2005	14:20	53	75		134		57		62	L
	E0019015	BSLN	09JUN2005	11:00	-11	81		210		44		150	
		VISIT 10	27JUL2005	15:30	38	148		219		36	#	153	
	E0020002	BSLN	19JUL2004	8:50	-7	110		189		45		122	
		VISIT 10	23SEP2004	11:45	60	81		154		39	#	99	
	E0020013	BSLN	06OCT2004	8:20	-7	143		237		55		153	
		VISIT 10	08DEC2004	10:10	57	101		261	H#	62		179	H#
	E0021001	BSLN	09JUL2004	10:15	-12	109		231		44		165	#

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0021008	BSLN	20SEP2004	13:40	-7	402	H#	263	#	37	#		
		VISIT 10	22NOV2004	11:33	57	454	H#	232		30	#		
	E0021016	BSLN	04NOV2004	13:24	-6	214	#	241	H#	36	#	162	#
		VISIT 10	06JAN2005	8:10	58	153		204		37	#	136	
	E0021027	BSLN	28MAR2005	13:20	-9	106		193		40	#	132	
		VISIT 10	02JUN2005	14:05	58	96		211		46		146	
	E0021034	BSLN	17MAY2005	10:16	-14	131		156	L	35	#	95	
	E0024002	BSLN	09AUG2004	11:45	-10	95		208		39	#	150	
	E0024003	BSLN	12OCT2004	10:15	-7	271	H#	179		24	L#	101	
		VISIT 10	15DEC2004	9:43	58	460	H#	182		22	L#		
	E0025020	BSLN	10SEP2004	13:30	-6	235	#	202		37	#	118	
		VISIT 10	09NOV2004	13:00	55	671	H#	262	#	32	L#		
	E0025028	BSLN	11NOV2004	15:00	-12	277	H#	236		49		132	
	E0025059	BSLN	29APR2005	12:15	-6	901	H#	252	#				
		VISIT 10	01JUL2005	11:00	58	753	H#	198					
	E0026021	BSLN	03FEB2005	10:25	-6	147		245	#	59		157	
		VISIT 10	08APR2005	10:40	59	180		212		54		122	
	E0028012	BSLN	11FEB2005	9:15	-5	108		236		41		173	#
		VISIT 10	13APR2005	9:30	57	160		229		42		155	
	E0029006	BSLN	14OCT2004	11:30	-7	379	H#	248	#	34	#	138	
	E0029009	BSLN	17NOV2004	8:45	-7	122		252	#	33	L#	195	H#
		VISIT 10	21JAN2005	12:40	59	160		260	#	39	#	189	H#

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0030006	BSLN		11AUG2004	9:40	-19	149		185		49		106	
		VISIT 10		25OCT2004	10:10	57	345H	#	253	#	44		140	
	E0030038	BSLN		15JUN2005	10:05	-7	272	#	199		57		88	L
		VISIT 10		16AUG2005	10:20	56	198		210		57		113	
	E0032002	BSLN		30NOV2004	11:45	-8	509H	#	188		28	L#		
		VISIT 10		02FEB2005	10:15	57	1054H	#	359	H#	46			
		VISIT 10	*	09FEB2005	10:15	64	703H	#	248	#	29	L#		
		VISIT 10	*	16MAR2005	9:30	99	625H	#	166		27	L#		
	E0032008	BSLN	*	10FEB2005	16:10	-47	210	#	199		44		113	
		BSLN		22MAR2005	7:30	-7	120		205		53		128	
		VISIT 10		20APR2005	17:00	23	76		207		50		142	
	E0032009	BSLN		16FEB2005	16:40	-7	304	#	227		27	L#	139	
		VISIT 10		20APR2005	15:05	57	234	#	196		28	#	121	
	E0033001	BSLN		23JUN2004	11:42	-7	134		182		42		113	
		VISIT 10		23AUG2004	10:46	55	179		127	L	34	#	57	L
	E0033004	BSLN		08SEP2004	18:15	-16	282	#	191		39	#	96	
		VISIT 10		19NOV2004	9:43	57	223	#	162		30	#	87	
	E0033007	BSLN		17NOV2004	12:41	-7	164		250	#	39	#	178	#
		VISIT 10		21JAN2005	9:12	59	241	#	253	#	29	#	176	#
	E0033019	BSLN		17MAY2005	9:19	-7	132		292	H#	92		174	#
	E0034010	BSLN		19APR2005	10:05	-14	194		146	L	44		63	L
		VISIT 10		12MAY2005	9:05	10	245	#	163	L	44		70	L
	E0035034	BSLN		16JUN2005	10:00	-13	247H	#	164		36	#	79	
		VISIT 10		26AUG2005	9:50	59	258H	#	159		33	L#	74	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 300 MG (BIPOLAR I)	E0037028	BSLN	27APR2005	17:40	-12	78	206	79	111
		VISIT 10	05JUL2005	10:00	58	149	248 #	68	150
	E0037029	BSLN	26MAY2005	12:45	-11	76	181	37 #	129
		VISIT 10	02AUG2005	10:30	58	52	175	44	121
	E0039009	BSLN	30SEP2004	13:00	-7	58	125	40 #	73
	E0039010	BSLN	04OCT2004	12:00	-8	309 #	189	33 #	94
		VISIT 10	08DEC2004	9:00	58	312 #	192	31 #	99
	E0040001	BSLN	23JUL2004	15:30	-7	122	235	35 #	176 #
		VISIT 10	24SEP2004	14:30	57	178	293 H#	36 #	221 H#
	E0040002	BSLN	28JUL2004	14:10	-9	408H#	292 H#	49	
	E0040003	BSLN	06AUG2004	12:00	-6	86	187	57	113
		VISIT 10	08OCT2004	11:00	58	288H#	202	51	93
	E0040006	BSLN	19AUG2004	16:00	-8	150H	219 H	39 #	150
		VISIT 10	22OCT2004	13:30	57	220H#	174	35 L#	95
	E0040011	BSLN	23FEB2005	14:45	-7	452H#	265 H#	30 #	
		VISIT 10	27APR2005	12:00	57	265 #	231	28 L#	150
	E0040017	BSLN	18MAY2005	14:45	-7	107	199	38 #	140
		VISIT 10	22JUL2005	11:00	59	77	184	36 #	133
	E0040018	BSLN	20MAY2005	12:00	-19	145	183	37 #	117
		VISIT 10	03AUG2005	15:30	57	234 #	206	41	118
	E0041008	BSLN	02NOV2004	10:44	-15	102	150	37 #	93
	E0042013	BSLN	07DEC2004	14:40	-7	163	160	31 L#	96

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR I)	E0044005	BSLN	24FEB2005	17:00	-21	265	#	244	#	45		146	
		VISIT 10	13MAY2005	15:00	58	239	#	213		40	#	125	
	E0044006	BSLN	18APR2005	15:45	-7	184		208		41		130	
		VISIT 10	20JUN2005	16:19	57	175		205		38	#	132	
	E0046008	BSLN	13JAN2005	18:20	-6	264	#	176		44		79	
		VISIT 10	14MAR2005	9:10	55	105		173		39	#	113	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0004004	BSLN		14JUL2004	11:40	-7	204H#		194		33	L#	120	
		VISIT 10		15SEP2004	10:55	57	206H#		222		39	#	142	
	E0004021	BSLN		29DEC2004	9:45	-27	231H#		332	H#	45		241	H#
		VISIT 10		23MAR2005	10:55	58	271H#		304	H#	38	#	212	H#
	E0006016	BSLN		07OCT2004	10:55	-8	181		313	H#	47		230	H#
		VISIT 10		10DEC2004	8:15	57	176		300	H#				
	E0010004	BSLN		10AUG2004	16:10	-3	313H#		246	#	42		141	
	E0010007	BSLN		02NOV2004	13:45	-6	77		164	L	33	#	116	
		VISIT 10		03JAN2005	14:10	57	72		183		36	#	133	
	E0011001	BSLN		09JUL2004	13:00	-7	193H		232		33	L#	160	#
		VISIT 10		10SEP2004	11:14	57	246H#		237		32	L#	156	
	E0011016	BSLN	*	07DEC2004	12:40	-9	606H#		222	H	38	#		
		BSLN		13DEC2004	9:37	-3	604H#		253	H#	49			
		VISIT 10		11FEB2005	11:38	58	758H#		232	H				
	E0011021	BSLN		10FEB2005	11:01	-7	171		253	H#	47		172	#
		VISIT 10		12APR2005	10:16	55	149		227		45		152	
	E0013003	BSLN		02AUG2004	11:20	-7	139		226		43		155	
		VISIT 10		04OCT2004	13:05	57	419H#		261	#	42			
	E0013014	BSLN		07FEB2005	12:10	-7	266H#		183		35	#	95	
		VISIT 10		11APR2005	9:00	57	328H#		185		37	#	82	
	E0014005	BSLN		16AUG2004	11:00	-14	113		194		57		114	
		VISIT 10		15SEP2004	9:35	17	186		258	#	61		160	#
	E0014008	BSLN		10NOV2004	10:30	-7	85		165		39	#	109	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0019002	BSLN	17AUG2004	10:20	-21	174		193		45		113	
		VISIT 10	03NOV2004	11:00	58	153		242	#	42		169	#
	E0019009	BSLN	06JAN2005	10:30	-6	141		186		33	#	125	
		VISIT 10	09MAR2005	13:45	57	354H	#	179		27	L#	81	
	E0020028	BSLN	10DEC2004	10:35	-5	190		212		48		126	
		VISIT 10	10FEB2005	9:40	58	237H	#	208		53		108	
	E0021019	BSLN	14DEC2004	10:04	-16	153H		177		39	#	107	
		VISIT 10	24FEB2005	14:40	57	102		154		50		84	
	E0025018	BSLN	07SEP2004	14:00	-6	138		265	#	46		191	H#
		VISIT 10	08NOV2004	13:00	57	160		253	#	42		179	#
	E0025033	BSLN	13JAN2005	10:50	-8	232H	#	310	H#	40	#	224	H#
		VISIT 10	23MAR2005	13:50	62	262H	#	274	H#	35	#	187	H#
	E0025037	BSLN	26JAN2005	11:25	-8	142		253	#	56		169	#
	E0025042	BSLN	09FEB2005	11:45	-9	63		234		65		156	
		VISIT 10	15APR2005	11:25	57	54		236		57		168	#
	E0026004	BSLN	16AUG2004	16:40	-9	67		252	H#	64		175	H#
		VISIT 10	28OCT2004	11:20	65	67		226		52		161	#
	E0029002	BSLN	30JUL2004	7:30	-7	152		194		33	L#	131	
	E0030008	BSLN	16AUG2004	10:35	-3	92		206		39	#	149	
		VISIT 10	13OCT2004	9:45	56	92		202		37	#	147	
	E0030023	BSLN	02DEC2004	11:00	-7	182H		148		64		48	L
		VISIT 10	16DEC2004	11:00	8	369H	#	169		55		40	L

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 300 MG (BIPOLAR II)	E0031002	BSLN		20JUL2004	15:15	-7	162		263	H#	75		156	
		VISIT 10		10AUG2004	10:05	15	159		257	H#	72		153	
	E0034002	BSLN		25OCT2004	8:40	-8	182		233		48		149	
		VISIT 10		28DEC2004	8:15	57	161		263	#	51		180	#
	E0034004	BSLN		22NOV2004	11:20	-10	100		163		33	L#	110	
		VISIT 10		01FEB2005	10:00	62	101		163		41		102	
	E0035007	BSLN	*	09AUG2004	11:12	-10	249	H#	186		24	L#	112	
		BSLN		12AUG2004	10:00	-7	330	H#	201		26	L#	109	
		VISIT 10		13OCT2004	8:30	56	351	H#	209		26	L#	113	
	E0036002	BSLN		11JAN2005	8:40	-1	367	H#	268	H#	36	#	159	
		VISIT 10		04FEB2005	10:00	24	203	#	246	H#	30	L#	175	H#
	E0037007	BSLN		08OCT2004	11:20	-10	92		252	#	47		187	#
		VISIT 10		16DEC2004	13:20	60	74		221		51		155	
	E0037008	BSLN		06OCT2004	12:25	-6	148		225		46		149	
		VISIT 10		08DEC2004	13:15	58	305	#	224		38	#	125	
	E0037021	BSLN		14MAR2005	10:50	-8	187		255	#	50		168	#
		VISIT 10		07APR2005	10:45	17	145		233		50		154	
	E0037026	BSLN		17MAR2005	11:55	-8	307	#	238		29	#	148	
		VISIT 10		19MAY2005	11:15	56	326	#	234		32	#	137	
	E0042005	BSLN	*	10AUG2004	15:10	-23	448	H#	333	H#	37	#		
		BSLN		20AUG2004	9:10	-13	727	H#	293	H#	30	L#		
		VISIT 10		28OCT2004	16:25	57	1387	H#	458	H#				

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0001009	BSLN	03DEC2004	14:10	-4	85		276	#	48		211	H#
	E0001010	BSLN	26JAN2005	9:30	-19	141		259	#	67		164	#
		VISIT 10	14APR2005	13:00	60	243	#	276	#	66		161	#
	E0003011	BSLN	21DEC2004	15:15	-10	563	H#	267	#	48			
		VISIT 10	03MAR2005	10:00	63	492	H#	189		41			
	E0004009	BSLN	09AUG2004	10:02	-7	61		120	L	38	#	70	L
	E0006011	BSLN	13AUG2004	12:05	-7	479	H#	266	H#	56			
	E0006012	BSLN	16AUG2004	14:06	-7	57		124	L	38	#	75	
	E0006014	BSLN	01SEP2004	10:40	-6	98		143		38	#	85	
		VISIT 10	02NOV2004	8:15	57	71		123		42		67	
	E0006017	BSLN	11OCT2004	12:15	-4	122		224		41		159	
		VISIT 10	01NOV2004	8:10	18	177		273	#	44		194	#
	E0008012	BSLN	31JAN2005	13:10	-7	326	H#	249	#	41		143	
		VISIT 10	21FEB2005	11:20	15	346	H#	240	#	41		130	
	E0010016	BSLN	02MAY2005	14:00	-3	592	H#	237		40	#		
	E0011023	BSLN	02MAR2005	12:52	-6	153		213		56		126	
		VISIT 10	03MAY2005	10:32	57	558	H#	284	#	38	#		
	E0012004	BSLN	23JUL2004	15:00	-7	158		254	#	49		173	#
		VISIT 10	03SEP2004	11:00	36	84		145	L	33	#	95	
	E0013008	BSLN	27OCT2004	11:50	-15	326	H#	236		36	#	135	
		VISIT 10	03JAN2005	15:00	54	549	H#	251	#	44			
		VISIT 10 *	19JAN2005	15:00	70	223	H#	264	#	40	#		

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0013008	VISIT 10	19JAN2005	15:00	70							179	H#
	E0013012	BSLN	17JAN2005	10:00	-7	73		226		73		138	
		VISIT 10	21MAR2005	10:10	57	67		262	#	70		179	H#
	E0013013	BSLN	17JAN2005	16:00	-14	220	H#	176		91	H	41	L
	E0014011	BSLN	09FEB2005	15:15	-8	238	H#	327	H#	65		214	H#
		VISIT 10	13APR2005	11:45	56	196		320	H#	76		205	H#
	E0014023	BSLN	16JUN2005	14:00	-7	216	H#	275	H#	60		172	#
		VISIT 10	03AUG2005	15:15	42	121		272	H#	54		194	H#
	E0015005	BSLN	20SEP2004	12:40	-7	262	H#	256	#	29	L#	175	H#
		VISIT 10	11OCT2004	12:20	15	551	H#	239		30	L#		
	E0015006	BSLN	28SEP2004	11:05	-6	142		360	H#	59		273	H#
		VISIT 10	25OCT2004	13:30	22	149		331	H#	54		247	H#
	E0015011	BSLN	11JAN2005	10:00	-8	210	#	140		31	#	67	
	E0015020	BSLN	29APR2005	9:20	-6	106		187		41		125	
		VISIT 10	29JUN2005	9:13	56	134		194		36	#	131	
	E0020032	BSLN	04JAN2005	8:00	-6	399	H#	191		37	#	74	L
	E0020046	BSLN	20APR2005	15:05	-7	457	H#	255	#	37	#		
	E0020048	BSLN	09JUN2005	16:15	-5	386	H#	231		45		109	
		VISIT 10	09AUG2005	16:25	57	203	#	199		45		113	
	E0021003	BSLN *	26JUL2004	11:45	-10	269	H#	208		36	#	118	
		BSLN	02AUG2004	9:25	-3	142		216		41		147	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0021005	BSLN		16AUG2004	11:15	-3	198		194		35	#	119	
	E0021029	BSLN		30MAR2005	17:50	-7	203	#	260	H#	58		161	#
		VISIT 10		03JUN2005	13:15	59	248	#	265	H#	47		168	H#
	E0021033	BSLN		25APR2005	12:25	-8	70		231		39	#	178	#
		VISIT 10		29JUN2005	13:42	58	108		236		36	#	178	#
	E0022001	BSLN		22JUL2004	13:30	-19	199		144	L	29	#	75	L
		VISIT 10		07OCT2004	13:00	59	179		161	L	36	#	89	
	E0022002	BSLN		16AUG2004	12:45	-11	376H	#	238		58		105	
		VISIT 10		22OCT2004	12:00	57	257H	#	199		64		84	
	E0025024	BSLN		05OCT2004	15:00	-13	203	#	150	L	32	#	77	L
		VISIT 10		13DEC2004	10:45	57	160		184		33	#	119	
	E0025040	BSLN		03FEB2005	17:05	-6	684H	#	230	H	34	#		
		VISIT 10		07APR2005	14:00	58	172H		189		38	#	117	
	E0025056	BSLN	*	26APR2005	16:30	-16	102		255	#	60		175	#
		BSLN		02MAY2005	14:35	-10	115		235		44		168	#
		VISIT 10		07JUN2005	13:05	27	139		239		48		163	#
	E0025057	BSLN		26APR2005	17:00	-6	206	#	177		53		83	
		VISIT 10		27JUN2005	12:20	57	316	#	153		34	#	56	L
	E0027001	BSLN		09JUL2004	11:00	-21	122		284	H#	68		192	H#
		VISIT 10		06AUG2004	10:00	8	164		314	H#	82		199	H#
	E0027008	BSLN		02AUG2004	9:00	-4	262	#	277	#	47		178	#
		VISIT 10		01OCT2004	9:00	57	554H	#	206		37	#		
	E0027016	BSLN		20OCT2004	14:00	-16	188H		206		41		127	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0027016	VISIT 10	21DEC2004	9:35	47	175H		211		36	#	140	
	E0028001	BSLN	08JUL2004	11:20	-7	123		212		42		145	
		VISIT 10	08SEP2004	9:40	56	90		235	H	40	#	177	H#
	E0028004	BSLN	14JUL2004	16:15	-5	136		251	H#	53		171	H#
	E0028008	BSLN	05NOV2004	12:15	-5	222H#		264	H#	38	#	182	H#
		VISIT 10	05JAN2005	9:10	57	265H#		201		42		106	
	E0028009	BSLN	18NOV2004	15:30	-11	148H		113	L	31	L#	52	L
		VISIT 10	24JAN2005	11:35	57	59		128		39	#	77	
	E0028017	BSLN	09MAY2005	14:20	-7	122		182		39	#	119	
	E0030005	BSLN	09AUG2004	13:00	-10	159		248	#	37	#	179	#
		VISIT 10	26AUG2004	12:45	8	257H#		247	#	40	#	156	
	E0030016	BSLN	27OCT2004	10:40	-7	206 #		259	#	30	#	188	#
		VISIT 10	10NOV2004	10:00	8	138		263	#	41		194	#
	E0030018	BSLN	09NOV2004	14:15	-8	139		213		46		139	
		VISIT 10	30DEC2004	11:15	44	113		271	#	51		197	H#
	E0030036	BSLN	26MAY2005	10:20	-7	121		131	L	30	#	77	L
	E0032010	BSLN	01MAR2005	15:30	-7	203 #		258	#	40	#	177	#
		VISIT 10	24MAR2005	12:45	17	211 #		235		39	#	154	
	E0032014	BSLN	16JUN2005	15:45	-6	96		152		36	#	97	
		VISIT 10	17AUG2005	17:15	57	172		160		40	#	86	
	E0034001	BSLN	03SEP2004	11:20	-13	300H#		193		32	L#	101	
		VISIT 10	11NOV2004	9:00	57	441H#		175		26	L#		

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0034005	BSLN	29NOV2004	9:40	-14	472H#		294	H#	34	#		
		VISIT 10	21JAN2005	12:10	40	502H#		253	#	34	#		
	E0034009	BSLN	22FEB2005	11:45	-8	238H#		227		47		132	
		VISIT 10	27APR2005	8:50	57	205 #		235		50		144	
	E0037030	BSLN	10JUN2005	12:00	-10	57		159	L	54		94	
		VISIT 10	19JUL2005	12:55	30	64		131	L	39	#	79	L
	E0038004	BSLN	03NOV2004	9:20	-8	219 #		161		35	#	82	
		VISIT 10	07JAN2005	12:38	58	92		166		36	#	112	
	E0039002	BSLN	10AUG2004	11:30	-21	101		256	#	62		174	#
		VISIT 10	28OCT2004	9:30	59	123		186		48		113	
	E0039007	BSLN	17SEP2004	9:35	-13	65		155		39	#	103	
		VISIT 10	01DEC2004	9:00	63	97		154		38	#	97	
	E0039013	BSLN	23NOV2004	10:00	-23	185		315	H#	47		231	H#
	E0040019	BSLN	01JUN2005	17:15	-6	269H#		223	H	55		114	
		VISIT 10	04AUG2005	17:45	59	155H		242	H#	66		145	
	E0042003	BSLN	05AUG2004	13:07	-7	81		245	H#	48		181	H#
	E0042008	BSLN	26AUG2004	10:32	-7	235H#		173		36	#	90	
		VISIT 10	28OCT2004	9:05	57	129		206		52		128	
	E0042009	BSLN	21SEP2004	12:25	-7	379H#		365	H#	45		244	H#
		VISIT 10	22NOV2004	12:16	56	276H#		311	H#	49		207	H#
	E0042010	BSLN	07OCT2004	11:35	-13	82		190		56		118	
		VISIT 10	16DEC2004	12:35	58	133		173		40	#	106	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR I)	E0042020	BSLN	28MAR2005	10:30	-14	83		209		53		139	
		VISIT 10	18APR2005	12:00	8	119		318	H#	71		223	H#
	E0044001	BSLN	14OCT2004	10:15	-26	380	H#	327	H#	66		185	H#
		VISIT 10	06JAN2005	10:00	59	83		264	H#	60		187	H#
	E0044002	BSLN	26OCT2004	12:55	-23	101		150	L	35	#	95	
		VISIT 10	13JAN2005	15:15	57	74		176		46		115	
	E0045003	BSLN	10FEB2005	9:15	-15	92		245	H#	46		181	H#
		VISIT 10	14MAR2005	8:45	18	140		272	H#	46		198	H#
	E0046012	BSLN	08FEB2005	11:50	-7	123		275	#	54		196	#
		VISIT 10	16MAR2005	15:30	30	186		177		39	#	101	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0004014	BSLN	05OCT2004	17:00	-7	111	166	35 #	109
		VISIT 10	20OCT2004	10:45	9	118	199	32 #	143
	E0011006	BSLN	21SEP2004	14:40	-9	144	163	46	88
		VISIT 10	07OCT2004	14:10	8	140	137 L	38 #	71 L
	E0011013	BSLN	19NOV2004	10:00	-10	97	223	54	150
		VISIT 10	06DEC2004	9:55	8	188H	260 H#	49	173 H#
	E0012002	BSLN	21JUL2004	13:00	-27	246H#	203	41	113
		VISIT 10	11OCT2004	9:50	56	226H#	200	33 L#	122
	E0014009	BSLN	19NOV2004	9:12	-20	73	125 L	33 #	77
		VISIT 10	27DEC2004	10:55	19	109	147	38 #	87
	E0019005	BSLN	10NOV2004	11:50	-19	261H#	265 #	58	155
		VISIT 10	24JAN2005	11:40	57	413H#	241 #	45	
	E0020021	BSLN	10NOV2004	7:55	-13	130	210	47	137
		VISIT 10	18JAN2005	14:15	57	227 #	236	50	141
	E0020040	BSLN	11FEB2005	11:30	-7	199	273 H#	37 #	196 H#
		VISIT 10	14APR2005	14:10	56	283 #	237	30 #	150
	E0025003	BSLN	19JUL2004	14:55	-8	283 #	216	49	110
	E0025012	BSLN	17AUG2004	16:00	-6	220 #	203	59	100
		VISIT 10	05OCT2004	12:00	44	117	208	72	113
	E0025017	BSLN	02SEP2004	17:00	-12	213 #	220	34 #	143
		VISIT 10	09NOV2004	14:25	57	181	201	40 #	125
	E0025021	*	28SEP2004	16:30		261H#	268 H#	43	173 H#

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
QUETIAPINE 600 MG (BIPOLAR II)	E0025030	BSLN	15DEC2004	16:15	-6	213 #	224	51	130
		VISIT 10	15FEB2005	17:30	57	184	188	50	101
	E0025045	BSLN	18FEB2005	15:00	-10	109	180	35 L#	123
		VISIT 10	15MAR2005	16:35	16	257H#	189	39 #	99
	E0026009	BSLN	18OCT2004	12:13	-2	175	201	45	121
		VISIT 10	17DEC2004	10:05	59	246 #	204	60	95
	E0030002	BSLN	15JUL2004	9:45	-6	165	223	40 #	150
	E0030024	BSLN	07DEC2004	13:22	-7	92	149 L	39 #	92
		VISIT 10	25JAN2005	9:20	43	66	147 L	43	91
	E0035009	BSLN	13AUG2004	8:30	-7	365H#	167	25 L#	69
	E0036005	BSLN	08FEB2005	10:35	-7	138	128 L	30 #	70 L
		VISIT 10	12APR2005	13:40	57	135	134 L	30 #	77 L
	E0036007	BSLN	14MAR2005	9:30	-4	202 #	258 #	30 #	188 #
		VISIT 10	29MAR2005	9:00	12	291 #	214	25 L#	131
	E0037001	BSLN	30AUG2004	9:45	-3	124	136 L	37 #	74 L
		VISIT 10	16SEP2004	12:05	15	185	152	43	72 L
	E0037006	BSLN	04OCT2004	13:50	-7	103	175	39 #	115
		VISIT 10	13DEC2004	12:25	64	177	194	46	113
	E0037015	BSLN	08DEC2004	15:40	-6	37L	118 L	34 #	77
		VISIT 10	08FEB2005	14:20	57	38L	141	39 #	94
	E0037022	BSLN	15MAR2005	12:30	-7	52L	240 #	63	167 #
		VISIT 10	18MAY2005	12:15	58	127	232	56	151
		VISIT 10 *	15JUN2005	13:50	86	104	247 #	56	170 #

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
QUETIAPINE 600 MG (BIPOLAR II)	E0038002	BSLN		01JUL2004	14:30	-8	180		201		38	#	127	
		VISIT 10		02SEP2004	10:30	56	139		163		34	L#	101	
	E0043003	BSLN		30NOV2004	11:30	-3	581H#		252	#	30	#		
		VISIT 10		27JAN2005	9:40	56	463H#		246	#	27	L#		
	E0046001	BSLN		04NOV2004	17:48	-6	119		256	H#	46		186	H#
		VISIT 10		05JAN2005	10:40	57	118		191		30	L#	137	
	E0046007	BSLN	*	22DEC2004	8:35	-13	135		238		60		151	
		BSLN		28DEC2004	8:13	-7	97		250	#	57		174	#
		VISIT 10		28FEB2005	8:05	56	221H#		289	H#	57		188	H#
	E0046011	BSLN		02FEB2005	11:55	-7	233H#		237		54		136	
		VISIT 10		06APR2005	11:25	57	221H#		204		47		113	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0001013	BSLN	28APR2005	12:30	-7	270H#	304 H#	44	206 #
		VISIT 10	02JUN2005	11:00	29	160	296 H#	43	221 H#
	E0003008	BSLN	27OCT2004	8:15	-13	83	221	63	141
		VISIT 10	01DEC2004	18:45	23	70	243 #	71	158
	E0004005	BSLN	19JUL2004	13:15	-7	158	163	30 L#	101
		VISIT 10	21SEP2004	8:25	58	120	169	37 #	108
	E0004007	BSLN	27JUL2004	16:52	-7	155	203	40 #	132
		VISIT 10	29SEP2004	11:40	58	163	210	43	134
	E0004008	BSLN	04AUG2004	11:00	-7	122	169	31 L#	114
		VISIT 10	06OCT2004	11:50	57	85	179	35 L#	127
	E0004018	BSLN	13DEC2004	9:15	-7	144	250 #	36 #	185 #
		VISIT 10	14FEB2005	10:40	57	202 #	289 H#	42	207 H#
	E0006003	BSLN	02AUG2004	10:45	-7	187	236	46	153
		VISIT 10	16AUG2004	8:20	8	191	199	39 #	122
	E0006019	BSLN	18NOV2004	7:45	-6	213 #	172	38 #	91
		VISIT 10	19JAN2005	11:35	57	395H#	197	30 L#	88
	E0006021	BSLN	31MAR2005	12:45	-7	914H#	280 #	29 #	
		VISIT 10	25MAY2005	14:15	49	1529H#	274 #		
	E0008008	BSLN	17JAN2005	9:35	-7	287H#	202	30 L#	115
		VISIT 10	14FEB2005	9:45	22	356H#	197	30 L#	96
	E0011011	BSLN	10NOV2004	11:30	-7	249H#	221	45	126
	E0012026	BSLN	08JUN2005	11:35	-7	187H	200	39 #	124
		VISIT 10	10AUG2005	10:10	57	233H#	215	40 #	128

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0013004	BSLN	24AUG2004	10:00	-6	263H#	193	33 #	107
		VISIT 10	27OCT2004	19:05	59	389H#	219 H	30 L#	111
	E0013015	BSLN	09MAY2005	13:10	-7	74	146	37 #	94
		VISIT 10	29JUN2005	16:00	45	136	163	33 #	103
	E0014020	BSLN	27APR2005	14:25	-6	107	167	37 #	109
	E0014021	BSLN	28APR2005	14:20	-6	65	231	53	165 #
		VISIT 10	30JUN2005	12:35	58	93	229	54	156
		VISIT 10 *	07JUL2005	12:32	65	95	230	50	161 #
	E0015007	BSLN	12OCT2004	15:05	-6	102	208	41	147
		VISIT 10	13DEC2004	11:45	57	139	207	39 #	140
	E0015018	BSLN	08MAR2005	14:35	-7	205 #	264 #	65 H	158
		VISIT 10	13MAY2005	9:15	60	137	260 #	66 H	167 #
	E0020008	BSLN	02SEP2004	9:45	-11	257 #	194	30 #	113
		VISIT 10	10NOV2004	16:00	59	175	202	29 #	138
	E0020024	BSLN	23NOV2004	8:00	-8	78	207	39 #	152
		VISIT 10	26JAN2005	10:00	57	78	227	42	169 H#
	E0020036	BSLN	28JAN2005	11:50	-10	109	212	42	148
		VISIT 10	06APR2005	11:30	59	78	184	36 #	132
	E0020043	BSLN	07APR2005	13:00	-14	200H#	249 H#	31 L#	178 H#
	E0020045	BSLN	18APR2005	10:45	-9	251H#	266 H#	57	159
		VISIT 10	01JUN2005	11:40	36	379H#	203	42	85
	E0021007	BSLN	10SEP2004	15:05	-7	412H#	209	33 L#	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0021030	BSLN	05APR2005	13:30	-8	146	169	36 #	104
		VISIT 10	08JUN2005	10:10	57	229 #	204	36 #	122
	E0022009	BSLN	04APR2005	11:30	-16	229 #	314 H#	54	214 H#
		VISIT 10	15JUN2005	11:00	57	177	295 H#	46	214 H#
	E0024001	BSLN	26JUL2004	13:35	-7	136	174	29 #	118
		VISIT 10	28SEP2004	12:38	58	134	185	36 #	122
	E0024004	BSLN	09NOV2004	12:00	-7	296H#	281 H#	41	181 #
		VISIT 10	10JAN2005	8:08	56	192	246 #	53	155
	E0025007	BSLN	27JUL2004	14:00	-22	404H#	168 L	33 #	
		VISIT 10	26AUG2004	11:00	9	148	152 L	32 #	90
		VISIT 10 *	15SEP2004	14:00	29	305H#	157 L	31 #	65 L
	E0025023	BSLN	05OCT2004	15:00	-7	232H#	158	31 L#	81
		VISIT 10	07DEC2004	11:00	57	105	178	42	115
	E0025055	BSLN	18APR2005	14:45	-10	97	118 L	44	55 L
		VISIT 10	23JUN2005	14:00	57	65	96 L	36 #	47 L
	E0026014	BSLN	01NOV2004	9:55	-3	97	205	56	130
		VISIT 10	28DEC2004	9:45	55	68	270 #	62	194 #
	E0026015	BSLN	02NOV2004	10:30	-14	119	183	42	117
		VISIT 10	13JAN2005	7:34	59	131	164	38 #	100
	E0027021	BSLN	23MAY2005	12:00	-8	137	180	44	109
		VISIT 10	27JUL2005	15:02	58	281 #	179	34 #	89
	E0027022	BSLN	21JUN2005	12:20	-7	292H#	303 H#	47	198 H#
		VISIT 10	22AUG2005	9:30	56	328H#	264 H#	35 #	163 #

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0028014	BSLN	18FEB2005	12:15	-7	320H#	309 H#	50	195 H#
		VISIT 10	21APR2005	10:20	56	273H#	258 #	55	148
	E0029004	BSLN	15SEP2004	15:50	-6	136	155	50	78
		VISIT 10	14OCT2004	9:00	24	286 #	173	44	72 L
	E0029011	BSLN	08FEB2005	8:11	-3	88	149	41	90
		VISIT 10	08APR2005	16:00	57	201 #	176	42	94
	E0030011	BSLN	25AUG2004	12:20	-5	55	118 L	35 L#	72
		VISIT 10	25OCT2004	11:00	57	47	116 L	34 L#	73
	E0030020	BSLN	17NOV2004	10:30	-7	334H#	324 H#	47	210 H#
		VISIT 10	19JAN2005	8:20	57	189	265 #	54	173 #
	E0030021	BSLN	18NOV2004	10:15	-5	148	234	38 #	166 #
		VISIT 10	19JAN2005	9:20	58	138	216	35 #	153
	E0030031	BSLN	01MAR2005	10:35	-7	243 #	209	41	119
		VISIT 10	03MAY2005	9:30	57	114	216	44	149
	E0032003	BSLN	29DEC2004	12:20	-7	166	181 L	40 #	108
		VISIT 10	01MAR2005	13:30	56	121	161 L	43	94 L
	E0033011	BSLN	11JAN2005	9:19	-7	112	239	43	174 #
		VISIT 10	14MAR2005	10:19	56	150	209	42	137
	E0033013	BSLN	21JAN2005	8:12	-10	134	275 H#	55	193 H#
		VISIT 10	01MAR2005	17:23	30	320H#	242 #	42	136
	E0033014	BSLN	22FEB2005	8:30	-6	373H#	204	26 L#	103
		VISIT 10	25APR2005	13:33	57	367H#	210	26 L#	111
	E0033016	BSLN	14MAR2005	12:57	-14	205H#	131	27 L#	63

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)		DIRECT HDL (MG/DL)		LDL (MG/DL)	
PLACEBO (BIPOLAR I)	E0033016	VISIT 10		24MAY2005	10:45	58	115		146		31	L#	92	
	E0034013	BSLN		27MAY2005	9:45	-7	283	#	262	#	41		164	#
		VISIT 10		01AUG2005	9:30	60	191		189		42		109	
	E0037011	BSLN		26OCT2004	11:30	-7	50		211		55		146	
		VISIT 10		12JAN2005	14:20	72	56		231		57		163	#
	E0039014	BSLN		23NOV2004	14:00	-14	265H	#	207		28	L#	126	
		VISIT 10		03JAN2005	10:00	28	187H		200		31	L#	132	
	E0039015	BSLN		30NOV2004	15:15	-13	60		265	H#	67		186	H#
		VISIT 10		07FEB2005	11:30	57	66		209		50		146	
	E0040009	BSLN		21JAN2005	14:00	-5	131		196		35	#	135	
		VISIT 10		23MAR2005	13:00	57	125		209		42		142	
	E0040013	BSLN		25MAR2005	15:00	-7	175		282	H#	45		202	H#
		VISIT 10		27MAY2005	14:00	57	132		256	#	46		184	#
	E0041004	BSLN		30AUG2004	11:04	-23	130		187		34	#	127	
		VISIT 10		17NOV2004	8:58	57	86		168		36	#	115	
	E0041007	BSLN		28OCT2004	12:22	-22	142		172		33	#	111	
	E0041015	BSLN		24MAR2005	15:27	-8	103		307	H#	81	H	205	H#
		VISIT 10		06MAY2005	16:02	36	160		263	#	63		168	#
	E0042024	BSLN		15JUN2005	16:15	-7	180		230		38	#	156	
		VISIT 10		18AUG2005	11:35	58	198		219		40	#	139	
	E0046006	BSLN	*	22DEC2004	7:50	-21	108		200		46		132	
		BSLN		06JAN2005	11:05	-6	113		184		40	#	121	
		VISIT 10		09MAR2005	11:00	57	135		187		39	#	121	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)		TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)		LDL (MG/DL)
PLACEBO (BIPOLAR I)	E0046016	BSLN	12MAY2005	6:20	-6	207	#	232	53		138
		VISIT 10	12JUL2005	10:35	56	160		203	43		128
	E0046019	BSLN	06JUN2005	7:25	-3	112		192	40	#	130
		VISIT 10	01AUG2005	16:45	54	171		209	38	#	137

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR II)	E0001007	BSLN	27OCT2004	15:00	-7	253 #	236	44	141
		VISIT 10	04JAN2005	12:00	63	233 #	224	42	135
	E0001008	BSLN	22NOV2004	11:00	-11	129	254 #	64	164 #
	E0004013	BSLN	28SEP2004	11:55	-9	54	298 H#	130 H	157
		VISIT 10	11NOV2004	11:30	36	47L	279 #	147 H	123
	E0004028	BSLN	16FEB2005	9:15	-6	101	227	62	145
		VISIT 10	20APR2005	14:00	58	73	256 #	63	178 #
	E0006013	BSLN	31AUG2004	11:25	-7	78	296 H#	63 H	217 H#
	E0008005	BSLN	11OCT2004	10:30	-8	328H#	235	34 #	135
	E0010003	BSLN	09AUG2004	9:30	-3	95	170	52	99
		VISIT 10	19AUG2004	17:25	8	331H#	191	44	81 L
	E0010012	BSLN	01FEB2005	9:30	-3	60	167	43	112
		VISIT 10	01APR2005	10:00	57	65	167	38 #	116
	E0011002	BSLN	15JUL2004	12:25	-12	85	189	37 #	135
		VISIT 10	23SEP2004	12:40	59	90	173	39 #	116
	E0011015	BSLN	03DEC2004	12:35	-6	123	214	34 #	155
	E0011019	BSLN	12JAN2005	10:00	-7	64	296 H#	41	242 H#
		VISIT 10	16MAR2005	8:30	57	62	256 H#	38 #	206 H#
	E0012008	BSLN	18AUG2004	10:00	-7	149	224	66	128
		VISIT 10	19OCT2004	10:30	56	141	261 #	84	149
	E0013007	BSLN	20OCT2004	13:50	-8	310 #	216	33 #	121

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR II)	E0014016	BSLN	09MAR2005	16:20	-8	143	194	41	124
		VISIT 10	11MAY2005	11:15	56	258H#	166	31 #	83
	E0020012	BSLN	05OCT2004	11:50	-6	108	188	40 #	126
	E0020019	BSLN	03NOV2004	8:05	-13	347H#	282 H#	53	160 #
		VISIT 10	11JAN2005	11:30	57	280H#	264 #	54	154
	E0020026	BSLN	10DEC2004	8:22	-6	142	234	56	150
		VISIT 10	10FEB2005	8:35	57	197	242 #	51	152
	E0020029	BSLN	15DEC2004	9:50	-6	81	277 #	122 H	139
		VISIT 10	15FEB2005	9:45	57	49L	269 #	128 H	131
	E0020030	BSLN	16DEC2004	16:00	-19	167	297 H#	50	214 H#
		VISIT 10	01MAR2005	13:15	57	245 #	288 #	46	193 #
	E0020034	BSLN	10JAN2005	12:10	-7	327H#	230 H	46	119
		VISIT 10	14MAR2005	10:00	57	232H#	204	41	117
	E0020035	BSLN	20JAN2005	12:36	-7	221 #	186	36 #	106
		VISIT 10 *	01MAR2005	15:50	34	135	206	47	132
		VISIT 10	24MAR2005	15:30	57	147	186	42	115
	E0020039	BSLN	07FEB2005	15:50	-7	193H	205	36 L#	130
	E0025001	BSLN	13JUL2004	12:00	-6	86	310 H#	79 H	214 H#
		VISIT 10	22SEP2004	12:00	66	107	275 H#	89 H	165 #
	E0025008	BSLN	28JUL2004	17:30	-7	164H	161	43	85
		VISIT 10	28SEP2004	14:30	56	108	137	40 #	75
	E0025041	BSLN	08FEB2005	12:00	-6	162	246 #	58	156

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)	LDL (MG/DL)
PLACEBO (BIPOLAR II)	E0025049	BSLN	01MAR2005	16:15	-7	158	234	63	139
		VISIT 10	04APR2005	10:10	28	101	240 #	63	157
	E0026002	BSLN	04AUG2004	11:10	-5	243 #	235	42	144
		VISIT 10	09SEP2004	9:20	32	332H#	281 H#	37 #	178 #
	E0026007	BSLN	20SEP2004	8:15	-7	320 #	201	43	94 L
		VISIT 10	17NOV2004	7:45	52	323 #	205	47	93 L
	E0026013	BSLN	26OCT2004	11:00	-6	106	186	45	120
		VISIT 10	27DEC2004	8:30	57	281 #	226	41	129
	E0026016	BSLN	01NOV2004	7:45	-4	201H#	199	35 L#	124
		VISIT 10	29DEC2004	9:25	55	94	177	40 #	118
	E0027015	BSLN	23SEP2004	11:20	-20	267H#	261 H#	48	160 H#
		VISIT 10	08DEC2004	15:00	57	316H#	175	31 L#	81
	E0028007	BSLN	26JUL2004	11:00	-7	349H#	210	28 #	112
		VISIT 10	27SEP2004	9:50	57	186	171	26 L#	108
	E0030014	BSLN	16SEP2004	11:10	-7	345H#	215	39 #	107
		VISIT 10	18NOV2004	11:00	57	256 #	198	34 #	113
		VISIT 10 *	07DEC2004	10:45	76	227 #	166	34 #	87
	E0030022	BSLN	29NOV2004	11:20	-9	99	213	48	145
		VISIT 10	01FEB2005	9:00	56	143	207	40 #	138
	E0037025	BSLN	11MAR2005	11:50	-17	89	280 #	108 H	154
		VISIT 10	24MAY2005	16:35	58	174	274 #	97 H	142
	E0041013	BSLN	28DEC2004	15:09	-8	57	162	42	109
		VISIT 10	02MAR2005	10:05	57	38	139	39 #	92

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM110.SAS
GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.5 Chemistry Data for Lipids - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TRIGLY-CERIDE (MG/DL)	TOTAL CHOLESTEROL (MG/DL)	DIRECT HDL (MG/DL)		LDL (MG/DL)
PLACEBO (BIPOLAR II)	E0042007	BSLN	25AUG2004	12:05	-36	82	127	37	#	74
		VISIT 10	22NOV2004	11:00	54	85	137	33	#	87

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

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GENERATED: 17NOV2005 13:46:14 iceadmn3

Table 11.3.7.2.2.6 Chemistry Data for Thyroid Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)		FREE (T4) (PMOL/L)		T3-UPTAKE (%)	
QUETIAPINE 300 MG (BIPOLAR I)	E0020044	BSLN		13APR2005	12:45	-7	2.09		10.30		33	
		VISIT 10		15JUN2005	8:30	57	6.31H#		6.44	L#	32	
		VISIT 10	*	12JUL2005	9:30	84	2.32		11.58		30	
	E0021022	BSLN		18JAN2005	15:31	-9	0.39		16.73		34	
		VISIT 10		22MAR2005	9:10	55	11.53H#		6.44	L#	33	
	E0032009	BSLN		16FEB2005	16:40	-7	5.11H#		10.30		34	
		VISIT 10		20APR2005	15:05	57	4.02		9.01		36	
	E0039010	BSLN	*	04OCT2004	12:00	-8	6.30H#		9.01		36	
		BSLN		07OCT2004	8:30	-5	5.49H#		12.87		38	
		VISIT 10	*	10NOV2004	10:00	30	7.93H#		11.58		39	
		VISIT 10		08DEC2004	9:00	58	0.61		12.87		38	
QUETIAPINE 300 MG (BIPOLAR II)	E0011017	BSLN		16DEC2004	10:10	-12	0.06L		10.30		32	
		VISIT 10		22FEB2005	9:45	57	8.08H#		9.01		31	
QUETIAPINE 600 MG (BIPOLAR I)	E0001010	BSLN	*	26JAN2005	9:30	-19	5.69H#		12.87		29	
		BSLN		01FEB2005	9:30	-13	4.18		11.58		26	L
		VISIT 10		14APR2005	13:00	60	2.99		7.72	L	25	L
	E0027003	BSLN	*	21JUL2004	9:00	-19	6.42H#		12.87		37	
		BSLN		26JUL2004	10:00	-14	3.98		12.87		40	
		VISIT 10		04OCT2004	9:30	57	9.02H#		10.30		38	
	E0028008	BSLN		05NOV2004	12:15	-5	1.36		11.58		30	
		VISIT 10		05JAN2005	9:10	57	5.43H#		7.72	L	30	
	E0039002	BSLN		10AUG2004	11:30	-21	0.43		10.30		32	
		VISIT 10	*	20OCT2004	12:00	51	0.30L		7.72	L	34	
		VISIT 10		28OCT2004	9:30	59	1.86		6.44	L#	36	

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM111.SAS
GENERATED: 17NOV2005 13:46:17 iceadmn3

Table 11.3.7.2.2.6 Chemistry Data for Thyroid Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	TIME	DAY	TSH (MIU/L)	FREE (T4) (PMOL/L)	T3-UPTAKE (%)	
QUETIAPINE 600 MG (BIPOLAR I)	E0042008	BSLN		26AUG2004	10:32	-7	1.58	11.58	26	L
		VISIT 10		28OCT2004	9:05	57	2.35	6.44 L#	29	
	E0042023	BSLN		27APR2005	14:45	-19	3.74	12.87	31	
		VISIT 10		13JUL2005	9:10	59	20.92H#	7.72 L	35	
		VISIT 10	*	20JUL2005	10:40	66	22.95H#	10.30	32	
	E0044001	BSLN	*	14OCT2004	10:15	-26	6.71H#	9.01	30	
		BSLN		03NOV2004	14:00	-6	2.33	14.16	30	
		VISIT 10		06JAN2005	10:00	59	2.64	11.58	33	
	E0046012	BSLN		08FEB2005	11:50	-7	2.51	11.58	41	
		VISIT 10		16MAR2005	15:30	30	6.01H#	11.58	40	
QUETIAPINE 600 MG (BIPOLAR II)	E0019005	BSLN		10NOV2004	11:50	-19	1.46	9.01	31	
		VISIT 10		24JAN2005	11:40	57	0.93	5.15 L#	38	
	E0042014	BSLN	*	15DEC2004	12:32	-14	6.06H#	10.30	30	
		BSLN		22DEC2004	9:25	-7	4.93	10.30	32	
		VISIT 10		21FEB2005	10:25	55	5.77H#	9.01	34	
PLACEBO (BIPOLAR I)	E0006019	BSLN		18NOV2004	7:45	-6	3.82	11.58	37	
		VISIT 10		19JAN2005	11:35	57	7.23H#	10.30	38	
	E0030031	BSLN		01MAR2005	10:35	-7	4.10	11.58	32	
		VISIT 10		03MAY2005	9:30	57	5.48H#	9.01	31	
PLACEBO (BIPOLAR II)	E0020019	BSLN		03NOV2004	8:05	-13	3.85	7.72 L	29	
		VISIT 10		11JAN2005	11:30	57	6.30H#	11.58	26	L
	E0037003	BSLN	*	31AUG2004	19:00	-21	1.82	10.30	24	L
		BSLN		07SEP2004	17:45	-14	5.29H#	10.30	25	L

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM111.SAS
GENERATED: 17NOV2005 13:46:17 iceadmn3

Table 11.3.7.2.2.6 Chemistry Data for Thyroid Tests - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	TIME	DAY	TSH (MIU/L)	FREE (T4) (PMOL/L)	T3-UPTAKE (%)	
PLACEBO (BIPOLAR II)	E0037003	VISIT 10	16NOV2004	17:20	57	0.80	10.30	22	L

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
#: potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/CHEM111.SAS
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11.3.7.3 Narratives for subjects with abnormal laboratory results

No narratives for subjects with abnormal laboratory results are presented in this clinical study report.

Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE PULSE (BPM)	WINDOWED VISIT																		
	SCREEN	168	69.7	10.00	69.5	40	96	167	69.6	10.27	69.0	40	94	166	67.3	10.23	66.5	40	105
	DAY 1	171	71.9	9.49	72.0	38	100	166	72.0	10.26	72.0	48	97	167	71.8	10.75	70.0	49	103
	DAY 8	156	74.9	10.08	76.0	45	100	149	76.2	11.18	76.0	52	108	161	71.9	10.35	70.0	48	103
	DAY 15	137	76.6	10.76	76.0	45	111	129	78.4	11.31	78.0	54	112	147	71.6	9.98	70.0	32	99
	DAY 22	125	76.4	10.24	76.0	51	100	120	78.1	11.26	78.0	51	114	140	71.8	9.67	72.0	52	95
	DAY 29	119	76.5	11.12	76.0	51	114	109	77.6	10.14	78.0	56	102	137	71.3	9.05	70.0	52	91
	DAY 36	111	77.4	11.47	78.0	45	108	105	78.0	10.09	80.0	54	111	127	74.0	10.97	73.0	52	108
	DAY 43	102	77.0	10.67	78.0	45	100	99	78.0	10.09	78.0	56	101	117	73.5	9.77	72.0	54	100
	DAY 50	103	77.1	9.51	78.0	42	100	89	77.7	9.56	76.0	60	105	113	72.6	10.20	72.0	50	111
	DAY 57	102	75.4	9.59	74.0	54	104	90	77.5	11.36	76.0	52	108	109	72.1	8.82	72.0	48	96
	FINAL	160	75.3	9.91	74.0	53	104	154	76.4	12.24	75.5	52	112	162	71.8	9.13	72.0	48	101
SUPINE SYSTOLIC BP (MMHG)	SCREEN	167	119.6	13.14	118.0	90	170	167	120.7	14.26	120.0	90	166	166	119.0	12.80	119.5	90	158
	DAY 1	171	118.9	13.18	120.0	92	157	166	120.6	14.32	120.0	92	164	167	119.0	13.16	118.0	80	171
	DAY 8	156	120.5	12.52	120.0	90	180	149	122.4	15.26	120.0	90	170	161	119.0	13.08	120.0	84	162
	DAY 15	137	119.1	13.14	119.0	88	185	129	122.6	16.38	120.0	90	206	147	118.8	12.84	120.0	90	157
	DAY 22	125	118.5	11.71	120.0	82	152	120	122.8	13.12	120.0	90	163	140	119.0	12.62	120.0	90	155

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT203.SAS
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Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE SYSTOLIC BP (MMHG)	WINDOWED VISIT																		
	DAY 29	119	118.1	12.80	120.0	83	154	109	121.3	14.28	120.0	94	170	137	118.1	12.01	118.0	90	144
	DAY 36	111	118.5	12.50	118.0	90	147	105	120.1	12.75	120.0	96	150	127	118.4	12.15	119.0	90	147
	DAY 43	102	118.1	12.66	118.0	90	150	99	121.4	12.84	120.0	90	156	117	119.5	14.24	118.0	90	173
	DAY 50	103	119.5	12.11	120.0	90	160	89	121.4	13.61	120.0	90	170	113	118.3	13.94	118.0	90	158
	DAY 57	102	120.0	11.70	118.5	96	160	90	121.3	12.43	123.5	98	157	109	118.7	13.53	118.0	90	160
	FINAL	160	119.9	12.79	118.5	90	185	154	122.5	15.51	122.0	98	206	162	118.7	13.04	118.0	90	160
SUPINE DIASTOLIC BP (MMHG)	SCREEN	167	77.7	9.06	78.0	59	118	167	78.6	9.05	80.0	58	102	166	77.4	9.37	78.0	58	100
	DAY 1	171	76.0	9.69	76.0	54	110	166	77.1	9.25	76.0	50	106	167	76.3	8.98	78.0	50	100
	DAY 8	156	77.3	9.09	78.0	60	110	149	79.3	10.04	78.0	52	120	161	77.0	9.08	78.0	58	110
	DAY 15	137	77.7	10.11	78.0	50	120	129	79.2	9.33	79.0	53	110	147	77.1	9.65	78.0	56	102
	DAY 22	125	77.5	9.43	78.0	52	110	120	78.8	9.57	80.0	58	110	140	76.5	9.59	78.0	50	104
	DAY 29	119	77.7	8.28	80.0	55	100	109	78.2	9.25	80.0	58	100	137	77.1	8.73	78.0	56	102
	DAY 36	111	77.9	8.92	78.0	50	100	105	78.8	8.93	80.0	58	110	127	76.4	8.23	76.0	57	94
	DAY 43	102	77.3	8.63	78.0	57	100	99	78.5	8.42	80.0	60	100	117	77.1	9.33	78.0	50	102
	DAY 50	103	77.2	8.79	78.0	60	100	89	79.6	8.98	79.0	58	112	113	76.7	8.87	78.0	40	102
	DAY 57	102	78.4	8.18	78.0	58	100	90	78.9	9.00	80.0	58	106	109	77.8	9.67	78.0	52	108

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT203.SAS
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Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE DIASTOLIC BP (MMHG)	WINDOWED VISIT																		
	FINAL	160	77.9	9.16	78.0	58	120	154	79.8	10.20	80.0	53	106	162	77.5	9.68	78.0	50	108
STANDING PULSE (BPM)	SCREEN	168	75.4	10.73	76.0	38	100	167	74.8	11.23	74.0	48	110	166	73.2	11.01	72.0	44	105
	DAY 1	171	78.4	10.31	78.0	38	111	166	77.5	10.76	78.0	51	103	167	77.5	11.40	76.0	55	115
	DAY 8	156	81.2	11.93	80.0	58	129	149	81.3	11.45	82.0	56	115	161	78.1	12.71	78.0	48	115
	DAY 15	137	82.8	11.93	82.0	57	123	129	84.2	12.09	84.0	58	112	147	78.2	11.78	78.0	59	126
	DAY 22	125	82.7	12.23	80.0	54	120	120	83.7	11.69	84.0	60	122	140	78.1	10.60	78.0	60	108
	DAY 29	119	80.8	11.87	80.0	52	131	109	83.5	12.13	84.0	60	121	137	77.6	9.96	78.0	56	100
	DAY 36	111	81.7	11.84	82.0	48	112	105	82.6	10.70	84.0	54	107	127	80.4	11.63	80.0	58	116
	DAY 43	102	82.3	11.38	84.0	53	121	99	84.2	11.09	84.0	64	109	117	80.1	10.87	80.0	53	108
	DAY 50	102	82.1	11.86	80.0	45	108	89	83.8	10.71	84.0	64	120	113	79.6	11.78	79.0	58	127
	DAY 57	102	80.7	10.56	80.0	54	116	90	83.8	12.14	82.0	58	112	109	78.3	9.82	78.0	52	106
	FINAL	160	81.0	11.63	80.0	54	120	154	82.4	12.37	81.0	54	112	162	77.8	10.83	78.0	48	116
STANDING SYSTOLIC BP (MMHG)	SCREEN	168	120.0	12.72	120.0	86	168	167	120.8	14.59	120.0	86	170	166	119.2	13.97	120.0	82	190
	DAY 1	171	119.3	13.15	120.0	90	159	166	119.4	14.39	120.0	88	162	167	118.3	12.80	118.0	84	159
	DAY 8	156	119.6	14.08	118.0	70	185	149	121.9	15.18	121.0	94	165	161	118.8	13.08	119.0	88	171
	DAY 15	137	119.4	13.21	120.0	90	185	129	121.8	15.87	120.0	90	203	147	117.9	12.37	118.0	88	160

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT203.SAS
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Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING SYSTOLIC BP (MMHG)	WINDOWED VISIT																		
	DAY 22	125	118.3	11.94	118.0	90	148	120	122.1	13.47	120.0	98	181	140	119.1	12.26	120.0	90	146
	DAY 29	119	118.8	12.30	120.0	90	149	109	120.2	12.66	120.0	94	148	137	118.1	12.24	118.0	90	158
	DAY 36	111	119.2	12.02	120.0	90	154	105	119.9	12.55	120.0	98	158	127	118.1	12.00	120.0	90	152
	DAY 43	102	119.1	12.34	118.0	90	158	99	121.2	12.96	120.0	80	152	117	118.7	14.30	116.0	90	168
	DAY 50	103	119.3	11.22	120.0	96	150	89	120.9	12.76	121.0	90	158	113	118.2	12.92	118.0	94	168
	DAY 57	102	119.1	12.12	120.0	94	156	90	122.1	13.19	122.0	85	160	109	118.8	13.87	118.0	88	180
	FINAL	160	118.9	13.51	118.0	70	185	154	122.4	15.29	120.5	85	203	162	118.5	13.29	118.0	88	180
STANDING DIASTOLIC BP (MMHG)	SCREEN	168	79.6	8.86	80.0	60	112	167	79.5	10.09	80.0	50	110	166	79.6	9.76	80.0	56	104
	DAY 1	171	78.6	9.71	78.0	58	106	166	79.7	9.83	80.0	53	110	167	78.9	9.66	80.0	50	110
	DAY 8	156	80.0	9.83	80.0	46	124	149	81.8	10.04	80.0	52	118	161	79.5	8.98	80.0	56	105
	DAY 15	137	80.5	9.73	82.0	56	125	129	81.4	10.11	80.0	60	110	147	78.9	9.69	80.0	58	99
	DAY 22	125	79.9	9.08	82.0	59	108	120	80.5	9.95	80.0	52	109	140	78.9	9.53	80.0	54	103
	DAY 29	119	80.2	8.73	80.0	57	106	109	79.9	9.10	80.0	56	103	137	79.3	8.69	80.0	60	104
	DAY 36	111	80.2	8.99	80.0	50	100	105	80.1	9.08	80.0	54	100	127	79.0	7.67	80.0	60	99
	DAY 43	102	80.0	9.04	80.0	60	104	99	81.0	8.53	80.0	60	102	117	79.5	9.17	80.0	60	102
	DAY 50	103	79.5	8.64	80.0	60	110	89	80.9	8.88	80.0	60	104	113	79.2	9.03	80.0	48	108

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT203.SAS
GENERATED: 17NOV2005 13:53:28 iceadmn3

Table 11.3.8.1.1.1 Pulse and Blood Pressure - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING DIASTOLIC BP (MMHG)	WINDOWED VISIT																		
	DAY 57	102	79.3	9.35	80.0	52	106	90	80.9	10.00	80.0	58	110	109	80.0	9.92	80.0	56	110
	FINAL	160	79.1	9.88	80.0	46	125	154	81.0	10.99	80.0	54	118	162	79.4	9.76	80.0	54	110

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT203.SAS
GENERATED: 17NOV2005 13:53:28 iceadmn3

Table 11.3.8.1.1.2 Vital Sign Orthostatic Changes - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
PULSE (BPM)	WINDOWED VISIT																		
	SCREEN	167	5.8	6.66	4.0	-14	31	167	5.2	6.51	4.0	-16	26	166	5.9	6.44	4.0	-10	32
	DAY 1	171	6.5	7.60	4.0	-8	42	166	5.5	6.43	4.0	-10	26	167	5.7	6.92	4.0	-8	28
	DAY 8	156	6.3	8.29	4.0	-8	44	149	5.1	8.17	4.0	-20	28	161	6.2	8.03	5.0	-12	37
	DAY 15	137	6.1	7.78	4.0	-10	44	129	5.8	7.83	4.0	-25	33	147	6.6	8.38	4.0	-12	47
	DAY 22	125	6.3	9.00	4.0	-14	52	120	5.6	7.44	4.0	-20	28	140	6.3	7.72	4.5	-10	51
	DAY 29	119	4.3	7.49	4.0	-24	27	109	5.9	7.61	4.0	-8	55	137	6.3	7.28	4.0	-12	28
	DAY 36	111	4.4	6.65	4.0	-35	22	105	4.6	5.84	4.0	-8	26	127	6.5	7.70	4.0	-12	28
	DAY 43	102	5.2	7.03	4.0	-20	28	99	6.2	6.41	4.0	-5	30	117	6.6	7.31	4.0	-6	43
	DAY 50	102	5.0	7.31	4.0	-18	24	89	6.1	5.55	4.0	-4	19	113	7.0	7.06	5.0	-12	31
	DAY 57	102	5.4	6.54	4.0	-8	27	90	6.3	6.66	4.0	-12	28	109	6.2	7.74	4.0	-12	34
	FINAL	160	5.7	7.82	4.0	-24	52	154	6.0	6.46	4.0	-12	28	162	6.1	7.31	4.0	-12	34
SYSTOLIC BP (mmHg)	SCREEN	167	0.4	6.89	0.0	-30	26	167	0.1	6.72	0.0	-20	22	166	0.1	8.64	0.0	-36	33
	DAY 1	171	0.5	7.13	0.0	-20	23	166	-1.3	7.35	-2.0	-22	32	167	-0.8	6.54	0.0	-26	17
	DAY 8	156	-0.9	7.16	-0.5	-34	22	149	-0.6	7.18	0.0	-28	37	161	-0.2	7.09	0.0	-21	29
	DAY 15	137	0.2	6.95	0.0	-26	22	129	-0.8	7.19	-2.0	-24	22	147	-0.9	7.52	-1.0	-38	17
	DAY 22	125	-0.3	7.05	0.0	-24	20	120	-0.7	7.85	-2.0	-24	34	140	0.1	6.67	0.0	-18	21

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT204.SAS
GENERATED: 17NOV2005 13:53:31 iceadmn3

Table 11.3.8.1.1.2 Vital Sign Orthostatic Changes - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SYSTOLIC BP (mmHg)	WINDOWED VISIT																		
	DAY 29	119	0.7	6.54	2.0	-18	20	109	-1.1	7.57	0.0	-30	14	137	0.0	8.04	0.0	-28	38
	DAY 36	111	0.7	5.96	0.0	-17	14	105	-0.2	6.91	0.0	-22	20	127	-0.3	7.34	0.0	-26	24
	DAY 43	102	0.9	6.18	0.0	-18	18	99	-0.2	7.01	0.0	-13	28	117	-0.8	7.28	0.0	-23	22
	DAY 50	103	-0.2	6.86	0.0	-22	20	89	-0.5	5.97	0.0	-18	18	113	-0.1	6.97	0.0	-25	20
	DAY 57	102	-0.8	6.55	-2.0	-26	20	90	0.8	7.29	0.0	-16	20	109	0.2	6.77	0.0	-16	27
	FINAL	160	-1.0	7.00	-2.0	-34	20	154	-0.1	7.63	0.0	-30	22	162	-0.2	7.07	0.0	-22	27
DIASTOLIC BP (mmHg)	SCREEN	167	2.0	6.46	2.0	-30	22	167	0.9	6.01	0.0	-16	20	166	2.3	5.51	2.0	-10	24
	DAY 1	171	2.6	6.06	2.0	-10	24	166	2.6	7.27	2.0	-20	30	167	2.6	6.16	2.0	-14	24
	DAY 8	156	2.7	6.32	2.0	-20	22	149	2.5	6.82	2.0	-26	21	161	2.5	6.92	2.0	-26	23
	DAY 15	137	2.8	6.28	3.0	-15	20	129	2.3	6.56	0.0	-18	28	147	1.8	6.81	2.0	-16	30
	DAY 22	125	2.4	5.93	2.0	-10	22	120	1.8	6.43	1.5	-13	23	140	2.4	5.04	2.0	-10	19
	DAY 29	119	2.6	5.22	2.0	-10	24	109	1.7	6.58	2.0	-28	20	137	2.2	5.49	2.0	-10	17
	DAY 36	111	2.3	5.48	2.0	-12	18	105	1.3	5.88	2.0	-16	20	127	2.6	5.74	2.0	-12	23
	DAY 43	102	2.7	6.11	2.0	-10	22	99	2.5	6.27	2.0	-8	30	117	2.4	6.50	2.0	-14	25
	DAY 50	103	2.3	5.80	2.0	-26	16	89	1.3	5.87	2.0	-13	14	113	2.6	6.46	2.0	-21	38
	DAY 57	102	0.9	5.37	2.0	-16	20	90	2.0	6.03	1.5	-10	24	109	2.2	5.33	2.0	-10	20

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT204.SAS
GENERATED: 17NOV2005 13:53:31 iceadmn3

Table 11.3.8.1.1.2 Vital Sign Orthostatic Changes - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIASTOLIC BP (mmHg)	WINDOWED VISIT																		
	FINAL	160	1.2	5.96	2.0	-20	20	154	1.2	6.82	0.0	-28	24	162	2.0	5.40	2.0	-10	20

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT204.SAS
GENERATED: 17NOV2005 13:53:31 iceadmn3

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE PULSE (BPM)	WINDOWED VISIT																		
	DAY 8	156	3.0	8.85	2.0	-26	31	149	4.0	9.49	4.0	-19	38	161	-0.1	8.69	0.0	-28	31
	DAY 15	137	4.8	10.96	3.0	-24	52	129	5.9	10.43	4.0	-16	34	147	-0.2	8.92	0.0	-32	28
	DAY 22	125	4.8	9.83	4.0	-18	33	120	5.8	9.66	4.0	-16	30	140	0.2	8.76	0.0	-30	24
	DAY 29	119	4.7	11.05	4.0	-18	40	109	5.5	9.41	4.0	-28	36	137	-1.2	10.06	0.0	-28	29
	DAY 36	111	5.4	10.82	6.0	-20	38	105	5.7	10.04	6.0	-26	28	127	1.9	9.80	0.0	-24	34
	DAY 43	102	4.7	10.60	5.5	-24	32	99	5.7	9.79	4.0	-20	36	117	1.0	9.10	0.0	-35	22
	DAY 50	103	5.1	11.01	5.0	-20	38	89	5.3	9.36	4.0	-12	35	113	0.4	10.21	0.0	-32	25
	DAY 57	102	3.6	10.46	4.0	-33	37	90	4.1	9.01	4.0	-16	27	109	0.1	9.82	0.0	-33	28
	FINAL	160	3.4	9.95	4.0	-33	37	154	4.3	10.18	4.0	-16	34	162	-0.2	9.65	0.0	-35	28
SUPINE SYSTOLIC BP (MMHG)	DAY 8	156	1.9	9.45	0.0	-30	30	149	1.0	9.62	0.0	-28	44	161	0.0	9.98	0.0	-44	26
	DAY 15	137	0.7	9.18	0.0	-30	35	129	1.2	12.45	0.0	-34	54	147	-0.3	10.30	0.0	-38	29
	DAY 22	125	0.4	10.82	0.0	-30	28	120	1.4	10.93	2.0	-44	28	140	0.1	9.70	0.0	-30	30
	DAY 29	119	-0.1	10.35	0.0	-20	40	109	0.9	11.16	0.0	-39	37	137	-1.2	11.19	0.0	-27	25
	DAY 36	111	0.0	11.11	0.0	-22	36	105	-1.0	10.62	0.0	-30	32	127	-1.0	10.97	0.0	-34	36
	DAY 43	102	0.4	11.41	0.0	-30	50	99	0.7	10.58	0.0	-26	26	117	0.4	10.35	0.0	-28	31
	DAY 50	103	1.6	11.41	0.0	-30	32	89	-0.5	11.66	-2.0	-26	26	113	-0.6	11.84	0.0	-33	34

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT205.SAS
GENERATED: 17NOV2005 13:53:33 iceadmn3

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
SUPINE SYSTOLIC BP (MMHG)	WINDOWED VISIT																		
	DAY 57	102	1.9	11.31	0.0	-26	34	90	-0.4	12.00	0.0	-34	31	109	-0.2	12.19	0.0	-30	38
	FINAL	160	1.2	11.49	0.0	-26	35	154	1.2	13.51	0.0	-34	56	162	-0.3	11.19	0.0	-30	38
SUPINE DIASTOLIC BP (MMHG)	DAY 8	156	1.3	7.31	1.0	-22	30	149	1.9	7.91	2.0	-20	44	161	0.7	7.81	0.0	-16	40
	DAY 15	137	1.7	8.40	2.0	-26	32	129	1.8	8.49	0.0	-28	34	147	0.5	7.72	0.0	-20	30
	DAY 22	125	1.7	8.48	2.0	-24	21	120	1.1	7.80	0.5	-20	24	140	-0.0	8.10	0.0	-22	24
	DAY 29	119	1.5	8.08	0.0	-22	24	109	1.5	8.84	2.0	-30	20	137	0.6	7.98	0.0	-20	22
	DAY 36	111	2.2	9.32	2.0	-22	31	105	1.9	8.30	2.0	-16	32	127	-0.3	8.14	0.0	-23	40
	DAY 43	102	1.5	8.41	1.5	-19	22	99	1.7	8.27	0.0	-18	20	117	0.6	8.69	0.0	-22	26
	DAY 50	103	1.5	8.47	2.0	-19	25	89	1.8	8.72	2.0	-15	23	113	0.2	8.68	0.0	-24	22
	DAY 57	102	2.3	8.97	3.0	-22	26	90	1.5	9.60	0.0	-23	28	109	1.3	9.32	0.0	-18	40
	FINAL	160	1.9	9.40	2.0	-26	32	154	2.6	10.08	2.0	-28	33	162	1.2	9.31	0.0	-18	40
STANDING PULSE (BPM)	DAY 8	156	2.7	9.88	2.0	-34	35	149	3.8	10.08	2.0	-24	38	161	0.3	9.06	0.0	-28	36
	DAY 15	137	4.3	11.40	2.0	-22	52	129	6.2	11.74	4.0	-32	42	147	0.7	10.09	0.0	-28	50
	DAY 22	125	4.4	11.04	4.0	-48	45	120	6.2	10.80	4.0	-20	34	140	0.5	9.38	0.0	-40	20
	DAY 29	119	2.7	10.74	4.0	-27	45	109	6.3	11.96	4.0	-22	56	137	-0.8	9.89	0.0	-28	25
	DAY 36	111	3.4	10.22	4.0	-22	34	105	5.2	10.48	4.0	-26	31	127	2.3	10.87	1.0	-30	44

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT205.SAS
GENERATED: 17NOV2005 13:53:33 iceadmn3

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING PULSE (BPM)	WINDOWED VISIT																		
	DAY 43	102	3.7	11.22	4.0	-20	35	99	6.7	9.95	6.0	-24	36	117	1.9	10.35	1.0	-39	31
	DAY 50	102	3.8	12.06	4.0	-29	40	89	6.3	10.96	4.0	-16	48	113	1.8	11.00	1.0	-26	30
	DAY 57	102	2.6	10.76	2.5	-36	32	90	5.4	10.18	4.0	-20	30	109	0.6	11.39	0.0	-30	32
	FINAL	160	2.4	10.54	2.0	-36	32	154	5.1	11.33	4.0	-20	49	162	0.0	11.29	0.0	-39	44
STANDING SYSTOLIC BP (MMHG)	DAY 8	156	0.4	10.06	0.0	-26	34	149	1.7	9.61	0.0	-22	40	161	0.7	9.34	0.0	-32	25
	DAY 15	137	0.1	9.63	0.0	-24	33	129	2.0	12.02	2.0	-30	53	147	-0.3	9.93	0.0	-22	33
	DAY 22	125	-0.6	11.38	0.0	-54	32	120	1.8	11.34	2.0	-34	41	140	0.6	10.18	0.0	-25	37
	DAY 29	119	-0.4	9.35	0.0	-34	24	109	1.3	10.93	2.0	-30	31	137	-0.2	10.65	0.0	-30	31
	DAY 36	111	-0.1	9.66	0.0	-34	30	105	0.2	11.81	0.0	-40	33	127	-0.3	10.70	-1.0	-26	34
	DAY 43	102	0.2	11.43	0.0	-39	44	99	1.6	12.15	2.0	-41	33	117	0.3	11.35	0.0	-26	43
	DAY 50	103	0.2	11.67	0.0	-50	26	89	0.3	13.31	1.0	-49	37	113	-0.2	10.75	-1.0	-28	32
	DAY 57	102	-0.2	9.98	0.0	-39	26	90	1.6	11.76	2.0	-33	30	109	0.4	12.09	0.0	-22	33
	FINAL	160	-0.3	10.55	0.0	-39	33	154	2.6	12.57	2.0	-33	58	162	0.3	11.61	0.0	-30	33
STANDING DIASTOLIC BP (MMHG)	DAY 8	156	1.3	8.26	0.5	-20	22	149	1.7	8.67	1.0	-21	38	161	0.5	7.80	0.0	-24	22
	DAY 15	137	1.7	8.08	0.0	-18	35	129	1.4	9.50	0.0	-34	28	147	-0.3	7.88	0.0	-24	21
	DAY 22	125	1.4	8.40	2.0	-31	20	120	0.7	8.40	0.0	-35	39	140	-0.2	8.13	0.0	-23	22

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT205.SAS
GENERATED: 17NOV2005 13:53:33 iceadmn3

Table 11.3.8.1.1.3 Pulse and Blood Pressure Change from Baseline - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STANDING DIASTOLIC BP (MMHG)	WINDOWED VISIT																		
	DAY 29	119	1.5	7.34	2.0	-22	22	109	0.9	8.60	0.0	-25	20	137	-0.1	7.87	0.0	-24	19
	DAY 36	111	1.8	9.15	2.0	-28	26	105	0.9	8.72	0.0	-24	30	127	-0.9	8.50	-2.0	-25	30
	DAY 43	102	1.5	8.54	0.0	-18	21	99	2.0	8.79	2.0	-24	22	117	0.0	8.92	0.0	-22	22
	DAY 50	103	1.0	7.81	2.0	-14	20	89	0.8	8.50	0.0	-17	20	113	-0.4	9.01	0.0	-26	24
	DAY 57	102	0.4	8.63	0.0	-28	20	90	1.2	7.39	0.0	-31	15	109	0.4	9.52	0.0	-26	36
	FINAL	160	0.4	8.91	0.0	-28	35	154	1.3	9.77	0.0	-34	38	162	0.5	9.57	0.0	-26	36

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT205.SAS
GENERATED: 17NOV2005 13:53:33 iceadmn3

Table 11.3.8.1.1.4 Vital Signs Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
SUPINE PULSE (BPM)	BASELINE												
	LOW	2	0	2	0	1	0	1	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	158	0	158	0	153	0	153	0	161	1	160	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
SUPINE SYSTOLIC BP (MMHG)	LOW	0	0	0	0	0	0	0	0	2	1	1	0
	NOT CLINICALLY IMPORTANT	160	1	158	1	154	0	153	1	160	1	159	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
SUPINE DIASTOLIC BP (MMHG)	LOW	0	0	0	0	1	0	1	0	2	0	2	0
	NOT CLINICALLY IMPORTANT	158	0	157	1	152	0	149	3	160	1	158	1
	HIGH	2	0	2	0	1	0	1	0	0	0	0	0
STANDING PULSE (BPM)	LOW	1	0	1	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	159	0	159	0	154	0	154	0	162	1	161	0

(Continued)

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT206.SAS
GENERATED: 17NOV2005 13:53:36 iceadmn3

Table 11.3.8.1.1.4 Vital Signs Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
STANDING PULSE (BPM)	BASELINE												
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
STANDING SYSTOLIC BP (MMHG)	LOW	1	0	1	0	1	0	1	0	3	1	2	0
	NOT CLINICALLY IMPORTANT	159	1	157	1	153	1	151	1	159	0	158	1
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
STANDING DIASTOLIC BP (MMHG)	LOW	0	0	0	0	0	0	0	0	1	0	1	0
	NOT CLINICALLY IMPORTANT	158	1	155	2	151	0	145	6	160	0	158	2
	HIGH	2	0	2	0	3	0	3	0	1	0	1	0

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT206.SAS
GENERATED: 17NOV2005 13:53:36 iceadmn3

Table 11.3.8.1.1.4 Vital Signs Potentially Clinically Important Shift to Final
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
			FINAL			FINAL			FINAL	
		TOTAL	CLINICALLY IMPORTANT CHANGE	NORMAL	TOTAL	CLINICALLY IMPORTANT CHANGE	NORMAL	TOTAL	CLINICALLY IMPORTANT CHANGE	NORMAL
ORTHOSTATIC CHANGE PULSE (BPM)	BASELINE									
	CLINICALLY IMPORTANT CHANGE	10	2	8	6	0	6	7	1	6
	NORMAL	150	6	144	148	3	145	155	6	149
ORTHOSTATIC CHANGE SYSTOLIC BP (MMHG)	CLINICALLY IMPORTANT CHANGE	2	0	2	1	0	1	1	1	0
	NORMAL	158	3	155	153	1	152	161	1	160
ORTHOSTATIC CHANGE DIASTOLIC BP (MMHG)	CLINICALLY IMPORTANT CHANGE	0	0	0	1	0	1	0	0	0
	NORMAL	160	1	159	153	1	152	162	0	162

See Statistical Analysis Plan Appendix B for definition of potentially clinically important.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT206.SAS
GENERATED: 17NOV2005 13:53:36 iceadmn3

Table 11.3.8.1.1.5 Potentially Clinically Important Vital Signs
Safety Population

		QUETIAPINE 300 MG (N=171)			QUETIAPINE 600 MG (N=168)			PLACEBO (N=167)		
		N*	n	%	N*	n	%	N*	n	%
Supine Pulse (bpm)	>120	160	0	0.0	154	0	0.0	162	0	0.0
	>=15 increase	160	31	19.4	154	36	23.4	162	7	4.3
	<50	158	1	0.6	153	0	0.0	161	1	0.6
	>=15 decrease	160	5	3.1	154	3	1.9	162	9	5.6
Supine Systolic BP (mmHg)	>=180	160	1	0.6	154	1	0.6	162	0	0.0
	>=20 increase	160	11	6.9	154	9	5.8	162	8	4.9
	<=90	160	4	2.5	154	2	1.3	160	0	0.0
	>=20 decrease	160	3	1.9	154	8	5.2	162	10	6.2
Supine Diastolic BP (mmHg)	>=105	158	1	0.6	153	1	0.7	162	1	0.6
	>=30 increase	160	2	1.3	154	1	0.6	162	1	0.6
	<=50	160	0	0.0	154	0	0.0	161	1	0.6
	>=20 decrease	160	2	1.3	154	2	1.3	162	2	1.2
Standing Pulse (bpm)	>120	160	0	0.0	154	0	0.0	162	0	0.0
	>=15 increase	160	26	16.3	154	40	26.0	162	13	8.0
	<50	159	0	0.0	154	0	0.0	162	2	1.2
	>=15 decrease	160	4	2.5	154	6	3.9	162	9	5.6

(Continued)

*Number of patients at risk, i.e. not fulfilling the criteria at baseline.
Percentages in total column are calculated as n/N* x 100, where n is the number of patients meeting criterion at least 30% of post baseline assessments.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT212.SAS
GENERATED: 17NOV2005 13:53:46 iceadmn3

Table 11.3.8.1.1.5 Potentially Clinically Important Vital Signs
Safety Population

		QUETIAPINE 300 MG (N=171)			QUETIAPINE 600 MG (N=168)			PLACEBO (N=167)		
		N*	n	%	N*	n	%	N*	n	%
Standing Systolic BP (mmHg)	>=180	160	1	0.6	154	1	0.6	162	0	0.0
	>=20 increase	160	6	3.8	154	11	7.1	162	7	4.3
	<=90	159	1	0.6	153	0	0.0	159	1	0.6
	>=20 decrease	160	6	3.8	154	8	5.2	162	7	4.3
Standing Diastolic BP (mmHg)	>=105	158	1	0.6	151	4	2.6	161	1	0.6
	>=30 increase	160	1	0.6	154	2	1.3	162	0	0.0
	<=50	160	1	0.6	154	0	0.0	161	0	0.0
	>=20 decrease	160	1	0.6	154	4	2.6	162	2	1.2

*Number of patients at risk, i.e. not fulfilling the criteria at baseline.
Percentages in total column are calculated as n/N* x 100, where n is the number of patients meeting criterion at least 30% of post baseline assessments.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT212.SAS
GENERATED: 17NOV2005 13:53:46 iceadmn3

Table 11.3.8.1.1.6 Potentially Clinically Important Orthostatic Change Findings
Safety Population

		QUETIAPINE 300 MG (N=171)			QUETIAPINE 600 MG (N=168)			PLACEBO (N=167)		
		N*	n	%	N*	n	%	N*	n	%
Pulse (bpm)	>=20 increase upon standing	150	7	4.7	148	2	1.4	155	12	7.7
Systolic blood pressure (mmHg)	>=20 decrease	158	2	1.3	153	1	0.7	161	1	0.6
Diastolic blood pressure (mmHg)	>=20 decrease	160	1	0.6	153	2	1.3	162	0	0.0
Combined pulse and systolic BP	>=20 bpm increase & >=20 mmHg decrease	148	0	0.0	147	0	0.0	154	0	0.0

*Number of patients at risk, i.e. not fulfilling the criteria at baseline.
Percentages in total column are calculated as n/N* x 100, where n is the number of patients meeting criterion at least 30% of post baseline assessments.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT213.SAS
GENERATED: 17NOV2005 13:53:52 iceadmn3

Table 11.3.8.1.2.1 ECG Rates and Intervals - Descriptive Statistics
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
HEART RATE (BEATS/MIN)	BSLN	170	68.78	11.66	67.0	45	104	167	68.81	12.28	68.0	40	108	164	65.88	11.42	66.0	44	111
	FINAL	126	72.17	11.80	72.0	40	109	129	77.95	13.18	78.0	53	109	143	69.49	12.11	70.0	39	102
	CHG FROM BSLN	125	4.21	11.38	4.0	-24	39	128	7.91	13.21	7.0	-23	61	140	3.28	12.07	4.0	-36	40
PR INTERVAL (MSEC)	BSLN	170	156.80	22.83	155.0	112	250	165	159.02	24.71	156.0	105	289	161	156.69	22.51	156.0	102	227
	FINAL	126	155.74	20.50	155.5	113	217	126	157.90	22.62	155.5	110	214	142	156.44	21.25	154.0	110	220
	CHG FROM BSLN	125	-0.26	13.62	0.0	-35	39	124	-0.37	13.21	-1.0	-35	40	136	0.82	11.57	-1.0	-31	29
QRS INTERVAL (MSEC)	BSLN	170	85.95	9.92	86.0	65	163	167	86.81	8.72	86.0	71	113	164	88.01	8.44	88.0	72	126
	FINAL	126	86.91	8.66	85.0	71	125	129	84.88	8.44	84.0	71	122	143	87.48	9.89	86.0	70	132
	CHG FROM BSLN	125	1.38	7.88	1.0	-17	27	128	-2.01	8.20	-3.0	-27	25	140	-0.87	8.29	-1.0	-21	28
QT INTERVAL (MSEC)	BSLN	170	387.71	32.31	384.0	314	513	167	385.03	32.80	383.0	304	532	164	393.92	30.21	392.0	328	500
	FINAL	126	380.26	30.42	377.5	311	531	129	367.03	28.04	365.0	301	438	143	384.62	31.04	383.0	321	484
	CHG FROM BSLN	125	-8.08	24.70	-8.0	-74	47	128	-14.38	30.48	-11.0	-116	83	140	-8.46	26.02	-7.5	-81	59
FRIDERICIA QTC INTERVAL (MSEC)	BSLN	170	402.95	21.10	402.0	355	498	167	399.89	19.15	402.0	352	463	164	403.54	18.42	403.0	351	451
	FINAL	126	401.84	22.84	400.0	352	511	129	397.91	19.87	396.0	356	488	143	400.89	18.49	400.0	363	454
	CHG FROM BSLN	125	-0.26	17.65	-2.0	-47	55	128	-0.61	19.99	-1.0	-43	103	140	-2.45	16.09	-4.0	-35	57

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG200.SAS
GENERATED: 17NOV2005 13:48:54 iceadmn3

FIGURE 11.3.8.1.2.2 BUBBLE PLOT OF CHANGE IN QTC (FRIDERICIA) INTERVALS

(SAFETY POPULATION)

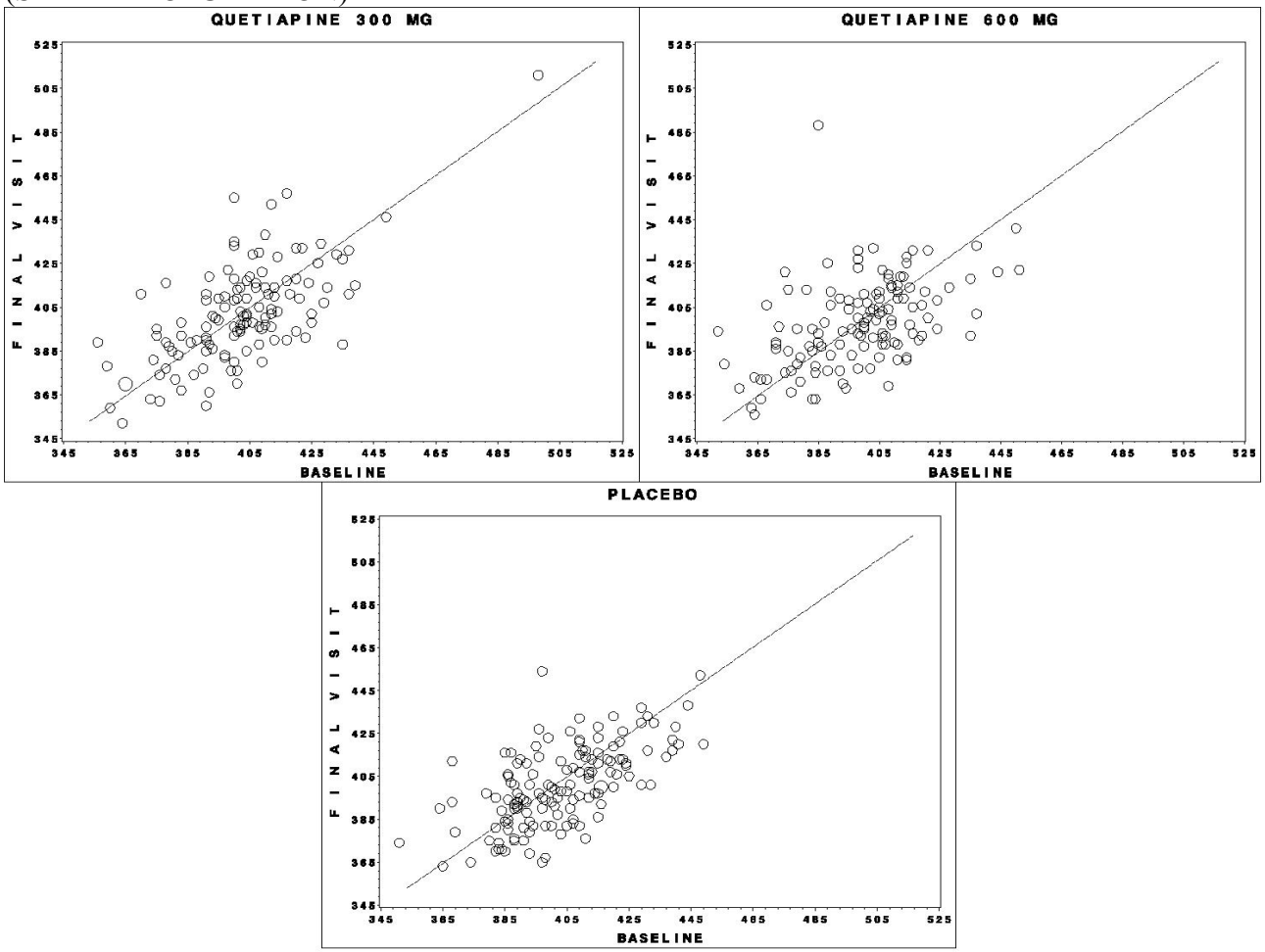

Table 11.3.8.1.2.3 ECG Overall Evaluation Shift to Final
Safety Population

	TREATMENT						
	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO		
	FINAL		FINAL		FINAL		
	ABNORMAL	NORMAL	ABNORMAL	NORMAL	ABNORMAL	NORMAL	TOTAL
BASELINE							
ABNORMAL	10	6	12	7	11	7	53
NORMAL	5	104	5	104	7	115	340
TOTAL	15	110	17	111	18	122	393

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG201.SAS
GENERATED: 17NOV2005 13:48:56 iceadmn3

Table 11.3.8.1.2.4 ECG Rates and Intervals Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
HEART RATE (BEATS/MIN)	BASELINE												
	LOW	7	0	7	0	9	0	9	0	8	2	6	0
	NOT CLINICALLY IMPORTANT	118	2	116	0	119	0	119	0	132	4	128	0
	HIGH	0	0	0	0	0	0	0	0	0	0	0	0
PR INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	124	0	123	1	121	0	121	0	132	0	132	0
	HIGH	1	0	0	1	3	0	2	1	4	0	3	1
QRS INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	125	0	125	0	128	0	127	1	139	0	138	1
	HIGH	0	0	0	0	0	0	0	0	1	0	0	1
QT INTERVAL (MSEC)	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	124	0	124	0	128	0	128	0	140	0	140	0
	HIGH	1	0	0	1	0	0	0	0	0	0	0	0

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG202.SAS
GENERATED: 17NOV2005 13:48:58 iceadmn3

Table 11.3.8.1.2.4 ECG Rates and Intervals Shift to Final
Safety Population

		TREATMENT											
		QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
			FINAL				FINAL				FINAL		
		TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH	TOTAL	LOW	NOT CLINICALLY IMPORTANT	HIGH
FRIDERICIA QTC INTERVAL (MSEC)	BASELINE												
	LOW	0	0	0	0	0	0	0	0	0	0	0	0
	NOT CLINICALLY IMPORTANT	124	0	121	3	126	0	125	1	140	0	138	2
	HIGH	1	0	0	1	2	0	2	0	0	0	0	0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG202.SAS
GENERATED: 17NOV2005 13:48:58 iceadmn3

Table 11.3.8.1.2.5 Potentially Clinically Important ECG Findings
Safety Population

		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=(171)			N=(168)			N=(167)		
		N*	n	%	N*	n	%	N*	n	%
Heart rate (bpm)	>120	125	0	0.0	128	0	0.0	140	0	0.0
	<50	118	2	1.7	119	0	0.0	132	4	3.0
	>=15 increase from baseline	125	26	20.8	128	34	26.6	140	23	16.4
	<=15 decrease from baseline	125	7	5.6	128	5	3.9	140	8	5.7
PR interval (msec)	>=210	124	1	0.8	121	0	0.0	132	0	0.0
QRS interval (msec)	>=120	125	0	0.0	128	1	0.8	139	1	0.7
	<=50	125	0	0.0	128	0	0.0	140	0	0.0
QT (msec)	>=500	124	0	0.0	128	0	0.0	140	0	0.0
	<=200	125	0	0.0	128	0	0.0	140	0	0.0
	>=60 increase from baseline	125	0	0.0	128	1	0.8	140	0	0.0
QTc Fridericia (msec)	>=450	124	3	2.4	126	1	0.8	140	2	1.4
	>=60 increase from baseline	125	0	0.0	128	1	0.8	140	0	0.0

*Number of patients at risk

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG204.SAS
GENERATED: 17NOV2005 13:49:01 iceadmn3

Table 11.3.8.1.3.1.1 Weight and BMI - Descriptive Statistics
Last Observation Carried Forward
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
WEIGHT(KG)	WINDOWED VISIT																		
	BASELINE	171	87.3	21.56	86.0	36	159	167	86.4	23.32	83.0	36	172	167	83.3	21.59	82.0	44	155
	FINAL	128	90.2	21.63	88.5	51	158	128	89.1	23.99	85.0	36	170	142	84.3	22.27	84.0	43	157
	CHG FRM BSLN	128	1.4	3.39	1.0	-5	27	128	1.3	4.27	1.0	-21	11	142	0.3	2.38	0.0	-7	10
BMI(KG/M^2)	BASELINE	171	30.2	7.21	28.8	17	58	167	30.4	8.19	28.6	17	64	167	28.7	6.92	28.1	18	54
	FINAL	128	31.1	7.31	30.0	19	58	128	31.4	8.38	30.1	17	63	142	28.9	6.96	28.0	18	54
	CHG FRM BSLN	128	0.5	1.19	0.4	-2	10	128	0.5	1.52	0.4	-8	4	142	0.1	0.83	0.0	-3	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT200.SAS
GENERATED: 17NOV2005 13:53:20 iceadmn3

Table 11.3.8.1.3.1.2 Weight and BMI - Descriptive Statistics
Observed Cases
Safety Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
WEIGHT(KG)	VISIT																		
	BASELINE	171	87.3	21.56	86.0	36	159	167	86.4	23.32	83.0	36	172	167	83.3	21.59	82.0	44	155
	FINAL	101	90.7	22.82	89.0	51	158	89	91.2	25.19	88.0	36	170	107	85.3	22.83	85.0	43	157
	CHG FRM BSLN	101	1.4	3.60	1.0	-5	27	89	1.8	4.07	2.0	-15	11	107	0.4	2.61	0.0	-7	10
BMI(KG/M^2)	BASELINE	171	30.2	7.21	28.8	17	58	167	30.4	8.19	28.6	17	64	167	28.7	6.92	28.1	18	54
	FINAL	101	31.3	7.48	30.4	19	58	89	32.1	8.98	30.6	17	63	107	29.3	7.34	28.1	18	54
	CHG FRM BSLN	101	0.5	1.27	0.4	-2	10	89	0.6	1.40	0.6	-5	4	107	0.1	0.91	0.0	-3	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT210.SAS
GENERATED: 17NOV2005 13:53:42 iceadmn3

Table 11.3.8.1.3.2 Weight and BMI by Baseline BMI Category - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
0 - <18.5	WEIGHT(-KG)	WINDOWED VISIT																		
		BASELINE	2	42.5	9.19	42.5	36	49	6	54.3	13.03	56.5	36	68	3	47.0	3.61	46.0	44	51
		FINAL	.	.	.	.	.	.	3	54.7	16.65	60.0	36	68	1	43.0	.	43.0	43	43
		CHG FRM BSLN	.	.	.	.	.	.	3	1.0	1.00	1.0	0	2	1	-1.0	.	-1.0	-1	-1
	BMI(KG/-M^2)	BASELINE	2	17.4	0.92	17.4	17	18	6	18.0	0.65	18.3	17	18	3	18.2	0.17	18.3	18	18
		FINAL	.	.	.	.	.	.	3	18.0	1.14	18.3	17	19	1	17.9	.	17.9	18	18
		CHG FRM BSLN	.	.	.	.	.	.	3	0.3	0.30	0.3	0	1	1	-0.4	.	-0.4	-0	-0
18.5 - <25	WEIGHT(-KG)	BASELINE	41	65.3	8.62	65.0	49	84	33	63.0	7.74	63.0	48	78	49	62.6	8.82	61.0	48	87
		FINAL	32	67.7	9.09	66.0	51	85	23	63.7	8.32	63.0	51	80	42	62.7	9.07	61.5	46	87
		CHG FRM BSLN	32	1.3	2.77	1.0	-5	10	23	1.1	2.50	1.0	-4	7	42	0.4	1.77	0.0	-4	5
	BMI(KG/-M^2)	BASELINE	41	22.6	1.90	23.5	19	25	33	22.3	1.72	22.7	19	25	49	21.8	1.80	21.6	19	25
		FINAL	32	23.1	2.23	23.7	19	27	23	22.8	1.96	23.1	19	26	42	21.9	2.01	21.7	18	26
		CHG FRM BSLN	32	0.5	0.98	0.3	-2	3	23	0.4	0.91	0.3	-2	3	42	0.2	0.65	0.0	-2	2
25 - <30	WEIGHT(-KG)	BASELINE	50	81.4	9.11	83.0	63	101	55	80.6	9.80	82.0	53	102	54	83.4	11.42	82.5	57	113
		FINAL	35	82.5	9.91	81.0	62	103	41	82.0	10.46	82.0	60	103	46	83.7	11.82	84.0	57	112

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT201.SAS
GENERATED: 17NOV2005 13:53:23 iceadmn3

Table 11.3.8.1.3.2 Weight and BMI by Baseline BMI Category - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT																	
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
25 - <30	WEIGHT(-KG)	WINDOWED VISIT																		
		CHG FRM BSLN	35	1.3	2.39	1.0	-3	8	41	1.6	3.99	1.0	-15	11	46	-0.2	2.03	0.0	-7	3
	BMI(KG/-M^2)	BASELINE	50	27.3	1.32	27.3	25	30	55	27.4	1.35	27.4	25	30	54	27.4	1.47	27.2	25	30
		FINAL	35	27.9	1.70	28.1	25	32	41	27.9	2.12	28.2	23	32	46	27.4	1.42	27.5	25	30
		CHG FRM BSLN	35	0.5	0.84	0.4	-1	3	41	0.5	1.38	0.4	-5	3	46	-0.1	0.64	0.0	-2	1
30 - <40	WEIGHT(-KG)	BASELINE	61	99.7	15.46	97.0	70	140	56	95.2	11.93	95.0	77	126	47	96.9	15.34	95.0	72	142
		FINAL	47	101.7	14.95	100.0	74	140	46	95.5	13.27	95.0	61	129	42	96.8	15.93	94.5	73	147
		CHG FRM BSLN	47	1.9	4.52	1.0	-3	27	46	1.2	4.91	1.0	-21	11	42	0.4	2.36	1.0	-7	5
	BMI(KG/-M^2)	BASELINE	61	34.1	2.88	33.6	30	40	56	33.9	2.78	33.7	30	40	47	33.6	2.63	32.8	30	39
		FINAL	47	34.6	3.13	33.6	30	41	46	34.2	3.49	33.7	24	43	42	33.6	2.92	32.8	29	41
		CHG FRM BSLN	47	0.7	1.58	0.4	-1	10	46	0.4	1.83	0.4	-8	4	42	0.1	0.82	0.3	-3	2
>=40	WEIGHT(-KG)	BASELINE	17	118.3	19.80	113.0	89	159	17	132.8	21.49	132.0	107	172	14	117.4	21.31	116.0	72	155
		FINAL	14	122.1	18.49	119.0	92	158	15	134.7	19.20	131.0	108	170	11	125.1	19.31	124.0	95	157
		CHG FRM BSLN	14	-0.2	1.72	0.0	-4	2	15	1.2	5.66	2.0	-13	8	11	1.9	4.64	1.0	-6	10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT201.SAS
GENERATED: 17NOV2005 13:53:23 iceadmn3

Table 11.3.8.1.3.2 Weight and BMI by Baseline BMI Category - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
>=40	BMI(KG/-M^2)	WINDOWED VISIT																		
		BASELINE	17	44.9	4.98	43.1	40	58	17	48.3	7.10	45.7	41	64	14	44.1	3.24	43.1	41	54
		FINAL	14	45.1	5.16	44.7	40	58	15	48.6	6.59	46.1	41	63	11	44.9	3.92	43.5	41	54
		CHG FRM BSLN	14	-0.1	0.62	0.0	-1	1	15	0.5	1.85	0.7	-4	3	11	0.7	1.75	0.4	-3	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT201.SAS
GENERATED: 17NOV2005 13:53:23 iceadmn3

Table 11.3.8.1.3.3 Weight and BMI by Diabetic Status (Fasting Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		WINDOWED VISIT																		
ALL	WEIGHT (KG)	BASELINE	171	87.3	21.56	86.0	36	159	167	86.4	23.32	83.0	36	172	167	83.3	21.59	82.0	44	155
		FINAL	128	90.2	21.63	88.5	51	158	128	89.1	23.99	85.0	36	170	142	84.3	22.27	84.0	43	157
		CHG FRM BSLN	128	1.4	3.39	1.0	-5	27	128	1.3	4.27	1.0	-21	11	142	0.3	2.38	0.0	-7	10
	BMI (KG/M^2)	BASELINE	171	30.2	7.21	28.8	17	58	167	30.4	8.19	28.6	17	64	167	28.7	6.92	28.1	18	54
		FINAL	128	31.1	7.31	30.0	19	58	128	31.4	8.38	30.1	17	63	142	28.9	6.96	28.0	18	54
		CHG FRM BSLN	128	0.5	1.19	0.4	-2	10	128	0.5	1.52	0.4	-8	4	142	0.1	0.83	0.0	-3	4
DIABETIC	WEIGHT (KG)	BASELINE	10	92.7	31.18	92.0	36	149	5	93.6	32.57	92.0	48	132	9	98.0	30.71	107.0	54	131
		FINAL	6	103.5	28.67	100.5	65	145	5	92.2	32.25	102.0	52	126	8	104.6	28.54	112.0	55	137
		CHG FRM BSLN	6	1.0	3.69	1.0	-4	6	5	-1.4	9.58	0.0	-15	10	8	1.1	2.42	0.0	-1	6
	BMI (KG/M^2)	BASELINE	10	32.6	8.64	34.1	17	49	5	35.7	13.15	34.2	19	52	9	34.1	9.14	34.7	20	47
		FINAL	6	36.2	7.44	36.4	25	47	5	35.3	13.37	37.9	21	52	8	35.9	9.08	36.2	20	47
		CHG FRM BSLN	6	0.5	1.39	0.4	-1	2	5	-0.4	3.42	0.0	-5	4	8	0.4	0.86	0.0	-0	2
DIABETIC RISK	WEIGHT (KG)	BASELINE	49	104.4	21.97	103.0	58	159	48	105.4	26.45	101.5	64	172	46	97.9	22.28	96.5	59	155
		FINAL	37	106.8	22.54	105.0	58	158	39	106.5	27.45	101.0	61	170	37	99.4	24.18	95.0	59	157

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT209.SAS
GENERATED: 17NOV2005 13:53:40 iceadmn3

Table 11.3.8.1.3.3 Weight and BMI by Diabetic Status (Fasting Glucose) - Descriptive Statistics
Last Observation Carried Forward
Safety Population

			TREATMENT															
			QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO			
			N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
DIABETES		WINDOWED VISIT																		
DIABETIC RISK	WEIGHT (KG)	CHG FRM BSLN	37	1.4	4.80	1.0	-3	27	39	0.8	5.41	1.0	-21	9	37	0.9	3.01	1.0	-7	10
	BMI(KG/M^2)	BASELINE	49	37.2	7.36	37.6	20	58	48	37.9	9.18	37.1	23	64	46	34.4	7.79	35.7	20	54
		FINAL	37	38.1	7.49	38.6	20	58	39	38.5	9.32	37.4	24	63	37	34.4	8.09	35.3	20	54
		CHG FRM BSLN	37	0.5	1.68	0.3	-1	10	39	0.3	2.00	0.3	-8	4	37	0.3	1.10	0.4	-3	4
NON DIABETIC	WEIGHT (KG)	BASELINE	112	79.3	15.11	77.5	49	113	114	78.1	15.65	79.0	36	118	112	76.1	16.41	76.5	44	124
		FINAL	85	82.0	15.46	80.0	51	117	84	80.8	16.51	81.0	36	129	97	76.9	16.52	78.0	43	127
		CHG FRM BSLN	85	1.4	2.58	1.0	-5	10	84	1.7	3.07	1.0	-8	11	97	-0.0	2.05	0.0	-7	5
	BMI(KG/M^2)	BASELINE	112	26.9	4.15	27.0	18	35	114	27.0	4.50	27.4	17	35	112	26.0	4.24	26.2	18	34
		FINAL	85	27.6	4.18	27.3	19	36	84	27.9	4.75	28.3	17	38	97	26.2	4.22	26.4	18	34
		CHG FRM BSLN	85	0.5	0.90	0.4	-2	3	84	0.6	1.04	0.4	-3	3	97	0.0	0.69	0.0	-2	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT209.SAS
GENERATED: 17NOV2005 13:53:40 iceadmn3

Table 11.3.8.1.3.4 Patients with Substantial Weight Gain (>=7%) by BMI Group
Safety Population

BMI GROUP	TREATMENT								
	QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
0 - <18.5	0	0	0	3	0	0.0	1	0	0.0
18.5 - <25	32	3	9.4	23	2	8.7	42	3	7.1
25 - <30	35	1	2.9	41	5	12.2	46	0	0.0
30 - <40	47	1	2.1	46	4	8.7	42	0	0.0
>=40	14	0	0.0	15	0	0.0	11	1	9.1
TOTAL	128	5	3.9	128	11	8.6	142	4	2.8

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT202.SAS
GENERATED: 17NOV2005 13:53:26 iceadmn3

Table 11.3.8.1.3.5 Patients with Substantial Weight Gain (>=7%) by BMI Group for Completers
Safety Population

BMI GROUP	TREATMENT								
	QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
	TOTAL	N	%	TOTAL	N	%	TOTAL	N	%
0 - <18.5	0	0	0	3	0	0.0	1	0	0.0
18.5 - <25	25	2	8.0	13	2	15.4	29	3	10.3
25 - <30	26	1	3.8	30	4	13.3	38	0	0.0
30 - <40	38	1	2.6	31	4	12.9	28	0	0.0
>=40	12	0	0.0	12	0	0.0	11	1	9.1
TOTAL	101	4	4.0	89	10	11.2	107	4	3.7

Note: Only subjects with baseline and final assessments are included in this table.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT211.SAS
GENERATED: 17NOV2005 13:53:44 iceadmn3

FIGURE 11.3.8.1.3.6 BUBBLE PLOT OF CHANGE IN WEIGHT (KG)

(SAFETY POPULATION)

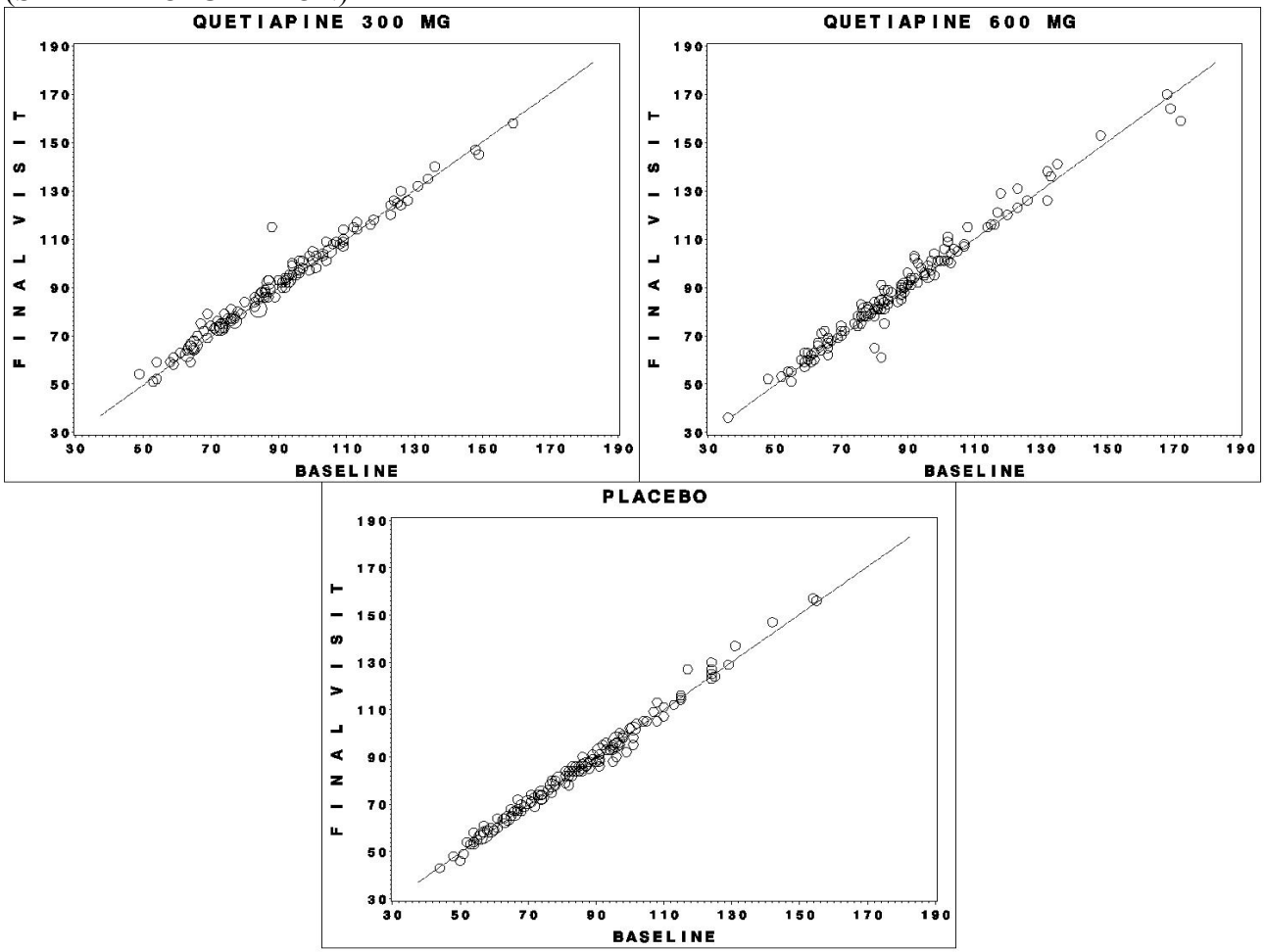

Table 11.3.8.1.4.1 Metabolic Risk Factors, Shift from Baseline To End of Treatment (Fasting Glucose)
Safety Population

Number of metabolic risk factors at baseline	END OF TREATMENT											
	QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
	N=139				N=137				N=154			
	<3factors		>=3factors		<3factors		>=3factors		<3factors		>=3factors	
	N	%	N	%	N	%	N	%	N	%	N	%
0	36	25.9	0	0	15	10.9	1	0.7	44	28.6	0	0
1	28	20.1	6	4.3	49	35.8	3	2.2	38	24.7	1	0.6
2	16	11.5	12	8.6	24	17.5	13	9.5	28	18.2	10	6.5
>=3	9	6.5	32	23.0	10	7.3	22	16.1	12	7.8	21	13.6
Total	89	64.0	50	36.0	98	71.5	39	28.5	122	79.2	32	20.8

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND200.SAS
GENERATED: 17NOV2005 13:52:43 iceadmn3

Table 11.3.8.1.4.2 Metabolic Risk Factors, Treatment Emergent Development of >=3 Risk Factors at Any Time by Sub-Criteria
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=139			N=137			N=154		
		N	n	%	N	n	%	N	n	%
METABOLIC SYNDROME	SHIFT TO >= 3 CRITERIA	98	18	18.4	105	17	16.2	121	11	9.1
BMI (Kg/m2)	SHIFT TO >= 30	72	4	5.6	73	6	8.2	96	2	2.1
BLOOD PRESSURE SYSTOLIC (mm Hg)	SHIFT TO >= 130	101	8	7.9	95	14	14.7	119	9	7.6
BLOOD PRESSURE DIASTOLIC (mm Hg)	SHIFT TO >= 85	105	10	9.5	101	11	10.9	118	9	7.6
BLOOD PRESSURE OVERALL (mm Hg)	SHIFT TO >= 130 systolic or >= 85 diastolic	92	12	13.0	91	19	20.9	109	9	8.3
TRIGLYCERIDES (mg/dL)	SHIFT TO >= 150	89	20	22.5	84	13	15.5	103	16	15.5
HDL CHOLESTEROL (mg/dL)	SHIFT TO < 40 (MEN) < 50 (WOMEN)	75	11	14.7	75	14	18.7	93	19	20.4
GLUCOSE (FASTING) (mg/dL)	SHIFT TO >= 110	130	10	7.7	131	10	7.6	144	10	6.9

* Number of Patients at risk, i.e., not fulfilling the criteria at baseline.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND203.SAS
GENERATED: 17NOV2005 13:52:45 iceadmn3

Table 11.3.8.1.4.3 Metabolic Risk Factors Without Increased Triglycerides
Treatment Emergent Development of >=3 Risk Factors at Any Time
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=139			N=137			N=154		
		N	n	%	N	n	%	N	n	%
METABOLIC SYNDROME FASTING GLUCOSE	SHIFT TO >= 3 CRITERIA	114	4	3.5	122	13	10.7	141	7	5.0

* Number of Patients at risk, i.e., not fulfilling the criteria at baseline.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND204.SAS
GENERATED: 17NOV2005 13:52:48 iceadmn3

Table 11.3.8.1.4.4 Metabolic Risk Factors, Shift from Baseline To End of Treatment (Fasting Glucose - Confirmed*)
Safety Population

Number of metabolic risk factors at baseline	END OF TREATMENT											
	QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
	N=113				N=104				N=127			
	<3factors		>=3factors		<3factors		>=3factors		<3factors		>=3factors	
	N	%	N	%	N	%	N	%	N	%	N	%
0	32	28.3	0	0	11	10.6	1	1.0	36	28.3	0	0
1	25	22.1	4	3.5	38	36.5	2	1.9	33	26.0	0	0
2	12	10.6	8	7.1	19	18.3	7	6.7	23	18.1	8	6.3
>=3	7	6.2	25	22.1	9	8.7	17	16.3	10	7.9	17	13.4
Total	76	67.3	37	32.7	77	74.0	27	26.0	102	80.3	25	19.7

*Confirmed by last meal date and time >8 hours before lab draw for both baseline and fasting labs.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND205.SAS
GENERATED: 17NOV2005 13:52:50 iceadmn3

Table 11.3.8.1.4.5 Metabolic Risk Factors, Treatment Emergent Development of >=3 Risk Factors at Any Time by Sub-Criteria (Fasting Glucose - Confirmed*)
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=113			N=104			N=127		
		N	n	%	N	n	%	N	n	%
METABOLIC SYNDROME	SHIFT TO >= 3 CRITERIA	81	12	14.8	78	10	12.8	100	8	8.0
BMI (Kg/m2)	SHIFT TO >= 30	58	4	6.9	53	4	7.5	79	2	2.5
BLOOD PRESSURE SYSTOLIC (mm Hg)	SHIFT TO >= 130	81	3	3.7	68	10	14.7	99	9	9.1
BLOOD PRESSURE DIASTOLIC (mm Hg)	SHIFT TO >= 85	87	7	8.0	73	8	11.0	97	7	7.2
BLOOD PRESSURE OVERALL (mm Hg)	SHIFT TO >= 130 systolic or >= 85 diastolic	76	6	7.9	65	13	20.0	89	8	9.0
TRIGLYCERIDES (mg/dL)	SHIFT TO >= 150	74	14	18.9	66	10	15.2	87	9	10.3
HDL CHOLESTEROL (mg/dL)	SHIFT TO < 40 (MEN) < 50 (WOMEN)	67	10	14.9	57	9	15.8	76	15	19.7
GLUCOSE (FASTING) (mg/dL)	SHIFT TO >= 110	107	8	7.5	100	7	7.0	120	10	8.3

*Confirmed by last meal date and time >8 hours before lab draw for both baseline and fasting labs.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND207.SAS
GENERATED: 17NOV2005 13:52:54 iceadmn3

Table 11.3.8.1.4.6 Metabolic Risk Factors Without Increased Triglycerides (Fasting Glucose - Confirmed*)
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=113			N=104			N=127		
		N	n	%	N	n	%	N	n	%
METABOLIC SYNDROME FASTING GLUCOSE	SHIFT TO >= 3 CRITERIA	94	3	3.2	90	8	8.9	116	6	5.2

*Confirmed by last meal date and time >8 hours before lab draw for both baseline and final labs.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND209.SAS
GENERATED: 17NOV2005 13:52:59 iceadmn3

Table 11.3.8.1.4.7 Metabolic Risk Factors, Shift from Baseline To End of Treatment
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

Number of metabolic risk factors at baseline	END OF TREATMENT											
	QUETIAPINE 300 MG				QUETIAPINE 600 MG				PLACEBO			
	N=46				N=42				N=52			
	<3factors		>=3factors		<3factors		>=3factors		<3factors		>=3factors	
	N	%	N	%	N	%	N	%	N	%	N	%
0	10	21.7	0	0	6	14.3	0	0	13	25.0	0	0
1	10	21.7	2	4.3	14	33.3	0	0	15	28.8	0	0
2	7	15.2	5	10.9	8	19.0	3	7.1	12	23.1	3	5.8
>=3	1	2.2	11	23.9	6	14.3	5	11.9	1	1.9	8	15.4
Total	28	60.9	18	39.1	34	81.0	8	19.0	41	78.8	11	21.2

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon for both baseline and f

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND206.SAS
GENERATED: 17NOV2005 13:52:52 iceadmn3

Table 11.3.8.1.4.8 Metabolic Risk Factors, Treatment Emergent Development of >=3 Risk Factors at Any Time by Sub-Criteria
(Fasting Glucose - Confirmed with Morning Lab Draw*)
Safety Population

		TREATMENT								
		QUETIAPINE 300 MG			QUETIAPINE 600 MG			PLACEBO		
		N=46			N=42			N=52		
		N	n	%	N	n	%	N	n	%
METABOLIC SYNDROME	SHIFT TO >= 3 CRITERIA	34	7	20.6	31	3	9.7	43	3	7.0
BMI (Kg/m2)	SHIFT TO >= 30	22	1	4.5	22	1	4.5	32	1	3.1
BLOOD PRESSURE SYSTOLIC (mm Hg)	SHIFT TO >= 130	30	2	6.7	28	2	7.1	39	3	7.7
BLOOD PRESSURE DIASTOLIC (mm Hg)	SHIFT TO >= 85	33	4	12.1	34	2	5.9	39	1	2.6
BLOOD PRESSURE OVERALL (mm Hg)	SHIFT TO >= 130 systolic or >= 85 diastolic	27	3	11.1	28	4	14.3	37	3	8.1
TRIGLYCERIDES (mg/dL)	SHIFT TO >= 150	29	9	31.0	27	4	14.8	35	4	11.4
HDL CHOLESTEROL (mg/dL)	SHIFT TO < 40 (MEN) < 50 (WOMEN)	29	5	17.2	20	6	30.0	31	6	19.4
GLUCOSE (FASTING) (mg/dL)	SHIFT TO >= 110	41	2	4.9	41	2	4.9	49	4	8.2

*Confirmed by last meal date and time >8 hours before lab draw and drawn between 6 a.m. and noon for both baseline and f

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SYND208.SAS
GENERATED: 17NOV2005 13:52:57 iceadmn3

Table 11.3.8.1.5.1 SAS Total Score and Change from Baseline - Descriptive Statistics
Safety Population

	TREATMENT																	
	QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STUDY DAY																		
DAY 1 (BASELINE)	171	0.40	1.10	0.0	0	8	167	0.28	0.78	0.0	0	6	167	0.41	1.04	0.0	0	8
FINAL	130	0.33	0.87	0.0	0	5	131	0.49	1.67	0.0	0	13	143	0.13	0.48	0.0	0	3
CHG FRM BSLN	130	-0.08	1.08	0.0	-5	5	130	0.19	1.58	0.0	-4	13	143	-0.28	1.05	0.0	-8	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SAS200.SAS
GENERATED: 17NOV2005 13:52:37 iceadmn3

Table 11.3.8.1.5.2 SAS Total Score Increase from Baseline (Logistic Regression)
Safety Population

	BASELINE SCORE			OBSERVED FREQUENCY			LOGISTIC REGRESSION ESTIMATED EFFECT			LOGISTIC REGRESSION EST. ODDS RATIO		
	TOTAL PTS	MEAN	SD	TOTAL OBS	NO. EVNTS	%	EST.	SE	P-VALUE	ODDS	LOWER	UPPER
TREATMENT												
Q300MG	130	0.4	1.15	130	13	10	.	.	.	.	.	.
Q600MG	130	0.3	0.80	130	12	9.2	.	.	.	.	.	.
P	143	0.4	1.06	143	5	3.5	.	.	.	.	.	.
Q300MG VS P	.	.	.	.	.	.	1.16	0.543	0.032	3.20	1.10	9.26
Q600MG VS P	.	.	.	.	.	.	1.06	0.549	0.054	2.88	0.98	8.43

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SAS201.SAS
GENERATED: 17NOV2005 13:35:52 iceadmn3

Table 11.3.8.1.5.3 SAS Total Score, Categorical Change from Baseline Summary
Safety Population

	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
	N	%	N	%	N	%
IMPROVED	17	13.1	13	10.0	28	19.6
NO CHANGE	100	76.9	105	80.8	110	76.9
WORSENED	13	10.0	12	9.2	5	3.5
TOTAL	130	100.0	130	100.0	143	100.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/SAS202.SAS
GENERATED: 17NOV2005 13:52:39 iceadmn3

FIGURE 11.3.8.1.5.4 BUBBLE PLOT OF SAS SCORE

(SAFETY POPULATION)

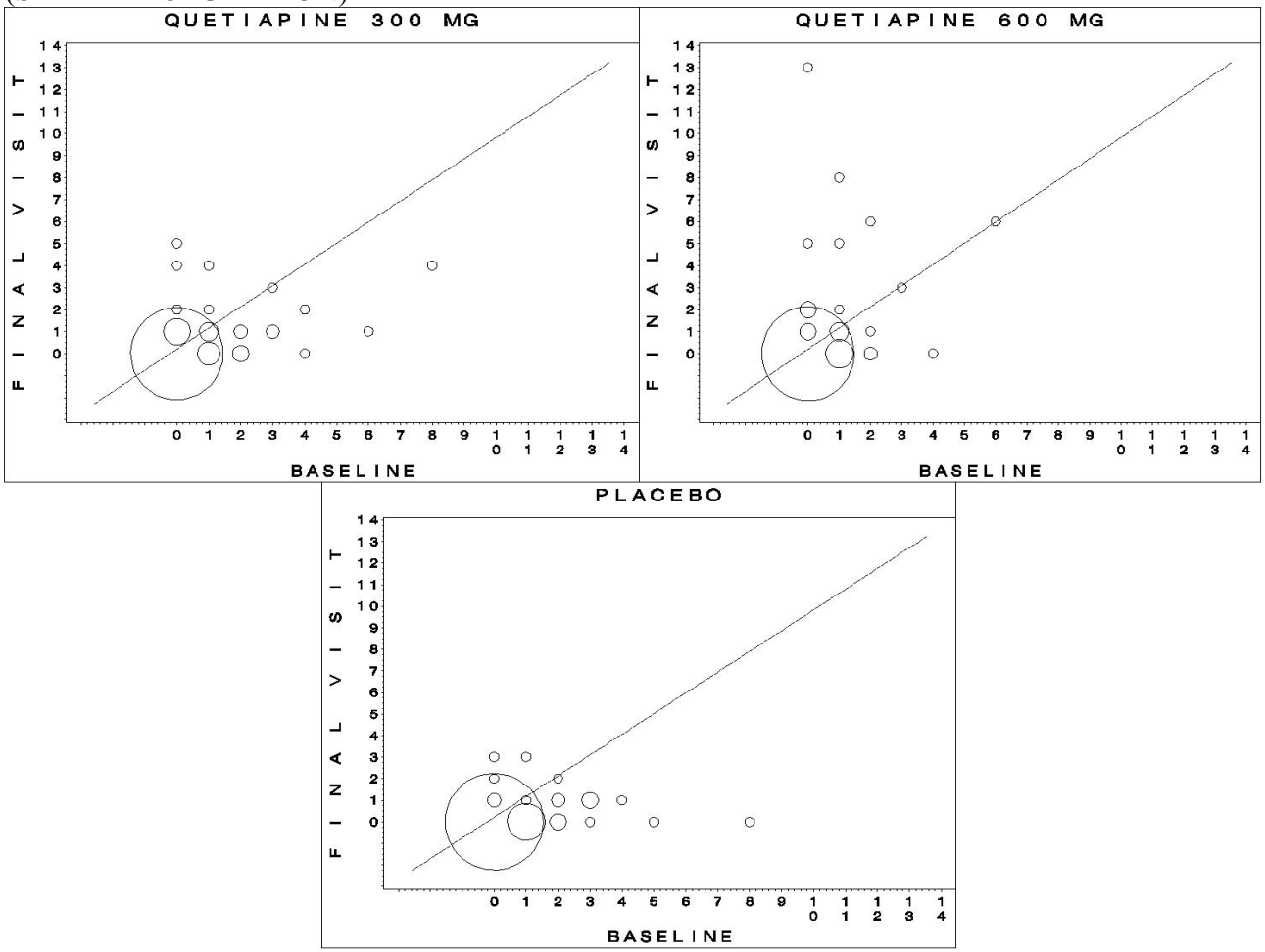

Table 11.3.8.1.6.1 BARS Global Assessment and Change from Baseline - Descriptive Statistics
Safety Population

	TREATMENT																	
	QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
STUDY DAY																		
DAY 1 (BASELINE)	171	0.21	0.56	0.0	0	4	166	0.22	0.52	0.0	0	4	167	0.24	0.58	0.0	0	4
FINAL	130	0.21	0.62	0.0	0	5	131	0.13	0.47	0.0	0	3	143	0.15	0.44	0.0	0	3
CHG FRM BSLN	130	0.04	0.60	0.0	-2	5	129	-0.11	0.71	0.0	-4	3	143	-0.11	0.61	0.0	-3	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/BARS200.SAS
GENERATED: 17NOV2005 13:45:05 iceadmn3

Table 11.3.8.1.6.2 BARS Global Assessment Increase from Baseline (Logistic Regression)
Safety Population

	BASELINE SCORE			OBSERVED FREQUENCY			LOGISTIC REGRESSION ESTIMATED EFFECT			LOGISTIC REGRESSION EST. ODDS RATIO		
	TOTAL PTS	MEAN	SD	TOTAL OBS	NO. EVNTS	%	EST.	SE	P-VALUE	ODDS	LOWER	UPPER
TREATMENT												
Q300MG	130	0.2	0.43	130	7	5.4	.	.	.	.	.	.
Q600MG	129	0.2	0.55	129	6	4.7	.	.	.	.	.	.
P	143	0.3	0.61	143	11	7.7	.	.	.	.	.	.
Q300MG VS P	.	.	.	.	.	.	-0.41	0.501	0.412	0.66	0.25	1.77
Q600MG VS P	.	.	.	.	.	.	-0.54	0.524	0.300	0.58	0.21	1.62

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/BARS201.SAS
GENERATED: 17NOV2005 13:30:44 iceadmn3

Table 11.3.8.1.6.3 BARS Global Assessment Change from Baseline Summary
Safety Population

	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
	N	%	N	%	N	%
IMPROVED	7	5.4	20	15.5	23	16.1
NO CHANGE	116	89.2	103	79.8	109	76.2
WORSENED	7	5.4	6	4.7	11	7.7
TOTAL	130	100.0	129	100.0	143	100.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/BARS202.SAS
GENERATED: 17NOV2005 13:45:08 iceadmn3

FIGURE 11.3.8.1.6.4 BUBBLE PLOT OF BARS SCORE

(SAFETY POPULATION)

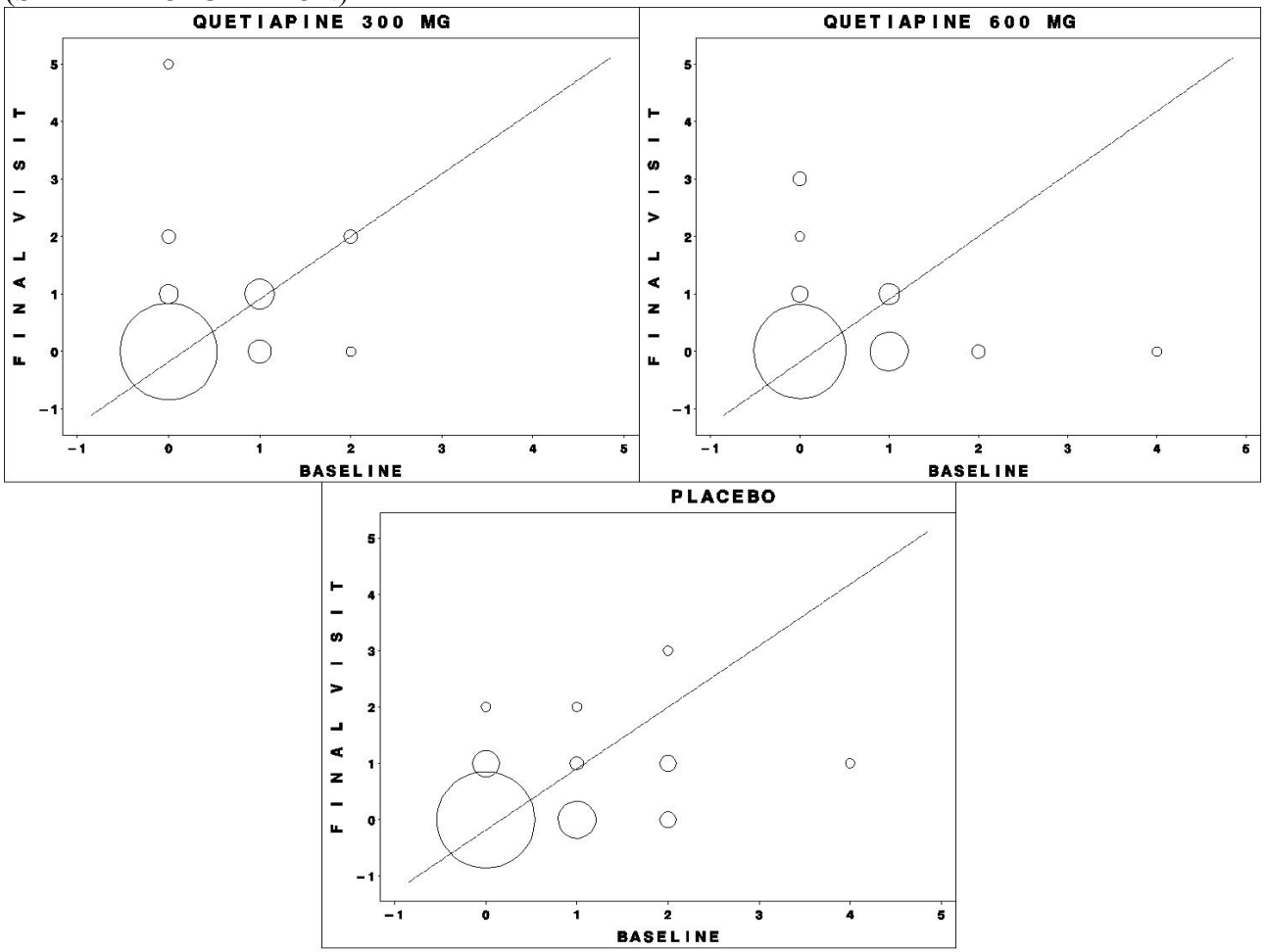

Table 11.3.8.1.7.1 YMRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	155	5.8	3.30	6.0	0	12	151	5.4	2.79	5.0	0	12	161	5.8	3.00	5.0	0	12
	DAY 1	155	6.1	3.22	6.0	0	12	151	5.6	2.70	5.0	0	12	161	5.9	3.15	5.0	0	12
	DAY 8	153	5.3	3.65	5.0	0	20	147	4.6	3.24	4.0	0	19	161	5.7	3.71	5.0	0	19
	DAY 15	155	5.1	3.86	4.0	0	20	148	4.4	3.54	4.0	0	19	161	5.5	4.21	4.0	0	19
	DAY 22	155	4.7	4.06	4.0	0	20	150	4.4	3.45	4.0	0	17	161	5.2	4.16	4.0	0	20
	DAY 29	155	4.3	3.90	3.0	0	20	150	4.4	3.59	3.0	0	17	161	5.1	4.37	4.0	0	24
	DAY 36	155	4.2	3.81	3.0	0	20	150	4.5	3.78	4.0	0	19	161	5.5	4.80	4.0	0	28
	DAY 43	155	4.3	4.16	3.0	0	29	151	4.3	4.18	3.0	0	24	161	5.1	4.48	4.0	0	28
	DAY 50	155	4.2	3.74	3.0	0	20	151	4.2	4.17	3.0	0	24	161	5.4	4.97	4.0	0	28
	DAY 57	155	4.1	3.68	3.0	0	20	151	4.3	4.10	3.0	0	24	161	5.1	4.77	4.0	0	24
CHG FROM BASELINE	DAY 8	153	-0.8	3.37	-1.0	-11	18	147	-1.0	3.00	-1.0	-8	11	161	-0.2	2.94	0.0	-8	12
	DAY 15	155	-1.1	3.64	-1.0	-11	18	148	-1.2	2.82	-1.0	-8	11	161	-0.4	3.47	-1.0	-9	12
	DAY 22	155	-1.5	3.83	-2.0	-11	18	150	-1.3	3.10	-1.0	-9	11	161	-0.7	3.73	-1.0	-9	16
	DAY 29	155	-1.8	4.14	-2.0	-11	18	150	-1.2	3.23	-1.0	-9	11	161	-0.8	4.08	-1.0	-11	19
	DAY 36	155	-1.9	3.81	-2.0	-11	18	150	-1.1	3.48	-1.0	-9	13	161	-0.4	4.39	-1.0	-7	20
	DAY 43	155	-1.8	3.88	-2.0	-11	18	151	-1.3	3.98	-2.0	-10	15	161	-0.7	4.21	-1.0	-9	20

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS201.SAS
GENERATED: 17NOV2005 13:53:59 iceadmn3

Table 11.3.8.1.7.1 YMRS Total Score and Change from Baseline - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	155	-2.0	3.69	-2.0	-11	18	151	-1.4	3.95	-2.0	-10	15	161	-0.5	4.41	-1.0	-10	20
	DAY 57	155	-2.1	3.72	-2.0	-11	18	151	-1.3	3.79	-1.0	-9	15	161	-0.7	4.35	-1.0	-10	16

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS201.SAS
GENERATED: 17NOV2005 13:53:59 iceadmn3

Table 11.3.8.1.7.2 YMRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	155	5.8	3.30	6.0	0	12	151	5.4	2.79	5.0	0	12	161	5.8	3.00	5.0	0	12
	DAY 1	155	6.1	3.22	6.0	0	12	151	5.6	2.70	5.0	0	12	161	5.9	3.15	5.0	0	12
	DAY 8	153	5.3	3.65	5.0	0	20	147	4.6	3.24	4.0	0	19	161	5.7	3.71	5.0	0	19
	DAY 15	134	5.0	3.67	4.0	0	15	126	4.2	3.51	3.0	0	19	146	5.3	4.12	4.0	0	19
	DAY 22	123	4.4	3.80	4.0	0	19	119	4.0	3.35	3.0	0	17	136	4.9	4.09	4.0	0	20
	DAY 29	116	3.9	3.49	3.0	0	19	109	3.8	3.48	3.0	0	17	133	4.8	4.08	4.0	0	24
	DAY 36	111	3.9	3.47	3.0	0	17	104	4.1	3.76	3.0	0	19	124	5.1	4.78	4.0	0	28
	DAY 43	98	4.0	4.20	3.0	0	29	97	3.5	3.88	2.0	0	24	114	4.5	3.41	4.0	0	16
	DAY 50	102	3.8	3.36	3.0	0	16	89	2.9	2.91	2.0	0	14	112	5.1	4.86	4.0	0	28
	DAY 57	97	3.5	3.08	3.0	0	16	86	3.0	2.89	2.0	0	13	103	4.7	4.42	4.0	0	24
CHG FROM BASELINE	DAY 8	153	-0.8	3.37	-1.0	-11	18	147	-1.0	3.00	-1.0	-8	11	161	-0.2	2.94	0.0	-8	12
	DAY 15	134	-1.2	3.08	-1.0	-10	7	126	-1.3	2.68	-1.0	-8	8	146	-0.6	3.37	-1.0	-9	11
	DAY 22	123	-1.7	3.42	-2.0	-10	14	119	-1.6	2.98	-1.0	-9	8	136	-0.9	3.73	-1.0	-9	16
	DAY 29	116	-2.0	3.77	-2.0	-10	15	109	-1.6	3.20	-2.0	-9	11	133	-1.0	3.91	-1.0	-11	19
	DAY 36	111	-2.1	3.31	-2.0	-11	12	104	-1.3	3.46	-2.0	-9	13	124	-0.7	4.45	-1.0	-7	20
	DAY 43	98	-2.0	3.58	-2.0	-10	17	97	-1.8	3.73	-2.0	-10	15	114	-1.4	3.42	-1.0	-9	10

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS200.SAS
GENERATED: 17NOV2005 13:53:57 iceadmn3

Table 11.3.8.1.7.2 YMRS Total Score and Change from Baseline - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	102	-2.1	3.20	-2.0	-10	6	89	-2.3	3.18	-2.0	-10	8	112	-0.7	4.23	-1.0	-10	20
	DAY 57	97	-2.3	3.18	-2.0	-9	6	86	-2.2	2.95	-2.0	-8	4	103	-1.1	4.11	-1.0	-10	15

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS200.SAS
GENERATED: 17NOV2005 13:53:57 iceadmn3

Table 11.3.8.1.7.3 YMRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	6.1	3.20	-0.8	3.37	-0.70	0.274	-1.24	-0.15	.
	Q600MG	147	5.6	2.70	-1.0	3.00	-1.06	0.281	-1.62	-0.51	.
	P	161	5.9	3.15	-0.2	2.94	-0.14	0.272	-0.68	0.40	.
	Q300MG VS P	.	.	.	.	.	-0.56	0.326	-1.20	0.08	0.089
	Q600MG VS P	.	.	.	.	.	-0.92	0.330	-1.57	-0.27	0.005
DAY 15	Q300MG	155	6.1	3.22	-1.1	3.64	-1.01	0.290	-1.58	-0.43	.
	Q600MG	148	5.6	2.69	-1.2	2.82	-1.34	0.298	-1.93	-0.75	.
	P	161	5.9	3.15	-0.4	3.47	-0.49	0.288	-1.06	0.08	.
	Q300MG VS P	.	.	.	.	.	-0.52	0.360	-1.23	0.19	0.151
	Q600MG VS P	.	.	.	.	.	-0.85	0.366	-1.57	-0.13	0.020
DAY 22	Q300MG	155	6.1	3.22	-1.5	3.83	-1.42	0.323	-2.06	-0.78	.
	Q600MG	150	5.6	2.71	-1.3	3.10	-1.46	0.331	-2.11	-0.80	.
	P	161	5.9	3.15	-0.7	3.73	-0.83	0.322	-1.47	-0.19	.
	Q300MG VS P	.	.	.	.	.	-0.59	0.374	-1.32	0.14	0.115
	Q600MG VS P	.	.	.	.	.	-0.63	0.378	-1.37	0.12	0.098
DAY 29	Q300MG	155	6.1	3.22	-1.8	4.14	-1.78	0.342	-2.45	-1.10	.
	Q600MG	150	5.6	2.71	-1.2	3.23	-1.42	0.350	-2.11	-0.73	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS204.SAS
GENERATED: 17NOV2005 13:36:12 iceadmn3

Table 11.3.8.1.7.3 YMRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	161	5.9	3.15	-0.8	4.08	-0.86	0.341	-1.53	-0.18	.
	Q300MG VS P	.	.	.	.	.	-0.92	0.397	-1.70	-0.14	0.021
	Q600MG VS P	.	.	.	.	.	-0.56	0.402	-1.35	0.23	0.163
DAY 36	Q300MG	155	6.1	3.22	-1.9	3.81	-1.88	0.335	-2.55	-1.22	.
	Q600MG	150	5.6	2.71	-1.1	3.48	-1.32	0.342	-2.00	-0.64	.
	P	161	5.9	3.15	-0.4	4.39	-0.54	0.332	-1.20	0.11	.
	Q300MG VS P	.	.	.	.	.	-1.34	0.416	-2.16	-0.52	0.001
	Q600MG VS P	.	.	.	.	.	-0.78	0.421	-1.60	0.05	0.066
DAY 43	Q300MG	155	6.1	3.22	-1.8	3.88	-1.83	0.341	-2.51	-1.16	.
	Q600MG	151	5.6	2.70	-1.3	3.98	-1.50	0.348	-2.19	-0.81	.
	P	161	5.9	3.15	-0.7	4.21	-0.87	0.338	-1.54	-0.21	.
	Q300MG VS P	.	.	.	.	.	-0.96	0.430	-1.80	-0.11	0.027
	Q600MG VS P	.	.	.	.	.	-0.63	0.435	-1.48	0.23	0.149
DAY 50	Q300MG	155	6.1	3.22	-2.0	3.69	-1.96	0.352	-2.65	-1.26	.
	Q600MG	151	5.6	2.70	-1.4	3.95	-1.62	0.359	-2.33	-0.91	.
	P	161	5.9	3.15	-0.5	4.41	-0.57	0.350	-1.26	0.12	.
	Q300MG VS P	.	.	.	.	.	-1.38	0.431	-2.23	-0.54	0.001

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS204.SAS
GENERATED: 17NOV2005 13:36:12 iceadmn3

Table 11.3.8.1.7.3 YMRS Total Score Change from Baseline (ANCOVA)
Last Observation Carried Forward
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-1.05	0.435	-1.91	-0.19	0.016
DAY 57	Q300MG	155	6.1	3.22	-2.1	3.72	-2.04	0.336	-2.70	-1.37	.
	Q600MG	151	5.6	2.70	-1.3	3.79	-1.49	0.342	-2.16	-0.81	.
	P	161	5.9	3.15	-0.7	4.35	-0.86	0.333	-1.52	-0.20	.
	Q300MG VS P	.	.	.	.	.	-1.18	0.423	-2.01	-0.35	0.006
	Q600MG VS P	.	.	.	.	.	-0.63	0.427	-1.47	0.21	0.141

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS204.SAS
GENERATED: 17NOV2005 13:36:12 iceadmn3

Table 11.3.8.1.7.4 YMRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 8	Q300MG	153	6.1	3.20	-0.8	3.37	-0.70	0.274	-1.24	-0.15	.
	Q600MG	147	5.6	2.70	-1.0	3.00	-1.06	0.281	-1.62	-0.51	.
	P	161	5.9	3.15	-0.2	2.94	-0.14	0.272	-0.68	0.40	.
	Q300MG VS P	.	.	.	.	.	-0.56	0.326	-1.20	0.08	0.089
	Q600MG VS P	.	.	.	.	.	-0.92	0.330	-1.57	-0.27	0.005
DAY 15	Q300MG	134	6.2	3.07	-1.2	3.08	-1.22	0.278	-1.77	-0.67	.
	Q600MG	126	5.5	2.73	-1.3	2.68	-1.53	0.289	-2.10	-0.96	.
	P	146	5.9	3.09	-0.6	3.37	-0.70	0.270	-1.24	-0.16	.
	Q300MG VS P	.	.	.	.	.	-0.52	0.358	-1.22	0.19	0.149
	Q600MG VS P	.	.	.	.	.	-0.83	0.364	-1.55	-0.11	0.023
DAY 22	Q300MG	123	6.1	3.09	-1.7	3.42	-1.59	0.334	-2.25	-0.93	.
	Q600MG	119	5.6	2.69	-1.6	2.98	-1.79	0.343	-2.47	-1.12	.
	P	136	5.9	3.07	-0.9	3.73	-1.02	0.324	-1.66	-0.38	.
	Q300MG VS P	.	.	.	.	.	-0.57	0.396	-1.35	0.21	0.151
	Q600MG VS P	.	.	.	.	.	-0.77	0.400	-1.56	0.02	0.055
DAY 29	Q300MG	116	5.9	3.14	-2.0	3.77	-1.95	0.360	-2.66	-1.24	.
	Q600MG	109	5.4	2.60	-1.6	3.20	-1.78	0.373	-2.52	-1.04	.

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS211.SAS
GENERATED: 17NOV2005 13:36:17 iceadmn3

Table 11.3.8.1.7.4 YMRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 29	P	133	5.8	3.10	-1.0	3.91	-1.02	0.343	-1.71	-0.34	.
	Q300MG VS P	.	.	.	.	.	-0.93	0.421	-1.76	-0.10	0.028
	Q600MG VS P	.	.	.	.	.	-0.76	0.428	-1.60	0.09	0.078
DAY 36	Q300MG	111	6.0	3.11	-2.1	3.31	-2.19	0.364	-2.91	-1.47	.
	Q600MG	104	5.4	2.64	-1.3	3.46	-1.60	0.376	-2.34	-0.86	.
	P	124	5.9	3.06	-0.7	4.45	-0.85	0.345	-1.54	-0.17	.
	Q300MG VS P	.	.	.	.	.	-1.34	0.473	-2.27	-0.41	0.005
	Q600MG VS P	.	.	.	.	.	-0.75	0.482	-1.70	0.20	0.122
DAY 43	Q300MG	98	6.0	3.15	-2.0	3.58	-1.97	0.353	-2.67	-1.27	.
	Q600MG	97	5.3	2.67	-1.8	3.73	-2.07	0.357	-2.78	-1.36	.
	P	114	5.9	3.15	-1.4	3.42	-1.48	0.330	-2.13	-0.82	.
	Q300MG VS P	.	.	.	.	.	-0.49	0.463	-1.40	0.42	0.287
	Q600MG VS P	.	.	.	.	.	-0.59	0.465	-1.51	0.32	0.203
DAY 50	Q300MG	102	5.9	3.16	-2.1	3.20	-2.03	0.367	-2.76	-1.31	.
	Q600MG	89	5.3	2.54	-2.3	3.18	-2.59	0.390	-3.36	-1.82	.
	P	112	5.8	3.12	-0.7	4.23	-0.67	0.355	-1.37	0.03	.
	Q300MG VS P	.	.	.	.	.	-1.36	0.464	-2.28	-0.45	0.004

(Continued)

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS211.SAS
GENERATED: 17NOV2005 13:36:17 iceadmn3

Table 11.3.8.1.7.4 YMRS Total Score Change from Baseline (ANCOVA)
Observed Cases
Intent-to-Treat Population

			BASELINE		CHANGE FROM BASELINE		ANCOVA: LS MEANS OR DIFFERENCE				
		N	MEAN	SD	MEAN	SD	EST.	SE	LOWER	UPPER	P-VALUE
VISIT	TREATMENT										
DAY 50	Q600MG VS P	.	.	.	.	.	-1.92	0.482	-2.87	-0.97	<.001
DAY 57	Q300MG	97	5.9	3.17	-2.3	3.18	-2.28	0.337	-2.94	-1.61	.
	Q600MG	86	5.2	2.56	-2.2	2.95	-2.46	0.359	-3.17	-1.75	.
	P	103	5.8	3.09	-1.1	4.11	-1.09	0.331	-1.74	-0.43	.
	Q300MG VS P	.	.	.	.	.	-1.19	0.452	-2.08	-0.30	0.009
	Q600MG VS P	.	.	.	.	.	-1.37	0.468	-2.29	-0.45	0.004

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS211.SAS
GENERATED: 17NOV2005 13:36:17 iceadmn3

FIGURE 11.3.8.1.7.5 YMRS TOTAL SCORE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

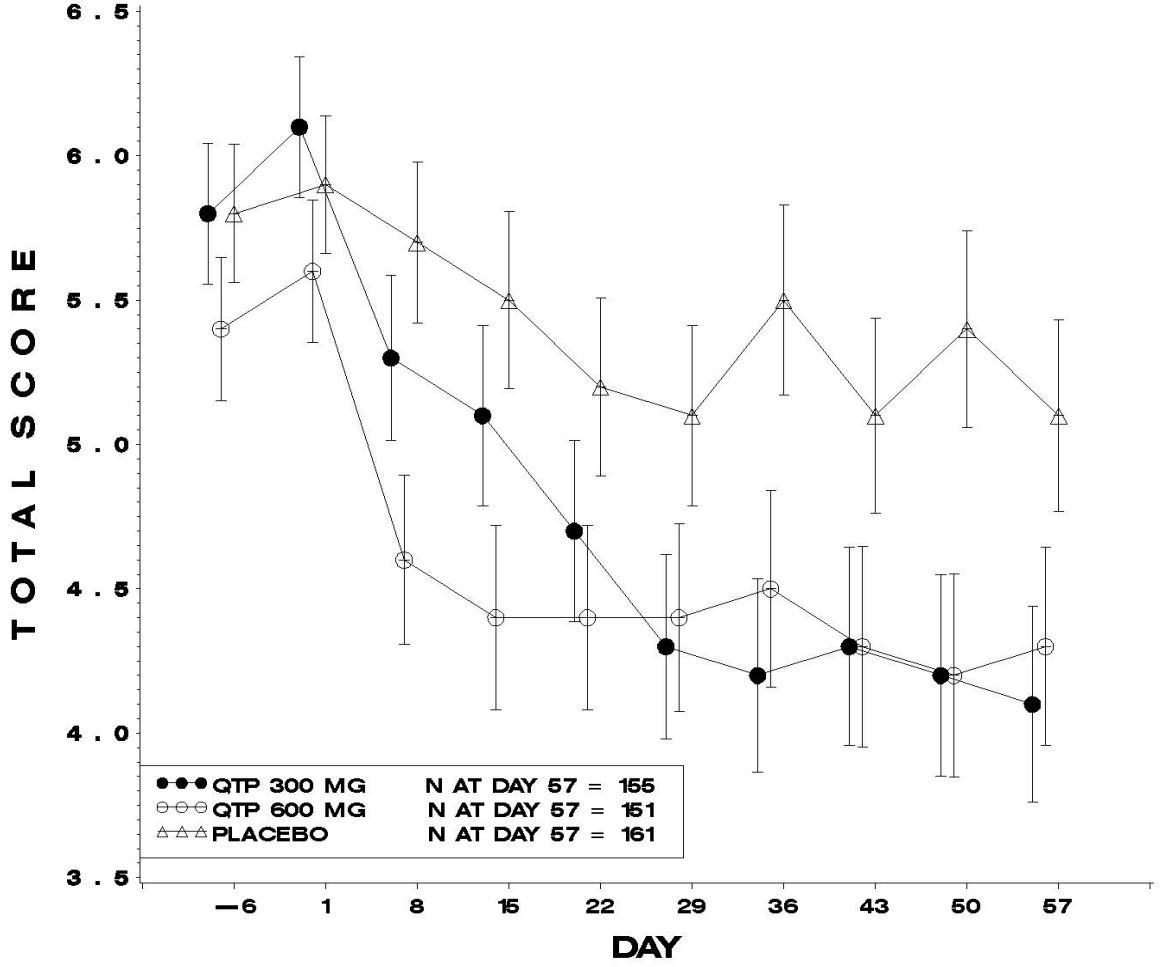

FIGURE 11.3.8.1.7.6 YMRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, SE)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

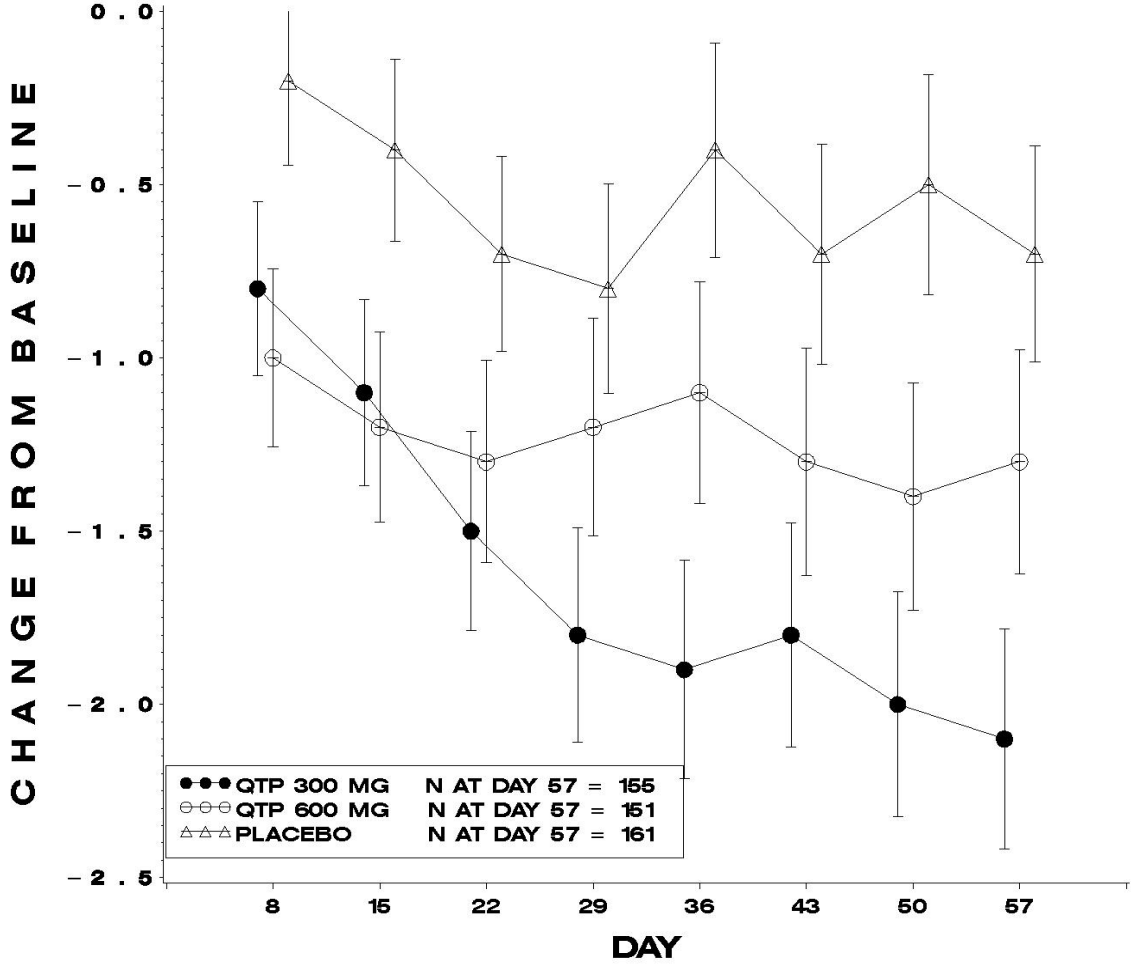

FIGURE 11.3.8.1.7.7 YMRS TOTAL SCORE CHANGE FROM BASELINE (LSMEAN, 95% CI)

(LAST OBSERVATION CARRIED FORWARD - INTENT TO TREAT)

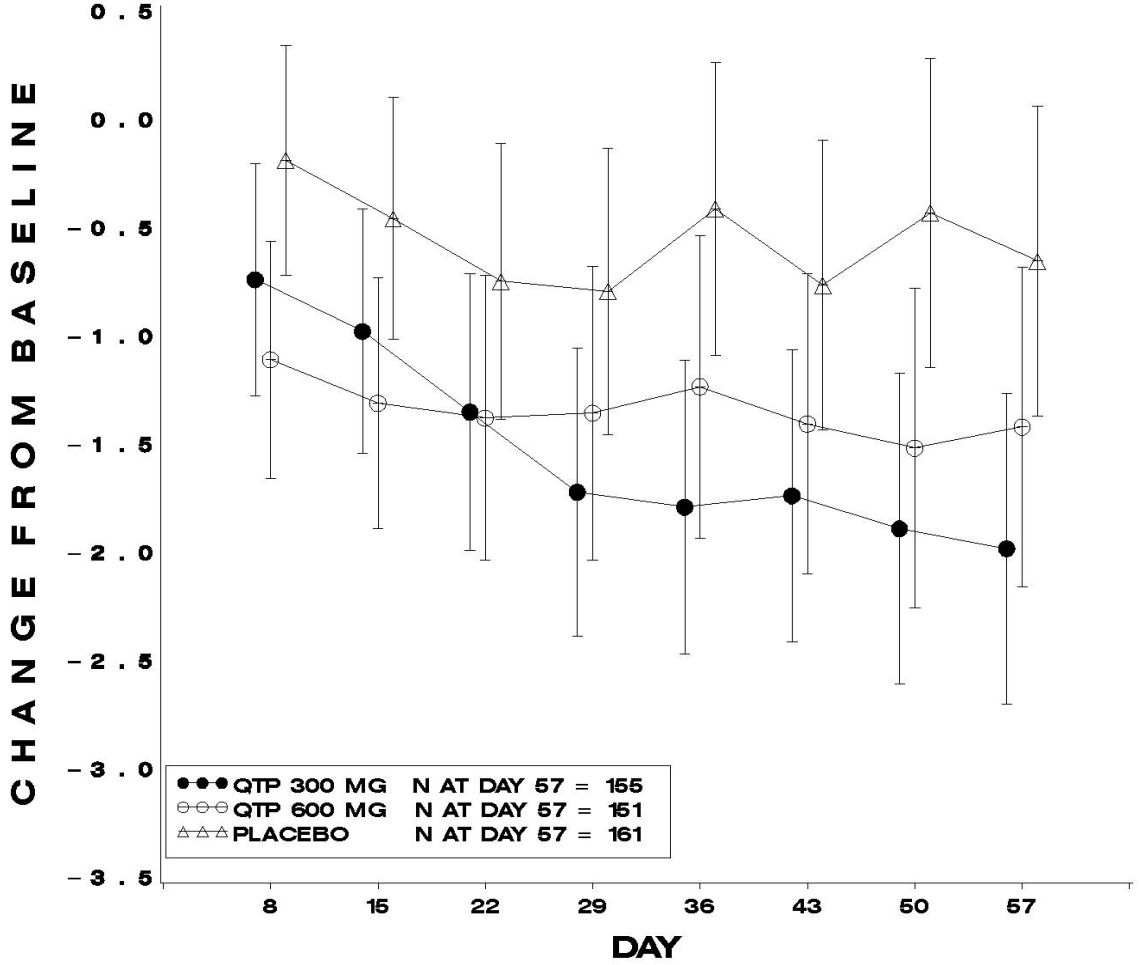

Table 11.3.8.1.7.8 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	104	6.0	3.45	6.0	0	12	101	5.4	2.93	5.0	0	12	110	5.5	2.91	5.0	0	12
	DAY 1	104	6.3	3.31	6.0	0	12	101	5.7	2.84	5.0	0	12	110	5.6	3.15	5.0	0	12
	DAY 8	102	5.3	3.35	5.0	0	14	98	4.6	3.23	4.0	0	19	110	5.5	3.52	5.0	0	16
	DAY 15	104	5.4	3.67	5.0	0	15	99	4.6	3.62	4.0	0	19	110	5.1	3.76	4.0	0	19
	DAY 22	104	5.0	4.21	4.0	0	19	101	4.4	3.55	4.0	0	17	110	5.1	4.22	4.0	0	20
	DAY 29	104	4.6	3.95	3.5	0	19	101	4.4	3.56	4.0	0	17	110	5.1	4.28	4.0	0	24
	DAY 36	104	4.5	3.85	4.0	0	17	101	4.5	3.79	4.0	0	18	110	5.6	5.14	4.0	0	28
	DAY 43	104	4.5	4.24	4.0	0	29	101	4.4	4.55	3.0	0	24	110	5.3	4.82	4.0	0	28
	DAY 50	104	4.3	3.72	4.0	0	16	101	4.3	4.56	3.0	0	24	110	5.6	5.28	5.0	0	28
	DAY 57	104	4.2	3.70	3.0	0	16	101	4.4	4.39	3.0	0	24	110	5.5	5.07	4.0	0	24
CHG FROM BASELINE	DAY 8	102	-0.9	3.08	-1.0	-8	9	98	-1.2	2.96	-1.0	-7	10	110	-0.1	2.81	0.0	-8	7
	DAY 15	104	-0.8	3.09	0.0	-10	9	99	-1.1	2.72	-1.0	-8	8	110	-0.5	3.32	-1.0	-9	11
	DAY 22	104	-1.3	3.60	-2.0	-10	14	101	-1.3	3.04	-1.0	-9	8	110	-0.6	3.84	-1.0	-9	16
	DAY 29	104	-1.7	4.09	-2.0	-10	15	101	-1.3	3.00	-1.0	-9	6	110	-0.6	4.05	-1.0	-9	19
	DAY 36	104	-1.8	3.62	-2.0	-11	12	101	-1.2	3.39	-1.0	-9	13	110	0.0	4.62	-0.5	-7	20
	DAY 43	104	-1.8	3.60	-2.0	-8	17	101	-1.3	4.32	-2.0	-9	15	110	-0.3	4.46	-1.0	-9	20

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS203.SAS
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Table 11.3.8.1.7.8 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR I		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	104	-2.0	3.12	-2.0	-8	6	101	-1.4	4.27	-2.0	-9	15	110	-0.0	4.60	0.0	-10	20
	DAY 57	104	-2.1	3.34	-2.0	-9	6	101	-1.3	4.04	-1.0	-9	15	110	-0.2	4.44	-1.0	-10	16

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS203.SAS
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Table 11.3.8.1.7.8 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	51	5.5	2.96	5.0	0	12	50	5.4	2.53	5.0	1	12	51	6.4	3.13	5.0	1	12
	DAY 1	51	5.9	3.04	5.0	0	12	50	5.5	2.42	5.0	0	12	51	6.4	3.12	7.0	1	12
	DAY 8	51	5.3	4.21	4.0	0	20	49	4.6	3.28	4.0	0	14	51	6.2	4.08	5.0	0	19
	DAY 15	51	4.4	4.16	3.0	0	20	49	4.1	3.37	3.0	0	14	51	6.2	5.00	4.0	0	19
	DAY 22	51	4.0	3.70	4.0	0	20	49	4.2	3.27	3.0	0	14	51	5.4	4.06	5.0	0	19
	DAY 29	51	3.6	3.72	3.0	0	20	49	4.5	3.67	3.0	0	17	51	5.3	4.58	4.0	1	22
	DAY 36	51	3.6	3.70	2.0	0	20	49	4.6	3.81	3.0	0	19	51	5.1	4.00	4.0	0	19
	DAY 43	51	3.9	3.99	3.0	0	20	50	4.2	3.35	3.0	0	14	51	4.8	3.63	4.0	0	19
	DAY 50	51	3.9	3.80	3.0	0	20	50	4.1	3.26	3.0	0	14	51	5.1	4.26	4.0	0	19
	DAY 57	51	3.9	3.68	3.0	0	20	50	4.1	3.47	3.5	0	14	51	4.4	3.99	4.0	0	19
CHG FROM BASELINE	DAY 8	51	-0.5	3.89	-1.0	-11	18	49	-0.8	3.09	-1.0	-8	11	51	-0.2	3.23	0.0	-7	12
	DAY 15	51	-1.5	4.57	-2.0	-11	18	49	-1.3	3.02	-1.0	-7	11	51	-0.2	3.81	-1.0	-7	12
	DAY 22	51	-1.8	4.27	-2.0	-11	18	49	-1.3	3.25	-1.0	-8	11	51	-1.1	3.51	-2.0	-8	12
	DAY 29	51	-2.2	4.26	-2.0	-11	18	49	-0.9	3.66	-1.0	-7	11	51	-1.2	4.14	-1.0	-11	12
	DAY 36	51	-2.2	4.20	-3.0	-11	18	49	-0.9	3.67	-1.0	-9	13	51	-1.3	3.72	-1.0	-7	12
	DAY 43	51	-1.9	4.45	-2.0	-11	18	50	-1.2	3.24	-1.0	-10	11	51	-1.6	3.49	-1.0	-9	12

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS203.SAS
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Table 11.3.8.1.7.8 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	51	-1.9	4.68	-2.0	-11	18	50	-1.4	3.26	-1.0	-10	11	51	-1.4	3.85	-2.0	-9	12
	DAY 57	51	-2.0	4.42	-2.0	-11	18	50	-1.3	3.26	-2.0	-8	11	51	-2.0	3.89	-2.0	-9	12

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS203.SAS
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Table 11.3.8.1.7.9 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	104	6.0	3.45	6.0	0	12	101	5.4	2.93	5.0	0	12	110	5.5	2.91	5.0	0	12
	DAY 1	104	6.3	3.31	6.0	0	12	101	5.7	2.84	5.0	0	12	110	5.6	3.15	5.0	0	12
	DAY 8	102	5.3	3.35	5.0	0	14	98	4.6	3.23	4.0	0	19	110	5.5	3.52	5.0	0	16
	DAY 15	88	5.4	3.65	5.0	0	15	88	4.5	3.72	4.0	0	19	100	5.1	3.78	4.0	0	19
	DAY 22	80	4.7	4.16	3.5	0	19	83	4.2	3.52	4.0	0	17	92	4.9	4.30	4.0	0	20
	DAY 29	78	4.2	3.73	3.0	0	19	76	4.0	3.55	3.0	0	17	87	4.8	4.00	4.0	0	24
	DAY 36	74	4.2	3.70	3.0	0	17	71	4.4	3.84	3.0	0	18	81	5.4	5.28	4.0	0	28
	DAY 43	63	4.3	4.56	3.0	0	29	64	3.8	4.37	2.0	0	24	76	4.6	3.63	4.0	0	16
	DAY 50	65	3.9	3.52	3.0	0	16	58	3.1	3.17	2.0	0	14	75	5.3	5.27	4.0	0	28
	DAY 57	61	3.5	3.19	3.0	0	16	57	3.2	2.89	3.0	0	12	69	5.1	4.79	4.0	0	24
CHG FROM BASELINE	DAY 8	102	-0.9	3.08	-1.0	-8	9	98	-1.2	2.96	-1.0	-7	10	110	-0.1	2.81	0.0	-8	7
	DAY 15	88	-1.0	2.78	-1.0	-10	7	88	-1.0	2.77	-1.0	-8	8	100	-0.7	3.30	-1.0	-9	11
	DAY 22	80	-1.5	3.61	-2.0	-10	14	83	-1.4	3.09	-1.0	-9	8	92	-0.8	3.99	-1.0	-9	16
	DAY 29	78	-1.8	4.20	-2.0	-10	15	76	-1.4	3.09	-2.0	-9	6	87	-0.8	3.94	-1.0	-9	19
	DAY 36	74	-1.9	3.64	-2.0	-11	12	71	-1.0	3.43	-1.0	-8	13	81	-0.3	4.87	-1.0	-7	20
	DAY 43	63	-1.8	3.87	-2.0	-8	17	64	-1.5	4.18	-2.0	-8	15	76	-1.1	3.55	-1.0	-9	10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS202.SAS
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Table 11.3.8.1.7.9 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR I		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	65	-2.1	3.00	-2.0	-8	6	58	-2.2	3.45	-2.0	-9	8	75	-0.3	4.53	-1.0	-10	20
	DAY 57	61	-2.5	3.25	-3.0	-9	6	57	-2.0	3.07	-2.0	-8	4	69	-0.5	4.25	-1.0	-10	15

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS202.SAS
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Table 11.3.8.1.7.9 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
YMRS TOTAL SCORE	WINDOWED VISIT																		
	SCREEN	51	5.5	2.96	5.0	0	12	50	5.4	2.53	5.0	1	12	51	6.4	3.13	5.0	1	12
	DAY 1	51	5.9	3.04	5.0	0	12	50	5.5	2.42	5.0	0	12	51	6.4	3.12	7.0	1	12
	DAY 8	51	5.3	4.21	4.0	0	20	49	4.6	3.28	4.0	0	14	51	6.2	4.08	5.0	0	19
	DAY 15	46	4.2	3.65	3.0	0	14	38	3.4	2.85	2.5	0	11	46	5.7	4.79	3.5	0	18
	DAY 22	43	3.8	2.98	4.0	0	12	36	3.4	2.87	3.0	0	11	44	5.0	3.65	4.5	0	14
	DAY 29	38	3.4	2.91	3.0	0	13	33	3.4	3.32	3.0	0	17	46	4.9	4.28	3.0	1	22
	DAY 36	37	3.3	2.93	2.0	0	11	33	3.5	3.56	3.0	0	19	43	4.7	3.66	4.0	0	13
	DAY 43	35	3.6	3.50	3.0	0	12	33	3.0	2.63	3.0	0	11	38	4.3	2.95	4.0	0	11
	DAY 50	37	3.7	3.09	3.0	0	12	31	2.7	2.38	2.0	0	10	37	4.8	3.95	4.0	0	17
	DAY 57	36	3.7	2.92	3.0	0	13	29	2.7	2.90	2.0	0	13	34	4.0	3.52	4.0	0	17
CHG FROM BASELINE	DAY 8	51	-0.5	3.89	-1.0	-11	18	49	-0.8	3.09	-1.0	-8	11	51	-0.2	3.23	0.0	-7	12
	DAY 15	46	-1.7	3.56	-2.0	-10	7	38	-2.0	2.33	-2.0	-7	2	46	-0.4	3.54	-1.0	-7	9
	DAY 22	43	-1.9	3.08	-2.0	-10	7	36	-2.1	2.66	-2.0	-8	3	44	-1.3	3.14	-2.0	-8	9
	DAY 29	38	-2.3	2.70	-2.0	-10	2	33	-1.9	3.47	-2.0	-7	11	46	-1.4	3.87	-1.0	-11	10
	DAY 36	37	-2.5	2.50	-2.0	-8	3	33	-1.8	3.52	-2.0	-9	13	43	-1.6	3.39	-1.0	-7	8
	DAY 43	35	-2.3	3.03	-2.0	-10	4	33	-2.3	2.64	-2.0	-10	4	38	-2.1	3.10	-1.5	-9	3

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS202.SAS
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Table 11.3.8.1.7.9 YMRS Total Score and Change from Baseline by Bipolar Diagnosis - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

BIPOLAR II		TREATMENT																
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
CHG FROM BASELINE	WINDOWED VISIT																		
	DAY 50	37	-2.0	3.57	-2.0	-10	5	31	-2.5	2.64	-2.0	-10	3	37	-1.4	3.49	-2.0	-7	9
	DAY 57	36	-2.0	3.08	-2.0	-8	5	29	-2.4	2.74	-2.0	-8	2	34	-2.4	3.52	-2.0	-9	9

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS202.SAS
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Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ELEVATED MOOD	WINDOWED VISIT																		
	SCREEN	155	0.2	0.45	0.0	0	2	151	0.2	0.38	0.0	0	2	161	0.2	0.46	0.0	0	2
	DAY 1	155	0.2	0.48	0.0	0	2	151	0.2	0.38	0.0	0	2	161	0.2	0.42	0.0	0	2
	DAY 8	153	0.2	0.58	0.0	0	2	147	0.2	0.48	0.0	0	2	161	0.2	0.52	0.0	0	3
	DAY 15	155	0.3	0.56	0.0	0	2	148	0.3	0.58	0.0	0	3	161	0.3	0.62	0.0	0	3
	DAY 22	155	0.2	0.57	0.0	0	3	150	0.3	0.55	0.0	0	3	161	0.2	0.54	0.0	0	2
	DAY 29	155	0.2	0.50	0.0	0	2	150	0.2	0.58	0.0	0	3	161	0.3	0.58	0.0	0	3
	DAY 36	155	0.1	0.43	0.0	0	2	150	0.3	0.54	0.0	0	2	161	0.3	0.59	0.0	0	2
	DAY 43	155	0.2	0.55	0.0	0	2	151	0.3	0.57	0.0	0	3	161	0.2	0.57	0.0	0	2
	DAY 50	155	0.2	0.52	0.0	0	2	151	0.2	0.52	0.0	0	3	161	0.3	0.62	0.0	0	2
	DAY 57	155	0.2	0.51	0.0	0	2	151	0.2	0.52	0.0	0	3	161	0.3	0.60	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
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Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. INCREASED MOTOR ACTIVITY	WINDOWED VISIT																		
	SCREEN	155	0.3	0.63	0.0	0	3	151	0.2	0.55	0.0	0	3	161	0.2	0.52	0.0	0	3
	DAY 1	155	0.2	0.47	0.0	0	2	151	0.2	0.49	0.0	0	3	161	0.2	0.53	0.0	0	3
	DAY 8	153	0.3	0.65	0.0	0	3	147	0.3	0.56	0.0	0	3	161	0.3	0.58	0.0	0	3
	DAY 15	155	0.3	0.65	0.0	0	3	148	0.3	0.55	0.0	0	3	161	0.3	0.64	0.0	0	3
	DAY 22	155	0.3	0.64	0.0	0	3	150	0.3	0.60	0.0	0	3	161	0.3	0.66	0.0	0	3
	DAY 29	155	0.3	0.60	0.0	0	3	150	0.3	0.51	0.0	0	2	161	0.3	0.69	0.0	0	3
	DAY 36	155	0.3	0.66	0.0	0	3	150	0.3	0.51	0.0	0	2	161	0.3	0.74	0.0	0	3
	DAY 43	155	0.3	0.60	0.0	0	3	151	0.3	0.53	0.0	0	3	161	0.2	0.65	0.0	0	3
	DAY 50	155	0.3	0.63	0.0	0	3	151	0.3	0.52	0.0	0	3	161	0.3	0.71	0.0	0	3
	DAY 57	155	0.2	0.55	0.0	0	3	151	0.2	0.50	0.0	0	3	161	0.3	0.69	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
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Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SEXUAL INTEREST	WINDOWED VISIT																		
	SCREEN	155	0.1	0.36	0.0	0	2	151	0.2	0.54	0.0	0	3	161	0.1	0.33	0.0	0	2
	DAY 1	155	0.1	0.33	0.0	0	2	151	0.1	0.29	0.0	0	2	161	0.0	0.22	0.0	0	2
	DAY 8	153	0.2	0.45	0.0	0	2	147	0.1	0.26	0.0	0	2	161	0.1	0.34	0.0	0	2
	DAY 15	155	0.1	0.45	0.0	0	2	148	0.1	0.32	0.0	0	2	161	0.1	0.43	0.0	0	3
	DAY 22	155	0.1	0.41	0.0	0	2	150	0.1	0.35	0.0	0	2	161	0.1	0.37	0.0	0	2
	DAY 29	155	0.1	0.34	0.0	0	2	150	0.1	0.31	0.0	0	2	161	0.0	0.23	0.0	0	2
	DAY 36	155	0.1	0.44	0.0	0	3	150	0.1	0.36	0.0	0	2	161	0.1	0.28	0.0	0	2
	DAY 43	155	0.1	0.44	0.0	0	2	151	0.1	0.36	0.0	0	3	161	0.1	0.32	0.0	0	2
	DAY 50	155	0.1	0.36	0.0	0	2	151	0.1	0.35	0.0	0	3	161	0.1	0.40	0.0	0	2
	DAY 57	155	0.1	0.44	0.0	0	3	151	0.1	0.43	0.0	0	3	161	0.1	0.30	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. SLEEP	WINDOWED VISIT																		
	SCREEN	155	1.1	0.99	2.0	0	3	151	1.2	0.95	1.0	0	3	161	1.2	0.91	2.0	0	3
	DAY 1	155	1.3	0.93	2.0	0	3	151	1.3	0.91	2.0	0	3	161	1.3	0.88	2.0	0	3
	DAY 8	153	0.4	0.72	0.0	0	3	147	0.4	0.70	0.0	0	2	161	1.0	0.89	1.0	0	3
	DAY 15	155	0.5	0.76	0.0	0	3	148	0.4	0.72	0.0	0	3	161	1.0	0.92	1.0	0	3
	DAY 22	155	0.5	0.82	0.0	0	3	150	0.3	0.67	0.0	0	3	161	0.9	0.90	1.0	0	4
	DAY 29	155	0.4	0.77	0.0	0	4	150	0.4	0.67	0.0	0	2	161	0.9	0.92	1.0	0	4
	DAY 36	155	0.4	0.78	0.0	0	3	150	0.4	0.69	0.0	0	3	161	0.9	0.92	1.0	0	4
	DAY 43	155	0.4	0.76	0.0	0	3	151	0.3	0.67	0.0	0	3	161	0.9	0.96	1.0	0	4
	DAY 50	155	0.4	0.73	0.0	0	3	151	0.4	0.71	0.0	0	3	161	0.8	0.94	0.0	0	4
	DAY 57	155	0.4	0.72	0.0	0	3	151	0.4	0.76	0.0	0	3	161	0.8	0.95	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. IRRITABILTY	WINDOWED VISIT																		
	SCREEN	155	2.0	1.22	2.0	0	5	151	1.9	1.00	2.0	0	4	161	2.1	1.05	2.0	0	4
	DAY 1	155	2.1	1.33	2.0	0	5	151	2.1	1.03	2.0	0	5	161	2.3	1.07	2.0	0	5
	DAY 8	153	1.9	1.34	2.0	0	6	147	1.8	1.06	2.0	0	4	161	1.9	1.19	2.0	0	5
	DAY 15	155	1.8	1.42	2.0	0	6	148	1.6	1.22	2.0	0	5	161	1.7	1.32	2.0	0	6
	DAY 22	155	1.6	1.30	2.0	0	6	150	1.6	1.23	2.0	0	5	161	1.7	1.27	2.0	0	6
	DAY 29	155	1.6	1.33	2.0	0	6	150	1.6	1.14	2.0	0	5	161	1.7	1.26	2.0	0	6
	DAY 36	155	1.5	1.39	2.0	0	6	150	1.5	1.17	2.0	0	5	161	1.8	1.46	2.0	0	6
	DAY 43	155	1.5	1.38	2.0	0	6	151	1.4	1.15	2.0	0	5	161	1.8	1.40	2.0	0	6
	DAY 50	155	1.5	1.42	1.0	0	6	151	1.4	1.16	1.0	0	5	161	1.7	1.41	2.0	0	6
	DAY 57	155	1.5	1.42	1.0	0	6	151	1.4	1.16	1.0	0	5	161	1.7	1.43	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. SPEECH (RATE AND AMOUNT)	WINDOWED VISIT																		
	SCREEN	155	0.4	0.75	0.0	0	4	151	0.4	0.79	0.0	0	4	161	0.5	0.95	0.0	0	4
	DAY 1	155	0.4	0.82	0.0	0	4	151	0.4	0.76	0.0	0	3	161	0.3	0.85	0.0	0	5
	DAY 8	153	0.6	0.99	0.0	0	4	147	0.6	0.99	0.0	0	4	161	0.7	1.05	0.0	0	5
	DAY 15	155	0.4	0.93	0.0	0	5	148	0.5	0.95	0.0	0	4	161	0.6	1.07	0.0	0	5
	DAY 22	155	0.4	0.95	0.0	0	5	150	0.5	0.93	0.0	0	4	161	0.4	0.91	0.0	0	4
	DAY 29	155	0.3	0.85	0.0	0	5	150	0.4	0.91	0.0	0	4	161	0.4	1.00	0.0	0	5
	DAY 36	155	0.3	0.78	0.0	0	4	150	0.5	0.93	0.0	0	4	161	0.5	1.08	0.0	0	6
	DAY 43	155	0.4	0.85	0.0	0	4	151	0.5	1.03	0.0	0	5	161	0.5	1.05	0.0	0	6
	DAY 50	155	0.4	0.87	0.0	0	4	151	0.5	0.96	0.0	0	4	161	0.5	1.00	0.0	0	5
	DAY 57	155	0.3	0.86	0.0	0	4	151	0.5	1.03	0.0	0	4	161	0.5	1.07	0.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LANGUAGE - THOUGHT DISORDER	WINDOWED VISIT																		
	SCREEN	155	0.7	0.76	0.0	0	2	151	0.6	0.71	0.0	0	2	161	0.6	0.74	0.0	0	2
	DAY 1	155	0.7	0.77	1.0	0	2	151	0.6	0.70	0.0	0	2	161	0.6	0.77	0.0	0	2
	DAY 8	153	0.5	0.67	0.0	0	2	147	0.5	0.66	0.0	0	2	161	0.6	0.74	0.0	0	2
	DAY 15	155	0.5	0.68	0.0	0	2	148	0.5	0.66	0.0	0	3	161	0.6	0.74	0.0	0	2
	DAY 22	155	0.4	0.66	0.0	0	2	150	0.5	0.64	0.0	0	3	161	0.6	0.73	0.0	0	2
	DAY 29	155	0.4	0.64	0.0	0	2	150	0.6	0.69	0.0	0	2	161	0.5	0.73	0.0	0	3
	DAY 36	155	0.4	0.62	0.0	0	2	150	0.6	0.70	0.0	0	2	161	0.6	0.72	0.0	0	2
	DAY 43	155	0.4	0.64	0.0	0	2	151	0.5	0.71	0.0	0	2	161	0.5	0.74	0.0	0	2
	DAY 50	155	0.4	0.66	0.0	0	2	151	0.5	0.67	0.0	0	2	161	0.5	0.72	0.0	0	2
	DAY 57	155	0.3	0.60	0.0	0	2	151	0.5	0.68	0.0	0	2	161	0.5	0.72	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. CONTENT	WINDOWED VISIT																		
	SCREEN	155	0.2	0.82	0.0	0	8	151	0.2	0.48	0.0	0	3	161	0.1	0.43	0.0	0	2
	DAY 1	155	0.2	0.65	0.0	0	6	151	0.1	0.41	0.0	0	2	161	0.2	0.47	0.0	0	3
	DAY 8	153	0.3	0.76	0.0	0	5	147	0.2	0.63	0.0	0	6	161	0.2	0.55	0.0	0	3
	DAY 15	155	0.3	0.71	0.0	0	4	148	0.2	0.68	0.0	0	6	161	0.2	0.73	0.0	0	6
	DAY 22	155	0.3	0.69	0.0	0	4	150	0.2	0.72	0.0	0	6	161	0.2	0.74	0.0	0	6
	DAY 29	155	0.2	0.61	0.0	0	4	150	0.2	0.71	0.0	0	6	161	0.2	0.64	0.0	0	3
	DAY 36	155	0.2	0.64	0.0	0	4	150	0.3	0.83	0.0	0	6	161	0.2	0.72	0.0	0	4
	DAY 43	155	0.2	0.63	0.0	0	5	151	0.3	0.82	0.0	0	6	161	0.3	0.77	0.0	0	4
	DAY 50	155	0.2	0.53	0.0	0	3	151	0.3	0.87	0.0	0	6	161	0.4	0.97	0.0	0	6
	DAY 57	155	0.2	0.49	0.0	0	2	151	0.2	0.74	0.0	0	6	161	0.3	0.78	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. DISRUPTIVE - AGGRESSIVE BEHAVIOUR	WINDOWED VISIT																		
	SCREEN	155	0.6	0.98	0.0	0	4	151	0.5	0.89	0.0	0	4	161	0.6	1.09	0.0	0	5
	DAY 1	155	0.7	1.06	0.0	0	4	151	0.6	0.94	0.0	0	4	161	0.5	0.96	0.0	0	4
	DAY 8	153	0.7	1.24	0.0	0	8	147	0.5	1.02	0.0	0	4	161	0.5	0.99	0.0	0	6
	DAY 15	155	0.7	1.26	0.0	0	8	148	0.5	1.03	0.0	0	4	161	0.5	0.98	0.0	0	4
	DAY 22	155	0.7	1.20	0.0	0	8	150	0.4	0.91	0.0	0	4	161	0.5	1.00	0.0	0	4
	DAY 29	155	0.6	1.19	0.0	0	8	150	0.5	1.03	0.0	0	4	161	0.5	0.96	0.0	0	4
	DAY 36	155	0.6	1.11	0.0	0	8	150	0.5	1.10	0.0	0	6	161	0.6	1.07	0.0	0	5
	DAY 43	155	0.5	1.15	0.0	0	8	151	0.5	0.99	0.0	0	4	161	0.5	1.02	0.0	0	5
	DAY 50	155	0.5	1.16	0.0	0	8	151	0.5	1.04	0.0	0	4	161	0.5	1.00	0.0	0	4
	DAY 57	155	0.6	1.22	0.0	0	8	151	0.5	1.04	0.0	0	4	161	0.5	0.99	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. APPEARANCE	WINDOWED VISIT																		
	SCREEN	155	0.2	0.50	0.0	0	3	151	0.1	0.38	0.0	0	2	161	0.1	0.37	0.0	0	2
	DAY 1	155	0.2	0.47	0.0	0	2	151	0.1	0.41	0.0	0	2	161	0.2	0.41	0.0	0	2
	DAY 8	153	0.2	0.48	0.0	0	2	147	0.1	0.39	0.0	0	2	161	0.2	0.42	0.0	0	2
	DAY 15	155	0.2	0.42	0.0	0	2	148	0.1	0.38	0.0	0	2	161	0.1	0.37	0.0	0	2
	DAY 22	155	0.2	0.36	0.0	0	1	150	0.2	0.42	0.0	0	2	161	0.1	0.38	0.0	0	2
	DAY 29	155	0.1	0.42	0.0	0	2	150	0.2	0.42	0.0	0	2	161	0.2	0.42	0.0	0	2
	DAY 36	155	0.2	0.43	0.0	0	2	150	0.2	0.43	0.0	0	2	161	0.2	0.43	0.0	0	2
	DAY 43	155	0.2	0.45	0.0	0	2	151	0.2	0.42	0.0	0	2	161	0.2	0.52	0.0	0	4
	DAY 50	155	0.1	0.42	0.0	0	2	151	0.2	0.43	0.0	0	2	161	0.1	0.43	0.0	0	2
	DAY 57	155	0.2	0.43	0.0	0	2	151	0.2	0.43	0.0	0	2	161	0.1	0.42	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.10 YMRS Individual Item Scores - Descriptive Statistics
Last Observation Carried Forward
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. INSIGHT	WINDOWED VISIT																		
	SCREEN	155	0.0	0.24	0.0	0	2	151	0.0	0.14	0.0	0	1	161	0.0	0.11	0.0	0	1
	DAY 1	155	0.0	0.35	0.0	0	4	151	0.0	0.11	0.0	0	1	161	0.0	0.11	0.0	0	1
	DAY 8	153	0.0	0.28	0.0	0	3	147	0.0	0.08	0.0	0	1	161	0.0	0.14	0.0	0	1
	DAY 15	155	0.0	0.25	0.0	0	3	148	0.0	0.12	0.0	0	1	161	0.0	0.14	0.0	0	1
	DAY 22	155	0.0	0.30	0.0	0	3	150	0.0	0.08	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 29	155	0.0	0.28	0.0	0	3	150	0.0	0.08	0.0	0	1	161	0.0	0.11	0.0	0	1
	DAY 36	155	0.1	0.32	0.0	0	3	150	0.0	0.12	0.0	0	1	161	0.0	0.16	0.0	0	1
	DAY 43	155	0.0	0.25	0.0	0	3	151	0.0	0.11	0.0	0	1	161	0.0	0.11	0.0	0	1
	DAY 50	155	0.0	0.35	0.0	0	3	151	0.0	0.11	0.0	0	1	161	0.0	0.14	0.0	0	1
	DAY 57	155	0.0	0.40	0.0	0	4	151	0.0	0.11	0.0	0	1	161	0.0	0.14	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS208.SAS
GENERATED: 17NOV2005 13:54:14 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
1. ELEVATED MOOD	WINDOWED VISIT																		
	SCREEN	155	0.2	0.45	0.0	0	2	151	0.2	0.38	0.0	0	2	161	0.2	0.46	0.0	0	2
	DAY 1	155	0.2	0.48	0.0	0	2	151	0.2	0.38	0.0	0	2	161	0.2	0.42	0.0	0	2
	DAY 8	153	0.2	0.58	0.0	0	2	147	0.2	0.48	0.0	0	2	161	0.2	0.52	0.0	0	3
	DAY 15	134	0.3	0.55	0.0	0	2	126	0.3	0.61	0.0	0	3	146	0.3	0.62	0.0	0	3
	DAY 22	123	0.3	0.58	0.0	0	3	119	0.3	0.56	0.0	0	3	136	0.2	0.52	0.0	0	2
	DAY 29	116	0.2	0.50	0.0	0	2	109	0.2	0.59	0.0	0	3	133	0.3	0.57	0.0	0	3
	DAY 36	111	0.1	0.42	0.0	0	2	104	0.3	0.55	0.0	0	2	124	0.2	0.59	0.0	0	2
	DAY 43	98	0.3	0.61	0.0	0	2	97	0.3	0.60	0.0	0	3	114	0.2	0.54	0.0	0	2
	DAY 50	102	0.2	0.53	0.0	0	2	89	0.1	0.39	0.0	0	2	112	0.3	0.62	0.0	0	2
	DAY 57	97	0.2	0.49	0.0	0	2	86	0.1	0.38	0.0	0	2	103	0.2	0.56	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
2. INCREASED MOTOR ACTIVITY	WINDOWED VISIT																		
	SCREEN	155	0.3	0.63	0.0	0	3	151	0.2	0.55	0.0	0	3	161	0.2	0.52	0.0	0	3
	DAY 1	155	0.2	0.47	0.0	0	2	151	0.2	0.49	0.0	0	3	161	0.2	0.53	0.0	0	3
	DAY 8	153	0.3	0.65	0.0	0	3	147	0.3	0.56	0.0	0	3	161	0.3	0.58	0.0	0	3
	DAY 15	134	0.3	0.50	0.0	0	2	126	0.3	0.54	0.0	0	3	146	0.3	0.64	0.0	0	3
	DAY 22	123	0.2	0.56	0.0	0	3	119	0.3	0.62	0.0	0	3	136	0.3	0.69	0.0	0	3
	DAY 29	116	0.2	0.51	0.0	0	3	109	0.2	0.50	0.0	0	2	133	0.3	0.68	0.0	0	3
	DAY 36	111	0.3	0.55	0.0	0	3	104	0.3	0.52	0.0	0	2	124	0.4	0.76	0.0	0	3
	DAY 43	98	0.2	0.51	0.0	0	3	97	0.3	0.55	0.0	0	3	114	0.2	0.55	0.0	0	3
	DAY 50	102	0.2	0.56	0.0	0	3	89	0.2	0.46	0.0	0	2	112	0.3	0.70	0.0	0	3
	DAY 57	97	0.1	0.29	0.0	0	1	86	0.2	0.41	0.0	0	2	103	0.3	0.68	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
3. SEXUAL INTEREST	WINDOWED VISIT																		
	SCREEN	155	0.1	0.36	0.0	0	2	151	0.2	0.54	0.0	0	3	161	0.1	0.33	0.0	0	2
	DAY 1	155	0.1	0.33	0.0	0	2	151	0.1	0.29	0.0	0	2	161	0.0	0.22	0.0	0	2
	DAY 8	153	0.2	0.45	0.0	0	2	147	0.1	0.26	0.0	0	2	161	0.1	0.34	0.0	0	2
	DAY 15	134	0.1	0.47	0.0	0	2	126	0.1	0.34	0.0	0	2	146	0.1	0.40	0.0	0	3
	DAY 22	123	0.1	0.42	0.0	0	2	119	0.1	0.33	0.0	0	2	136	0.1	0.32	0.0	0	2
	DAY 29	116	0.1	0.35	0.0	0	2	109	0.1	0.28	0.0	0	1	133	0.0	0.17	0.0	0	1
	DAY 36	111	0.1	0.45	0.0	0	3	104	0.1	0.36	0.0	0	2	124	0.0	0.25	0.0	0	2
	DAY 43	98	0.1	0.48	0.0	0	2	97	0.1	0.37	0.0	0	3	114	0.1	0.30	0.0	0	2
	DAY 50	102	0.1	0.36	0.0	0	2	89	0.0	0.21	0.0	0	1	112	0.1	0.43	0.0	0	2
	DAY 57	97	0.1	0.39	0.0	0	3	86	0.1	0.38	0.0	0	2	103	0.1	0.30	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
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Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
4. SLEEP	WINDOWED VISIT																		
	SCREEN	155	1.1	0.99	2.0	0	3	151	1.2	0.95	1.0	0	3	161	1.2	0.91	2.0	0	3
	DAY 1	155	1.3	0.93	2.0	0	3	151	1.3	0.91	2.0	0	3	161	1.3	0.88	2.0	0	3
	DAY 8	153	0.4	0.72	0.0	0	3	147	0.4	0.70	0.0	0	2	161	1.0	0.89	1.0	0	3
	DAY 15	134	0.4	0.73	0.0	0	2	126	0.4	0.73	0.0	0	3	146	1.0	0.91	1.0	0	3
	DAY 22	123	0.4	0.78	0.0	0	3	119	0.3	0.67	0.0	0	3	136	0.9	0.89	1.0	0	4
	DAY 29	116	0.4	0.73	0.0	0	4	109	0.3	0.64	0.0	0	2	133	0.9	0.88	1.0	0	3
	DAY 36	111	0.4	0.74	0.0	0	3	104	0.3	0.68	0.0	0	3	123	0.9	0.88	1.0	0	3
	DAY 43	98	0.3	0.64	0.0	0	3	97	0.3	0.59	0.0	0	2	114	0.8	0.92	0.0	0	3
	DAY 50	102	0.4	0.64	0.0	0	2	89	0.3	0.66	0.0	0	2	112	0.8	0.91	0.5	0	3
	DAY 57	97	0.3	0.61	0.0	0	2	86	0.4	0.73	0.0	0	2	103	0.8	0.93	0.0	0	3

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
5. IRRITABILTY	WINDOWED VISIT																		
	SCREEN	155	2.0	1.22	2.0	0	5	151	1.9	1.00	2.0	0	4	161	2.1	1.05	2.0	0	4
	DAY 1	155	2.1	1.33	2.0	0	5	151	2.1	1.03	2.0	0	5	161	2.3	1.07	2.0	0	5
	DAY 8	153	1.9	1.34	2.0	0	6	147	1.8	1.06	2.0	0	4	161	1.9	1.19	2.0	0	5
	DAY 15	134	1.7	1.37	2.0	0	6	126	1.5	1.22	2.0	0	5	146	1.7	1.35	2.0	0	6
	DAY 22	123	1.5	1.23	1.0	0	4	119	1.5	1.24	2.0	0	5	136	1.6	1.27	2.0	0	6
	DAY 29	116	1.5	1.25	2.0	0	5	109	1.4	1.12	1.0	0	5	133	1.7	1.22	2.0	0	6
	DAY 36	111	1.4	1.34	1.0	0	5	104	1.4	1.12	1.0	0	5	124	1.7	1.45	2.0	0	6
	DAY 43	98	1.4	1.34	1.0	0	5	97	1.3	1.07	1.0	0	4	114	1.6	1.31	2.0	0	6
	DAY 50	102	1.3	1.39	1.0	0	6	89	1.1	1.06	1.0	0	4	112	1.6	1.39	2.0	0	6
	DAY 57	97	1.4	1.41	1.0	0	6	86	1.1	1.08	1.0	0	4	103	1.6	1.43	2.0	0	6

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
6. SPEECH (RATE AND AMOUNT)	WINDOWED VISIT																		
	SCREEN	155	0.4	0.75	0.0	0	4	151	0.4	0.79	0.0	0	4	161	0.5	0.95	0.0	0	4
	DAY 1	155	0.4	0.82	0.0	0	4	151	0.4	0.76	0.0	0	3	161	0.3	0.85	0.0	0	5
	DAY 8	153	0.6	0.99	0.0	0	4	147	0.6	0.99	0.0	0	4	161	0.7	1.05	0.0	0	5
	DAY 15	134	0.4	0.90	0.0	0	5	126	0.4	0.92	0.0	0	4	146	0.5	1.01	0.0	0	4
	DAY 22	123	0.4	0.89	0.0	0	4	119	0.5	0.90	0.0	0	4	136	0.4	0.89	0.0	0	4
	DAY 29	116	0.3	0.78	0.0	0	4	109	0.4	0.84	0.0	0	4	133	0.4	0.98	0.0	0	5
	DAY 36	111	0.4	0.78	0.0	0	3	104	0.4	0.90	0.0	0	4	124	0.5	1.10	0.0	0	6
	DAY 43	98	0.5	0.89	0.0	0	4	97	0.4	0.93	0.0	0	5	114	0.4	0.91	0.0	0	4
	DAY 50	102	0.5	0.91	0.0	0	4	89	0.2	0.53	0.0	0	2	112	0.5	1.00	0.0	0	5
	DAY 57	97	0.4	0.79	0.0	0	4	86	0.3	0.76	0.0	0	4	103	0.5	1.11	0.0	0	5

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
7. LANGUAGE - THOUGHT DISORDER	WINDOWED VISIT																		
	SCREEN	155	0.7	0.76	0.0	0	2	151	0.6	0.71	0.0	0	2	161	0.6	0.74	0.0	0	2
	DAY 1	155	0.7	0.77	1.0	0	2	151	0.6	0.70	0.0	0	2	161	0.6	0.77	0.0	0	2
	DAY 8	153	0.5	0.67	0.0	0	2	147	0.5	0.66	0.0	0	2	161	0.6	0.74	0.0	0	2
	DAY 15	134	0.5	0.67	0.0	0	2	126	0.4	0.63	0.0	0	3	146	0.5	0.71	0.0	0	2
	DAY 22	123	0.4	0.64	0.0	0	2	119	0.4	0.60	0.0	0	3	136	0.6	0.69	0.0	0	2
	DAY 29	116	0.3	0.57	0.0	0	2	109	0.5	0.67	0.0	0	2	133	0.5	0.71	0.0	0	3
	DAY 36	111	0.3	0.56	0.0	0	2	104	0.5	0.67	0.0	0	2	124	0.5	0.68	0.0	0	2
	DAY 43	98	0.4	0.59	0.0	0	2	97	0.4	0.65	0.0	0	2	114	0.5	0.72	0.0	0	2
	DAY 50	102	0.4	0.61	0.0	0	2	89	0.3	0.54	0.0	0	2	112	0.5	0.70	0.0	0	2
	DAY 57	97	0.3	0.49	0.0	0	2	86	0.2	0.52	0.0	0	2	103	0.5	0.70	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
8. CONTENT	WINDOWED VISIT																		
	SCREEN	155	0.2	0.82	0.0	0	8	151	0.2	0.48	0.0	0	3	161	0.1	0.43	0.0	0	2
	DAY 1	155	0.2	0.65	0.0	0	6	151	0.1	0.41	0.0	0	2	161	0.2	0.47	0.0	0	3
	DAY 8	153	0.3	0.76	0.0	0	5	147	0.2	0.63	0.0	0	6	161	0.2	0.55	0.0	0	3
	DAY 15	134	0.3	0.75	0.0	0	4	126	0.2	0.49	0.0	0	2	146	0.2	0.72	0.0	0	6
	DAY 22	123	0.3	0.64	0.0	0	3	119	0.2	0.55	0.0	0	3	136	0.2	0.76	0.0	0	6
	DAY 29	116	0.2	0.51	0.0	0	2	109	0.1	0.47	0.0	0	3	133	0.2	0.59	0.0	0	3
	DAY 36	111	0.2	0.65	0.0	0	4	104	0.3	0.76	0.0	0	4	124	0.2	0.72	0.0	0	4
	DAY 43	98	0.2	0.67	0.0	0	5	97	0.2	0.67	0.0	0	3	114	0.3	0.70	0.0	0	4
	DAY 50	102	0.2	0.53	0.0	0	3	89	0.2	0.73	0.0	0	5	112	0.4	1.00	0.0	0	6
	DAY 57	97	0.2	0.47	0.0	0	2	86	0.1	0.36	0.0	0	2	103	0.2	0.64	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
9. DISRUPTIVE - AGGRESSIVE BEHAVIOUR	WINDOWED VISIT																		
	SCREEN	155	0.6	0.98	0.0	0	4	151	0.5	0.89	0.0	0	4	161	0.6	1.09	0.0	0	5
	DAY 1	155	0.7	1.06	0.0	0	4	151	0.6	0.94	0.0	0	4	161	0.5	0.96	0.0	0	4
	DAY 8	153	0.7	1.24	0.0	0	8	147	0.5	1.02	0.0	0	4	161	0.5	0.99	0.0	0	6
	DAY 15	134	0.7	1.11	0.0	0	5	126	0.5	0.95	0.0	0	4	146	0.5	0.97	0.0	0	4
	DAY 22	123	0.6	1.02	0.0	0	5	119	0.3	0.78	0.0	0	4	136	0.4	0.91	0.0	0	4
	DAY 29	116	0.5	0.95	0.0	0	4	109	0.4	0.89	0.0	0	4	133	0.4	0.86	0.0	0	4
	DAY 36	111	0.5	0.83	0.0	0	4	104	0.4	0.99	0.0	0	6	124	0.5	0.99	0.0	0	5
	DAY 43	98	0.4	0.88	0.0	0	4	97	0.3	0.77	0.0	0	4	114	0.3	0.76	0.0	0	4
	DAY 50	102	0.4	0.91	0.0	0	5	89	0.3	0.79	0.0	0	4	112	0.4	0.86	0.0	0	4
	DAY 57	97	0.5	1.05	0.0	0	6	86	0.3	0.81	0.0	0	4	103	0.4	0.84	0.0	0	4

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
10. APPEARANCE	WINDOWED VISIT																		
	SCREEN	155	0.2	0.50	0.0	0	3	151	0.1	0.38	0.0	0	2	161	0.1	0.37	0.0	0	2
	DAY 1	155	0.2	0.47	0.0	0	2	151	0.1	0.41	0.0	0	2	161	0.2	0.41	0.0	0	2
	DAY 8	153	0.2	0.48	0.0	0	2	147	0.1	0.39	0.0	0	2	161	0.2	0.42	0.0	0	2
	DAY 15	134	0.2	0.43	0.0	0	2	126	0.1	0.35	0.0	0	2	146	0.1	0.33	0.0	0	2
	DAY 22	123	0.2	0.38	0.0	0	1	119	0.1	0.35	0.0	0	2	136	0.1	0.36	0.0	0	2
	DAY 29	116	0.2	0.45	0.0	0	2	109	0.1	0.35	0.0	0	2	133	0.2	0.40	0.0	0	2
	DAY 36	111	0.2	0.47	0.0	0	2	104	0.2	0.39	0.0	0	2	124	0.2	0.43	0.0	0	2
	DAY 43	98	0.2	0.50	0.0	0	2	97	0.1	0.28	0.0	0	1	114	0.1	0.52	0.0	0	4
	DAY 50	102	0.2	0.46	0.0	0	2	89	0.1	0.30	0.0	0	1	112	0.1	0.42	0.0	0	2
	DAY 57	97	0.2	0.49	0.0	0	2	86	0.1	0.29	0.0	0	1	103	0.1	0.38	0.0	0	2

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.11 YMRS Individual Item Scores - Descriptive Statistics
Observed Cases
Intent-to-Treat Population

		TREATMENT																	
		QUETIAPINE 300 MG						QUETIAPINE 600 MG						PLACEBO					
		N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX	N	MEAN	SD	MEDIAN	MIN	MAX
11. INSIGHT	WINDOWED VISIT																		
	SCREEN	155	0.0	0.24	0.0	0	2	151	0.0	0.14	0.0	0	1	161	0.0	0.11	0.0	0	1
	DAY 1	155	0.0	0.35	0.0	0	4	151	0.0	0.11	0.0	0	1	161	0.0	0.11	0.0	0	1
	DAY 8	153	0.0	0.28	0.0	0	3	147	0.0	0.08	0.0	0	1	161	0.0	0.14	0.0	0	1
	DAY 15	134	0.0	0.27	0.0	0	3	126	0.0	0.13	0.0	0	1	146	0.0	0.12	0.0	0	1
	DAY 22	123	0.0	0.34	0.0	0	3	119	0.0	0.09	0.0	0	1	136	0.0	0.15	0.0	0	1
	DAY 29	116	0.1	0.32	0.0	0	3	109	0.0	0.10	0.0	0	1	133	0.0	0.09	0.0	0	1
	DAY 36	111	0.1	0.37	0.0	0	3	104	0.0	0.14	0.0	0	1	124	0.0	0.15	0.0	0	1
	DAY 43	98	0.0	0.10	0.0	0	1	97	0.0	0.10	0.0	0	1	114	0.0	0.00	0.0	0	0
	DAY 50	102	0.0	0.31	0.0	0	3	89	0.0	0.11	0.0	0	1	112	0.0	0.09	0.0	0	1
	DAY 57	97	0.0	0.41	0.0	0	4	86	0.0	0.11	0.0	0	1	103	0.0	0.10	0.0	0	1

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS207.SAS
GENERATED: 17NOV2005 13:54:09 iceadmn3

Table 11.3.8.1.7.12 Treatment Emergent Mania (Events Criteria Met)
Safety Population

	QUETIAPINE 300 MG		QUETIAPINE 600 MG		PLACEBO	
	N=171		N=168		N=167	
	n	%	n	%	n	%
MedDRA or YMRS	3	1.8	6	3.6	11	6.6
YMRS Alone	2	1.2	5	3.0	9	5.4
MedDRA Alone	2	1.2	1	0.6	5	3.0

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/YMRS205.SAS
GENERATED: 17NOV2005 13:54:07 iceadmn3

Table 11.3.8.1.7.13 Treatment Emergent Mania (CMH)
Safety Population

	TREATMENT										RELATIVE RISK (MANTEL-HAENSZEL ADJUSTED)			
	Q300MG			Q600MG			P							
	N	TOTAL	%	N	TOTAL	%	N	TOTAL	%	P-VALUE	ESTIMATE	LOWER	UPPER	
STRATA														
BIPOLAR I	2	112	1.79	6	112	5.36	8	112	7.14	.	.	.	.	
BIPOLAR II	1	59	1.69	0	56	0.00	3	55	5.45	.	.	.	.	
ALL	3	171	1.75	6	168	3.57	11	167	6.59	.	.	.	.	
Q300 VS P	.	.	.	.	.	.	.	.	.	0.027	0.27	0.08	0.94	
Q600 VS P	.	.	.	.	.	.	.	.	.	0.211	0.54	0.21	1.43	

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/STAT/YMRS210.SAS
GENERATED: 17NOV2005 13:36:15 iceadmn3

Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0003012	SCREEN	15MAR2005	-24	48 L	100	70	52	102	72	4	2	2
		DAY 1	08APR2005	1	63	92	59	83	98	64	20 Y	6	5
		BASELINE			63	92	59	83	98	64	20 Y	6	5
		DAY 8	15APR2005	8	78	114	67	83	120	70	5	6	3
		DAY 15	20APR2005	13	77	102	62	83	107	58	6	5	-4
		DAY 22	29APR2005	22	84	91	59	91	90 L	59	7	-1	0
		DAY 29	09MAY2005	32	84	93	55	91	95	57	7	2	2
		DAY 36	13MAY2005	36	79	100	64	90	102	63	11	2	-1
		DAY 43	23MAY2005	46	78	92	62	81	103	64	3	11	2
		DAY 50	26MAY2005	49	93	92	68	96	104	68	3	12	0
		DAY 57	07JUN2005	61	87	96	67	87	96	61	0	0	-6
		FINAL			87	96	67	87	96	61	0	0	-6
	E0004017	SCREEN	02NOV2004	-15	68	116	72	76	110	70	8	-6	-2
		DAY 1	17NOV2004	1	60	110	70	70	106	70	10	-4	0
		BASELINE			60	110	70	70	106	70	10	-4	0
		DAY 8	24NOV2004	8	80	118	80	84	112	78	4	-6	-2
		DAY 22 *	06DEC2004	20	64	102	78	80	106	76	16	4	-2
		DAY 22	09DEC2004	23	80	100	68	84	98	66	4	-2	-2
		DAY 29	15DEC2004	29	72	96	62	80	90 L	60	8	-6	-2
		DAY 36	22DEC2004	36	76	110	72	80	104	80	4	-6	8
		DAY 43	28DEC2004	42	72	106	80	84	110	82	12	4	2
		DAY 50	05JAN2005	50	84	100	68	96	98	70	12	-2	2
		DAY 57	13JAN2005	58	72	112	76	80	114	80	8	2	4
		FINAL			72	112	76	80	114	80	8	2	4
	E0006007	SCREEN	05AUG2004	-7	62	102	70	76	108	78	14	6	8
		DAY 1	12AUG2004	1	74	100	66	78	100	64	4	0	-2
		BASELINE			74	100	66	78	100	64	4	0	-2
		DAY 8	20AUG2004	9	60	108	68	80	110	74	20 Y	2	6
		DAY 15	30AUG2004	19	84	104	68	82	102	74	-2	-2	6

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L: Potentially Clinically Important low.
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0006007	DAY 29 *	07SEP2004	27	78	110	76	80	108	80	2	-2	4
		DAY 29	10SEP2004	30	75	104	68	80	102	72	5	-2	4
		DAY 36	17SEP2004	37	78	102	74	80	102	78	2	0	4
		DAY 43	24SEP2004	44	66	118	88	74	116	84	8	-2	-4
		DAY 50	01OCT2004	51	78	112	72	80	112	70	2	0	-2
		DAY 57	21OCT2004	71	72	106	70	76	102	72	4	-4	2
		FINAL			72	106	70	76	102	72	4	-4	2
	E0007003	SCREEN	28OCT2004	-7	81	124	78	96	116	83	15	-8	5
		DAY 1	04NOV2004	1	90	136	88	98	118	82	8	-18	-6
		BASELINE			90	136	88	98	118	82	8	-18	-6
		DAY 8	11NOV2004	8	89	126	79	103	125	83	14	-1	4
		DAY 15	18NOV2004	15	89	118	74	100	129	84	11	11	10
		DAY 29	30NOV2004	27	80	116	77	91	121	85	11	5	8
		DAY 36	08DEC2004	35	93	124	78	96	124	81	3	0	3
		DAY 43	15DEC2004	42	77	118	69	97	117	80	20 Y	-1	11
		DAY 50	21DEC2004	48	86	128	71	100	132	84	14	4	13
		DAY 57	30DEC2004	57	78	110	75	93	117	81	15	7	6
		FINAL			78	110	75	93	117	81	15	7	6
	E0007004	SCREEN	05NOV2004	-10	67	115	83	80	114	88	13	-1	5
		DAY 1	15NOV2004	1	69	119	80	86	115	88	17	-4	8
		BASELINE			69	119	80	86	115	88	17	-4	8
		DAY 8	22NOV2004	8	86	110	79	96	105	81	10	-5	2
		DAY 15	30NOV2004	16	76	108	77	98	112	83	22 Y	4	6
		FINAL			76	108	77	98	112	83	22 Y	4	6
	E0008010	SCREEN	24JAN2005	-7	60	144	110 H	62	140	106 H	2	-4	-4
		DAY 1	31JAN2005	1	66	146	110 H	70	140	102	4	-6	-8
		BASELINE			66	146	110 H	70	140	102	4	-6	-8
		DAY 8	07FEB2005	8	64	136	101	68	134	96	4	-2	-5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)		FINAL			64	136	101	68	134	96	4	-2	-5
	E0008010	SCREEN	26JUL2004	-7	71	120	80	78	120	84	7	0	4
		DAY 1	02AUG2004	1	62	118	76	80	120	82	18	2	6
		BASELINE			62	118	76	80	120	82	18	2	6
		DAY 8	10AUG2004	9	66	118	80	84	120	84	18	2	4
		DAY 15	19AUG2004	18	62	120	78	76	118	80	14	-2	2
		DAY 22	24AUG2004	23	54	122	74	86	112	82	32 Y	-10	8
		DAY 29	31AUG2004	30	66	110	76	88	108	80	22 Y	-2	4
		DAY 36	07SEP2004	37	72	122	78	86	124	78	14	2	0
		DAY 43	15SEP2004	45	66	108	70	80	118	80	14	10	10
		DAY 50	22SEP2004	52	70	118	70	78	124	74	8	6	4
		DAY 57	28SEP2004	58	76	118	78	88	116	74	12	-2	-4
		FINAL			76	118	78	88	116	74	12	-2	-4
	E0014018	SCREEN	20APR2005	-6	76	110	92	80	112	93	4	2	1
		DAY 1	26APR2005	1	70	114	88	90	124	95	20 Y	10	7
		BASELINE			70	114	88	90	124	95	20 Y	10	7
		DAY 8	04MAY2005	9	74	116	89	82	122	91	8	6	2
		DAY 15	12MAY2005	17	73	115	89	84	123	93	11	8	4
		DAY 22	18MAY2005	23	75	117	84	83	122	90	8	5	6
		DAY 29	26MAY2005	31	76	115	83	82	120	88	6	5	5
		DAY 36	02JUN2005	38	77	115	85	82	120	87	5	5	2
		DAY 50	14JUN2005	50	75	116	87	80	120	89	5	4	2
		DAY 50 *	16JUN2005	52	76	118	86	80	122	90	4	4	4
		DAY 57	22JUN2005	58	78	114	88	82	120	92	4	6	4
		FINAL			78	114	88	82	120	92	4	6	4
	E0016001	SCREEN	17AUG2004	-15	53	137	94	59	134	96	6	-3	2
		DAY 1	01SEP2004	1	64	110	78	68	120	80	4	10	2
		BASELINE			64	110	78	68	120	80	4	10	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	DAY 8	08SEP2004	8	64	122	94	60	121	98	-4	-1	4
		DAY 15	16SEP2004	16	72	116	91	92	114	90	20 Y	-2	-1
		DAY 22	23SEP2004	23	72	130	97	102	126	98	30 Y	-4	1
		DAY 29	30SEP2004	30	76	132	86	78	128	84	2	-4	-2
		DAY 36	07OCT2004	37	79	115	80	93	122	91	14	7	11
		DAY 43	14OCT2004	44	78	112	82	91	122	89	13	10	7
		DAY 50	21OCT2004	51	68	132	90	89	128	99	21 Y	-4	9
		DAY 57	29OCT2004	59	66	133	90	80	124	97	14	-9	7
		FINAL			66	133	90	80	124	97	14	-9	7
	E0020002	SCREEN	12JUL2004	-14	68	106	72	80	132	82	12	26	10
		DAY 1	26JUL2004	1	68	112	74	110	128	78	42 Y	16	4
		BASELINE			68	112	74	110	128	78	42 Y	16	4
		DAY 8	03AUG2004	9	64	118	76	76	110	60	12	-8	-16
		DAY 15	10AUG2004	16	72	116	70	88	112	60	16	-4	-10
		DAY 22	17AUG2004	23	62	112	80	62	110	84	0	-2	4
		DAY 29	24AUG2004	30	92	108	72	96	120	82	4	12	10
		DAY 36	31AUG2004	37	76	108	76	88	100	70	12	-8	-6
		DAY 43	07SEP2004	44	96	120	70	96	110	80	0	-10	10
		DAY 50	14SEP2004	51	84	120	70	96	116	70	12	-4	0
		DAY 57	23SEP2004	60	88	110	70	96	120	80	8	10	10
		FINAL			88	110	70	96	120	80	8	10	10
	E0020017	SCREEN	22OCT2004	-5	80	100	70	92	102	68	12	2	-2
		DAY 1	27OCT2004	1	84	96	69	96	98	68	12	2	-1
		BASELINE			84	96	69	96	98	68	12	2	-1
		DAY 8	03NOV2004	8	82	95	60	98	103	75	16	8	15
		DAY 15	10NOV2004	15	84	90 L	60	88	100	68	4	10	8
		DAY 22	17NOV2004	22	76	110	70	88	110	80	12	0	10
		FINAL			76	110	70	88	110	80	12	0	10

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0020038	SCREEN	07FEB2005	-7	76	120	80	84	130	80	8	10	0
		DAY 1	14FEB2005	1	72	109	70	78	111	80	6	2	10
		BASELINE			72	109	70	78	111	80	6	2	10
		DAY 8	21FEB2005	8	72	110	74	86	110	90	14	0	16
		DAY 15	28FEB2005	15	84	122	82	86	122	82	2	0	0
		DAY 22	07MAR2005	22	84	122	82	100	119	90	16	-3	8
		DAY 29	14MAR2005	29	74	120	80	78	117	80	4	-3	0
		DAY 36	22MAR2005	37	78	112	80	84	120	84	6	8	4
		DAY 43	29MAR2005	44	82	140	90	102	140	100	20 Y	0	10
		DAY 50	05APR2005	51	74	130	90	76	130	98	2	0	8
		DAY 57	12APR2005	58	76	126	96	84	132	88	8	6	-8
		FINAL			76	126	96	84	132	88	8	6	-8
	E0021008	SCREEN	20SEP2004	-7	88	142	64	92	136	80	4	-6	16
		DAY 1	27SEP2004	1	75	144	78	87	134	88	12	-10	10
		BASELINE			75	144	78	87	134	88	12	-10	10
		DAY 8	04OCT2004	8	82	126	70	87	118	74	5	-8	4
		DAY 15	11OCT2004	15	75	138	84	92	112	82	17	-26 Y	-2
		DAY 22	18OCT2004	22	81	120	80	102	102	82	21 Y	-18	2
		DAY 29	25OCT2004	29	66	136	82	72	138	86	6	2	4
		DAY 36	01NOV2004	36	63	132	84	68	144	90	5	12	6
		DAY 43	08NOV2004	43	69	134	82	88	142	90	19	8	8
		DAY 50	15NOV2004	50	86	146	90	100	124	86	14	-22 Y	-4
		DAY 57	22NOV2004	57	70	132	82	84	137	88	14	5	6
		FINAL			70	132	82	84	137	88	14	5	6
	E0021009	SCREEN	22SEP2004	-8	51	120	66	57	126	70	6	6	4
		DAY 1	30SEP2004	1	62	106	60	74	120	72	12	14	12
		BASELINE			62	106	60	74	120	72	12	14	12
		DAY 8	07OCT2004	8	51	114	74	69	108	78	18	-6	4
		DAY 15	13OCT2004	14	45 L	100	64	57	106	74	12	6	10

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0021009	DAY 22		20OCT2004	21	51	104	70	63	106	84	12	2	14
		DAY 29		27OCT2004	28	57	104	64	63	114	70	6	10	6
		DAY 36		04NOV2004	36	45 L	100	62	54	114	72	9	14	10
		DAY 50		17NOV2004	49	42 L	98	62	45 L	110	74	3	12	12
		DAY 50	*	22NOV2004	54	44 L	110	62	49 L	110	78	5	0	16
		DAY 57		02DEC2004	64	60	110	70	75	128	78	15	18	8
		FINAL				60	110	70	75	128	78	15	18	8
	E0021016	SCREEN		04NOV2004	-6	63	130	62	63	118	66	0	-12	4
		DAY 1		10NOV2004	1	60	120	68	64	118	70	4	-2	2
		BASELINE				60	120	68	64	118	70	4	-2	2
		DAY 8		18NOV2004	9	57	102	66	84	118	76	27 Y	16	10
		DAY 15		24NOV2004	15	58	124	66	86	116	86	28 Y	-8	20
		DAY 22		01DEC2004	22	74	118	60	68	122	74	-6	4	14
		DAY 29		09DEC2004	30	51	102	62	78	108	84	27 Y	6	22
		DAY 36		16DEC2004	37	58	110	76	63	112	80	5	2	4
		DAY 43		23DEC2004	44	60	106	58	72	110	80	12	4	22
		DAY 50		30DEC2004	51	85	136	60	88	134	70	3	-2	10
		DAY 57		06JAN2005	58	57	112	76	84	122	76	27 Y	10	0
		FINAL				57	112	76	84	122	76	27 Y	10	0
	E0021022	SCREEN		18JAN2005	-9	87	126	72	90	124	78	3	-2	6
		DAY 1		27JAN2005	1	78	114	74	93	112	88	15	-2	14
		BASELINE				78	114	74	93	112	88	15	-2	14
		DAY 8		02FEB2005	7	75	110	70	81	108	88	6	-2	18
		DAY 15		09FEB2005	14	78	120	70	80	110	80	2	-10	10
		DAY 29		23FEB2005	28	96	112	68	84	118	92	-12	6	24
		DAY 36		03MAR2005	36	78	116	78	90	118	76	12	2	-2
		DAY 43		09MAR2005	42	75	106	72	84	120	78	9	14	6
		DAY 50		16MAR2005	49	75	106	66	81	110	74	6	4	8
		DAY 57		22MAR2005	55	72	124	76	96	118	78	24 Y	-6	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0021022	FINAL			72	124	76	96	118	78	24 Y	-6	2
	E0021024	SCREEN	27JAN2005	-7	72	138	92	96	138	92	24 Y	0	0
		DAY 1	03FEB2005	1	81	138	96	93	128	104	12	-10	8
		BASELINE			81	138	96	93	128	104	12	-10	8
		DAY 8	10FEB2005	8	87	132	90	99	122	98	12	-10	8
		DAY 15	17FEB2005	15	99	118	70	120	124	88	21 Y	6	18
		DAY 22	24FEB2005	22									
		FINAL			99	118	70	120	124	88	21 Y	6	18
	E0021027	SCREEN	28MAR2005	-9	69	132	86	63	128	88	-6	-4	2
		DAY 1	06APR2005	1	66	118	72	75	118	74	9	0	2
		BASELINE			66	118	72	75	118	74	9	0	2
		DAY 8	13APR2005	8	63	112	74	81	116	74	18	4	0
		DAY 15	20APR2005	15	63	118	78	75	124	96	12	6	18
		DAY 22	27APR2005	22	57	128	82	81	120	92	24 Y	-8	10
		DAY 29	04MAY2005	29	69	128	84	81	116	84	12	-12	0
		DAY 36	11MAY2005	36	72	134	92	69	134	100	-3	0	8
		DAY 50 *	23MAY2005	48	66	128	88	78	130	94	12	2	6
		DAY 50	26MAY2005	51	80	120	84	92	102	86	12	-18	2
		DAY 57	02JUN2005	58	63	124	84	75	118	92	12	-6	8
		FINAL			63	124	84	75	118	92	12	-6	8
	E0025059	SCREEN	29APR2005	-6	61	124	86	92	116	80	31 Y	-8	-6
		DAY 1	05MAY2005	1	62	126	86	90	120	80	28 Y	-6	-6
		BASELINE			62	126	86	90	120	80	28 Y	-6	-6
		DAY 8	12MAY2005	8	80	118	82	88	112	90	8	-6	8
		DAY 15	19MAY2005	15	72	122	88	76	118	90	4	-4	2
		DAY 22	26MAY2005	22	95	117	73	95	121	93	0	4	20
		DAY 29	02JUN2005	29	78	116	82	84	112	84	6	-4	2
		DAY 36	09JUN2005	36	78	132	88	88	124	86	10	-8	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0025059	DAY 43	16JUN2005	43	72	110	84	80	118	80	8	8	-4
		DAY 50	23JUN2005	50	76	118	86	80	110	84	4	-8	-2
		DAY 57	01JUL2005	58	66	124	88	78	126	95	12	2	7
		FINAL			66	124	88	78	126	95	12	2	7
	E0027002	SCREEN	13JUL2004	-7	66	148	88	70	150	90	4	2	2
		DAY 1	20JUL2004	1	68	150	88	74	152	90	6	2	2
		BASELINE			68	150	88	74	152	90	6	2	2
		DAY 8	27JUL2004	8	88	180 H	110 H	88	185 H	112 H	0	5	2
		DAY 15	05AUG2004	17	82	185 H	120 H	84	185 H	125 H	2	0	5
		FINAL			82	185 H	120 H	84	185 H	125 H	2	0	5
	E0030009	SCREEN	18AUG2004	-6	76	108	66	86	100	68	10	-8	2
		DAY 1	24AUG2004	1	74	121	65	86	117	69	12	-4	4
		BASELINE			74	121	65	86	117	69	12	-4	4
		DAY 8	31AUG2004	8	76	118	69	93	113	78	17	-5	9
		DAY 15	07SEP2004	15	78	130	73	80	121	76	2	-9	3
		DAY 22	14SEP2004	22	74	110	56	90	106	63	16	-4	7
		DAY 29	23SEP2004	31	114	138	76	131 H	120	78	17	-18	2
		DAY 36	30SEP2004	38	95	147	81	109	137	82	14	-10	1
		DAY 43	08OCT2004	46	93	139	79	121 H	127	70	28 Y	-12	-9
		DAY 50	13OCT2004	51	89	130	78	108	127	77	19	-3	-1
		DAY 57	21OCT2004	59	100	138	70	92	130	72	-8	-8	2
		FINAL			100	138	70	92	130	72	-8	-8	2
	E0033001	SCREEN	22JUN2004	-8	72	110	88	76	116	84	4	6	-4
		DAY 1	30JUN2004	1	58	116	78	64	118	80	6	2	2
		BASELINE			58	116	78	64	118	80	6	2	2
		DAY 8	07JUL2004	8	88	116	72	90	114	74	2	-2	2
		DAY 15	14JUL2004	15	80	112	80	80	116	82	0	4	2
		DAY 22	21JUL2004	22	62	100	62	78	94	66	16	-6	4

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L: Potentially Clinically Important low.
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0033001	DAY 29	28JUL2004	29	76	114	80	78	116	82	2	2	2
		DAY 36	04AUG2004	36	78	108	70	80	110	72	2	2	2
		DAY 43	11AUG2004	43	82	90 L	70	86	92	68	4	2	-2
		DAY 50	18AUG2004	50	78	130	88	78	132	88	0	2	0
		DAY 57	23AUG2004	55	72	110	76	76	114	80	4	4	4
		FINAL			72	110	76	76	114	80	4	4	4
	E0033017	SCREEN	17MAR2005	-13	58	96	66	64	92	70	6	-4	4
		DAY 1	30MAR2005	1	74	102	72	70	100	74	-4	-2	2
		BASELINE			74	102	72	70	100	74	-4	-2	2
		DAY 8	08APR2005	10	70	110	82	76	108	80	6	-2	-2
		DAY 15	13APR2005	15	74	110	70	74	108	74	0	-2	4
		DAY 22	18APR2005	20	70	116	78	76	110	70	6	-6	-8
		DAY 29	27APR2005	29	64	90 L	66	66	92	66	2	2	0
		DAY 36	02MAY2005	34	60	102	82	64	100	80	4	-2	-2
		DAY 43	09MAY2005	41	64	110	78	74	112	76	10	2	-2
		DAY 50	16MAY2005	48	60	124	64	64	118	68	4	-6	4
		DAY 57	23MAY2005	55	72	112	72	68	108	76	-4	-4	4
		FINAL			72	112	72	68	108	76	-4	-4	4
	E0033019	SCREEN	16MAY2005	-8	58	92	70	64	106	76	6	14	6
		DAY 1	24MAY2005	1	64	96	72	68	110	74	4	14	2
		BASELINE			64	96	72	68	110	74	4	14	2
		DAY 8	31MAY2005	8	58	90 L	68	58	98	70	0	8	2
		FINAL			58	90 L	68	58	98	70	0	8	2
	E0035034	SCREEN	15JUN2005	-14	74	116	80	72	110	80	-2	-6	0
		DAY 1	29JUN2005	1	80	142	98	88	140	106 H	8	-2	8
		BASELINE			80	142	98	88	140	106 H	8	-2	8
		DAY 8	08JUL2005	10	96	142	94	92	138	86	-4	-4	-8
		DAY 15	12JUL2005	14	96	142	90	90	140	90	-6	-2	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE			STANDING			ORTHOSTATIC CHANGE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0035034	DAY 22	20JUL2005	22	76	138	90	74	136	86	-2	-2	-4
		DAY 29	27JUL2005	29	66	130	80	78	134	84	12	4	4
		DAY 36	03AUG2005	36	74	140	90	76	140	78	2	0	-12
		DAY 43	09AUG2005	42	90	142	100	84	142	100	-6	0	0
		DAY 50	18AUG2005	51	88	142	96	88	145	100	0	3	4
		DAY 57	25AUG2005	58	70	140	98	80	142	100	10	2	2
		FINAL			70	140	98	80	142	100	10	2	2
	E0037029	SCREEN	26MAY2005	-11	84	120	88	96	120	94	12	0	6
		DAY 1	06JUN2005	1	84	128	86	96	130	90	12	2	4
		BASELINE			84	128	86	96	130	90	12	2	4
		DAY 15	20JUN2005	15	84	130	86	96	130	90	12	0	4
		DAY 22	27JUN2005	22	86	120	88	92	138	92	6	18	4
		DAY 29	05JUL2005	30	84	120	86	92	130	90	8	10	4
		DAY 36	11JUL2005	36	86	120	84	96	130	90	10	10	6
		DAY 43	18JUL2005	43	92	130	88	100	130	90	8	0	2
		DAY 50	26JUL2005	51	76	160	100	84	150	110 H	8	-10	10
		DAY 57	02AUG2005	58	88	160	100	92	150	106 H	4	-10	6
		FINAL			88	160	100	92	150	106 H	4	-10	6
	E0039009	SCREEN	30SEP2004	-7	74	110	70	80	110	70	6	0	0
		DAY 1	07OCT2004	1	74	122	60	88	118	58	14	-4	-2
		BASELINE			74	122	60	88	118	58	14	-4	-2
		DAY 8	18OCT2004	12	66	130	70	84	120	80	18	-10	10
		DAY 15	25OCT2004	19	68	110	50 L	84	104	68	16	-6	18
		DAY 22	01NOV2004	26	74	118	76	78	118	70	4	0	-6
		DAY 36	09NOV2004	34	78	108	60	84	102	68	6	-6	8
		DAY 43	17NOV2004	42	62	120	74	68	118	70	6	-2	-4
		FINAL			62	120	74	68	118	70	6	-2	-4
	E0039012	SCREEN	19OCT2004	-9	64	120	90	78	110	60	14	-10	-30 Y

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039012	DAY 1	28OCT2004	1	76	104	54	80	102	70	4	-2	16
		BASELINE			76	104	54	80	102	70	4	-2	16
		DAY 8	03NOV2004	7	80	120	60	84	100	58	4	-20 Y	-2
		FINAL			80	120	60	84	100	58	4	-20 Y	-2
	E0040001	SCREEN	23JUL2004	-7	67	108	76	83	103	76	16	-5	0
		DAY 1	30JUL2004	1	64	102	72	75	101	76	11	-1	4
		BASELINE			64	102	72	75	101	76	11	-1	4
		DAY 8	06AUG2004	8	81	106	73	86	110	80	5	4	7
		DAY 15	12AUG2004	14	71	107	74	95	105	83	24 Y	-2	9
		DAY 22	20AUG2004	22	76	113	82	90	110	77	14	-3	-5
		DAY 29	27AUG2004	29	74	106	74	96	108	79	22 Y	2	5
		DAY 36	03SEP2004	36	78	110	78	86	109	85	8	-1	7
		DAY 43	10SEP2004	43	78	116	74	84	118	78	6	2	4
		DAY 50	17SEP2004	50	70	110	73	94	123	83	24 Y	13	10
		DAY 57	24SEP2004	57	77	108	79	97	98	81	20 Y	-10	2
		FINAL			77	108	79	97	98	81	20 Y	-10	2
	E0040002	SCREEN	27JUL2004	-10	78	128	85	84	130	88	6	2	3
		DAY 1	06AUG2004	1	82	138	82	90	140	88	8	2	6
		BASELINE			82	138	82	90	140	88	8	2	6
		DAY 8	12AUG2004	7	85	146	89	90	148	88	5	2	-1
		DAY 15	20AUG2004	15	90	145	92	98	150	98	8	5	6
		DAY 22	27AUG2004	22	90	128	75	115	134	86	25 Y	6	11
		DAY 29	03SEP2004	29	101	154	92	107	148	102	6	-6	10
		DAY 36	10SEP2004	36	92	146	86	100	148	90	8	2	4
		FINAL			92	146	86	100	148	90	8	2	4
	E0040003	SCREEN	06AUG2004	-6	61	125	79	70	128	82	9	3	3
		DAY 1	12AUG2004	1	63	112	68	80	115	70	17	3	2
		BASELINE			63	112	68	80	115	70	17	3	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0040003	DAY 15	*	24AUG2004	13	79	126	73	79	122	76	0	-4	3
		DAY 15		27AUG2004	16	78	122	68	86	128	72	8	6	4
		DAY 22		02SEP2004	22	78	120	68	86	126	78	8	6	10
		DAY 29		10SEP2004	30	78	124	70	82	126	74	4	2	4
		DAY 36		18SEP2004	38	88	116	80	90	120	81	2	4	1
		DAY 43		24SEP2004	44	74	121	79	77	125	91	3	4	12
		DAY 50		01OCT2004	51	81	122	77	78	114	76	-3	-8	-1
		DAY 57		08OCT2004	58	74	146	78	87	120	74	13	-26 Y	-4
		FINAL				74	146	78	87	120	74	13	-26 Y	-4
	E0040011	SCREEN		23FEB2005	-7	88	130	85	100	140	90	12	10	5
		DAY 1		02MAR2005	1	94	131	92	94	154	99	0	23	7
		BASELINE				94	131	92	94	154	99	0	23	7
		DAY 8		09MAR2005	8	95	130	78	129 H	128	84	34 Y	-2	6
		DAY 15		16MAR2005	15	90	132	82	100	130	89	10	-2	7
		DAY 22		23MAR2005	22	88	109	72	100	100	68	12	-9	-4
		DAY 29		30MAR2005	29	94	118	88	105	120	85	11	2	-3
		DAY 36		06APR2005	36	105	116	83	98	120	90	-7	4	7
		DAY 43		13APR2005	43	88	117	78	102	115	84	14	-2	6
		DAY 50		20APR2005	50	90	111	81	105	104	90	15	-7	9
		DAY 57		27APR2005	57	95	116	78	109	115	88	14	-1	10
		FINAL				95	116	78	109	115	88	14	-1	10
	E0040017	SCREEN		18MAY2005	-7	52	101	64	69	116	73	17	15	9
		DAY 1		25MAY2005	1	45 L	105	61	73	102	68	28 Y	-3	7
		BASELINE				45 L	105	61	73	102	68	28 Y	-3	7
		DAY 8		01JUN2005	8	45 L	105	62	74	102	66	29 Y	-3	4
		DAY 15		10JUN2005	17	97	97	68	90	107	61	-7	10	-7
		DAY 22		17JUN2005	24	66	109	57	83	106	79	17	-3	22
		DAY 29		24JUN2005	31	84	101	61	93	97	68	9	-4	7
		DAY 36		30JUN2005	37	60	93	58	68	107	70	8	14	12

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0040017	DAY 43	08JUL2005	45	45 L	99	57	53	97	70	8	-2	13
		DAY 50	15JUL2005	52	83	116	86	83	99	60	0	-17	-26 Y
		DAY 57	22JUL2005	59	82	114	80	76	100	64	-6	-14	-16
		FINAL			82	114	80	76	100	64	-6	-14	-16
	E0041008	SCREEN	02NOV2004	-15	80	112	68	88	118	70	8	6	2
		DAY 1	17NOV2004	1	60	112	68	88	110	82	28 Y	-2	14
		BASELINE			60	112	68	88	110	82	28 Y	-2	14
		DAY 8	24NOV2004	8	80	108	82	88	112	88	8	4	6
		DAY 15	01DEC2004	15	88	106	78	120	116	82	32 Y	10	4
		DAY 22	08DEC2004	22	68	114	72	120	110	76	52 Y	-4	4
		FINAL			68	114	72	120	110	76	52 Y	-4	4
	E0041009	SCREEN	04NOV2004	-15	68	118	78	80	116	74	12	-2	-4
		DAY 1	19NOV2004	1	68	108	76	76	106	76	8	-2	0
		BASELINE			68	108	76	76	106	76	8	-2	0
		DAY 8	24NOV2004	6	80	126	78	100	126	74	20 Y	0	-4
		FINAL			80	126	78	100	126	74	20 Y	0	-4
	E0044005	SCREEN	24FEB2005	-21	68	130	86	68	140	90	0	10	4
		DAY 1	17MAR2005	1	68	100	76	84	114	86	16	14	10
		BASELINE			68	100	76	84	114	86	16	14	10
		DAY 8	22MAR2005	6	76	118	72	80	114	76	4	-4	4
		DAY 15	31MAR2005	15	80	116	84	88	118	90	8	2	6
		DAY 22	07APR2005	22	76	124	68	100	126	66	24 Y	2	-2
		DAY 29	14APR2005	29	88	130	92	80	126	84	-8	-4	-8
		DAY 36	22APR2005	37	84	118	90	88	116	92	4	-2	2
		DAY 43	28APR2005	43	100	150	88	80	158	104	-20	8	16
		DAY 50	06MAY2005	51	80	116	80	104	114	84	24 Y	-2	4
		DAY 57	13MAY2005	58	80	126	76	80	124	84	0	-2	8
		FINAL			80	126	76	80	124	84	0	-2	8

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0044006	SCREEN	18APR2005	-7	68	122	88	80	126	88	12	4	0
		DAY 1	25APR2005	1	64	122	68	84	124	70	20 Y	2	2
		BASELINE			64	122	68	84	124	70	20 Y	2	2
		DAY 8	02MAY2005	8	72	122	78	84	122	82	12	0	4
		DAY 15	09MAY2005	15	76	120	84	92	130	92	16	10	8
		DAY 22	16MAY2005	22	84	132	78	84	132	82	0	0	4
		DAY 29	23MAY2005	29	76	118	68	92	128	80	16	10	12
		DAY 36	31MAY2005	37	64	118	86	72	118	78	8	0	-8
		DAY 43	06JUN2005	43	72	112	78	76	118	88	4	6	10
		DAY 50	13JUN2005	50	76	116	78	80	116	82	4	0	4
		DAY 57	20JUN2005	57	72	116	72	72	114	68	0	-2	-4
		FINAL			72	116	72	72	114	68	0	-2	-4
	E0046008	SCREEN	12JAN2005	-7	76	140	60	100	110	70	24 Y	-30 Y	10
		DAY 1	19JAN2005	1	72	139	79	95	125	78	23 Y	-14	-1
		BASELINE			72	139	79	95	125	78	23 Y	-14	-1
		DAY 8	25JAN2005	7	84	133	72	128 H	100	67	44 Y	-33 Y	-5
		DAY 22	07FEB2005	20	76	142	71	97	118	75	21 Y	-24 Y	4
		DAY 29	14FEB2005	27	70	133	76	85	134	82	15	1	6
		DAY 36	21FEB2005	34	75	138	71	97	121	76	22 Y	-17	5
		DAY 43	28FEB2005	41	71	136	72	87	135	77	16	-1	5
		DAY 50	08MAR2005	49	78	134	74	98	119	73	20 Y	-15	-1
		DAY 57	14MAR2005	55	69	136	80	79	124	75	10	-12	-5
		FINAL			69	136	80	79	124	75	10	-12	-5
QUETIAPINE 300 MG (BIPOLAR II)	E0003002	SCREEN	05AUG2004	-19	63	110	70	67	110	75	4	0	5
		DAY 1	24AUG2004	1	60	100	60	60	105	65	0	5	5
		BASELINE			60	100	60	60	105	65	0	5	5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0003002	DAY 8	01SEP2004	9	60	90 L	60	60	95	65	0	5	5
		DAY 15	08SEP2004	16	60	88 L	55	62	90 L	60	2	2	5
		DAY 22	16SEP2004	24	70	82 L	52	70	98	62	0	16	10
		DAY 29	22SEP2004	30	62	83 L	55	64	97	60	2	14	5
		DAY 36	30SEP2004	38	66	105	55	60	110	65	-6	5	10
		DAY 43	06OCT2004	44	60	105	75	65	110	77	5	5	2
		DAY 50	13OCT2004	51	60	103	65	64	105	70	4	2	5
		DAY 57	20OCT2004	58	60	110	70	58	110	80	-2	0	10
		FINAL			60	110	70	58	110	80	-2	0	10
	E0006016	SCREEN	07OCT2004	-8	65	170	118 H	76	168	112 H	11	-2	-6
		DAY 1	15OCT2004	1	68	140	110 H	86	140	106 H	18	0	-4
		BASELINE			68	140	110 H	86	140	106 H	18	0	-4
		DAY 8	22OCT2004	8	80	156	110 H	92	160	124 H	12	4	14
		DAY 15	28OCT2004	14	76	138	100	82	140	98	6	2	-2
		DAY 22	03NOV2004	20	70	138	110 H	80	132	108 H	10	-6	-2
		DAY 29	15NOV2004	32	78	130	100	76	140	106 H	-2	10	6
		DAY 43	24NOV2004	41	80	138	94	78	140	100	-2	2	6
		DAY 57	10DEC2004	57	80	138	88	84	136	90	4	-2	2
		FINAL			80	138	88	84	136	90	4	-2	2
	E0008007	SCREEN	12JAN2005	-7	66	105	59	70	108	74	4	3	15
		DAY 1	19JAN2005	1	70	112	70	86	96	64	16	-16	-6
		BASELINE			70	112	70	86	96	64	16	-16	-6
		DAY 8	26JAN2005	8	72	104	66	88	70 L	46 L	16	-34 Y	-20 Y
		FINAL			72	104	66	88	70 L	46 L	16	-34 Y	-20 Y
	E0010005	SCREEN	13OCT2004	-13	52	110	70	72	102	64	20 Y	-8	-6
		DAY 1	26OCT2004	1	70	104	72	72	100	68	2	-4	-4
		BASELINE			70	104	72	72	100	68	2	-4	-4

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0010005	DAY 8	01NOV2004	7	74	108	64	84	102	66	10	-6	2
		DAY 15	08NOV2004	14	70	106	60	78	104	68	8	-2	8
		DAY 22	15NOV2004	21	80	110	68	86	106	62	6	-4	-6
		DAY 29	22NOV2004	28	78	112	64	84	104	62	6	-8	-2
		DAY 36	01DEC2004	37	68	112	70	64	108	68	-4	-4	-2
		DAY 43	06DEC2004	42	72	106	70	70	108	74	-2	2	4
		DAY 50	13DEC2004	49	80	110	68	84	106	62	4	-4	-6
		DAY 57	20DEC2004	56	58	118	68	66	108	62	8	-10	-6
		FINAL			58	118	68	66	108	62	8	-10	-6
	E0011009	SCREEN	29OCT2004	-7	40 L	130	70	38 L	126	68	-2	-4	-2
		DAY 1	05NOV2004	1	38 L	128	60	38 L	126	60	0	-2	0
		BASELINE			38 L	128	60	38 L	126	60	0	-2	0
		DAY 8	12NOV2004	8	60	112	62	60	110	60	0	-2	-2
		DAY 15	19NOV2004	15	56	128	60	60	130	62	4	2	2
		DAY 22	24NOV2004	20	52	128	64	54	128	64	2	0	0
		DAY 29	03DEC2004	29	54	126	68	52	124	64	-2	-2	-4
		DAY 36	10DEC2004	36	48 L	118	72	48 L	112	62	0	-6	-10
		DAY 43	17DEC2004	43	56	126	64	54	122	60	-2	-4	-4
		DAY 50	27DEC2004	53	52	130	70	52	128	64	0	-2	-6
		DAY 57	30DEC2004	56	54	128	72	54	126	68	0	-2	-4
		FINAL			54	128	72	54	126	68	0	-2	-4
	E0014005	SCREEN	16AUG2004	-14	72	140	82	76	140	84	4	0	2
		DAY 1	30AUG2004	1	60	128	70	80	126	72	20 Y	-2	2
		BASELINE			60	128	70	80	126	72	20 Y	-2	2
		DAY 8	07SEP2004	9	72	130	80	80	136	80	8	6	0
		DAY 15	14SEP2004	16	68	140	100	76	136	86	8	-4	-14
		FINAL			68	140	100	76	136	86	8	-4	-14

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0020028	SCREEN	09DEC2004	-6	88	120	80	86	123	84	-2	3	4
		DAY 1	15DEC2004	1	100	120	80	100	120	90	0	0	10
		BASELINE			100	120	80	100	120	90	0	0	10
		DAY 8	22DEC2004	8	100	120	80	110	120	82	10	0	2
		DAY 15	30DEC2004	16	90	130	90	100	140	100	10	10	10
		DAY 22	06JAN2005	23	88	140	96	118	142	100	30 Y	2	4
		DAY 29	13JAN2005	30	94	120	90	104	120	102	10	0	12
		DAY 36	20JAN2005	37	86	140	100	92	140	95	6	0	-5
		DAY 43	27JAN2005	44	100	132	90	102	130	100	2	-2	10
		DAY 50	03FEB2005	51	88	130	90	86	130	90	-2	0	0
		DAY 57	10FEB2005	58	91	130	92	100	130	98	9	0	6
		FINAL			91	130	92	100	130	98	9	0	6
	E0020041	SCREEN	01MAR2005	-15	66	110	70	82	120	70	16	10	0
		DAY 1	16MAR2005	1	66	110	72	82	90 L	70	16	-20 Y	-2
		BASELINE			66	110	72	82	90 L	70	16	-20 Y	-2
		DAY 8	23MAR2005	8	80	122	74	108	124	76	28 Y	2	2
		DAY 15	31MAR2005	16	60	110	70	68	115	70	8	5	0
		DAY 22	07APR2005	23	90	100	68	108	102	74	18	2	6
		DAY 29	14APR2005	30	80	100	70	95	100	72	15	0	2
		DAY 36	21APR2005	37	100	110	50 L	106	120	50 L	6	10	0
		DAY 43	28APR2005	44	89	100	60	90	100	62	1	0	2
		FINAL			89	100	60	90	100	62	1	0	2
	E0021019	SCREEN	14DEC2004	-16	60	112	62	72	100	64	12	-12	2
		DAY 1	30DEC2004	1	63	102	68	72	96	72	9	-6	4
		BASELINE			63	102	68	72	96	72	9	-6	4
		DAY 8	06JAN2005	8	63	90 L	68	81	112	68	18	22	0
		DAY 15	13JAN2005	15	66	98	60	84	102	68	18	4	8
		DAY 22	20JAN2005	22	60	92	58	75	94	66	15	2	8

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0021019	DAY 29	27JAN2005	29	63	98	64	78	106	68	15	8	4
		DAY 43	10FEB2005	43	72	94	64	87	108	72	15	14	8
		DAY 50	17FEB2005	50	66	102	66	87	122	76	21 Y	20	10
		DAY 57	24FEB2005	57	63	118	70	80	108	64	17	-10	-6
		FINAL			63	118	70	80	108	64	17	-10	-6
	E0025009	SCREEN	04AUG2004	-7	58	128	82	44 L	126	80	-14	-2	-2
		DAY 1	11AUG2004	1	57	138	73	56	136	72	-1	-2	-1
		BASELINE			57	138	73	56	136	72	-1	-2	-1
		DAY 8	18AUG2004	8	88	136	86	86	135	86	-2	-1	0
		DAY 15	25AUG2004	15	82	138	84	83	137	84	1	-1	0
		DAY 22	31AUG2004	21	63	131	87	65	132	88	2	1	1
		DAY 29	08SEP2004	29	70	128	84	69	127	83	-1	-1	-1
		DAY 36	15SEP2004	36	64	116	82	65	117	83	1	1	1
		DAY 43	22SEP2004	43	70	122	84	68	122	82	-2	0	-2
		DAY 50	29SEP2004	50	76	128	82	75	126	80	-1	-2	-2
		DAY 57	06OCT2004	57	74	126	80	75	125	80	1	-1	0
		FINAL			74	126	80	75	125	80	1	-1	0
	E0025029	SCREEN	16NOV2004	-14	61	117	68	64	101	66	3	-16	-2
		DAY 1	30NOV2004	1	68	104	67	65	121	78	-3	17	11
		BASELINE			68	104	67	65	121	78	-3	17	11
		DAY 8	07DEC2004	8	60	120	73	61	118	70	1	-2	-3
		DAY 15	14DEC2004	15	111	106	72	105	128	85	-6	22	13
		DAY 22	21DEC2004	22	80	132	88	110	108	84	30 Y	-24 Y	-4
		DAY 36	04JAN2005	36	76	140	98	82	134	94	6	-6	-4
		DAY 43	11JAN2005	43	82	110	60	80	116	70	-2	6	10
		DAY 50	18JAN2005	50	76	124	84	70	120	82	-6	-4	-2
		DAY 57	25JAN2005	57	79	118	82	76	106	80	-3	-12	-2
		FINAL			79	118	82	76	106	80	-3	-12	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0025039	SCREEN	03FEB2005	-7	58	112	68	66	108	78	8	-4	10
		DAY 1	10FEB2005	1	64	136	68	88	138	92	24 Y	2	24
		BASELINE			64	136	68	88	138	92	24 Y	2	24
		DAY 8	18FEB2005	9	84	118	80	86	116	82	2	-2	2
		DAY 15	25FEB2005	16	78	122	78	78	120	76	0	-2	-2
		DAY 22	04MAR2005	23	84	122	84	86	112	84	2	-10	0
		DAY 29	11MAR2005	30	92	138	92	100	128	90	8	-10	-2
		DAY 36	18MAR2005	37	94	146	76	96	142	88	2	-4	12
		DAY 43	25MAR2005	44	80	120	78	82	118	76	2	-2	-2
		DAY 50	01APR2005	51	76	128	72	96	120	78	20 Y	-8	6
		FINAL			76	128	72	96	120	78	20 Y	-8	6
	E0025042	SCREEN	09FEB2005	-9	70	108	80	82	110	78	12	2	-2
		DAY 1	18FEB2005	1	76	106	76	80	108	82	4	2	6
		BASELINE			76	106	76	80	108	82	4	2	6
		DAY 8	25FEB2005	8	80	104	78	78	100	80	-2	-4	2
		DAY 15	03MAR2005	14	66	120	76	84	106	72	18	-14	-4
		DAY 22	11MAR2005	22	68	118	80	68	114	84	0	-4	4
		DAY 29	18MAR2005	29	74	104	74	88	92	74	14	-12	0
		DAY 43 *	30MAR2005	41	76	108	74	76	106	74	0	-2	0
		DAY 43	01APR2005	43	80	102	74	88	98	70	8	-4	-4
		DAY 57 *	13APR2005	55	88	122	80	96	98	68	8	-24 Y	-12
		DAY 57	15APR2005	57	68	106	76	84	94	78	16	-12	2
		FINAL			68	106	76	84	94	78	16	-12	2
	E0030008	SCREEN	16AUG2004	-3	56	129	63	80	129	85	24 Y	0	22
		DAY 1	19AUG2004	1	54	123	77	71	132	82	17	9	5
		BASELINE			54	123	77	71	132	82	17	9	5
		DAY 8	26AUG2004	8	72	137	82	103	133	89	31 Y	-4	7
		DAY 15	02SEP2004	15	79	115	78	123 H	132	94	44 Y	17	16

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0030008	DAY 22	09SEP2004	22	80	106	74	66	102	82	-14	-4	8
		DAY 57	13OCT2004	56	64	119	81	74	129	82	10	10	1
		FINAL			64	119	81	74	129	82	10	10	1
	E0035016	SCREEN	24SEP2004	-11	58	90 L	60	70	86 L	62	12	-4	2
		DAY 1	05OCT2004	1	76	94	60	80	104	60	4	10	0
		BASELINE			76	94	60	80	104	60	4	10	0
		DAY 8	12OCT2004	8	76	98	66	76	100	70	0	2	4
		DAY 15	19OCT2004	15	64	98	68	68	92	68	4	-6	0
		DAY 22	26OCT2004	22	70	104	68	80	92	68	10	-12	0
		DAY 29	01NOV2004	28	64	90 L	60	68	94	68	4	4	8
		DAY 36	08NOV2004	35	64	90 L	60	80	90 L	58	16	0	-2
		DAY 43	15NOV2004	42	60	90 L	60	60	90 L	60	0	0	0
		DAY 50	22NOV2004	49	80	90 L	60	70	96	70	-10	6	10
		DAY 57	30NOV2004	57	64	98	60	74	96	60	10	-2	0
		FINAL			64	98	60	74	96	60	10	-2	0
	E0039018	SCREEN	16DEC2004	-26				69	122	84			
		DAY 1	11JAN2005	1	64	120	60	72	100	60	8	-20 Y	0
		BASELINE			64	120	60	72	100	60	8	-20 Y	0
		DAY 8	18JAN2005	8	72	110	60	84	102	58	12	-8	-2
		DAY 15	24JAN2005	14	64	116	66	72	112	60	8	-4	-6
		DAY 22	02FEB2005	23	88	104	70	88	100	64	0	-4	-6
		DAY 29	09FEB2005	30	76	108	68	76	110	68	0	2	0
		DAY 36	17FEB2005	38	72	116	62	80	108	70	8	-8	8
		DAY 50	28FEB2005	49	74	118	70	76	116	68	2	-2	-2
		DAY 57	08MAR2005	57	72	110	64	76	106	62	4	-4	-2
		FINAL			72	110	64	76	106	62	4	-4	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0003011	SCREEN	21DEC2004	-10	92	139	96	98	147	102	6	8	6
		DAY 1	31DEC2004	1	94	147	89	103	136	88	9	-11	-1
		BASELINE			94	147	89	103	136	88	9	-11	-1
		DAY 8	07JAN2005	8	103	157	99	109	165	105 H	6	8	6
		DAY 15	14JAN2005	15	98	136	90	103	148	99	5	12	9
		DAY 22	21JAN2005	22	114	163	107 H	109	161	94	-5	-2	-13
		DAY 29	28JAN2005	29	94	151	94	105	148	86	11	-3	-8
		DAY 36	02FEB2005	34	111	147	90	107	143	90	-4	-4	0
		DAY 43	11FEB2005	43	101	139	84	109	151	80	8	12	-4
		DAY 50	22FEB2005	54	105	170	112 H	103	158	102	-2	-12	-10
		DAY 57	03MAR2005	63	93	120	83	98	134	89	5	14	6
		FINAL			93	120	83	98	134	89	5	14	6
	E0004009	SCREEN	09AUG2004	-7	56	128	62	64	110	68	8	-18	6
		DAY 1	16AUG2004	1	56	120	60	68	108	70	12	-12	10
		BASELINE			56	120	60	68	108	70	12	-12	10
		DAY 8	23AUG2004	8	60	120	62	72	120	70	12	0	8
		DAY 15	30AUG2004	15	72	118	66	80	120	74	8	2	8
		DAY 22	07SEP2004	23	68	118	60	96	108	58	28 Y	-10	-2
		DAY 29	13SEP2004	29	56	120	60	60	122	68	4	2	8
		DAY 36	20SEP2004	36	64	120	76	72	120	80	8	0	4
		FINAL			64	120	76	72	120	80	8	0	4
	E0004012	SCREEN	13SEP2004	-7	48 L	140	88	52	150	90	4	10	2
		DAY 1	20SEP2004	1	56	140	84	52	128	80	-4	-12	-4
		BASELINE			56	140	84	52	128	80	-4	-12	-4
		DAY 8	29SEP2004	10	84	140	86	64	140	88	-20	0	2
		DAY 15	04OCT2004	15	64	150	92	68	144	90	4	-6	-2
		DAY 22	11OCT2004	22	72	140	80	72	132	80	0	-8	0
		DAY 29	19OCT2004	30	56	128	82	64	120	80	8	-8	-2
		DAY 36	25OCT2004	36	64	150	88	72	158	90	8	8	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA	
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	DAY 43		01NOV2004	43	56	150	98	68	144	90	12	-6	-8	
		DAY 50		08NOV2004	50	76	138	100	80	130	98	4	-8	-2	
		DAY 57		17NOV2004	59	60	128	90	64	140	86	4	12	-4	
		FINAL				60	128	90	64	140	86	4	12	-4	
	E0006017	SCREEN		08OCT2004	-7	65	122	82	84	128	88	19	6	6	
		DAY 1		15OCT2004	1	60	116	76	74	120	80	14	4	4	
		BASELINE				60	116	76	74	120	80	14	4	4	
		DAY 8		22OCT2004	8	89	160	120 H	94	160	118 H	5	0	-2	
		DAY 15		29OCT2004	15	88	166	110 H	96	170	108 H	8	4	-2	
		DAY 15	*	01NOV2004	18	86	172	106 H	102	178	118 H	16	6	12	
		FINAL				86	172	106 H	102	178	118 H	16	6	12	
	E0008012	SCREEN		31JAN2005	-7	80	135	88	84	138	90	4	3	2	
		DAY 1		07FEB2005	1	84	140	90	99	136	95	15	-4	5	
		BASELINE				84	140	90	99	136	95	15	-4	5	
		DAY 8		14FEB2005	8	98	152	100	94	146	74	-4	-6	-26	Y
		DAY 15		21FEB2005	15	92	130	88	90	134	86	-2	4	-2	
		FINAL				92	130	88	90	134	86	-2	4	-2	
	E0013008	SCREEN		27OCT2004	-15	62	122	86	60	118	78	-2	-4	-8	
		DAY 1		11NOV2004	1	64	122	72	62	120	76	-2	-2	4	
		BASELINE				64	122	72	62	120	76	-2	-2	4	
		DAY 8		17NOV2004	7	60	118	70	64	122	74	4	4	4	
		DAY 8	*	22NOV2004	12	68	127	93	70	127	95	2	0	2	
		DAY 15		29NOV2004	19	91	135	88	99	125	95	8	-10	7	
		DAY 29		08DEC2004	28	95	123	83	95	121	90	0	-2	7	
		DAY 36		16DEC2004	36	90	117	86	82	131	94	-8	14	8	
		DAY 36	*	20DEC2004	40	80	126	94	80	133	96	0	7	2	
		DAY 50		29DEC2004	49	76	138	88	88	132	92	12	-6	4	
		DAY 50	*	03JAN2005	54	98	142	105 H	111	142	97	13	0	-8	

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)		FINAL				98	142	105 H	111	142	97	13	0	-8
	E0013008	SCREEN		17JAN2005	-14	70	147	102	83	148	108 H	13	1	6
		DAY 1		31JAN2005	1	70	132	87	71	133	100	1	1	13
		BASELINE				70	132	87	71	133	100	1	1	13
		DAY 8		07FEB2005	8	76	127	92	82	164	103	6	37	11
		DAY 15		16FEB2005	17	88	130	95	83	122	108 H	-5	-8	13
		DAY 22		21FEB2005	22	73	136	104	85	134	106 H	12	-2	2
		FINAL				73	136	104	85	134	106 H	12	-2	2
	E0015005	SCREEN		20SEP2004	-7	84	102	80	86	96	74	2	-6	-6
		DAY 1		27SEP2004	1	67	100	70	88	98	88	21 Y	-2	18
		BASELINE				67	100	70	88	98	88	21 Y	-2	18
		DAY 8		05OCT2004	9	76	122	84	86	112	80	10	-10	-4
		DAY 15		11OCT2004	15	60	100	70	68	98	70	8	-2	0
		FINAL				60	100	70	68	98	70	8	-2	0
	E0015012	SCREEN		19JAN2005	-9	74	104	80	80	102	76	6	-2	-4
		DAY 1		28JAN2005	1	60	118	72	80	106	88	20 Y	-12	16
		BASELINE				60	118	72	80	106	88	20 Y	-12	16
		DAY 8		03FEB2005	7	84	120	70	88	114	72	4	-6	2
		DAY 15		14FEB2005	18	88	110	82	86	112	84	-2	2	2
		DAY 22		18FEB2005	22	78	116	70	86	122	82	8	6	12
		DAY 22	*	22FEB2005	26	82	108	88	86	118	88	4	10	0
		DAY 36		02MAR2005	34	82	124	88	88	108	88	6	-16	0
		DAY 50		21MAR2005	53	62	112	70	66	108	74	4	-4	4
		FINAL				62	112	70	66	108	74	4	-4	4
	E0020005	SCREEN		18AUG2004	-28	48 L	120	60	48 L	120	50 L	0	0	-10
		DAY 1		15SEP2004	1	56	112	58	60	110	60	4	-2	2
		BASELINE				56	112	58	60	110	60	4	-2	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020005	DAY 8		22SEP2004	8	60	118	70	56	120	60	-4	2	-10
		DAY 22	*	04OCT2004	20	60	120	60	60	116	60	0	-4	0
		DAY 22		07OCT2004	23	64	126	60	72	120	70	8	-6	10
		DAY 29		14OCT2004	30	64	116	60	72	120	70	8	4	10
		DAY 36		21OCT2004	37	60	110	70	72	110	60	12	0	-10
		DAY 43		28OCT2004	44	72	120	76	80	110	70	8	-10	-6
		DAY 50		04NOV2004	51	72	120	75	84	125	80	12	5	5
		DAY 57		11NOV2004	58	60	110	80	66	124	70	6	14	-10
		FINAL				60	110	80	66	124	70	6	14	-10
	E0020022	SCREEN		09NOV2004	-14	60	110	84	72	120	100	12	10	16
		DAY 1		23NOV2004	1	76	100	70	80	110	80	4	10	10
		BASELINE				76	100	70	80	110	80	4	10	10
		DAY 8		30NOV2004	8	70	110	78	86	110	80	16	0	2
		DAY 15		09DEC2004	17	65	100	60	68	110	70	3	10	10
		DAY 22		14DEC2004	22	72	110	60	72	100	70	0	-10	10
		DAY 29		20DEC2004	28	72	100	60	70	108	72	-2	8	12
		DAY 36		28DEC2004	36	80	102	70	86	102	76	6	0	6
		DAY 43		04JAN2005	43	80	110	80	88	110	80	8	0	0
		DAY 50		11JAN2005	50	78	90 L	58	86	98	72	8	8	14
		DAY 57		20JAN2005	59	68	98	70	80	110	80	12	12	10
		FINAL				68	98	70	80	110	80	12	12	10
	E0020032	SCREEN		29DEC2004	-12	80	140	80	100	140	84	20 Y	0	4
		DAY 1		10JAN2005	1	82	120	80	90	130	110 H	8	10	30
		BASELINE				82	120	80	90	130	110 H	8	10	30
		DAY 8		17JAN2005	8	102	120	80	102	130	100	0	10	20
		DAY 15		24JAN2005	15	80	125	75	84	120	80	4	-5	5
		DAY 22		31JAN2005	22	86	110	70	88	110	75	2	0	5
		DAY 29		07FEB2005	29	88	125	85	86	120	85	-2	-5	0
		FINAL				88	125	85	86	120	85	-2	-5	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020037	SCREEN	01FEB2005	-7	48 L	110	62	60	110	74	12	0	12
		DAY 1	08FEB2005	1	51	100	74	51	100	72	0	0	-2
		BASELINE			51	100	74	51	100	72	0	0	-2
		DAY 8	14FEB2005	7	62	109	70	74	120	60	12	11	-10
		FINAL			62	109	70	74	120	60	12	11	-10
	E0020048	SCREEN	09JUN2005	-5	66	119	86	70	120	90	4	1	4
		DAY 1	14JUN2005	1	70	120	80	80	126	90	10	6	10
		BASELINE			70	120	80	80	126	90	10	6	10
		DAY 8	21JUN2005	8	80	128	78	82	122	84	2	-6	6
		DAY 15	28JUN2005	15	76	122	72	104	138	90	28 Y	16	18
		DAY 22	05JUL2005	22	70	118	76	84	119	90	14	1	14
		DAY 29	12JUL2005	29	80	114	88	84	128	90	4	14	2
		DAY 36	19JUL2005	36	70	130	90	84	120	88	14	-10	-2
		DAY 43	26JUL2005	43	78	129	84	98	129	100	20 Y	0	16
		DAY 50	02AUG2005	50	78	132	90	88	134	88	10	2	-2
		DAY 57	09AUG2005	57	76	120	88	86	128	94	10	8	6
		FINAL			76	120	88	86	128	94	10	8	6
	E0021003	SCREEN	26JUL2004	-10	58	116	68	64	118	68	6	2	0
		DAY 1	05AUG2004	1	56	120	70	66	120	72	10	0	2
		BASELINE			56	120	70	66	120	72	10	0	2
		DAY 8	16AUG2004	12	70	118	74	68	118	78	-2	0	4
		DAY 15	19AUG2004	15	75	112	66	78	114	78	3	2	12
		DAY 22	25AUG2004	21	66	102	66	87	116	84	21 Y	14	18
		DAY 29	01SEP2004	28	66	110	70	81	114	80	15	4	10
		DAY 36	08SEP2004	35	69	116	78	63	116	78	-6	0	0
		DAY 43	14SEP2004	41	69	112	76	88	120	78	19	8	2
		DAY 50	23SEP2004	50	80	116	66	99	108	80	19	-8	14
		DAY 57	29SEP2004	56	75	118	58	96	110	82	21 Y	-8	24
		FINAL			75	118	58	96	110	82	21 Y	-8	24

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0021029	SCREEN	30MAR2005	-7	72	132	90	90	124	92	18	-8	2
		DAY 1	06APR2005	1	69	116	72	72	112	88	3	-4	16
		BASELINE			69	116	72	72	112	88	3	-4	16
		DAY 8	13APR2005	8	98	112	74	104	108	84	6	-4	10
		DAY 15	21APR2005	16	86	124	88	105	110	96	19	-14	8
		DAY 22	28APR2005	23	87	128	74	93	116	94	6	-12	20
		DAY 29	05MAY2005	30	94	126	82	110	100	70	16	-26 Y	-12
		DAY 36	11MAY2005	36	92	106	80	103	124	84	11	18	4
		DAY 43	19MAY2005	44	94	114	84	108	110	96	14	-4	12
		DAY 50	26MAY2005	51	104	120	94	120	138	104	16	18	10
		DAY 57	03JUN2005	59	96	126	82	102	126	94	6	0	12
		FINAL			96	126	82	102	126	94	6	0	12
	E0021032	SCREEN	18APR2005	-7	40 L	122	84	54	126	84	14	4	0
		DAY 1	25APR2005	1	48 L	102	66	58	104	68	10	2	2
		BASELINE			48 L	102	66	58	104	68	10	2	2
		DAY 8	04MAY2005	10	57	94	60	81	94	72	24 Y	0	12
		DAY 15	09MAY2005	15	54	92	60	69	108	78	15	16	18
		DAY 22	16MAY2005	22	51	94	62	72	106	76	21 Y	12	14
		DAY 29	23MAY2005	29	57	96	68	78	106	84	21 Y	10	16
		DAY 36	01JUN2005	38	54	100	62	72	98	78	18	-2	16
		DAY 43	06JUN2005	43	56	102	64	66	108	84	10	6	20
		FINAL			56	102	64	66	108	84	10	6	20
	E0025054	SCREEN	31MAR2005	-5	72	166	101	74	167	102	2	1	1
		DAY 1	05APR2005	1	76	161	98	78	158	97	2	-3	-1
		BASELINE			76	161	98	78	158	97	2	-3	-1
		DAY 8	15APR2005	11	80	160	97	77	158	97	-3	-2	0
		DAY 22	26APR2005	22	96	148	104	98	148	108 H	2	0	4
		FINAL			96	148	104	98	148	108 H	2	0	4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0025056	SCREEN	26APR2005	-16	92	122	88	110	120	84	18	-2	-4
		DAY 1	12MAY2005	1	88	102	82	90	100	82	2	-2	0
		BASELINE			88	102	82	90	100	82	2	-2	0
		DAY 8	17MAY2005	6	72	108	86	88	104	88	16	-4	2
		DAY 15	24MAY2005	13	83	117	74	58	121	83	-25	4	9
		DAY 22	31MAY2005	20	82	104	75	106	102	78	24 Y	-2	3
		DAY 29	07JUN2005	27	74	139	92	91	109	64	17	-30 Y	-28 Y
		FINAL			74	139	92	91	109	64	17	-30 Y	-28 Y
	E0025057	SCREEN	26APR2005	-6	68	138	88	72	144	88	4	6	0
		DAY 1	02MAY2005	1	68	132	68	84	122	84	16	-10	16
		BASELINE			68	132	68	84	122	84	16	-10	16
		DAY 8	10MAY2005	9	68	138	72	88	128	86	20 Y	-10	14
		DAY 15	17MAY2005	16	72	144	74	88	132	86	16	-12	12
		DAY 22	24MAY2005	23	85	129	82	87	124	84	2	-5	2
		DAY 29	31MAY2005	30	78	125	83	80	126	86	2	1	3
		DAY 36	07JUN2005	37	76	125	75	78	127	87	2	2	12
		DAY 43	13JUN2005	43	86	125	74	92	130	89	6	5	15
		DAY 50	21JUN2005	51	84	127	79	82	132	86	-2	5	7
		DAY 57	27JUN2005	57	64	125	77	81	127	92	17	2	15
		FINAL			64	125	77	81	127	92	17	2	15
	E0028009	SCREEN	18NOV2004	-11	88	110	80	100	120	70	12	10	-10
		DAY 1	29NOV2004	1	96	100	70	100	110	70	4	10	0
		BASELINE			96	100	70	100	110	70	4	10	0
		DAY 8	06DEC2004	8	108	104	80	112	102	84	4	-2	4
		DAY 15	16DEC2004	18	88	98	68	104	100	66	16	2	-2
		DAY 22	20DEC2004	22	104	90 L	70	108	100	60	4	10	-10
		DAY 29	27DEC2004	29	102	98	62	106	98	70	4	0	8
		DAY 36	03JAN2005	36	88	100	70	96	100	70	8	0	0
		DAY 43	10JAN2005	43	88	90 L	60	96	80 L	60	8	-10	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028009	DAY 50	17JAN2005	50	96	90 L	70	100	90 L	60	4	0	-10
		DAY 57	24JAN2005	57	100	100	70	104	100	70	4	0	0
		FINAL			100	100	70	104	100	70	4	0	0
	E0028016	SCREEN	24FEB2005	-7	72	110	80	76	110	80	4	0	0
		DAY 1	03MAR2005	1	84	110	90	84	120	80	0	10	-10
		BASELINE			84	110	90	84	120	80	0	10	-10
		DAY 8	10MAR2005	8	80	110	70	88	110	80	8	0	10
		DAY 15	17MAR2005	15	72	100	70	80	90 L	70	8	-10	0
		DAY 22	24MAR2005	22	76	110	70	92	114	80	16	4	10
		DAY 29	31MAR2005	29	84	100	60	96	100	70	12	0	10
		DAY 36	07APR2005	36	72	110	80	80	110	90	8	0	10
		DAY 43	14APR2005	43	84	120	80	84	110	80	0	-10	0
		DAY 50	21APR2005	50	72	108	80	78	108	80	6	0	0
		DAY 57	27APR2005	56	88	120	70	92	110	80	4	-10	10
		FINAL			88	120	70	92	110	80	4	-10	10
	E0030010	SCREEN	23AUG2004	-7	61	137	84	72	141	92	11	4	8
		DAY 1	30AUG2004	1	62	159	94	76	148	98	14	-11	4
		BASELINE			62	159	94	76	148	98	14	-11	4
		DAY 8	07SEP2004	9	75	131	79	88	128	88	13	-3	9
		DAY 15	13SEP2004	15	75	135	78	80	127	80	5	-8	2
		DAY 22	20SEP2004	22	72	131	85	80	127	91	8	-4	6
		DAY 29	27SEP2004	29	66	170	92	121 H	142	103	55 Y	-28 Y	11
		DAY 36	04OCT2004	36	72	136	85	86	114	87	14	-22 Y	2
		DAY 43	11OCT2004	43	75	133	81	81	152	85	6	19	4
		DAY 50	18OCT2004	50	80	133	80	96	125	85	16	-8	5
		DAY 57	25OCT2004	57	76	136	86	95	144	107 H	19	8	21
		FINAL			76	136	86	95	144	107 H	19	8	21
	E0030015	SCREEN	04OCT2004	-7	66	138	73	82	125	76	16	-13	3

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030015	DAY 1	11OCT2004	1	76	128	82	96	132	86	20 Y	4	4
		BASELINE			76	128	82	96	132	86	20 Y	4	4
		DAY 8	21OCT2004	11	68	124	76	96	122	84	28 Y	-2	8
		DAY 15	26OCT2004	16	89	135	79	111	133	107 H	22 Y	-2	28
		DAY 22	05NOV2004	26	97	151	87	111	164	93	14	13	6
		DAY 29	10NOV2004	31	84	126	82	96	120	84	12	-6	2
		DAY 36	17NOV2004	38	80	124	76	88	118	80	8	-6	4
		DAY 43	23NOV2004	44	76	124	72	88	134	84	12	10	12
		DAY 57	10DEC2004	61	89	129	78	101	149	96	12	20	18
		FINAL			89	129	78	101	149	96	12	20	18
	E0030016	SCREEN	27OCT2004	-7	76	121	80	86	143	84	10	22	4
		DAY 1	03NOV2004	1	76	133	77	98	130	81	22 Y	-3	4
		BASELINE			76	133	77	98	130	81	22 Y	-3	4
		DAY 8	10NOV2004	8	72	118	78	84	120	80	12	2	2
		FINAL			72	118	78	84	120	80	12	2	2
	E0030018	SCREEN	09NOV2004	-8	60	129	84	64	136	85	4	7	1
		DAY 1	17NOV2004	1	62	138	86	61	140	70	-1	2	-16
		BASELINE			62	138	86	61	140	70	-1	2	-16
		DAY 8	24NOV2004	8	83	150	78	88	144	94	5	-6	16
		DAY 15	30NOV2004	14	96	149	76	103	150	93	7	1	17
		DAY 22	08DEC2004	22	74	147	86	86	181 H	109 H	12	34	23
		DAY 29	15DEC2004	29	98	151	79	117	143	82	19	-8	3
		DAY 36	23DEC2004	37	80	140	98	88	144	100	8	4	2
		DAY 43	30DEC2004	44	65	156	90	74	144	90	9	-12	0
		FINAL			65	156	90	74	144	90	9	-12	0
	E0030036	SCREEN	26MAY2005	-7	69	164	91	84	157	97	15	-7	6
		DAY 1	02JUN2005	1	60	132	80	72	140	88	12	8	8
		BASELINE			60	132	80	72	140	88	12	8	8

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030036	DAY 8	10JUN2005	9	74	159	101	88	144	113 H	14	-15	12
		FINAL			74	159	101	88	144	113 H	14	-15	12
	E0032014	SCREEN	16JUN2005	-6	69	102	70	72	110	82	3	8	12
		DAY 1	22JUN2005	1	70	100	70	73	105	75	3	5	5
		BASELINE			70	100	70	73	105	75	3	5	5
		DAY 8	30JUN2005	9	88	108	72	91	110	84	3	2	12
		DAY 15	06JUL2005	15	76	107	73	76	110	80	0	3	7
		DAY 22	13JUL2005	22	74	110	72	76	110	80	2	0	8
		DAY 29	20JUL2005	29	92	126	76	112	130	80	20 Y	4	4
		DAY 36	27JUL2005	36	84	100	68	88	110	70	4	10	2
		DAY 43	02AUG2005	42	88	110	80	88	110	80	0	0	0
		DAY 50	10AUG2005	50	88	110	88	86	110	75	-2	0	-13
		DAY 57	17AUG2005	57	84	104	78	93	108	80	9	4	2
		FINAL			84	104	78	93	108	80	9	4	2
	E0034005	SCREEN	29NOV2004	-14	84	130	80	80	128	82	-4	-2	2
		DAY 1	13DEC2004	1	80	118	78	82	120	76	2	2	-2
		BASELINE			80	118	78	82	120	76	2	2	-2
		DAY 8	20DEC2004	8	78	116	82	82	118	86	4	2	4
		DAY 15	27DEC2004	15	76	118	82	82	116	86	6	-2	4
		DAY 22	03JAN2005	22	76	120	80	84	140	82	8	20	2
		DAY 29	10JAN2005	29	84	118	74	88	116	84	4	-2	10
		DAY 36	17JAN2005	36	88	140	110 H	88	138	100	0	-2	-10
		DAY 36 *	21JAN2005	40	84	138	92	88	130	92	4	-8	0
		FINAL			84	138	92	88	130	92	4	-8	0
	E0037017	SCREEN	04FEB2005	-14	52	110	70	60	110	80	8	0	10
		DAY 1	18FEB2005	1	52	110	70	72	102	80	20 Y	-8	10
		BASELINE			52	110	70	72	102	80	20 Y	-8	10

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0037030	SCREEN	10JUN2005	-10	50	90 L	70	72	110	78	22 Y	20	8
		DAY 1	20JUN2005	1	60	100	68	72	100	72	12	0	4
		BASELINE			60	100	68	72	100	72	12	0	4
		DAY 8	29JUN2005	10	60	90 L	60	68	100	80	8	10	20
		DAY 15	06JUL2005	17	60	90 L	64	64	100	70	4	10	6
		DAY 29	19JUL2005	30	56	100	62	64	108	70	8	8	8
		FINAL			56	100	62	64	108	70	8	8	8
	E0039002	SCREEN	10AUG2004	-21	64	108	60	78	94	60	14	-14	0
		DAY 1	31AUG2004	1	58	108	60	60	92	70	2	-16	10
		BASELINE			58	108	60	60	92	70	2	-16	10
		DAY 8	07SEP2004	8	68	108	64	88	100	70	20 Y	-8	6
		DAY 15	14SEP2004	15	76	110	60	88	98	60	12	-12	0
		DAY 22	21SEP2004	22	88	110	58	92	110	58	4	0	0
		DAY 29	28SEP2004	29	78	102	60	88	94	56	10	-8	-4
		DAY 36	05OCT2004	36	76	110	64	80	108	62	4	-2	-2
		DAY 43	12OCT2004	43	80	110	70	80	102	70	0	-8	0
		DAY 50	20OCT2004	51	74	100	64	82	98	60	8	-2	-4
		DAY 57	28OCT2004	59	68	110	74	70	104	70	2	-6	-4
		FINAL			68	110	74	70	104	70	2	-6	-4
	E0039007	SCREEN	15SEP2004	-15	62	100	60	68	96	50 L	6	-4	-10
		DAY 1	30SEP2004	1	76	108	50 L	84	90 L	60	8	-18	10
		BASELINE			76	108	50 L	84	90 L	60	8	-18	10
		DAY 8	07OCT2004	8	76	110	58	88	98	52	12	-12	-6
		DAY 15	13OCT2004	14	96	120	68	88	114	60	-8	-6	-8
		DAY 22	20OCT2004	21	88	122	62	94	102	52	6	-20 Y	-10
		DAY 29	28OCT2004	29	98	108	68	104	100	60	6	-8	-8
		DAY 36	08NOV2004	40	96	104	60	102	100	60	6	-4	0
		DAY 43	15NOV2004	47	86	110	60	98	102	64	12	-8	4
		DAY 57 *	24NOV2004	56	88	102	64	100	98	58	12	-4	-6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039007	DAY 57		01DEC2004	63	98	110	64	104	100	60	6	-10	-4
		FINAL				98	110	64	104	100	60	6	-10	-4
	E0040014	SCREEN		12APR2005	-14	76	123	84	92	118	88	16	-5	4
		DAY 1		26APR2005	1	74	125	82	100	120	90	26 Y	-5	8
		BASELINE				74	125	82	100	120	90	26 Y	-5	8
	E0041006	SCREEN		19OCT2004	-10	52	124	72	56	118	74	4	-6	2
		DAY 1		29OCT2004	1	56	106	70	72	102	78	16	-4	8
		BASELINE				56	106	70	72	102	78	16	-4	8
		DAY 8		05NOV2004	8	52	110	72	68	108	72	16	-2	0
		DAY 15		12NOV2004	15	64	108	74	84	108	82	20 Y	0	8
		DAY 22		19NOV2004	22	60	102	72	64	106	76	4	4	4
		DAY 22	*	23NOV2004	26	72	108	70	72	104	68	0	-4	-2
		DAY 36		02DEC2004	35	76	108	68	84	102	76	8	-6	8
		DAY 43		10DEC2004	43	68	106	62	76	102	76	8	-4	14
		DAY 50		17DEC2004	50	64	104	68	68	110	76	4	6	8
		DAY 50	*	21DEC2004	54	60	108	66	60	102	68	0	-6	2
		FINAL				60	108	66	60	102	68	0	-6	2
	E0045003	SCREEN		08FEB2005	-17	92	130	90	92	140	90	0	10	0
		DAY 1		24FEB2005	-1	86	140	90	82	136	82	-4	-4	-8
		BASELINE				86	140	90	82	136	82	-4	-4	-8
		DAY 8		04MAR2005	8	80	158	85	80	130	65	0	-28 Y	-20 Y
		DAY 15		11MAR2005	15	112	132	92	112	120	90	0	-12	-2
		FINAL				112	132	92	112	120	90	0	-12	-2
	E0046004	SCREEN		17NOV2004	-15	68	132	90	84	129	83	16	-3	-7
		DAY 1		02DEC2004	1	61	130	83	77	124	84	16	-6	1
		BASELINE				61	130	83	77	124	84	16	-6	1
		DAY 8		09DEC2004	8	99	126	84	115	132	86	16	6	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0046004	DAY 15		16DEC2004	15	80	126	78	105	110	78	25 Y	-16	0
		DAY 22		22DEC2004	21	90	148	93	104	124	82	14	-24 Y	-11
		DAY 29		29DEC2004	28	86	129	86	100	112	76	14	-17	-10
		DAY 36		05JAN2005	35	89	136	83	102	128	80	13	-8	-3
		DAY 43		12JAN2005	42	97	137	83	105	128	76	8	-9	-7
		DAY 50		19JAN2005	49	88	143	85	96	125	87	8	-18	2
		DAY 50	*	24JAN2005	54	88	110	78	80	110	78	-8	0	0
		FINAL				88	110	78	80	110	78	-8	0	0
	E0046012	SCREEN		08FEB2005	-7	45 L	140	81	56	122	79	11	-18	-2
		DAY 1		15FEB2005	1	50	122	70	60	105	69	10	-17	-1
		BASELINE				50	122	70	60	105	69	10	-17	-1
		DAY 29		16MAR2005	30	56	130	78	60	116	62	4	-14	-16
		FINAL				56	130	78	60	116	62	4	-14	-16
QUETIAPINE 600 MG (BIPOLAR II)	E0004011	SCREEN		13SEP2004	-7	60	90 L	58	64	86 L	58	4	-4	0
		DAY 1		20SEP2004	1	60	92	60	68	88 L	58	8	-4	-2
		BASELINE				60	92	60	68	88 L	58	8	-4	-2
	E0004014	SCREEN		05OCT2004	-7	48 L	120	80	60	116	74	12	-4	-6
		DAY 1		12OCT2004	1	56	112	72	60	108	66	4	-4	-6
		BASELINE				56	112	72	60	108	66	4	-4	-6
		DAY 8		20OCT2004	9	68	110	78	76	114	82	8	4	4
		FINAL				68	110	78	76	114	82	8	4	4
	E0010015	SCREEN		16FEB2005	-7	66	140	82	80	120	80	14	-20 Y	-2
		DAY 1		23FEB2005	1	74	120	78	90	120	74	16	0	-4
		BASELINE				74	120	78	90	120	74	16	0	-4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0010015	DAY 8	03MAR2005	9	84	128	88	78	124	92	-6	-4	4
		DAY 15	10MAR2005	16	92	126	92	86	124	90	-6	-2	-2
		DAY 22	17MAR2005	23	96	116	82	76	120	80	-20	4	-2
		DAY 29	24MAR2005	30	86	126	84	90	130	88	4	4	4
		DAY 36	31MAR2005	37	82	124	92	90	124	88	8	0	-4
		DAY 43	07APR2005	44	88	118	88	84	124	86	-4	6	-2
		DAY 50	14APR2005	51	76	118	88	88	116	86	12	-2	-2
		DAY 57	21APR2005	58	88	128	70	76	118	74	-12	-10	4
		FINAL			88	128	70	76	118	74	-12	-10	4
	E0019005	SCREEN	10NOV2004	-19	78	120	84	76	116	80	-2	-4	-4
		DAY 1	29NOV2004	1	64	164	106 H	76	152	108 H	12	-12	2
		BASELINE			64	164	106 H	76	152	108 H	12	-12	2
		DAY 8	06DEC2004	8	76	142	108 H	80	140	100	4	-2	-8
		DAY 15	13DEC2004	15	80	130	90	80	128	86	0	-2	-4
		DAY 22	22DEC2004	24	70	120	90	72	118	90	2	-2	0
		DAY 29	27DEC2004	29	80	125	90	80	122	88	0	-3	-2
		DAY 36	04JAN2005	37	68	136	90	80	130	90	12	-6	0
		DAY 43	10JAN2005	43	68	150	88	70	148	88	2	-2	0
		DAY 50	18JAN2005	51	68	138	100	80	138	98	12	0	-2
		DAY 57	24JAN2005	57	80	130	88	88	130	90	8	0	2
		FINAL			80	130	88	88	130	90	8	0	2
	E0020040	SCREEN	11FEB2005	-7	66	120	80	92	120	100	26 Y	0	20
		DAY 1	18FEB2005	1	84	134	92	98	140	100	14	6	8
		BASELINE			84	134	92	98	140	100	14	6	8
		DAY 8	24FEB2005	7	100	132	94	104	150	106 H	4	18	12
		DAY 15	03MAR2005	14	96	150	100	98	150	95	2	0	-5
		DAY 22	10MAR2005	21	88	140	95	86	145	100	-2	5	5
		DAY 29	17MAR2005	28	84	140	90	84	145	95	0	5	5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0020040	DAY 36	24MAR2005	35	92	110	90	100	114	90	8	4	0
		DAY 43	31MAR2005	42	88	130	96	100	130	102	12	0	6
		DAY 50	07APR2005	49	94	120	96	100	120	98	6	0	2
		DAY 57	14APR2005	56	96	140	106 H	102	160	110 H	6	20	4
		FINAL			96	140	106 H	102	160	110 H	6	20	4
	E0025002	SCREEN	14JUL2004	-34	82	108	72	82	108	74	0	0	2
		DAY 1	17AUG2004	1	79	111	73	74	99	53	-5	-12	-20 Y
		BASELINE			79	111	73	74	99	53	-5	-12	-20 Y
		DAY 8	24AUG2004	8	89	99	71	89	98	70	0	-1	-1
		FINAL			89	99	71	89	98	70	0	-1	-1
	E0025017	SCREEN	02SEP2004	-12	75	140	80	76	138	79	1	-2	-1
		DAY 1	14SEP2004	1	70	116	66	91	110	74	21 Y	-6	8
		BASELINE			70	116	66	91	110	74	21 Y	-6	8
		DAY 8	22SEP2004	9	82	105	70	100	109	74	18	4	4
		DAY 15	29SEP2004	16	82	101	66	104	106	73	22 Y	5	7
		DAY 29	13OCT2004	30	76	108	76	76	118	78	0	10	2
		DAY 36	20OCT2004	37	76	98	67	102	111	78	26 Y	13	11
		DAY 43	27OCT2004	44	88	110	66	107	138	96	19	28	30
		DAY 57	09NOV2004	57	74	132	89	81	132	88	7	0	-1
		FINAL			74	132	89	81	132	88	7	0	-1
	E0025036	SCREEN	21JAN2005	-5	54	104	70	79	118	82	25 Y	14	12
		DAY 1	26JAN2005	1	60	104	60	76	108	88	16	4	28
		BASELINE			60	104	60	76	108	88	16	4	28
		DAY 8	02FEB2005	8	56	112	52	83	113	73	27 Y	1	21
		DAY 15	09FEB2005	15	62	118	82	80	112	82	18	-6	0
		DAY 22	15FEB2005	21	80	112	84	96	106	80	16	-6	-4
		DAY 29	23FEB2005	29	84	124	80	100	122	90	16	-2	10

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0025036	DAY 36	02MAR2005	36	70	111	78	72	120	84	2	9	6
		DAY 43	09MAR2005	43	62	124	78	92	141	92	30 Y	17	14
		DAY 50	16MAR2005	50	72	106	80	88	109	82	16	3	2
		DAY 57	24MAR2005	58	68	114	82	96	104	86	28 Y	-10	4
		FINAL			68	114	82	96	104	86	28 Y	-10	4
	E0025050	SCREEN	03MAR2005	-5	74	108	74	74	102	80	0	-6	6
		DAY 1	08MAR2005	1	70	120	80	80	114	84	10	-6	4
		BASELINE			70	120	80	80	114	84	10	-6	4
		DAY 8	14MAR2005	7	76	112	80	72	100	78	-4	-12	-2
		DAY 15	21MAR2005	14	76	118	82	92	94	80	16	-24 Y	-2
		DAY 22	28MAR2005	21	74	120	80	76	118	78	2	-2	-2
		DAY 29	04APR2005	28	68	124	84	72	106	80	4	-18	-4
		DAY 36	11APR2005	35	80	118	84	84	114	90	4	-4	6
		DAY 43	18APR2005	42	68	114	78	88	106	78	20 Y	-8	0
		DAY 50	26APR2005	50	69	118	82	68	112	78	-1	-6	-4
		FINAL			69	118	82	68	112	78	-1	-6	-4
	E0030002	SCREEN	15JUL2004	-6	55	153	80	62	161	82	7	8	2
		DAY 1	21JUL2004	1	68	152	82	78	150	88	10	-2	6
		BASELINE			68	152	82	78	150	88	10	-2	6
		DAY 8	28JUL2004	8	58	170	80	62	162	90	4	-8	10
		DAY 15	04AUG2004	15	54	206 H	94	66	203 H	91	12	-3	-3
		FINAL			54	206 H	94	66	203 H	91	12	-3	-3
	E0030003	SCREEN	03AUG2004	-16	74	112	78	89	101	76	15	-11	-2
		DAY 1	19AUG2004	1	80	120	91	93	98	74	13	-22 Y	-17
		BASELINE			80	120	91	93	98	74	13	-22 Y	-17
		DAY 8	26AUG2004	8	80	116	83	90	106	82	10	-10	-1
		DAY 15	03SEP2004	16	74	121	86	82	108	86	8	-13	0

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L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0030003	DAY 22	08SEP2004	21	77	107	77	86	108	82	9	1	5
		DAY 29	16SEP2004	29	80	102	71	86	95	71	6	-7	0
		DAY 36	24SEP2004	37	70	107	81	76	104	79	6	-3	-2
		DAY 43	30SEP2004	43	86	132	90	90	119	93	4	-13	3
		DAY 50	07OCT2004	50	77	108	77	90	117	74	13	9	-3
		DAY 57	12OCT2004	55	64	101	68	80	85 L	62	16	-16	-6
		FINAL			64	101	68	80	85 L	62	16	-16	-6
	E0030024	SCREEN	07DEC2004	-7	59	110	71	74	120	86	15	10	15
		DAY 1	14DEC2004	1	57	106	68	70	121	74	13	15	6
		BASELINE			57	106	68	70	121	74	13	15	6
		DAY 8	21DEC2004	8	70	113	69	88	132	82	18	19	13
		DAY 15	28DEC2004	15	78	121	69	88	119	76	10	-2	7
		DAY 22	05JAN2005	23	68	122	68	88	110	70	20 Y	-12	2
		DAY 43	25JAN2005	43	56	110	78	72	118	78	16	8	0
		FINAL			56	110	78	72	118	78	16	8	0
	E0036003	SCREEN	20JAN2005	-6	84	118	64	90	116	64	6	-2	0
		DAY 1	26JAN2005	1	80	142	82	80	136	84	0	-6	2
		BASELINE			80	142	82	80	136	84	0	-6	2
		DAY 8	02FEB2005	8	100	142	90	100	118	80	0	-24 Y	-10
		DAY 15	09FEB2005	15	96	116	82	100	122	84	4	6	2
		DAY 22	16FEB2005	22	100	118	80	100	128	88	0	10	8
		DAY 29	23FEB2005	29	88	148	90	92	128	86	4	-20 Y	-4
		DAY 36	02MAR2005	36	96	138	86	92	132	80	-4	-6	-6
		DAY 43	09MAR2005	43	100	122	78	100	118	88	0	-4	10
		DAY 50	15MAR2005	49	96	138	82	100	136	78	4	-2	-4
		DAY 57	23MAR2005	57	100	142	88	104	138	92	4	-4	4
		FINAL			100	142	88	104	138	92	4	-4	4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0037006	SCREEN	04OCT2004	-7	68	100	68	80	110	80	12	10	12
		DAY 1	11OCT2004	1	72	110	70	80	110	70	8	0	0
		BASELINE			72	110	70	80	110	70	8	0	0
		DAY 8	18OCT2004	8	68	98	70	84	102	72	16	4	2
		DAY 22	02NOV2004	23	60	110	75	80	110	70	20 Y	0	-5
		DAY 29	12NOV2004	33	72	110	80	84	110	84	12	0	4
		DAY 36	19NOV2004	40	72	118	80	84	104	84	12	-14	4
		DAY 43	23NOV2004	44	72	110	70	88	110	82	16	0	12
		DAY 50	30NOV2004	51	72	100	76	88	102	80	16	2	4
		DAY 57	13DEC2004	64	68	110	80	84	120	80	16	10	0
		FINAL			68	110	80	84	120	80	16	10	0
	E0037020	SCREEN	08MAR2005	-7	72	140	100	72	150	110 H	0	10	10
		DAY 1	15MAR2005	1	76	150	100	80	150	102	4	0	2
		BASELINE			76	150	100	80	150	102	4	0	2
		DAY 8	22MAR2005	8	76	148	100	84	150	110 H	8	2	10
		DAY 15	29MAR2005	15	80	140	100	84	142	110 H	4	2	10
		DAY 22	07APR2005	24	72	130	90	84	132	100	12	2	10
		DAY 29	12APR2005	29	84	140	100	92	138	96	8	-2	-4
		DAY 36	20APR2005	37	80	120	90	96	110	88	16	-10	-2
		DAY 43	26APR2005	43	80	130	100	92	120	98	12	-10	-2
		DAY 50	03MAY2005	50	80	140	100	82	136	102	2	-4	2
		DAY 57	10MAY2005	57	80	130	90	108	120	100	28 Y	-10	10
		FINAL			80	130	90	108	120	100	28 Y	-10	10
	E0042014	SCREEN	15DEC2004	-14	72	144	98	78	144	92	6	0	-6
		DAY 1	29DEC2004	1	80	152	104	80	146	110 H	0	-6	6
		BASELINE			80	152	104	80	146	110 H	0	-6	6
		DAY 8	05JAN2005	8	76	158	104	76	156	110 H	0	-2	6
		DAY 15	12JAN2005	15	76	146	102	80	144	106 H	4	-2	4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0042014	DAY 22	19JAN2005	22	80	144	110 H	88	140	106 H	8	-4	-4
		DAY 29	26JAN2005	29	84	142	94	80	138	96	-4	-4	2
		DAY 36	02FEB2005	36	88	146	96	84	142	90	-4	-4	-6
		DAY 43	10FEB2005	44	80	130	88	84	126	86	4	-4	-2
		DAY 50	16FEB2005	50	76	132	90	80	130	94	4	-2	4
		DAY 57	21FEB2005	55	78	134	96	84	136	100	6	2	4
		FINAL			78	134	96	84	136	100	6	2	4
	E0046001	SCREEN	03NOV2004	-7	76	120	78	84	130	82	8	10	4
		DAY 1	10NOV2004	1	80	130	76	88	130	80	8	0	4
		BASELINE			80	130	76	88	130	80	8	0	4
		DAY 8	17NOV2004	8	73	132	72	85	126	74	12	-6	2
		DAY 15	24NOV2004	15	72	113	80	93	121	89	21 Y	8	9
		DAY 22	01DEC2004	22	100	143	89	122 H	131	88	22 Y	-12	-1
		DAY 29	08DEC2004	29	79	126	86	92	133	96	13	7	10
		DAY 36	14DEC2004	35	89	123	81	94	125	86	5	2	5
		DAY 43	22DEC2004	43	88	132	90	103	136	97	15	4	7
		DAY 50	29DEC2004	50	92	126	78	100	124	82	8	-2	4
		DAY 57	05JAN2005	57	84	118	64	100	114	64	16	-4	0
		FINAL			84	118	64	100	114	64	16	-4	0
	E0046007	SCREEN	21DEC2004	-14	68	154	90	72	170	90	4	16	0
		DAY 1	04JAN2005	1	63	147	87	73	162	90	10	15	3
		BASELINE			63	147	87	73	162	90	10	15	3
		DAY 8	11JAN2005	8	81	144	85	103	154	84	22 Y	10	-1
		DAY 15	18JAN2005	15	75	166	82	86	169	98	11	3	16
		DAY 22	25JAN2005	22	76	142	87	99	135	91	23 Y	-7	4
		DAY 29	01FEB2005	29	72	153	87	86	141	93	14	-12	6
		DAY 36	08FEB2005	36	84	142	80	96	131	86	12	-11	6
		DAY 43	15FEB2005	43	87	142	81	103	131	88	16	-11	7

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0046007	DAY 50	22FEB2005	50	84	127	73	100	122	82	16	-5	9
		DAY 57	28FEB2005	56	80	157	97	95	156	95	15	-1	-2
		FINAL			80	157	97	95	156	95	15	-1	-2
	E0046011	SCREEN	01FEB2005	-8	73	136	88	96	138	96	23 Y	2	8
		DAY 1	09FEB2005	1	73	128	80	93	136	87	20 Y	8	7
		BASELINE			73	128	80	93	136	87	20 Y	8	7
		DAY 8	16FEB2005	8	66	120	78	90	114	82	24 Y	-6	4
		DAY 15	23FEB2005	15	72	138	77	105	146	84	33 Y	8	7
		DAY 22	02MAR2005	22	65	118	77	88	141	85	23 Y	23	8
		DAY 29	10MAR2005	30	65	113	77	86	120	79	21 Y	7	2
		DAY 36	16MAR2005	36	75	127	83	98	145	89	23 Y	18	6
		DAY 43	22MAR2005	42	60	130	80	80	120	80	20 Y	-10	0
		DAY 50	30MAR2005	50	69	131	87	83	141	84	14	10	-3
		DAY 57	06APR2005	57	72	132	80	82	126	82	10	-6	2
		FINAL			72	132	80	82	126	82	10	-6	2
PLACEBO (BIPOLAR I)	E0001013	SCREEN	28APR2005	-7	68	120	96	84	136	100	16	16	4
		DAY 1	05MAY2005	1	72	160	100	80	148	104	8	-12	4
		BASELINE			72	160	100	80	148	104	8	-12	4
		DAY 8	12MAY2005	8	70	140	92	76	140	90	6	0	-2
		DAY 15	19MAY2005	15	64	146	90	84	128	90	20 Y	-18	0
		DAY 29	02JUN2005	29	72	136	90	76	118	80	4	-18	-10
		FINAL			72	136	90	76	118	80	4	-18	-10
	E0003008	SCREEN	21OCT2004	-19	40 L	145	80	44 L	138	82	4	-7	2
		DAY 1	09NOV2004	1	49 L	138	94	56	138	90	7	0	-4
		BASELINE			49 L	138	94	56	138	90	7	0	-4
		DAY 8	16NOV2004	8	55	140	110 H	48 L	140	105 H	-7	0	-5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0003008	DAY 15	23NOV2004	15	63	145	85	65	144	88	2	-1	3
		DAY 22	01DEC2004	23	52	140	95	60	145	95	8	5	0
		FINAL			52	140	95	60	145	95	8	5	0
	E0004008	SCREEN	04AUG2004	-7	56	100	68	60	102	72	4	2	4
		DAY 1	11AUG2004	1	60	92	62	70	96	68	10	4	6
		BASELINE			60	92	62	70	96	68	10	4	6
		DAY 8	18AUG2004	8	60	92	58	68	92	56	8	0	-2
		DAY 15	25AUG2004	15	72	90 L	60	76	92	68	4	2	8
		DAY 22	01SEP2004	22	68	90 L	62	76	94	64	8	4	2
		DAY 29	08SEP2004	29	72	100	68	80	98	70	8	-2	2
		DAY 36	15SEP2004	36	76	92	72	80	90 L	68	4	-2	-4
		DAY 43	22SEP2004	43	64	94	66	76	90 L	62	12	-4	-4
		DAY 50	29SEP2004	50	76	92	68	80	94	70	4	2	2
		DAY 57	06OCT2004	57	72	100	70	80	96	68	8	-4	-2
		FINAL			72	100	70	80	96	68	8	-4	-2
	E0006003	SCREEN	02AUG2004	-7	60	130	82	64	128	74	4	-2	-8
		DAY 1	09AUG2004	1	60	118	70	62	124	78	2	6	8
		BASELINE			60	118	70	62	124	78	2	6	8
		DAY 8	16AUG2004	8	56	118	80	48 L	120	84	-8	2	4
		FINAL			56	118	80	48 L	120	84	-8	2	4
	E0006019	SCREEN	17NOV2004	-7	68	124	82	72	130	88	4	6	6
		DAY 1	24NOV2004	1	84	118	80	80	124	84	-4	6	4
		BASELINE			84	118	80	80	124	84	-4	6	4
		DAY 8	01DEC2004	8	80	118	82	88	120	84	8	2	2
		DAY 15	08DEC2004	15	88	120	98	84	118	98	-4	-2	0
		DAY 22	15DEC2004	22	88	128	104	88	126	98	0	-2	-6
		DAY 29	22DEC2004	29	80	138	102	76	136	102	-4	-2	0
		DAY 36	29DEC2004	36	103	140	80	108	152	96	5	12	16
		DAY 43	07JAN2005	45	83	106	78	84	120	100	1	14	22

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0006019	DAY 50	12JAN2005	50	82	122	70	84	132	108 H	2	10	38
		DAY 57	19JAN2005	57	84	138	108 H	88	140	108 H	4	2	0
		FINAL			84	138	108 H	88	140	108 H	4	2	0
	E0008013	SCREEN	15MAR2005	-14	52	124	80	56	114	78	4	-10	-2
		DAY 1	29MAR2005	1	70	108	68	68	106	66	-2	-2	-2
		BASELINE			70	108	68	68	106	66	-2	-2	-2
		DAY 8	05APR2005	8	69	116	63	67	106	75	-2	-10	12
		DAY 15	12APR2005	15	70	116	66	80	104	66	10	-12	0
		DAY 22	19APR2005	22	60	118	50 L	64	108	54	4	-10	4
		FINAL			60	118	50 L	64	108	54	4	-10	4
	E0010001	SCREEN	22JUL2004	-6	52	124	82	66	128	86	14	4	4
		DAY 1	28JUL2004	1	70	122	68	74	118	84	4	-4	16
		BASELINE			70	122	68	74	118	84	4	-4	16
		DAY 8	05AUG2004	9	60	112	82	70	118	80	10	6	-2
		DAY 15	12AUG2004	16	58	116	78	62	114	82	4	-2	4
		DAY 22	19AUG2004	23	66	132	82	73	130	92	7	-2	10
		DAY 29	26AUG2004	30	66	130	80	84	130	90	18	0	10
		DAY 36	03SEP2004	38	64	122	74	84	130	80	20 Y	8	6
		DAY 43	09SEP2004	44	72	112	80	86	114	78	14	2	-2
		DAY 50	16SEP2004	51	68	132	90	84	130	86	16	-2	-4
		DAY 57	23SEP2004	58	64	128	80	80	128	84	16	0	4
		FINAL			64	128	80	80	128	84	16	0	4
	E0018003	SCREEN	22NOV2004	-14	105	129	62	105	132	68	0	3	6
		DAY 1	06DEC2004	1	96	114	64	107	115	68	11	1	4
		BASELINE			96	114	64	107	115	68	11	1	4
		DAY 8	14DEC2004	9	87	121	63	102	127	76	15	6	13
		DAY 15	21DEC2004	16	84	120	70	100	124	80	16	4	10
		DAY 22	28DEC2004	23	83	129	63	93	139	64	10	10	1
		DAY 29	04JAN2005	30	81	114	63	94	135	80	13	21	17

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0018003	DAY 36	11JAN2005	37	102	134	66	115	123	72	13	-11	6
		DAY 43	20JAN2005	46	98	135	76	108	134	77	10	-1	1
		DAY 50	27JAN2005	53	111	148	76	127 H	147	74	16	-1	-2
		DAY 57	03FEB2005	60	84	126	69	89	114	79	5	-12	10
		FINAL			84	126	69	89	114	79	5	-12	10
	E0020008	SCREEN	01SEP2004	-12	80	140	80	84	140	90	4	0	10
		DAY 1	13SEP2004	1	88	135	80	80	138	80	-8	3	0
		BASELINE			88	135	80	80	138	80	-8	3	0
		DAY 8	22SEP2004	10	72	140	70	76	136	80	4	-4	10
		DAY 15	27SEP2004	15	80	142	80	84	140	78	4	-2	-2
		DAY 22	04OCT2004	22	64	140	80	72	138	80	8	-2	0
		DAY 29	13OCT2004	31	68	138	80	80	134	80	12	-4	0
		DAY 43	25OCT2004	43	76	150	94	80	140	100	4	-10	6
		DAY 50	01NOV2004	50	76	145	70	86	120	70	10	-25 Y	0
		DAY 57	10NOV2004	59	72	130	100	88	132	110 H	16	2	10
		FINAL			72	130	100	88	132	110 H	16	2	10
	E0020024	SCREEN	22NOV2004	-9	62	108	76	84	120	72	22 Y	12	-4
		DAY 1	01DEC2004	1	68	122	78	80	124	80	12	2	2
		BASELINE			68	122	78	80	124	80	12	2	2
		DAY 8	08DEC2004	8	68	120	90	60	120	80	-8	0	-10
		DAY 15	15DEC2004	15	66	110	68	84	120	80	18	10	12
		DAY 22	22DEC2004	22	62	102	80	84	102	80	22 Y	0	0
		DAY 29	29DEC2004	29	68	122	80	96	130	92	28 Y	8	12
		DAY 36	05JAN2005	36	68	110	78	88	110	80	20 Y	0	2
		DAY 43	12JAN2005	43	72	111	90	92	110	90	20 Y	-1	0
		DAY 50	19JAN2005	50	66	100	70	94	120	80	28 Y	20	10
		DAY 57	26JAN2005	57	72	102	70	74	102	84	2	0	14
		FINAL			72	102	70	74	102	84	2	0	14
	E0020043	SCREEN	07APR2005	-14	60	119	76	80	110	78	20 Y	-9	2

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0020043	DAY 1	21APR2005	1	70	102	66	94	100	70	24 Y	-2	4
		BASELINE			70	102	66	94	100	70	24 Y	-2	4
		DAY 8	27APR2005	7	70	100	70	84	110	84	14	10	14
		FINAL			70	100	70	84	110	84	14	10	14
	E0020045	SCREEN	18APR2005	-9	56	98	80	60	98	82	4	0	2
		DAY 1	27APR2005	1	68	90 L	70	84	90 L	76	16	0	6
		BASELINE			68	90 L	70	84	90 L	76	16	0	6
		DAY 8	03MAY2005	7	70	100	70	80	114	80	10	14	10
		DAY 15	11MAY2005	15	66	104	72	76	111	82	10	7	10
		DAY 22	18MAY2005	22	62	120	76	68	120	82	6	0	6
		DAY 29	25MAY2005	29	66	106	72	78	100	76	12	-6	4
		DAY 36	01JUN2005	36	80	110	76	84	110	70	4	0	-6
		FINAL			80	110	76	84	110	70	4	0	-6
	E0021004	SCREEN	04AUG2004	-14	45 L	116	78	57	120	82	12	4	4
		DAY 1	18AUG2004	1	58	98	78	74	102	70	16	4	-8
		BASELINE			58	98	78	74	102	70	16	4	-8
		DAY 8	24AUG2004	7	60	112	70	74	102	76	14	-10	6
		DAY 15	01SEP2004	15	61	104	64	68	110	70	7	6	6
		DAY 22	12SEP2004	26	60	108	64	72	114	66	12	6	2
		DAY 29	16SEP2004	30	66	104	64	81	104	76	15	0	12
		FINAL			66	104	64	81	104	76	15	0	12
	E0021007	SCREEN	08SEP2004	-9	48 L	120	66	57	114	72	9	-6	6
		DAY 1	16SEP2004	-1	54	118	62	58	114	68	4	-4	6
		BASELINE			54	118	62	58	114	68	4	-4	6
	E0021030	SCREEN	05APR2005	-8	54	126	90	72	134	94	18	8	4
		DAY 1	13APR2005	1	63	116	74	75	112	86	12	-4	12
		BASELINE			63	116	74	75	112	86	12	-4	12
		DAY 8	19APR2005	7	69	116	74	72	122	92	3	6	18

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0021030	DAY 15	27APR2005	15	68	112	84	76	122	90	8	10	6
		DAY 22	04MAY2005	22	72	116	74	93	110	86	21 Y	-6	12
		DAY 29	09MAY2005	27	63	124	76	72	120	82	9	-4	6
		DAY 36	18MAY2005	36	69	118	74	72	112	82	3	-6	8
		DAY 43	25MAY2005	43	69	134	82	72	122	90	3	-12	8
		DAY 50	01JUN2005	50	72	108	66	78	124	88	6	16	22
		DAY 57	08JUN2005	57	72	110	90	96	118	96	24 Y	8	6
		FINAL			72	110	90	96	118	96	24 Y	8	6
	E0025023	SCREEN	05OCT2004	-7	78	117	80	91	132	86	13	15	6
		DAY 1	12OCT2004	1	87	116	76	80	123	85	-7	7	9
		BASELINE			87	116	76	80	123	85	-7	7	9
		DAY 8	19OCT2004	8	84	109	72	82	138	80	-2	29	8
		DAY 15	26OCT2004	15	92	129	68	99	117	76	7	-12	8
		DAY 22	02NOV2004	22	76	125	73	92	146	80	16	21	7
		DAY 29	09NOV2004	29	71	129	87	91	148	89	20 Y	19	2
		DAY 36	15NOV2004	35	89	117	75	88	116	78	-1	-1	3
		DAY 43	23NOV2004	43	87	105	71	85	127	84	-2	22	13
		DAY 50	30NOV2004	50	84	97	60	92	115	69	8	18	9
		DAY 57	07DEC2004	57	87	135	88	88	130	86	1	-5	-2
		FINAL			87	135	88	88	130	86	1	-5	-2
	E0025046	SCREEN	24FEB2005	-8	69	122	84	78	118	84	9	-4	0
		DAY 1	04MAR2005	1	70	116	80	72	118	82	2	2	2
		BASELINE			70	116	80	72	118	82	2	2	2
		DAY 8	14MAR2005	11	83	129	80	72	118	82	-11	-11	2
		DAY 36	07APR2005	35	88	118	72	116	104	74	28 Y	-14	2
		FINAL			88	118	72	116	104	74	28 Y	-14	2
	E0025055	SCREEN	18APR2005	-10	78	130	78	80	124	84	2	-6	6
		DAY 1	28APR2005	1	78	128	68	106	130	88	28 Y	2	20
		BASELINE			78	128	68	106	130	88	28 Y	2	20

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0025055	DAY 8	05MAY2005	8	88	128	80	110	110	84	22 Y	-18	4
		DAY 15	12MAY2005	15	80	120	84	84	112	78	4	-8	-6
		DAY 22	19MAY2005	22	88	124	80	96	120	80	8	-4	0
		DAY 29	26MAY2005	29	90	118	80	98	112	82	8	-6	2
		DAY 36	02JUN2005	36	94	132	70	98	130	76	4	-2	6
		DAY 43	09JUN2005	43	96	126	80	98	110	78	2	-16	-2
		DAY 50	17JUN2005	51	89	115	69	108	113	78	19	-2	9
		DAY 57	23JUN2005	57	84	112	68	92	118	82	8	6	14
		FINAL			84	112	68	92	118	82	8	6	14
	E0026024	SCREEN	30MAR2005	-12	62	122	80	66	116	78	4	-6	-2
		DAY 1	11APR2005	1	66	110	70	71	104	72	5	-6	2
		BASELINE			66	110	70	71	104	72	5	-6	2
		DAY 8	18APR2005	8	64	110	74	67	112	76	3	2	2
		DAY 15	25APR2005	15	66	106	70	77	116	66	11	10	-4
		DAY 22	02MAY2005	22	65	96	62	75	104	68	10	8	6
		DAY 29	09MAY2005	29	64	96	60	72	100	70	8	4	10
		DAY 36	16MAY2005	36	67	92	60	73	98	64	6	6	4
		DAY 43	23MAY2005	43	62	92	60	70	98	68	8	6	8
		DAY 43 *	27MAY2005	47	60	90 L	64	67	100	70	7	10	6
		DAY 50	31MAY2005	51	65	94	62	66	96	66	1	2	4
		FINAL			65	94	62	66	96	66	1	2	4
	E0030011	SCREEN	25AUG2004	-5	67	135	71	83	123	79	16	-12	8
		DAY 1	30AUG2004	1	93	138	80	109	127	81	16	-11	1
		BASELINE			93	138	80	109	127	81	16	-11	1
		DAY 8	07SEP2004	9	78	150	70	106	144	93	28 Y	-6	23
		DAY 15	13SEP2004	15	88	157	80	103	119	76	15	-38 Y	-4
		DAY 22	20SEP2004	22	94	155	81	98	137	75	4	-18	-6
		DAY 29	27SEP2004	29	84	122	76	87	125	75	3	3	-1
		DAY 36	04OCT2004	36	81	147	74	95	121	70	14	-26 Y	-4
		DAY 43	11OCT2004	43	82	149	76	100	145	67	18	-4	-9

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0030011	DAY 50	18OCT2004	50	89	152	89	91	143	68	2	-9	-21 Y
		DAY 57	25OCT2004	57	60	152	66	79	160	79	19	8	13
		FINAL			60	152	66	79	160	79	19	8	13
	E0030020	SCREEN	17NOV2004	-7	76	158	81	92	190 H	97	16	32	16
		DAY 1	24NOV2004	1	84	171	95	93	159	103	9	-12	8
		BASELINE			84	171	95	93	159	103	9	-12	8
		DAY 8	01DEC2004	8	85	162	88	94	171	102	9	9	14
		DAY 15	08DEC2004	15	80	150	88	92	160	92	12	10	4
		DAY 22	15DEC2004	22	88	148	88	100	142	90	12	-6	2
		DAY 29	22DEC2004	29	80	144	98	88	158	100	8	14	2
		DAY 36	29DEC2004	36	79	137	78	86	152	90	7	15	12
		DAY 43	05JAN2005	43	79	173	89	84	168	92	5	-5	3
		DAY 50	12JAN2005	50	82	158	92	88	168	104	6	10	12
		DAY 57	19JAN2005	57	96	160	98	104	180 H	102	8	20	4
		FINAL			96	160	98	104	180 H	102	8	20	4
	E0030021	SCREEN	18NOV2004	-5	64	143	93	74	127	95	10	-16	2
		DAY 1	23NOV2004	1	64	140	96	86	124	82	22 Y	-16	-14
		BASELINE			64	140	96	86	124	82	22 Y	-16	-14
		DAY 8	01DEC2004	9	76	130	90	86	116	90	10	-14	0
		DAY 15	08DEC2004	16	65	137	95	80	135	99	15	-2	4
		DAY 22	15DEC2004	23	66	151	95	74	138	103	8	-13	8
		DAY 29	22DEC2004	30	62	134	91	78	121	97	16	-13	6
		DAY 36	29DEC2004	37	68	145	94	82	129	91	14	-16	-3
		DAY 43	05JAN2005	44	71	161	97	93	167	88	22 Y	6	-9
		DAY 50	12JAN2005	51	66	139	89	83	137	94	17	-2	5
		DAY 57	19JAN2005	58	65	142	89	83	131	92	18	-11	3
		FINAL			65	142	89	83	131	92	18	-11	3
	E0030031	SCREEN	01MAR2005	-7	48 L	137	89	60	132	95	12	-5	6
		DAY 1	08MAR2005	1	60	145	81	76	127	89	16	-18	8

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0030031	BASELINE			60	145	81	76	127	89	16	-18	8
		DAY 8	15MAR2005	8	60	119	77	65	126	86	5	7	9
		DAY 15	22MAR2005	15	50	123	76	68	138	92	18	15	16
		DAY 22	29MAR2005	22	60	115	86	74	131	92	14	16	6
		DAY 29	05APR2005	29	63	121	78	80	138	87	17	17	9
		DAY 36	12APR2005	36	56	122	80	77	123	86	21 Y	1	6
		DAY 43	19APR2005	43	54	134	91	62	150	94	8	16	3
		DAY 50	26APR2005	50	72	112	78	88	120	80	16	8	2
		DAY 57	03MAY2005	57	64	120	78	72	112	80	8	-8	2
		FINAL			64	120	78	72	112	80	8	-8	2
	E0030034	SCREEN	03MAY2005	-7	64	128	84	72	122	82	8	-6	-2
		DAY 1	10MAY2005	1	60	108	72	72	110	80	12	2	8
		BASELINE			60	108	72	72	110	80	12	2	8
		DAY 8	17MAY2005	8	64	124	70	76	122	78	12	-2	8
		DAY 15	25MAY2005	16	76	136	69	102	142	74	26 Y	6	5
		DAY 22	01JUN2005	23	60	124	72	88	122	80	28 Y	-2	8
		DAY 29	08JUN2005	30	69	121	67	97	133	71	28 Y	12	4
		DAY 36	15JUN2005	37	60	144	72	76	144	66	16	0	-6
		DAY 43	22JUN2005	44	59	139	69	78	131	82	19	-8	13
		DAY 50	29JUN2005	51	64	142	71	89	135	85	25 Y	-7	14
		DAY 57	06JUL2005	58	62	142	72	96	130	76	34 Y	-12	4
		FINAL			62	142	72	96	130	76	34 Y	-12	4
	E0032003	SCREEN	29DEC2004	-7	68	128	90	70	105	88	2	-23 Y	-2
		DAY 1	05JAN2005	1	80	110	83	86	95	75	6	-15	-8
		BASELINE			80	110	83	86	95	75	6	-15	-8
		DAY 8	12JAN2005	8	80	134	88	92	118	86	12	-16	-2
		DAY 15	19JAN2005	15	80	124	90	84	128	92	4	4	2
		DAY 22	26JAN2005	22	76	128	90	78	132	86	2	4	-4
		DAY 29	03FEB2005	30	86	120	90	83	110	88	-3	-10	-2
		DAY 36	09FEB2005	36	88	124	82	89	119	80	1	-5	-2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0032003	DAY 43	16FEB2005	43	88	120	84	86	102	80	-2	-18	-4
		DAY 50	23FEB2005	50	68	110	80	72	107	81	4	-3	1
		DAY 57	01MAR2005	56	69	115	84	72	107	88	3	-8	4
		FINAL			69	115	84	72	107	88	3	-8	4
	E0032005	SCREEN	02FEB2005	-7	60	110	68	62	108	68	2	-2	0
		DAY 1	09FEB2005	1	60	112	70	64	108	70	4	-4	0
		BASELINE			60	112	70	64	108	70	4	-4	0
		DAY 8	16FEB2005	8	58	104	64	60	108	70	2	4	6
		DAY 15	23FEB2005	15	64	114	70	68	108	68	4	-6	-2
		DAY 22	02MAR2005	22	58	104	64	64	106	70	6	2	6
		DAY 29	09MAR2005	29	54	112	72	58	110	74	4	-2	2
		DAY 36	16MAR2005	36	56	102	72	58	106	72	2	4	0
		DAY 43	23MAR2005	43	56	104	68	60	102	68	4	-2	0
		DAY 50	31MAR2005	51	56	110	80	59	117	88	3	7	8
		DAY 57	05APR2005	56	48 L	104	68	52	102	70	4	-2	2
		FINAL			48 L	104	68	52	102	70	4	-2	2
	E0033003	SCREEN	19AUG2004	-7	58	118	68	60	114	68	2	-4	0
		DAY 1	26AUG2004	1	60	102	78	68	106	80	8	4	2
		BASELINE			60	102	78	68	106	80	8	4	2
		DAY 8	02SEP2004	8	64	100	76	66	102	78	2	2	2
		DAY 15	08SEP2004	14	86	96	68	82	96	74	-4	0	6
		DAY 22	15SEP2004	21	60	112	80	64	114	82	4	2	2
		DAY 29	22SEP2004	28	66	90 L	70	66	94	76	0	4	6
		DAY 36	29SEP2004	35	58	100	80	60	102	80	2	2	0
		DAY 43	06OCT2004	42	80	96	60	82	102	64	2	6	4
		DAY 50	13OCT2004	49	68	92	70	72	100	76	4	8	6
		DAY 57	20OCT2004	56	66	100	70	68	98	74	2	-2	4
		FINAL			66	100	70	68	98	74	2	-2	4
	E0033010	SCREEN	03JAN2005	-3	68	92	60	68	88 L	64	0	-4	4

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS		SUPINE DIA	STANDING PULSE	STANDING SYS		STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0033010	DAY 1		06JAN2005	1	68	80	L	60	66	84	L	64	-2	4	4
		BASELINE				68	80	L	60	66	84	L	64	-2	4	4
		DAY 8		13JAN2005	8	58	84	L	60	56	88	L	68	-2	4	8
		DAY 15		21JAN2005	16	66	98		70	64	96		76	-2	-2	6
		DAY 22		26JAN2005	21	76	94		70	74	98		70	-2	4	0
		DAY 22	*	31JAN2005	26	64	90	L	64	66	94		70	2	4	6
		DAY 29		07FEB2005	33	58	90	L	62	58	90	L	72	0	0	10
		DAY 43		15FEB2005	41	80	90	L	62	76	96		72	-4	6	10
		DAY 50		23FEB2005	49	86	100		68	84	102		70	-2	2	2
		DAY 57		02MAR2005	56	60	90	L	62	58	88	L	62	-2	-2	0
		FINAL				60	90	L	62	58	88	L	62	-2	-2	0
	E0033011	SCREEN		10JAN2005	-8	64	100		78	64	102		74	0	2	-4
		DAY 1		18JAN2005	1	88	100		86	86	104		86	-2	4	0
		BASELINE				88	100		86	86	104		86	-2	4	0
		DAY 8		25JAN2005	8	68	90	L	72	66	92		72	-2	2	0
		DAY 15		01FEB2005	15	70	104		80	72	102		82	2	-2	2
		DAY 22		08FEB2005	22	58	94		70	60	90	L	72	2	-4	2
		DAY 29		14FEB2005	28	60	102		70	58	100		66	-2	-2	-4
		DAY 36		21FEB2005	35	64	108		86	60	106		80	-4	-2	-6
		DAY 43		28FEB2005	42	68	100		80	70	98		76	2	-2	-4
		DAY 50		07MAR2005	49	56	90	L	72	60	94		74	4	4	2
		DAY 57		14MAR2005	56	74	98		70	72	102		68	-2	4	-2
		FINAL				74	98		70	72	102		68	-2	4	-2
	E0033013	SCREEN		21JAN2005	-10	78	94		68	76	96		72	-2	2	4
		DAY 1		31JAN2005	1	68	106		64	74	108		70	6	2	6
		BASELINE				68	106		64	74	108		70	6	2	6
		DAY 8		07FEB2005	8	58	90	L	68	64	94		72	6	4	4
		DAY 15		14FEB2005	15	70	94		72	76	98		76	6	4	4
		DAY 22		21FEB2005	22	68	100		62	72	114		64	4	14	2
		DAY 29		01MAR2005	30	64	118		74	66	120		76	2	2	2

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT102.SAS
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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0033013	FINAL			64	118	74	66	120	76	2	2	2
	E0035010	SCREEN	12AUG2004	-11	84	128	70	92	130	80	8	2	10
		DAY 1	23AUG2004	1	84	120	68	96	120	80	12	0	12
		BASELINE			84	120	68	96	120	80	12	0	12
		DAY 8	01SEP2004	10	72	128	74	100	118	78	28 Y	-10	4
		DAY 15	07SEP2004	16	80	122	78	100	120	82	20 Y	-2	4
		DAY 22	16SEP2004	25	88	126	70	100	120	76	12	-6	6
		DAY 29	22SEP2004	31	60	138	80	72	130	80	12	-8	0
		DAY 36	01OCT2004	40	92	122	70	96	130	72	4	8	2
		DAY 43	08OCT2004	47	70	124	80	80	112	80	10	-12	0
		DAY 50	12OCT2004	51	76	122	72	96	120	80	20 Y	-2	8
		DAY 57	18OCT2004	57	62	120	72	80	120	78	18	0	6
		FINAL			62	120	72	80	120	78	18	0	6
	E0035033	SCREEN	17MAY2005	-14	50	118	70	54	82 L	60	4	-36 Y	-10
		DAY 1	31MAY2005	1	62	100	80	60	100	80	-2	0	0
		BASELINE			62	100	80	60	100	80	-2	0	0
		DAY 8	06JUN2005	7	62	100	80	64	102	82	2	2	2
		DAY 15	15JUN2005	16	62	100	80	64	102	82	2	2	2
		FINAL			62	100	80	64	102	82	2	2	2
	E0037011	SCREEN	26OCT2004	-7	56	90 L	70	64	102	76	8	12	6
		DAY 1	02NOV2004	1	76	128	80	84	110	80	8	-18	0
		BASELINE			76	128	80	84	110	80	8	-18	0
		DAY 8	10NOV2004	9	80	116	80	68	110	80	-12	-6	0
		DAY 15	17NOV2004	16	72	102	70	72	118	78	0	16	8
		DAY 29	03DEC2004	32	76	110	80	76	108	80	0	-2	0
		DAY 36	08DEC2004	37	72	100	70	84	110	82	12	10	12
		DAY 43	15DEC2004	44	72	100	72	76	118	80	4	18	8
		DAY 57	12JAN2005	72	76	98	80	76	100	80	0	2	0
		FINAL			76	98	80	76	100	80	0	2	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0039008	SCREEN	29SEP2004	-7	64	110	64	68	100	60	4	-10	-4
		DAY 1	06OCT2004	1	60	100	50 L	76	90 L	50 L	16	-10	0
		BASELINE			60	100	50 L	76	90 L	50 L	16	-10	0
		DAY 8	13OCT2004	8	60	110	90	68	98	64	8	-12	-26 Y
		DAY 15	21OCT2004	16	54	120	80	68	98	64	14	-22 Y	-16
		DAY 22	27OCT2004	22	62	110	72	74	98	70	12	-12	-2
		DAY 29	04NOV2004	30	60	112	68	66	100	62	6	-12	-6
		DAY 36	10NOV2004	36	68	110	90	68	110	80	0	0	-10
		FINAL			68	110	90	68	110	80	0	0	-10
	E0039014	SCREEN	23NOV2004	-14	64	108	60	70	100	68	6	-8	8
		DAY 1	07DEC2004	1	78	110	60	82	110	70	4	0	10
		BASELINE			78	110	60	82	110	70	4	0	10
		DAY 8	14DEC2004	8	100	112	70	107	106	80	7	-6	10
		DAY 15	21DEC2004	15	88	100	60	102	88 L	60	14	-12	0
		DAY 29	03JAN2005	28	80	120	78	84	110	68	4	-10	-10
		FINAL			80	120	78	84	110	68	4	-10	-10
	E0039015	SCREEN	30NOV2004	-13	64	110	60	66	98	60	2	-12	0
		DAY 1	13DEC2004	1	64	110	64	72	102	74	8	-8	10
		BASELINE			64	110	64	72	102	74	8	-8	10
		DAY 8	21DEC2004	9	64	110	70	68	98	70	4	-12	0
		DAY 15	30DEC2004	18	64	118	60	78	98	60	14	-20 Y	0
		DAY 22	06JAN2005	25	64	110	60	76	104	70	12	-6	10
		DAY 29	13JAN2005	32	58	104	60	78	98	60	20 Y	-6	0
		DAY 36	19JAN2005	38	76	102	64	80	108	70	4	6	6
		DAY 43	24JAN2005	43	64	108	60	68	108	64	4	0	4
		DAY 50	31JAN2005	50	50	100	40 L	58	100	48 L	8	0	8
		DAY 57	07FEB2005	57	60	96	60	60	98	60	0	2	0
		FINAL			60	96	60	60	98	60	0	2	0
	E0040004	SCREEN	06AUG2004	-6	48 L	114	63	44 L	120	66	-4	6	3

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0040004	DAY 1	12AUG2004	1	50	118	64	55	126	67	5	8	3
		BASELINE			50	118	64	55	126	67	5	8	3
		DAY 8	20AUG2004	9	49 L	134	68	55	138	78	6	4	10
		DAY 15	25AUG2004	14	52	124	68	83	131	88	31 Y	7	20
		DAY 22	31AUG2004	20	59	123	76	75	135	86	16	12	10
		FINAL			59	123	76	75	135	86	16	12	10
	E0040009	SCREEN	21JAN2005	-5	88	125	80	98	124	90	10	-1	10
		DAY 1	26JAN2005	1	90	125	86	98	123	85	8	-2	-1
		BASELINE			90	125	86	98	123	85	8	-2	-1
		DAY 8	02FEB2005	8	98	126	80	100	124	90	2	-2	10
		DAY 15	09FEB2005	15	83	122	89	98	120	80	15	-2	-9
		DAY 22	16FEB2005	22	80	112	64	95	110	62	15	-2	-2
		DAY 29	23FEB2005	29	82	114	66	98	112	68	16	-2	2
		DAY 36	02MAR2005	36	90	126	81	96	130	88	6	4	7
		DAY 43	09MAR2005	43	80	112	64	94	110	72	14	-2	8
		DAY 50	16MAR2005	50	70	114	68	92	112	72	22 Y	-2	4
		DAY 57	23MAR2005	57	80	120	72	92	118	70	12	-2	-2
		FINAL			80	120	72	92	118	70	12	-2	-2
	E0040013	SCREEN	25MAR2005	-7	72	104	64	89	110	88	17	6	24
		DAY 1	01APR2005	1	89	130	82	81	131	84	-8	1	2
		BASELINE			89	130	82	81	131	84	-8	1	2
		DAY 8	08APR2005	8	73	122	67	83	109	83	10	-13	16
		DAY 15	15APR2005	15	76	129	83	85	110	88	9	-19	5
		DAY 22	22APR2005	22	82	120	78	88	116	74	6	-4	-4
		DAY 29	29APR2005	29	83	123	81	85	126	98	2	3	17
		DAY 36	06MAY2005	36	84	121	76	102	114	73	18	-7	-3
		DAY 43	11MAY2005	41	82	124	80	84	122	84	2	-2	4
		DAY 50	20MAY2005	50	76	109	69	107	103	78	31 Y	-6	9
		DAY 57	27MAY2005	57	71	113	77	73	111	82	2	-2	5
		FINAL			71	113	77	73	111	82	2	-2	5

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0040016	SCREEN		17MAY2005	-3	76	110	70	87	108	76	11	-2	6
		DAY 1		20MAY2005	1	74	108	70	85	107	74	11	-1	4
		BASELINE				74	108	70	85	107	74	11	-1	4
		DAY 8		27MAY2005	8	74	112	72	90	106	74	16	-6	2
		DAY 8	*	31MAY2005	12	70	92	54	104	96	67	34 Y	4	13
		DAY 15		07JUN2005	19	70	99	66	79	107	75	9	8	9
		DAY 22		14JUN2005	26	74	98	62	93	104	70	19	6	8
		DAY 36		23JUN2005	35	88	106	74	93	120	82	5	14	8
		DAY 36	*	28JUN2005	40	77	106	69	94	102	72	17	-4	3
		DAY 50		07JUL2005	49	72	104	68	82	100	74	10	-4	6
		DAY 57		15JUL2005	57	70	113	74	76	124	83	6	11	9
		FINAL				70	113	74	76	124	83	6	11	9
	E0041004	SCREEN		30AUG2004	-23	60	120	80	68	124	86	8	4	6
		DAY 1		22SEP2004	1	60	108	80	64	110	84	4	2	4
		BASELINE				60	108	80	64	110	84	4	2	4
		DAY 8		29SEP2004	8	60	120	84	64	120	78	4	0	-6
		DAY 15		06OCT2004	15	60	108	60	62	112	72	2	4	12
		DAY 22		13OCT2004	22	64	112	82	84	110	90	20 Y	-2	8
		DAY 29		21OCT2004	30	64	118	82	68	114	80	4	-4	-2
		DAY 36		27OCT2004	36	64	118	80	84	120	78	20 Y	2	-2
		DAY 43		03NOV2004	43	64	112	82	76	116	82	12	4	0
		DAY 50		10NOV2004	50	56	114	84	76	118	86	20 Y	4	2
		DAY 57		17NOV2004	57	64	118	84	96	124	88	32 Y	6	4
		FINAL				64	118	84	96	124	88	32 Y	6	4
	E0041007	SCREEN		28OCT2004	-22	48 L	112	80	52	106	84	4	-6	4
		DAY 1		19NOV2004	1	60	110	78	76	100	78	16	-10	0
		BASELINE				60	110	78	76	100	78	16	-10	0
		DAY 8		24NOV2004	6	68	118	72	88	116	76	20 Y	-2	4
		DAY 15		03DEC2004	15	56	112	76	68	108	80	12	-4	4
		DAY 22		09DEC2004	21	68	120	66	72	110	76	4	-10	10

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0041007	DAY 29	17DEC2004	29	56	132	80	56	122	76	0	-10	-4
		DAY 36	22DEC2004	34	92	120	72	114	102	72	22 Y	-18	0
		DAY 43	30DEC2004	42	68	114	80	72	110	78	4	-4	-2
		FINAL			68	114	80	72	110	78	4	-4	-2
	E0041015	SCREEN	24MAR2005	-8	48 L	120	66	60	130	78	12	10	12
		DAY 1	01APR2005	1	60	128	68	80	124	74	20 Y	-4	6
		BASELINE			60	128	68	80	124	74	20 Y	-4	6
		DAY 8	07APR2005	7	48 L	132	84	60	130	78	12	-2	-6
		DAY 15	15APR2005	15	60	122	68	60	130	82	0	8	14
		DAY 22	22APR2005	22	60	138	66	76	132	72	16	-6	6
		DAY 29	29APR2005	29	60	120	60	76	112	72	16	-8	12
		DAY 36	06MAY2005	36	52	110	66	64	120	82	12	10	16
		FINAL			52	110	66	64	120	82	12	10	16
	E0042006	SCREEN	11AUG2004	-8	60	110	68	56	114	74	-4	4	6
		DAY 1	19AUG2004	1	84	124	60	100	114	66	16	-10	6
		BASELINE			84	124	60	100	114	66	16	-10	6
		DAY 8	25AUG2004	7	64	100	64	72	90 L	56	8	-10	-8
		DAY 15	02SEP2004	15	72	104	56	72	100	60	0	-4	4
		DAY 22	09SEP2004	22	60	102	76	60	100	70	0	-2	-6
		DAY 29	16SEP2004	29	64	102	56	72	104	60	8	2	4
		DAY 36	23SEP2004	36	68	100	60	70	106	74	2	6	14
		DAY 43	30SEP2004	43	76	104	50 L	80	108	68	4	4	18
		DAY 50	08OCT2004	51	80	114	62	80	110	74	0	-4	12
		DAY 57	14OCT2004	57	78	102	64	78	96	66	0	-6	2
		FINAL			78	102	64	78	96	66	0	-6	2
	E0044004	SCREEN	27JAN2005	-21	64	102	58	72	106	60	8	4	2
		DAY 1	17FEB2005	1	72	102	50 L	76	106	52	4	4	2
		BASELINE			72	102	50 L	76	106	52	4	4	2
		DAY 8	24FEB2005	8	56	98	66	66	106	68	10	8	2

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0044004	DAY 15		03MAR2005	15	70	102	60	64	102	58	-6	0	-2
		DAY 22		10MAR2005	22	56	104	58	60	106	60	4	2	2
		DAY 29		17MAR2005	29	56	100	62	68	102	62	12	2	0
		DAY 29	*	21MAR2005	33	60	100	76	60	112	78	0	12	2
		DAY 43		30MAR2005	42	68	102	62	72	106	62	4	4	0
		DAY 50		06APR2005	49	80	108	68	84	112	70	4	4	2
		DAY 57		14APR2005	57	64	110	90	80	120	88	16	10	-2
		FINAL				64	110	90	80	120	88	16	10	-2
	E0046006	SCREEN		16DEC2004	-27	54	120	70	80	128	74	26 Y	8	4
		DAY 1		12JAN2005	1	56	110	70	72	124	70	16	14	0
		BASELINE				56	110	70	72	124	70	16	14	0
		DAY 8		19JAN2005	8	66	103	64	87	119	77	21 Y	16	13
		DAY 15		26JAN2005	15	53	104	67	61	110	72	8	6	5
		DAY 22		02FEB2005	22	65	112	73	79	109	78	14	-3	5
		DAY 29		10FEB2005	30	68	112	68	72	124	80	4	12	12
		DAY 36		16FEB2005	36	60	104	58	72	110	60	12	6	2
		DAY 43		23FEB2005	43	54	107	69	65	110	74	11	3	5
		DAY 50		02MAR2005	50	66	111	67	79	117	74	13	6	7
		DAY 57		09MAR2005	57	71	113	69	83	114	77	12	1	8
		FINAL				71	113	69	83	114	77	12	1	8
	E0046016	SCREEN		11MAY2005	-7	56	112	80	73	110	72	17	-2	-8
		DAY 1		18MAY2005	1	60	116	64	64	120	80	4	4	16
		BASELINE				60	116	64	64	120	80	4	4	16
		DAY 8		24MAY2005	7	60	138	70	76	123	62	16	-15	-8
		DAY 15		31MAY2005	14	76	145	76	86	134	73	10	-11	-3
		DAY 22		07JUN2005	21	63	137	66	84	128	76	21 Y	-9	10
		DAY 29		14JUN2005	28	52	135	76	67	133	81	15	-2	5
		DAY 36		21JUN2005	35	54	121	58	82	121	72	28 Y	0	14
		DAY 43		28JUN2005	42	70	127	72	70	128	61	0	1	-11
		DAY 50		05JUL2005	49	54	137	70	75	125	71	21 Y	-12	1

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR I)	E0046016	DAY 57		12JUL2005	56	60	112	70	64	110	74	4	-2	4
		FINAL				60	112	70	64	110	74	4	-2	4
	E0046017	SCREEN		12MAY2005	-11	60	110	62	80	108	80	20 Y	-2	18
		DAY 1		23MAY2005	1	59	115	75	61	120	84	2	5	9
		BASELINE				59	115	75	61	120	84	2	5	9
		DAY 8		31MAY2005	9	60	106	69	74	108	82	14	2	13
		DAY 15		07JUN2005	16	70	111	70	79	109	79	9	-2	9
		DAY 22		13JUN2005	22	72	110	73	81	112	80	9	2	7
		DAY 29		20JUN2005	29	88	118	77	76	118	93	-12	0	16
		DAY 36		27JUN2005	36	55	109	72	74	126	85	19	17	13
		DAY 43		06JUL2005	45	71	113	71	77	116	80	6	3	9
		DAY 50		11JUL2005	50	63	98	78	68	112	79	5	14	1
		DAY 57		18JUL2005	57	75	111	74	88	115	80	13	4	6
		FINAL				75	111	74	88	115	80	13	4	6
	E0046019	SCREEN		02JUN2005	-7	76	112	90	80	120	100	4	8	10
		DAY 1		09JUN2005	1	80	120	76	76	122	100	-4	2	24
		BASELINE				80	120	76	76	122	100	-4	2	24
		DAY 8		16JUN2005	8	85	133	87	112	133	98	27 Y	0	11
		DAY 15		23JUN2005	15	99	136	89	126 H	127	99	27 Y	-9	10
		DAY 22		30JUN2005	22	74	130	78	93	126	84	19	-4	6
		DAY 29		07JUL2005	29	66	124	66	87	126	81	21 Y	2	15
		DAY 36		14JUL2005	36	70	117	67	85	121	75	15	4	8
		DAY 43		21JUL2005	43	78	123	75	101	124	78	23 Y	1	3
		DAY 50		28JUL2005	50	83	133	76	102	138	84	19	5	8
		DAY 50	*	01AUG2005	54	64	123	75	75	126	85	11	3	10
		FINAL				64	123	75	75	126	85	11	3	10
PLACEBO (BIPOLAR II)	E0010010	SCREEN		24JAN2005	-4	61	106	70	74	92	64	13	-14	-6

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0010010	DAY 1		28JAN2005	1	66	114	70	62	114	60	-4	0	-10
		BASELINE				66	114	70	62	114	60	-4	0	-10
		DAY 8		04FEB2005	8	68	110	64	68	112	68	0	2	4
		DAY 15		11FEB2005	15	70	108	60	68	110	64	-2	2	4
		DAY 22		18FEB2005	22	78	108	60	68	104	72	-10	-4	12
		DAY 29		28FEB2005	32	70	116	72	74	110	66	4	-6	-6
		DAY 36		04MAR2005	36	74	110	70	68	108	74	-6	-2	4
		DAY 43		14MAR2005	46	68	108	64	88	106	60	20 Y	-2	-4
		DAY 50		18MAR2005	50	84	100	62	84	104	64	0	4	2
		DAY 57		24MAR2005	56	70	100	64	76	110	60	6	10	-4
		FINAL				70	100	64	76	110	60	6	10	-4
	E0020019	SCREEN		02NOV2004	-14	64	115	75	68	118	80	4	3	5
		DAY 1		16NOV2004	1	64	100	80	68	111	84	4	11	4
		BASELINE				64	100	80	68	111	84	4	11	4
		DAY 8		23NOV2004	8	64	120	80	86	112	70	22 Y	-8	-10
		DAY 15		29NOV2004	14	32 L	100	70	64	117	70	32 Y	17	0
		DAY 22		06DEC2004	21	70	100	82	60	100	80	-10	0	-2
		DAY 22	*	09DEC2004	24	42 L	110	82	66	110	90	24 Y	0	8
		DAY 43		28DEC2004	43	62	104	88	88	110	84	26 Y	6	-4
		DAY 50		04JAN2005	50	61	100	80	64	100	80	3	0	0
		DAY 57		11JAN2005	57	66	111	80	66	112	82	0	1	2
		FINAL				66	111	80	66	112	82	0	1	2
	E0020026	SCREEN		08DEC2004	-8	56	110	70	60	115	70	4	5	0
		DAY 1		16DEC2004	1	62	112	76	64	120	70	2	8	-6
		BASELINE				62	112	76	64	120	70	2	8	-6
		DAY 8		23DEC2004	8	54	90 L	70	70	100	80	16	10	10
		DAY 15		30DEC2004	15	64	95	70	66	100	60	2	5	-10
		DAY 22		06JAN2005	22	60	100	60	62	95	60	2	-5	0
		DAY 29		13JAN2005	29	52	110	70	60	100	70	8	-10	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0020026	DAY 36	20JAN2005	36	64	102	70	72	110	80	8	8	10
		DAY 43	27JAN2005	43	64	115	75	74	115	75	10	0	0
		DAY 50	03FEB2005	50	60	110	70	64	110	70	4	0	0
		DAY 57	10FEB2005	57	54	104	64	60	100	70	6	-4	6
		FINAL			54	104	64	60	100	70	6	-4	6
	E0020034	SCREEN	10JAN2005	-7	68	110	70	82	100	70	14	-10	0
		DAY 1	17JAN2005	1	54	92	70	64	100	80	10	8	10
		BASELINE			54	92	70	64	100	80	10	8	10
		DAY 8	24JAN2005	8	62	95	70	66	100	70	4	5	0
		DAY 15	31JAN2005	15	60	100	70	62	95	60	2	-5	-10
		DAY 22	07FEB2005	22	62	90 L	65	64	100	60	2	10	-5
		DAY 29	14FEB2005	29	68	110	80	72	109	80	4	-1	0
		DAY 36	21FEB2005	36	72	104	70	82	100	70	10	-4	0
		DAY 43	28FEB2005	43	68	110	80	68	105	80	0	-5	0
		DAY 50	07MAR2005	50	64	110	80	72	102	90	8	-8	10
		DAY 57	14MAR2005	57	80	90 L	70	78	100	70	-2	10	0
		FINAL			80	90 L	70	78	100	70	-2	10	0
	E0020035	SCREEN	20JAN2005	-7	50	110	78	48 L	140	98	-2	30	20
		DAY 1	27JAN2005	1	56	130	75	60	130	80	4	0	5
		BASELINE			56	130	75	60	130	80	4	0	5
		DAY 8	03FEB2005	8	60	120	80	66	124	82	6	4	2
		DAY 15	10FEB2005	15	72	118	76	80	120	80	8	2	4
		DAY 22	17FEB2005	22	74	120	80	70	118	78	-4	-2	-2
		DAY 29	24FEB2005	29	80	140	80	80	120	80	0	-20 Y	0
		DAY 36	03MAR2005	36	84	120	70	80	130	80	-4	10	10
		DAY 43	10MAR2005	43	78	120	70	84	120	80	6	0	10
		DAY 50	17MAR2005	50	78	118	80	82	120	82	4	2	2
		DAY 57	24MAR2005	57	84	118	80	88	120	80	4	2	0
		FINAL			84	118	80	88	120	80	4	2	0

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0020039	SCREEN	07FEB2005	-7	54	130	90	60	130	80	6	0	-10
		DAY 1	14FEB2005	1	60	110	85	68	115	80	8	5	-5
		BASELINE			60	110	85	68	115	80	8	5	-5
		DAY 8	21FEB2005	8	60	110	82	74	111	84	14	1	2
		DAY 15	28FEB2005	15	59	122	90	70	119	98	11	-3	8
		DAY 22	07MAR2005	22	52	114	78	60	120	80	8	6	2
		DAY 29	14MAR2005	29	56	110	80	60	120	80	4	10	0
		DAY 36	21MAR2005	36	60	120	74	72	100	80	12	-20 Y	6
		FINAL			60	120	74	72	100	80	12	-20 Y	6
	E0021015	SCREEN	03NOV2004	-7	57	120	72	72	114	86	15	-6	14
		DAY 1	10NOV2004	1	54	114	70	72	108	88	18	-6	18
		BASELINE			54	114	70	72	108	88	18	-6	18
		DAY 8	17NOV2004	8	63	112	70	81	116	88	18	4	18
		DAY 15	26NOV2004	17	66	116	72	69	102	86	3	-14	14
		DAY 22	01DEC2004	22	66	110	74	72	130	88	6	20	14
		DAY 29	08DEC2004	29	66	104	68	78	110	84	12	6	16
		DAY 36	14DEC2004	35	70	98	68	80	122	82	10	24	14
		DAY 43	21DEC2004	42	63	106	64	81	108	78	18	2	14
		DAY 50	29DEC2004	50	72	109	64	93	104	74	21 Y	-5	10
		DAY 57	05JAN2005	57	66	118	76	87	108	84	21 Y	-10	8
		FINAL			66	118	76	87	108	84	21 Y	-10	8
	E0025001	SCREEN	13JUL2004	-6	72	100	64	78	102	66	6	2	2
		DAY 1	19JUL2004	1	87	117	80	84	114	76	-3	-3	-4
		BASELINE			87	117	80	84	114	76	-3	-3	-4
		DAY 8	27JUL2004	9	63	104	64	85	114	73	22 Y	10	9
		DAY 15	05AUG2004	18	65	94	64	109	104	66	44 Y	10	2
		DAY 22	12AUG2004	25	64	110	60	74	110	70	10	0	10
		DAY 29	19AUG2004	32	69	94	60	97	132	74	28 Y	38	14
		DAY 36	25AUG2004	38	73	90 L	57	64	110	80	-9	20	23

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0025001	DAY 43		02SEP2004	46	81	112	64	102	133	89	21 Y	21	25
		DAY 50		09SEP2004	53	56	115	72	69	114	79	13	-1	7
		DAY 57		22SEP2004	66	80	118	80	82	116	76	2	-2	-4
		FINAL				80	118	80	82	116	76	2	-2	-4
	E0025019	SCREEN		07SEP2004	-6	48 L	112	74	50	110	72	2	-2	-2
		DAY 1		13SEP2004	1	56	117	67	58	115	66	2	-2	-1
		BASELINE				56	117	67	58	115	66	2	-2	-1
		DAY 8		22SEP2004	10	60	115	76	61	114	74	1	-1	-2
		DAY 15		01OCT2004	19	60	120	72	59	118	71	-1	-2	-1
		DAY 29		11OCT2004	29	68	125	78	67	123	77	-1	-2	-1
		DAY 36		20OCT2004	38	64	122	84	65	118	78	1	-4	-6
		DAY 43		25OCT2004	43	66	118	79	65	118	78	-1	0	-1
		DAY 50		01NOV2004	50	70	120	80	71	118	77	1	-2	-3
		DAY 57	*	09NOV2004	58	52	114	72	54	110	70	2	-4	-2
		DAY 57		16NOV2004	65	70	122	80	72	120	76	2	-2	-4
		FINAL				70	122	80	72	120	76	2	-2	-4
	E0025041	SCREEN		08FEB2005	-6	80	156	92	92	132	102	12	-24 Y	10
		DAY 1		14FEB2005	1	92	158	88	84	132	110 H	-8	-26 Y	22
		BASELINE				92	158	88	84	132	110 H	-8	-26 Y	22
		DAY 8		24FEB2005	11	64	138	86	72	129	86	8	-9	0
		DAY 15		03MAR2005	18	68	120	90	80	114	98	12	-6	8
		DAY 29		14MAR2005	29	68	134	84	88	112	88	20 Y	-22 Y	4
		DAY 36		24MAR2005	39	68	144	94	81	122	92	13	-22 Y	-2
		FINAL				68	144	94	81	122	92	13	-22 Y	-2
	E0026016	SCREEN		29OCT2004	-7	71	90 L	66	83	98	78	12	8	12
		DAY 1		05NOV2004	1	77	110	70	86	106	76	9	-4	6
		BASELINE				77	110	70	86	106	76	9	-4	6
		DAY 8		12NOV2004	8	78	106	64	85	112	80	7	6	16

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0026016	DAY 15		17NOV2004	13	78	110	64	84	116	74	6	6	10
		DAY 15	*	23NOV2004	19	74	118	70	78	120	78	4	2	8
		DAY 29		01DEC2004	27	72	110	70	77	114	74	5	4	4
		DAY 36		08DEC2004	34	73	104	60	78	100	66	5	-4	6
		DAY 43		15DEC2004	41	74	112	70	79	116	72	5	4	2
		DAY 50		22DEC2004	48	78	110	80	84	110	80	6	0	0
		DAY 57		29DEC2004	55	72	110	70	81	108	76	9	-2	6
		FINAL				72	110	70	81	108	76	9	-2	6
	E0030014	SCREEN		16SEP2004	-7	57	130	78	88	143	90	31 Y	13	12
		DAY 1		23SEP2004	1	70	130	78	93	139	86	23 Y	9	8
		BASELINE				70	130	78	93	139	86	23 Y	9	8
		DAY 8		30SEP2004	8	56	121	72	93	124	88	37 Y	3	16
		DAY 15		07OCT2004	15	62	121	65	109	126	95	47 Y	5	30
		DAY 22		14OCT2004	22	57	130	71	108	130	90	51 Y	0	19
		DAY 29		21OCT2004	29	64	122	78	88	118	80	24 Y	-4	2
		DAY 36		26OCT2004	34	60	118	76	88	120	80	28 Y	2	4
		DAY 43		04NOV2004	43	62	138	71	105	147	87	43 Y	9	16
		DAY 50		11NOV2004	50	72	138	78	90	136	86	18	-2	8
		DAY 57		18NOV2004	57	59	127	69	91	120	85	32 Y	-7	16
		FINAL				59	127	69	91	120	85	32 Y	-7	16
	E0030017	SCREEN		09NOV2004	-8	83	110	87	95	143	84	12	33	-3
		DAY 1		17NOV2004	1	103	116	69	115	115	66	12	-1	-3
		BASELINE				103	116	69	115	115	66	12	-1	-3
		DAY 8		24NOV2004	8	86	127	75	102	106	83	16	-21 Y	8
		DAY 15		30NOV2004	14	92	132	78	120	118	70	28 Y	-14	-8
		DAY 22		07DEC2004	21	93	128	74	106	130	75	13	2	1
		DAY 29		14DEC2004	28	77	141	76	95	113	85	18	-28 Y	9
		DAY 36		22DEC2004	36	88	120	78	100	122	80	12	2	2
		DAY 43		29DEC2004	43	85	115	65	101	129	79	16	14	14

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TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0030017	FINAL			85	115	65	101	129	79	16	14	14
	E0030028	SCREEN	10FEB2005	-7	70	112	67	77	118	77	7	6	10
		DAY 1	17FEB2005	1	74	115	68	90	107	72	16	-8	4
		BASELINE			74	115	68	90	107	72	16	-8	4
		DAY 8	24FEB2005	8	83	115	72	102	120	82	19	5	10
		DAY 15	04MAR2005	16	62	112	70	76	120	68	14	8	-2
		DAY 22	10MAR2005	22	71	113	66	88	109	71	17	-4	5
		DAY 29	17MAR2005	29	70	90 L	66	90	100	68	20 Y	10	2
		DAY 36	23MAR2005	35	80	118	73	108	110	77	28 Y	-8	4
		DAY 43	30MAR2005	42	94	115	62	103	92	77	9	-23 Y	15
		DAY 50	06APR2005	49	72	120	78	80	122	80	8	2	2
		DAY 57	13APR2005	56	72	106	65	86	121	72	14	15	7
		FINAL			72	106	65	86	121	72	14	15	7
	E0037003	SCREEN	31AUG2004	-21	72	125	90	72	135	90	0	10	0
		DAY 1	21SEP2004	1	88	112	80	84	110	82	-4	-2	2
		BASELINE			88	112	80	84	110	82	-4	-2	2
		DAY 8	28SEP2004	8	78	122	82	82	120	80	4	-2	-2
		DAY 15	05OCT2004	15	82	120	82	80	118	80	-2	-2	-2
		DAY 22	12OCT2004	22	92	120	80	100	110	84	8	-10	4
		DAY 29	19OCT2004	29	88	110	76	100	100	74	12	-10	-2
		DAY 36	26OCT2004	36	88	114	82	92	110	78	4	-4	-4
		DAY 43	02NOV2004	43	82	112	76	84	106	78	2	-6	2
		DAY 50	09NOV2004	50	84	102	80	92	110	80	8	8	0
		DAY 57	16NOV2004	57	76	120	80	96	118	84	20 Y	-2	4
		FINAL			76	120	80	96	118	84	20 Y	-2	4
	E0037025	SCREEN	11MAR2005	-17	60	120	88	76	130	90	16	10	2
		DAY 1	28MAR2005	1	68	124	78	80	128	80	12	4	2
		BASELINE			68	124	78	80	128	80	12	4	2

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE	ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0037025	DAY 8	04APR2005	8	68	126	80	80	126	80	12	0	0
		DAY 15	11APR2005	15	72	124	78	80	124	80	8	0	2
		DAY 22	18APR2005	22	60	120	78	84	124	84	24 Y	4	6
		DAY 29	25APR2005	29	68	120	74	76	128	86	8	8	12
		DAY 36	02MAY2005	36	68	124	72	76	124	74	8	0	2
		DAY 57	24MAY2005	58	60	122	86	72	122	84	12	0	-2
		FINAL			60	122	86	72	122	84	12	0	-2
	E0039011	SCREEN	18OCT2004	-8	58	110	60	62	108	66	4	-2	6
		DAY 1	26OCT2004	1	56	102	70	62	98	60	6	-4	-10
		BASELINE			56	102	70	62	98	60	6	-4	-10
		DAY 8	02NOV2004	8	58	108	60	64	98	60	6	-10	0
		DAY 15	09NOV2004	15	70	100	62	70	94	60	0	-6	-2
		DAY 22	16NOV2004	22	72	92	54	68	90 L	60	-4	-2	6
		DAY 29	24NOV2004	30	60	98	64	62	90 L	60	2	-8	-4
		DAY 36	01DEC2004	37	64	108	70	68	98	62	4	-10	-8
		DAY 43	08DEC2004	44	72	98	62	88	100	80	16	2	18
		DAY 50	14DEC2004	50	64	118	60	70	100	70	6	-18	10
		DAY 57	22DEC2004	58	64	100	52	72	92	56	8	-8	4
		FINAL			64	100	52	72	92	56	8	-8	4
	E0041012	SCREEN	29NOV2004	-14	76	118	72	80	120	76	4	2	4
		DAY 1	13DEC2004	1	80	118	78	108	112	82	28 Y	-6	4
		BASELINE			80	118	78	108	112	82	28 Y	-6	4
		DAY 8	20DEC2004	8	84	110	70	96	100	68	12	-10	-2
		FINAL			84	110	70	96	100	68	12	-10	-2
	E0041013	SCREEN	28DEC2004	-8	72	112	64	80	106	68	8	-6	4
		DAY 1	05JAN2005	1	64	106	58	88	96	64	24 Y	-10	6
		BASELINE			64	106	58	88	96	64	24 Y	-10	6
		DAY 8	12JAN2005	8	88	108	60	108	108	64	20 Y	0	4

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
SYS: Systolic blood pressure DIA: Diastolic blood pressure.
L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

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Table 11.3.8.2.1.1 Vital Signs - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE PULSE	SUPINE SYS	SUPINE DIA	STANDING PULSE	STANDING SYS	STANDING DIA	ORTHOSTATIC CHANGE PULSE		ORTHOSTATIC CHANGE SYS	ORTHOSTATIC CHANGE DIA
PLACEBO (BIPOLAR II)	E0041013	DAY 15		19JAN2005	15	92	106	66	100	110	68	8		4	2
		DAY 22		27JAN2005	23	80	112	68	84	108	68	4		-4	0
		DAY 29		02FEB2005	29	60	110	70	80	110	74	20	Y	0	4
		DAY 36		10FEB2005	37	84	116	78	96	112	80	12		-4	2
		DAY 43		16FEB2005	43	84	108	70	100	104	74	16		-4	4
		DAY 50		23FEB2005	50	84	110	76	104	100	74	20	Y	-10	-2
		DAY 57		02MAR2005	57	68	110	68	84	112	72	16		2	4
		FINAL				68	110	68	84	112	72	16		2	4
	E0042007	SCREEN		25AUG2004	-36	64	110	64	96	102	60	32	Y	-8	-4
		DAY 1		30SEP2004	1	80	126	80	84	124	80	4		-2	0
		BASELINE				80	126	80	84	124	80	4		-2	0
		DAY 8		06OCT2004	7	76	124	82	80	128	86	4		4	4
		DAY 15		13OCT2004	14	82	134	92	88	134	96	6		0	4
		DAY 22		20OCT2004	21	78	126	78	80	122	84	2		-4	6
		DAY 29		27OCT2004	28	84	126	78	82	128	84	-2		2	6
		DAY 36		03NOV2004	35	84	124	82	84	128	86	0		4	4
		DAY 43		11NOV2004	43	78	118	78	80	114	82	2		-4	4
		DAY 50		17NOV2004	49	76	122	78	80	124	82	4		2	4
		DAY 50	*	22NOV2004	54	80	116	78	76	120	78	-4		4	0
		FINAL				80	116	78	76	120	78	-4		4	0

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L: Potentially Clinically Important low.
H: Potentially Clinically Important high.
Y: Potentially Clinically Important Orthostatic Change.

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0003012	SCREEN		15MAR2005	-24	48L	100	70				52	102	72			
		DAY 1		08APR2005	1	63	92	59				83	98	64			
		BASELINE				63	92	59				83	98	64			
		DAY 8		15APR2005	8	78	114	67	15I	22I	8	83	120	70	0	22I	6
		DAY 15		20APR2005	13	77	102	62	14	10	3	83	107	58	0	9	-6
		DAY 22		29APR2005	22	84	91	59	21I	-1	0	91	90L	59	8	-8	-5
		DAY 29		09MAY2005	32	84	93	55	21I	1	-4	91	95	57	8	-3	-7
		DAY 36		13MAY2005	36	79	100	64	16I	8	5	90	102	63	7	4	-1
		DAY 43		23MAY2005	46	78	92	62	15I	0	3	81	103	64	-2	5	0
		DAY 50		26MAY2005	49	93	92	68	30I	0	9	96	104	68	13	6	4
		DAY 57		07JUN2005	61	87	96	67	24I	4	8	87	96	61	4	-2	-3
		FINAL				87	96	67	24I	4	8	87	96	61	4	-2	-3
	E0004017	SCREEN		02NOV2004	-15	68	116	72				76	110	70			
		DAY 1		17NOV2004	1	60	110	70				70	106	70			
		BASELINE				60	110	70				70	106	70			
		DAY 8		24NOV2004	8	80	118	80	20I	8	10	84	112	78	14	6	8
		DAY 22	*	06DEC2004	20	64	102	78	4	-8	8	80	106	76	10	0	6
		DAY 22		09DEC2004	23	80	100	68	20I	-10	-2	84	98	66	14	-8	-4
		DAY 29		15DEC2004	29	72	96	62	12	-14	-8	80	90L	60	10	-16	-10
		DAY 36		22DEC2004	36	76	110	72	16I	0	2	80	104	80	10	-2	10
		DAY 43		28DEC2004	42	72	106	80	12	-4	10	84	110	82	14	4	12
		DAY 50		05JAN2005	50	84	100	68	24I	-10	-2	96	98	70	26I	-8	0
		DAY 57		13JAN2005	58	72	112	76	12	2	6	80	114	80	10	8	10
		FINAL				72	112	76	12	2	6	80	114	80	10	8	10
	E0004024	SCREEN		01FEB2005	-20	64	118	76				68	110	70			
		DAY 1		21FEB2005	1	80	120	70				84	112	68			
		BASELINE				80	120	70				84	112	68			
		DAY 8		28FEB2005	8	100	114	70	20I	-6	0	108	106	68	24I	-6	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0004024	FINAL			100	114	70	20I	-6	0	108	106	68	24I	-6	0
	E0004029	SCREEN	14APR2005	-14	74	132	84				72	136	88			
		DAY 1	28APR2005	1	76	130	80				80	128	76			
		BASELINE			76	130	80				80	128	76			
		DAY 8	05MAY2005	8	84	126	80	8	-4	0	76	120	78	-4	-8	2
		DAY 15	12MAY2005	15	76	122	80	0	-8	0	80	120	78	0	-8	2
		DAY 22	19MAY2005	22	78	114	82	2	-16	2	80	116	82	0	-12	6
		DAY 29	26MAY2005	29	78	118	80	2	-12	0	80	122	82	0	-6	6
		DAY 36	02JUN2005	36	84	110	70	8	-20D	-10	86	112	68	6	-16	-8
		DAY 43	09JUN2005	43	84	116	70	8	-14	-10	88	112	68	8	-16	-8
		DAY 50	16JUN2005	50	88	116	70	12	-14	-10	88	108	68	8	-20D	-8
		DAY 57	23JUN2005	57	86	120	68	10	-10	-12	86	122	70	6	-6	-6
		FINAL			86	120	68	10	-10	-12	86	122	70	6	-6	-6
	E0006001	SCREEN	28JUL2004	-7	78	120	88				86	132	90			
		DAY 1	04AUG2004	1	76	132	90				88	126	88			
		BASELINE			76	132	90				88	126	88			
		DAY 8	11AUG2004	8	80	132	84	4	0	-6	84	128	80	-4	2	-8
		DAY 15	18AUG2004	15	78	128	82	2	-4	-8	86	132	88	-2	6	0
		DAY 22	24AUG2004	21	88	120	82	12	-12	-8	90	122	82	2	-4	-6
		DAY 29	02SEP2004	30	88	120	86	12	-12	-4	88	120	82	0	-6	-6
		DAY 36	09SEP2004	37	76	112	70	0	-20D	-20D	78	116	72	-10	-10	-16
		DAY 43	14SEP2004	42	72	130	82	-4	-2	-8	72	122	88	-16D	-4	0
		DAY 50	21SEP2004	49	68	118	76	-8	-14	-14	74	116	76	-14	-10	-12
		DAY 57	30SEP2004	58	74	118	78	-2	-14	-12	78	118	76	-10	-8	-12
		FINAL			74	118	78	-2	-14	-12	78	118	76	-10	-8	-12
	E0007003	SCREEN	28OCT2004	-7	81	124	78				96	116	83			
		DAY 1	04NOV2004	1	90	136	88				98	118	82			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0007003	BASELINE			90	136	88				98	118	82			
		DAY 8	11NOV2004	8	89	126	79	-1	-10	-9	103	125	83	5	7	1
		DAY 15	18NOV2004	15	89	118	74	-1	-18	-14	100	129	84	2	11	2
		DAY 29	30NOV2004	27	80	116	77	-10	-20D	-11	91	121	85	-7	3	3
		DAY 36	08DEC2004	35	93	124	78	3	-12	-10	96	124	81	-2	6	-1
		DAY 43	15DEC2004	42	77	118	69	-13	-18	-19	97	117	80	-1	-1	-2
		DAY 50	21DEC2004	48	86	128	71	-4	-8	-17	100	132	84	2	14	2
		DAY 57	30DEC2004	57	78	110	75	-12	-26D	-13	93	117	81	-5	-1	-1
		FINAL			78	110	75	-12	-26D	-13	93	117	81	-5	-1	-1
	E0007004	SCREEN	05NOV2004	-10	67	115	83				80	114	88			
		DAY 1	15NOV2004	1	69	119	80				86	115	88			
		BASELINE			69	119	80				86	115	88			
		DAY 8	22NOV2004	8	86	110	79	17I	-9	-1	96	105	81	10	-10	-7
		DAY 15	30NOV2004	16	76	108	77	7	-11	-3	98	112	83	12	-3	-5
		FINAL			76	108	77	7	-11	-3	98	112	83	12	-3	-5
	E0010017	SCREEN	06MAY2005	-7	74	134	94				78	132	98			
		DAY 1	13MAY2005	1	66	134	94				84	132	98			
		BASELINE			66	134	94				84	132	98			
		DAY 8	20MAY2005	8	82	126	72	16I	-8	-22D	86	140	94	2	8	-4
		DAY 29	10JUN2005	29	88	132	88	22I	-2	-6	64	134	94	-20D	2	-4
		FINAL			88	132	88	22I	-2	-6	64	134	94	-20D	2	-4
	E0012010	SCREEN	01SEP2004	-7	80	112	84				80	120	80			
		DAY 1	08SEP2004	1	80	112	68				80	112	78			
		BASELINE			80	112	68				80	112	78			
		DAY 8	14SEP2004	7	76	136	82	-4	24I	14	74	138	80	-6	26I	2
		FINAL			76	136	82	-4	24I	14	74	138	80	-6	26I	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0013009	SCREEN		01NOV2004	-7	66	136	78				70	134	76			
		DAY 1		08NOV2004	1	70	142	80				76	136	82			
		BASELINE				70	142	80				76	136	82			
		DAY 8		15NOV2004	8	72	136	84	2	-6	4	70	138	80	-6	2	-2
		DAY 15		24NOV2004	17	102	134	83	32I	-8	3	92	136	81	16I	0	-1
		DAY 22		02DEC2004	25	52	132	90	-18D	-10	10	68	134	88	-8	-2	6
		DAY 29		06DEC2004	29	88	144	90	18I	2	10	76	138	86	0	2	4
		DAY 36		13DEC2004	36	94	146	83	24I	4	3	95	139	79	19I	3	-3
		DAY 43		20DEC2004	43	99	135	79	29I	-7	-1	99	140	82	23I	4	0
		DAY 50		27DEC2004	50	98	136	84	28I	-6	4	102	142	81	26I	6	-1
		DAY 57		05JAN2005	59	79	153	86	9	11	6	87	151	84	11	15	2
		FINAL				79	153	86	9	11	6	87	151	84	11	15	2
	E0014003	SCREEN		23JUL2004	-14	60	108	70				64	110	80			
		DAY 1		06AUG2004	1	80	104	68				84	106	70			
		BASELINE				80	104	68				84	106	70			
		DAY 8		12AUG2004	7	80	118	78	0	14	10	84	116	78	0	10	8
		DAY 15		20AUG2004	15	72	112	72	-8	8	4	80	122	78	-4	16	8
		DAY 22		26AUG2004	21	72	104	64	-8	0	-4	76	110	76	-8	4	6
		DAY 29		03SEP2004	29	68	118	80	-12	14	12	76	110	76	-8	4	6
		DAY 36		08SEP2004	34	68	104	68	-12	0	0	72	110	80	-12	4	10
		DAY 43		17SEP2004	43	72	126	78	-8	22I	10	72	120	88	-12	14	18
		DAY 50		22SEP2004	48	60	110	60	-20D	6	-8	68	110	70	-16D	4	0
		DAY 50	*	28SEP2004	54	64	120	76	-16D	16	8	72	116	74	-12	10	4
		FINAL				64	120	76	-16D	16	8	72	116	74	-12	10	4
	E0014010	SCREEN		14DEC2004	-20	64	128	86				76	118	86			
		DAY 1		03JAN2005	1	72	132	90				76	130	86			
		BASELINE				72	132	90				76	130	86			
		DAY 8		10JAN2005	8	80	140	90	8	8	0	84	142	100	8	12	14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0014010	DAY 15	19JAN2005	17	75	136	95	3	4	5	90	128	90	14	-2	4
		DAY 22	25JAN2005	23	88	122	82	16I	-10	-8	92	124	90	16I	-6	4
		DAY 29	01FEB2005	30	96	122	88	24I	-10	-2	104	124	92	28I	-6	6
		DAY 36	09FEB2005	38	72	110	72	0	-22D	-18	76	124	90	0	-6	4
		FINAL			72	110	72	0	-22D	-18	76	124	90	0	-6	4
	E0015003	SCREEN	20AUG2004	-5	76	116	84				72	110	82			
		DAY 1	25AUG2004	1	70	110	70				68	100	68			
		BASELINE			70	110	70				68	100	68			
		DAY 8	01SEP2004	8	80	130	80	10	20I	10	82	130	76	14	30I	8
		DAY 15	07SEP2004	14	76	132	84	6	22I	14	82	132	82	14	32I	14
		DAY 22	14SEP2004	21	74	138	80	4	28I	10	78	132	82	10	32I	14
		FINAL			74	138	80	4	28I	10	78	132	82	10	32I	14
	E0015014	SCREEN	28JAN2005	-13	82	100	70				88	100	66			
		DAY 1	10FEB2005	1	84	98	74				80	104	70			
		BASELINE			84	98	74				80	104	70			
		DAY 8	18FEB2005	9	82	108	78	-2	10	4	86	100	80	6	-4	10
		DAY 15	24FEB2005	15	60	100	70	-24D	2	-4	64	96	74	-16D	-8	4
		DAY 29	08MAR2005	27	66	102	74	-18D	4	0	70	100	70	-10	-4	0
		DAY 43	22MAR2005	41	68	100	72	-16D	2	-2	68	100	70	-12	-4	0
		FINAL			68	100	72	-16D	2	-2	68	100	70	-12	-4	0
	E0015016	SCREEN	16FEB2005	-8	68	102	80				74	100	76			
		DAY 1	24FEB2005	1	68	114	82				76	108	80			
		BASELINE			68	114	82				76	108	80			
		DAY 8	04MAR2005	9	66	112	76	-2	-2	-6	72	108	76	-4	0	-4
		DAY 15	10MAR2005	15	62	110	84	-6	-4	2	68	104	80	-8	-4	0
		DAY 22	21MAR2005	26	70	112	80	2	-2	-2	72	108	78	-4	0	-2
		DAY 29	25MAR2005	30	88	102	76	20I	-12	-6	82	100	80	6	-8	0

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0015016	DAY 36	31MAR2005	36	72	116	84	4	2	2	80	120	82	4	12	2
		DAY 43	07APR2005	43	68	112	76	0	-2	-6	74	108	72	-2	0	-8
		DAY 50	15APR2005	51	68	110	70	0	-4	-12	70	110	74	-6	2	-6
		DAY 57	22APR2005	58	60	100	74	-8	-14	-8	60	102	70	-16D	-6	-10
		FINAL			60	100	74	-8	-14	-8	60	102	70	-16D	-6	-10
	E0015019	SCREEN	15APR2005	-20	50	132	80				56	122	82			
		DAY 1	05MAY2005	1	74	124	80				80	120	76			
		BASELINE			74	124	80				80	120	76			
		DAY 8	12MAY2005	8	72	124	78	-2	0	-2	72	122	78	-8	2	2
		DAY 15	19MAY2005	15	66	130	82	-8	6	2	70	124	78	-10	4	2
		DAY 22	26MAY2005	22	64	118	82	-10	-6	2	68	110	80	-12	-10	4
		DAY 29	02JUN2005	29	62	118	78	-12	-6	-2	62	116	80	-18D	-4	4
		DAY 36	09JUN2005	36	68	122	82	-6	-2	2	70	118	80	-10	-2	4
		DAY 43	17JUN2005	44	68	120	80	-6	-4	0	72	118	82	-8	-2	6
		DAY 50	27JUN2005	54	68	124	82	-6	0	2	70	120	80	-10	0	4
		DAY 57	05JUL2005	62	70	124	80	-4	0	0	70	122	80	-10	2	4
		FINAL			70	124	80	-4	0	0	70	122	80	-10	2	4
	E0016001	SCREEN	17AUG2004	-15	53	137	94				59	134	96			
		DAY 1	01SEP2004	1	64	110	78				68	120	80			
		BASELINE			64	110	78				68	120	80			
		DAY 8	08SEP2004	8	64	122	94	0	12	16	60	121	98	-8	1	18
		DAY 15	16SEP2004	16	72	116	91	8	6	13	92	114	90	24I	-6	10
		DAY 22	23SEP2004	23	72	130	97	8	20I	19	102	126	98	34I	6	18
		DAY 29	30SEP2004	30	76	132	86	12	22I	8	78	128	84	10	8	4
		DAY 36	07OCT2004	37	79	115	80	15I	5	2	93	122	91	25I	2	11
		DAY 43	14OCT2004	44	78	112	82	14	2	4	91	122	89	23I	2	9
		DAY 50	21OCT2004	51	68	132	90	4	22I	12	89	128	99	21I	8	19
		DAY 57	29OCT2004	59	66	133	90	2	23I	12	80	124	97	12	4	17

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0016001	FINAL			66	133	90	2	23I	12	80	124	97	12	4	17
	E0020002	SCREEN	12JUL2004	-14	68	106	72				80	132	82			
		DAY 1	26JUL2004	1	68	112	74				110	128	78			
		BASELINE			68	112	74				110	128	78			
		DAY 8	03AUG2004	9	64	118	76	-4	6	2	76	110	60	-34D	-18	-18
		DAY 15	10AUG2004	16	72	116	70	4	4	-4	88	112	60	-22D	-16	-18
		DAY 22	17AUG2004	23	62	112	80	-6	0	6	62	110	84	-48D	-18	6
		DAY 29	24AUG2004	30	92	108	72	24I	-4	-2	96	120	82	-14	-8	4
		DAY 36	31AUG2004	37	76	108	76	8	-4	2	88	100	70	-22D	-28D	-8
		DAY 43	07SEP2004	44	96	120	70	28I	8	-4	96	110	80	-14	-18	2
		DAY 50	14SEP2004	51	84	120	70	16I	8	-4	96	116	70	-14	-12	-8
		DAY 57	23SEP2004	60	88	110	70	20I	-2	-4	96	120	80	-14	-8	2
		FINAL			88	110	70	20I	-2	-4	96	120	80	-14	-8	2
	E0020013	SCREEN	05OCT2004	-8	72	110	70				80	106	70			
		DAY 1	13OCT2004	1	76	110	64				80	110	70			
		BASELINE			76	110	64				80	110	70			
		DAY 8	20OCT2004	8	64	110	64	-12	0	0	80	110	70	0	0	0
		DAY 15	27OCT2004	15	68	105	70	-8	-5	6	74	110	74	-6	0	4
		DAY 22	03NOV2004	22	76	120	70	0	10	6	80	110	76	0	0	6
		DAY 29	10NOV2004	29	64	110	76	-12	0	12	68	108	70	-12	-2	0
		DAY 36	17NOV2004	36	60	110	76	-16D	0	12	64	110	70	-16D	0	0
		DAY 43	24NOV2004	43	84	100	68	8	-10	4	100	118	70	20I	8	0
		DAY 50	02DEC2004	51	71	104	76	-5	-6	12	72	102	80	-8	-8	10
		DAY 57	08DEC2004	57	81	110	70	5	0	6	90	111	90	10	1	20
		FINAL			81	110	70	5	0	6	90	111	90	10	1	20
	E0020038	SCREEN	07FEB2005	-7	76	120	80				84	130	80			
		DAY 1	14FEB2005	1	72	109	70				78	111	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0020038	BASELINE			72	109	70				78	111	80			
		DAY 8	21FEB2005	8	72	110	74	0	1	4	86	110	90	8	-1	10
		DAY 15	28FEB2005	15	84	122	82	12	13	12	86	122	82	8	11	2
		DAY 22	07MAR2005	22	84	122	82	12	13	12	100	119	90	22I	8	10
		DAY 29	14MAR2005	29	74	120	80	2	11	10	78	117	80	0	6	0
		DAY 36	22MAR2005	37	78	112	80	6	3	10	84	120	84	6	9	4
		DAY 43	29MAR2005	44	82	140	90	10	31I	20	102	140	100	24I	29I	20
		DAY 50	05APR2005	51	74	130	90	2	21I	20	76	130	98	-2	19	18
		DAY 57	12APR2005	58	76	126	96	4	17	26	84	132	88	6	21I	8
		FINAL			76	126	96	4	17	26	84	132	88	6	21I	8
	E0020044	SCREEN	13APR2005	-7	64	116	78				64	112	78			
		DAY 1	20APR2005	1	64	96	70				66	110	76			
		BASELINE			64	96	70				66	110	76			
		DAY 8	27APR2005	8	64	118	82	0	22I	12	66	120	84	0	10	8
		DAY 15	04MAY2005	15	68	104	80	4	8	10	62	112	82	-4	2	6
		DAY 22	11MAY2005	22	60	106	80	-4	10	10	68	110	82	2	0	6
		DAY 29	18MAY2005	29	76	112	84	12	16	14	80	120	90	14	10	14
		DAY 36	26MAY2005	37	76	110	74	12	14	4	84	116	76	18I	6	0
		DAY 43	01JUN2005	43	82	110	78	18I	14	8	84	110	82	18I	0	6
		DAY 50	08JUN2005	50	76	100	74	12	4	4	79	102	82	13	-8	6
		DAY 57	15JUN2005	57	73	110	82	9	14	12	74	111	86	8	1	10
		FINAL			73	110	82	9	14	12	74	111	86	8	1	10
	E0021001	SCREEN	09JUL2004	-12	57	104	72				64	108	80			
		DAY 1	21JUL2004	1	61	114	80				58	120	70			
		BASELINE			61	114	80				58	120	70			
		DAY 8	28JUL2004	8	60	106	62	-1	-8	-18	74	112	70	16I	-8	0
		DAY 15	04AUG2004	15	63	114	62	2	0	-18	67	108	70	9	-12	0
		DAY 22	11AUG2004	22	68	116	76	7	2	-4	70	114	72	12	-6	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0021001	DAY 29		19AUG2004	30	53	104	64	-8	-10	-16	70	110	68	12	-10	-2
		FINAL				53	104	64	-8	-10	-16	70	110	68	12	-10	-2
	E0021008	SCREEN		20SEP2004	-7	88	142	64				92	136	80			
		DAY 1		27SEP2004	1	75	144	78				87	134	88			
		BASELINE				75	144	78				87	134	88			
		DAY 8		04OCT2004	8	82	126	70	7	-18	-8	87	118	74	0	-16	-14
		DAY 15		11OCT2004	15	75	138	84	0	-6	6	92	112	82	5	-22D	-6
		DAY 22		18OCT2004	22	81	120	80	6	-24D	2	102	102	82	15I	-32D	-6
		DAY 29		25OCT2004	29	66	136	82	-9	-8	4	72	138	86	-15D	4	-2
		DAY 36		01NOV2004	36	63	132	84	-12	-12	6	68	144	90	-19D	10	2
		DAY 43		08NOV2004	43	69	134	82	-6	-10	4	88	142	90	1	8	2
		DAY 50		15NOV2004	50	86	146	90	11	2	12	100	124	86	13	-10	-2
		DAY 57		22NOV2004	57	70	132	82	-5	-12	4	84	137	88	-3	3	0
		FINAL				70	132	82	-5	-12	4	84	137	88	-3	3	0
	E0021009	SCREEN		22SEP2004	-8	51	120	66				57	126	70			
		DAY 1		30SEP2004	1	62	106	60				74	120	72			
		BASELINE				62	106	60				74	120	72			
		DAY 8		07OCT2004	8	51	114	74	-11	8	14	69	108	78	-5	-12	6
		DAY 15		13OCT2004	14	45L	100	64	-17D	-6	4	57	106	74	-17D	-14	2
		DAY 22		20OCT2004	21	51	104	70	-11	-2	10	63	106	84	-11	-14	12
		DAY 29		27OCT2004	28	57	104	64	-5	-2	4	63	114	70	-11	-6	-2
		DAY 36		04NOV2004	36	45L	100	62	-17D	-6	2	54	114	72	-20D	-6	0
		DAY 50		17NOV2004	49	42L	98	62	-20D	-8	2	45L	110	74	-29D	-10	2
		DAY 50	*	22NOV2004	54	44L	110	62	-18D	4	2	49L	110	78	-25D	-10	6
		DAY 57		02DEC2004	64	60	110	70	-2	4	10	75	128	78	1	8	6
		FINAL				60	110	70	-2	4	10	75	128	78	1	8	6
	E0021016	SCREEN		04NOV2004	-6	63	130	62				63	118	66			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0021016	DAY 1	10NOV2004	1	60	120	68				64	118	70			
		BASELINE			60	120	68				64	118	70			
		DAY 8	18NOV2004	9	57	102	66	-3	-18	-2	84	118	76	20I	0	6
		DAY 15	24NOV2004	15	58	124	66	-2	4	-2	86	116	86	22I	-2	16
		DAY 22	01DEC2004	22	74	118	60	14	-2	-8	68	122	74	4	4	4
		DAY 29	09DEC2004	30	51	102	62	-9	-18	-6	78	108	84	14	-10	14
		DAY 36	16DEC2004	37	58	110	76	-2	-10	8	63	112	80	-1	-6	10
		DAY 43	23DEC2004	44	60	106	58	0	-14	-10	72	110	80	8	-8	10
		DAY 50	30DEC2004	51	85	136	60	25I	16	-8	88	134	70	24I	16	0
		DAY 57	06JAN2005	58	57	112	76	-3	-8	8	84	122	76	20I	4	6
		FINAL			57	112	76	-3	-8	8	84	122	76	20I	4	6
	E0021022	SCREEN	18JAN2005	-9	87	126	72				90	124	78			
		DAY 1	27JAN2005	1	78	114	74				93	112	88			
		BASELINE			78	114	74				93	112	88			
		DAY 8	02FEB2005	7	75	110	70	-3	-4	-4	81	108	88	-12	-4	0
		DAY 15	09FEB2005	14	78	120	70	0	6	-4	80	110	80	-13	-2	-8
		DAY 29	23FEB2005	28	96	112	68	18I	-2	-6	84	118	92	-9	6	4
		DAY 36	03MAR2005	36	78	116	78	0	2	4	90	118	76	-3	6	-12
		DAY 43	09MAR2005	42	75	106	72	-3	-8	-2	84	120	78	-9	8	-10
		DAY 50	16MAR2005	49	75	106	66	-3	-8	-8	81	110	74	-12	-2	-14
		DAY 57	22MAR2005	55	72	124	76	-6	10	2	96	118	78	3	6	-10
		FINAL			72	124	76	-6	10	2	96	118	78	3	6	-10
	E0021024	SCREEN	27JAN2005	-7	72	138	92				96	138	92			
		DAY 1	03FEB2005	1	81	138	96				93	128	104			
		BASELINE			81	138	96				93	128	104			
		DAY 8	10FEB2005	8	87	132	90	6	-6	-6	99	122	98	6	-6	-6
		DAY 15	17FEB2005	15	99	118	70	18I	-20D	-26D	120	124	88	27I	-4	-16
		DAY 22	24FEB2005	22												

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			SUPINE CHANGE FROM BASELINE			STANDING			STANDING CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0021024	FINAL				99	118	70	18I	-20D	-26D	120	124	88	27I	-4	-16
	E0021027	SCREEN		28MAR2005	-9	69	132	86				63	128	88			
		DAY 1		06APR2005	1	66	118	72				75	118	74			
		BASELINE				66	118	72				75	118	74			
		DAY 8		13APR2005	8	63	112	74	-3	-6	2	81	116	74	6	-2	0
		DAY 15		20APR2005	15	63	118	78	-3	0	6	75	124	96	0	6	22
		DAY 22		27APR2005	22	57	128	82	-9	10	10	81	120	92	6	2	18
		DAY 29		04MAY2005	29	69	128	84	3	10	12	81	116	84	6	-2	10
		DAY 36		11MAY2005	36	72	134	92	6	16	20	69	134	100	-6	16	26
		DAY 50	*	23MAY2005	48	66	128	88	0	10	16	78	130	94	3	12	20
		DAY 50		26MAY2005	51	80	120	84	14	2	12	92	102	86	17I	-16	12
		DAY 57		02JUN2005	58	63	124	84	-3	6	12	75	118	92	0	0	18
		FINAL				63	124	84	-3	6	12	75	118	92	0	0	18
	E0024002	SCREEN		09AUG2004	-10	84	118	72				84	118	78			
		DAY 1		19AUG2004	1	72	118	78				88	110	78			
		BASELINE				72	118	78				88	110	78			
		DAY 8		26AUG2004	8	90	116	68	18I	-2	-10	96	112	72	8	2	-6
		DAY 15		02SEP2004	15	88	120	74	16I	2	-4	92	114	80	4	4	2
		DAY 22		10SEP2004	23	86	116	64	14	-2	-14	88	118	72	0	8	-6
		DAY 29		15SEP2004	28	80	110	70	8	-8	-8	76	106	74	-12	-4	-4
		FINAL				80	110	70	8	-8	-8	76	106	74	-12	-4	-4
	E0024003	SCREEN		12OCT2004	-7	70	110	82				76	110	86			
		DAY 1		19OCT2004	1	88	126	92				80	120	90			
		BASELINE				88	126	92				80	120	90			
		DAY 8		27OCT2004	9	80	122	82	-8	-4	-10	72	116	84	-8	-4	-6
		DAY 15		03NOV2004	16	80	114	80	-8	-12	-12	98	106	84	18I	-14	-6
		DAY 22		10NOV2004	23	78	126	80	-10	0	-12	80	124	84	0	4	-6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0024003	DAY 29	18NOV2004	31	72	122	70	-16D	-4	-22D	68	122	82	-12	2	-8
		DAY 36	24NOV2004	37	68	118	78	-20D	-8	-14	72	118	88	-8	-2	-2
		DAY 43	01DEC2004	44	80	110	78	-8	-16	-14	76	108	72	-4	-12	-18
		DAY 50	07DEC2004	50	68	118	78	-20D	-8	-14	80	118	84	0	-2	-6
		DAY 57	15DEC2004	58	72	112	74	-16D	-14	-18	74	110	74	-6	-10	-16
		FINAL			72	112	74	-16D	-14	-18	74	110	74	-6	-10	-16
	E0025047	SCREEN	24FEB2005	-12	72	104	72				84	110	82			
		DAY 1	08MAR2005	1	78	108	74				80	110	72			
		BASELINE			78	108	74				80	110	72			
		DAY 8	15MAR2005	8	72	114	76	-6	6	2	88	114	78	8	4	6
		DAY 15	22MAR2005	15	88	118	80	10	10	6	92	122	84	12	12	12
		DAY 22	29MAR2005	22	76	112	84	-2	4	10	84	104	82	4	-6	10
		DAY 29	05APR2005	29	96	124	88	18I	16	14	100	120	92	20I	10	20
		DAY 36	12APR2005	36	80	122	82	2	14	8	92	112	84	12	2	12
		DAY 43	19APR2005	43	88	110	78	10	2	4	98	112	80	18I	2	8
		DAY 50	26APR2005	50	84	112	82	6	4	8	84	106	80	4	-4	8
		FINAL			84	112	82	6	4	8	84	106	80	4	-4	8
	E0025059	SCREEN	29APR2005	-6	61	124	86				92	116	80			
		DAY 1	05MAY2005	1	62	126	86				90	120	80			
		BASELINE			62	126	86				90	120	80			
		DAY 8	12MAY2005	8	80	118	82	18I	-8	-4	88	112	90	-2	-8	10
		DAY 15	19MAY2005	15	72	122	88	10	-4	2	76	118	90	-14	-2	10
		DAY 22	26MAY2005	22	95	117	73	33I	-9	-13	95	121	93	5	1	13
		DAY 29	02JUN2005	29	78	116	82	16I	-10	-4	84	112	84	-6	-8	4
		DAY 36	09JUN2005	36	78	132	88	16I	6	2	88	124	86	-2	4	6
		DAY 43	16JUN2005	43	72	110	84	10	-16	-2	80	118	80	-10	-2	0
		DAY 50	23JUN2005	50	76	118	86	14	-8	0	80	110	84	-10	-10	4
		DAY 57	01JUL2005	58	66	124	88	4	-2	2	78	126	95	-12	6	15

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0025059	FINAL			66	124	88	4	-2	2	78	126	95	-12	6	15
	E0027002	SCREEN	13JUL2004	-7	66	148	88				70	150	90			
		DAY 1	20JUL2004	1	68	150	88				74	152	90			
		BASELINE			68	150	88				74	152	90			
		DAY 8	27JUL2004	8	88	180H	110H	20I	30I	22	88	185H	112H	14	33I	22
		DAY 15	05AUG2004	17	82	185H	120H	14	35I	32I	84	185H	125H	10	33I	35I
		FINAL			82	185H	120H	14	35I	32I	84	185H	125H	10	33I	35I
	E0028011	SCREEN	31JAN2005	-7	80	100	70				84	110	70			
		DAY 1	07FEB2005	1	72	100	60				88	100	68			
		BASELINE			72	100	60				88	100	68			
		DAY 8	14FEB2005	8	76	110	70	4	10	10	84	100	70	-4	0	2
		DAY 15	21FEB2005	15	96	100	60	24I	0	0	100	100	70	12	0	2
		DAY 22	28FEB2005	22	100	100	70	28I	0	10	100	100	70	12	0	2
		DAY 29	07MAR2005	29	84	110	70	12	10	10	84	100	70	-4	0	2
		DAY 36	14MAR2005	36	88	100	70	16I	0	10	96	100	74	8	0	6
		DAY 43	21MAR2005	43	76	100	70	4	0	10	84	100	70	-4	0	2
		DAY 50	28MAR2005	50	80	100	60	8	0	0	92	110	70	4	10	2
		DAY 57	04APR2005	57	80	100	60	8	0	0	92	100	70	4	0	2
		FINAL			80	100	60	8	0	0	92	100	70	4	0	2
	E0028012	SCREEN	10FEB2005	-6	80	110	80				84	120	90			
		DAY 1	16FEB2005	1	80	120	94				88	130	100			
		BASELINE			80	120	94				88	130	100			
		DAY 8	23FEB2005	8	80	120	80	0	0	-14	92	118	80	4	-12	-20D
		DAY 15	02MAR2005	15	92	110	80	12	-10	-14	96	120	90	8	-10	-10
		DAY 22	09MAR2005	22	92	110	70	12	-10	-24D	92	120	90	4	-10	-10
		DAY 29	16MAR2005	29	88	110	84	8	-10	-10	88	130	90	0	0	-10
		DAY 36	23MAR2005	36	88	120	82	8	0	-12	92	130	90	4	0	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0028012	DAY 43	30MAR2005	43	96	130	90	16I	10	-4	96	130	90	8	0	-10
		DAY 50	06APR2005	50	100	120	100	20I	0	6	108	120	90	20I	-10	-10
		DAY 57	13APR2005	57	76	110	80	-4	-10	-14	80	120	90	-8	-10	-10
		FINAL			76	110	80	-4	-10	-14	80	120	90	-8	-10	-10
	E0028015	SCREEN	23FEB2005	-6	76	100	70				80	100	78			
		DAY 1	01MAR2005	1	88	100	60				92	110	70			
		BASELINE			88	100	60				92	110	70			
		DAY 8	07MAR2005	7	92	120	68	4	20I	8	108	110	70	16I	0	0
		DAY 15	14MAR2005	14	80	120	80	-8	20I	20	88	120	80	-4	10	10
		DAY 22	21MAR2005	21	96	120	80	8	20I	20	108	130	70	16I	20I	0
		DAY 29	28MAR2005	28	96	108	80	8	8	20	96	122	78	4	12	8
		DAY 36	04APR2005	35	108	100	70	20I	0	10	112	110	80	20I	0	10
		DAY 43	11APR2005	42	96	120	70	8	20I	10	108	120	80	16I	10	10
		DAY 50	18APR2005	49	80	110	70	-8	10	10	84	110	80	-8	0	10
		DAY 57	25APR2005	56	96	110	80	8	10	20	96	120	70	4	10	0
		FINAL			96	110	80	8	10	20	96	120	70	4	10	0
	E0029009	SCREEN	17NOV2004	-7	72	118	74				78	120	72			
		DAY 1	24NOV2004	1	78	98	76				78	109	84			
		BASELINE			78	98	76				78	109	84			
		DAY 8	03DEC2004	10	78	120	80	0	22I	4	72	112	82	-6	3	-2
		DAY 15	10DEC2004	17	72	102	72	-6	4	-4	76	102	80	-2	-7	-4
		DAY 22	17DEC2004	24	80	114	80	2	16	4	78	118	82	0	9	-2
		DAY 29	22DEC2004	29	91	106	72	13	8	-4	78	108	70	0	-1	-14
		DAY 36	31DEC2004	38	68	118	76	-10	20I	0	76	110	78	-2	1	-6
		DAY 43	07JAN2005	45	86	110	80	8	12	4	80	104	82	2	-5	-2
		DAY 50	14JAN2005	52	70	118	72	-8	20I	-4	80	114	82	2	5	-2
		DAY 57	21JAN2005	59	84	112	80	6	14	4	90	111	78	12	2	-6
		FINAL			84	112	80	6	14	4	90	111	78	12	2	-6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030006	SCREEN	11AUG2004	-19	67	151	86				72	146	85			
		DAY 1	30AUG2004	1	62	142	89				72	159	93			
		BASELINE			62	142	89				72	159	93			
		DAY 8	07SEP2004	9	67	142	87	5	0	-2	80	148	94	8	-11	1
		DAY 15	14SEP2004	16	83	138	92	21I	-4	3	86	146	96	14	-13	3
		DAY 22	21SEP2004	23	75	152	94	13	10	5	84	141	101	12	-18	8
		DAY 29	27SEP2004	29	68	128	80	6	-14	-9	76	130	84	4	-29D	-9
		DAY 36	04OCT2004	36	71	142	89	9	0	0	89	143	82	17I	-16	-11
		DAY 43	12OCT2004	44	62	138	90	0	-4	1	66	145	90	-6	-14	-3
		DAY 50	18OCT2004	50	67	121	74	5	-21D	-15	70	135	79	-2	-24D	-14
		DAY 57	25OCT2004	57	67	136	82	5	-6	-7	72	156	90	0	-3	-3
		FINAL			67	136	82	5	-6	-7	72	156	90	0	-3	-3
	E0030009	SCREEN	18AUG2004	-6	76	108	66				86	100	68			
		DAY 1	24AUG2004	1	74	121	65				86	117	69			
		BASELINE			74	121	65				86	117	69			
		DAY 8	31AUG2004	8	76	118	69	2	-3	4	93	113	78	7	-4	9
		DAY 15	07SEP2004	15	78	130	73	4	9	8	80	121	76	-6	4	7
		DAY 22	14SEP2004	22	74	110	56	0	-11	-9	90	106	63	4	-11	-6
		DAY 29	23SEP2004	31	114	138	76	40I	17	11	131H	120	78	45I	3	9
		DAY 36	30SEP2004	38	95	147	81	21I	26I	16	109	137	82	23I	20I	13
		DAY 43	08OCT2004	46	93	139	79	19I	18	14	121H	127	70	35I	10	1
		DAY 50	13OCT2004	51	89	130	78	15I	9	13	108	127	77	22I	10	8
		DAY 57	21OCT2004	59	100	138	70	26I	17	5	92	130	72	6	13	3
		FINAL			100	138	70	26I	17	5	92	130	72	6	13	3
	E0030029	SCREEN	24FEB2005	-7	59	133	77				67	148	92			
		DAY 1	03MAR2005	1	74	130	68				82	141	79			
		BASELINE			74	130	68				82	141	79			
		DAY 8	10MAR2005	8	74	120	60	0	-10	-8	90	117	76	8	-24D	-3

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0030029	FINAL			74	120	60	0	-10	-8	90	117	76	8	-24D	-3
	E0030038	SCREEN	15JUN2005	-7	71	117	82				77	132	89			
		DAY 1	22JUN2005	1	84	121	78				90	130	84			
		BASELINE			84	121	78				90	130	84			
		DAY 8	29JUN2005	8	76	134	82	-8	13	4	80	128	90	-10	-2	6
		DAY 15	08JUL2005	17	84	113	71	0	-8	-7	100	122	84	10	-8	0
		DAY 22	13JUL2005	22	76	117	77	-8	-4	-1	83	120	89	-7	-10	5
		DAY 29	21JUL2005	30	84	121	82	0	0	4	101	120	93	11	-10	9
		DAY 36	27JUL2005	36	88	126	84	4	5	6	96	120	82	6	-10	-2
		DAY 43	03AUG2005	43	60	112	78	-24D	-9	0	72	120	82	-18D	-10	-2
		DAY 50	11AUG2005	51	86	116	81	2	-5	3	88	132	85	-2	2	1
		DAY 57	16AUG2005	56	83	143	97	-1	22I	19	88	140	97	-2	10	13
		FINAL			83	143	97	-1	22I	19	88	140	97	-2	10	13
	E0032002	SCREEN	30NOV2004	-8	76	128	86				78	118	88			
		DAY 1	08DEC2004	1	84	120	90				87	120	90			
		BASELINE			84	120	90				87	120	90			
		DAY 8	16DEC2004	9	96	120	83	12	0	-7	92	120	85	5	0	-5
		DAY 15	22DEC2004	15	102	118	90	18I	-2	0	104	100	85	17I	-20D	-5
		DAY 22	29DEC2004	22	95	120	90	11	0	0	98	110	90	11	-10	0
		DAY 29	05JAN2005	29	81	112	90	-3	-8	0	60	100	80	-27D	-20D	-10
		DAY 36	12JAN2005	36	96	105	90	12	-15	0	100	110	80	13	-10	-10
		DAY 43	20JAN2005	44	84	128	90	0	8	0	87	120	87	0	0	-3
		DAY 50	27JAN2005	51	82	120	83	-2	0	-7	84	120	80	-3	0	-10
		DAY 57	02FEB2005	57	96	120	85	12	0	-5	104	104	72	17I	-16	-18
		FINAL			96	120	85	12	0	-5	104	104	72	17I	-16	-18
	E0032009	SCREEN	16FEB2005	-7	70	118	76				74	118	70			
		DAY 1	23FEB2005	1	60	110	68				72	104	68			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0032009	BASELINE			60	110	68				72	104	68			
		DAY 8	02MAR2005	8	64	118	76	4	8	8	68	114	76	-4	10	8
		DAY 15	09MAR2005	15	82	118	76	22I	8	8	96	104	74	24I	0	6
		DAY 22	16MAR2005	22	80	124	76	20I	14	8	84	120	74	12	16	6
		DAY 29	23MAR2005	29	80	118	84	20I	8	16	88	114	82	16I	10	14
		DAY 36	30MAR2005	36	84	120	82	24I	10	14	88	118	82	16I	14	14
		DAY 43	06APR2005	43	66	120	84	6	10	16	76	120	80	4	16	12
		DAY 50	13APR2005	50	74	122	76	14	12	8	80	118	78	8	14	10
		DAY 57	20APR2005	57	76	122	76	16I	12	8	80	120	78	8	16	10
		FINAL			76	122	76	16I	12	8	80	120	78	8	16	10
	E0033001	SCREEN	22JUN2004	-8	72	110	88				76	116	84			
		DAY 1	30JUN2004	1	58	116	78				64	118	80			
		BASELINE			58	116	78				64	118	80			
		DAY 8	07JUL2004	8	88	116	72	30I	0	-6	90	114	74	26I	-4	-6
		DAY 15	14JUL2004	15	80	112	80	22I	-4	2	80	116	82	16I	-2	2
		DAY 22	21JUL2004	22	62	100	62	4	-16	-16	78	94	66	14	-24D	-14
		DAY 29	28JUL2004	29	76	114	80	18I	-2	2	78	116	82	14	-2	2
		DAY 36	04AUG2004	36	78	108	70	20I	-8	-8	80	110	72	16I	-8	-8
		DAY 43	11AUG2004	43	82	90L	70	24I	-26D	-8	86	92	68	22I	-26D	-12
		DAY 50	18AUG2004	50	78	130	88	20I	14	10	78	132	88	14	14	8
		DAY 57	23AUG2004	55	72	110	76	14	-6	-2	76	114	80	12	-4	0
		FINAL			72	110	76	14	-6	-2	76	114	80	12	-4	0
	E0033007	SCREEN	17NOV2004	-7	68	98	76				66	114	82			
		DAY 1	24NOV2004	1	64	110	56				72	108	74			
		BASELINE			64	110	56				72	108	74			
		DAY 8	01DEC2004	8	72	116	86	8	6	30I	76	118	80	4	10	6
		DAY 15	07DEC2004	14	64	112	68	0	2	12	70	116	72	-2	8	-2
		DAY 22	15DEC2004	22	66	110	64	2	0	8	68	110	70	-4	2	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0033007	DAY 29	21DEC2004	28	60	98	70	-4	-12	14	70	102	74	-2	-6	0
		DAY 36	29DEC2004	36	64	110	82	0	0	26	66	112	88	-6	4	14
		DAY 43	05JAN2005	43	70	124	74	6	14	18	66	126	74	-6	18	0
		DAY 50	13JAN2005	51	70	108	70	6	-2	14	76	110	74	4	2	0
		DAY 57	21JAN2005	59	68	114	74	4	4	18	70	116	76	-2	8	2
		FINAL			68	114	74	4	4	18	70	116	76	-2	8	2
	E0033015	SCREEN	28FEB2005	-14	70	112	76				74	118	78			
		DAY 1	14MAR2005	1	72	110	78				76	116	76			
		BASELINE			72	110	78				76	116	76			
		DAY 8	21MAR2005	8	74	124	80	2	14	2	76	124	82	0	8	6
		DAY 15	28MAR2005	15	76	126	80	4	16	2	78	122	78	2	6	2
		DAY 22	06APR2005	24	90	102	70	18I	-8	-8	90	106	78	14	-10	2
		DAY 29	13APR2005	31	76	102	68	4	-8	-10	84	110	76	8	-6	0
		DAY 36	18APR2005	36	78	96	72	6	-14	-6	76	96	70	0	-20D	-6
		DAY 43	25APR2005	43	88	116	80	16I	6	2	76	114	84	0	-2	8
		DAY 50	02MAY2005	50	78	94	74	6	-16	-4	80	100	76	4	-16	0
		DAY 57	09MAY2005	57	70	108	70	-2	-2	-8	76	106	74	0	-10	-2
		FINAL			70	108	70	-2	-2	-8	76	106	74	0	-10	-2
	E0033017	SCREEN	17MAR2005	-13	58	96	66				64	92	70			
		DAY 1	30MAR2005	1	74	102	72				70	100	74			
		BASELINE			74	102	72				70	100	74			
		DAY 8	08APR2005	10	70	110	82	-4	8	10	76	108	80	6	8	6
		DAY 15	13APR2005	15	74	110	70	0	8	-2	74	108	74	4	8	0
		DAY 22	18APR2005	20	70	116	78	-4	14	6	76	110	70	6	10	-4
		DAY 29	27APR2005	29	64	90L	66	-10	-12	-6	66	92	66	-4	-8	-8
		DAY 36	02MAY2005	34	60	102	82	-14	0	10	64	100	80	-6	0	6
		DAY 43	09MAY2005	41	64	110	78	-10	8	6	74	112	76	4	12	2
		DAY 50	16MAY2005	48	60	124	64	-14	22I	-8	64	118	68	-6	18	-6

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT103.SAS
GENERATED: 17NOV2005 13:53:15 iceadmn3

Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0033017	DAY 57	23MAY2005	55	72	112	72	-2	10	0	68	108	76	-2	8	2
		FINAL			72	112	72	-2	10	0	68	108	76	-2	8	2
	E0033018	SCREEN	13MAY2005	-6	62	112	80				66	108	72			
		DAY 1	19MAY2005	1	80	102	84				88	104	82			
		BASELINE			80	102	84				88	104	82			
		DAY 8	26MAY2005	8	76	106	82	-4	4	-2	80	104	80	-8	0	-2
		DAY 15	02JUN2005	15	88	110	80	8	8	-4	90	110	82	2	6	0
		DAY 22	09JUN2005	22	78	120	80	-2	18	-4	80	126	78	-8	22I	-4
		DAY 29	17JUN2005	30	68	124	86	-12	22I	2	72	126	84	-16D	22I	2
		DAY 36	22JUN2005	35	84	92	74	4	-10	-10	80	96	76	-8	-8	-6
		DAY 43	29JUN2005	42	80	114	74	0	12	-10	88	110	72	0	6	-10
		DAY 50	07JUL2005	50	78	110	80	-2	8	-4	76	120	88	-12	16	6
		DAY 57	13JUL2005	56	76	122	74	-4	20I	-10	80	116	70	-8	12	-12
		FINAL			76	122	74	-4	20I	-10	80	116	70	-8	12	-12
	E0035034	SCREEN	15JUN2005	-14	74	116	80				72	110	80			
		DAY 1	29JUN2005	1	80	142	98				88	140	106H			
		BASELINE			80	142	98				88	140	106H			
		DAY 8	08JUL2005	10	96	142	94	16I	0	-4	92	138	86	4	-2	-20D
		DAY 15	12JUL2005	14	96	142	90	16I	0	-8	90	140	90	2	0	-16
		DAY 22	20JUL2005	22	76	138	90	-4	-4	-8	74	136	86	-14	-4	-20D
		DAY 29	27JUL2005	29	66	130	80	-14	-12	-18	78	134	84	-10	-6	-22D
		DAY 36	03AUG2005	36	74	140	90	-6	-2	-8	76	140	78	-12	0	-28D
		DAY 43	09AUG2005	42	90	142	100	10	0	2	84	142	100	-4	2	-6
		DAY 50	18AUG2005	51	88	142	96	8	0	-2	88	145	100	0	5	-6
		DAY 57	25AUG2005	58	70	140	98	-10	-2	0	80	142	100	-8	2	-6
		FINAL			70	140	98	-10	-2	0	80	142	100	-8	2	-6
	E0036009	SCREEN	11APR2005	-8												

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0036009	DAY 1	19APR2005	1	68	116	70				68	116	78			
		BASELINE			68	116	70				68	116	78			
		DAY 8	26APR2005	8	80	116	70	12	0	0	76	98	70	8	-18	-8
		DAY 15	03MAY2005	15	80	118	78	12	2	8	72	118	86	4	2	8
		DAY 22	10MAY2005	22	76	108	78	8	-8	8	72	112	80	4	-4	2
		DAY 29	17MAY2005	29	72	120	76	4	4	6	76	102	80	8	-14	2
		DAY 36	24MAY2005	36	76	118	78	8	2	8	72	115	82	4	-1	4
		DAY 43	31MAY2005	43	84	116	72	16I	0	2	88	116	78	20I	0	0
		DAY 50	07JUN2005	50	76	110	74	8	-6	4	72	104	70	4	-12	-8
		DAY 57	14JUN2005	57	88	114	74	20I	-2	4	96	120	76	28I	4	-2
		FINAL			88	114	74	20I	-2	4	96	120	76	28I	4	-2
	E0037028	SCREEN	27APR2005	-12	68	122	82				80	122	86			
		DAY 1	09MAY2005	1	64	130	80				80	130	90			
		BASELINE			64	130	80				80	130	90			
		DAY 8	17MAY2005	9	64	122	84	0	-8	4	72	120	84	-8	-10	-6
		DAY 15	24MAY2005	16	72	124	84	8	-6	4	76	120	88	-4	-10	-2
		DAY 22	31MAY2005	23	68	116	80	4	-14	0	80	110	82	0	-20D	-8
		DAY 29	07JUN2005	30	68	116	72	4	-14	-8	80	120	82	0	-10	-8
		DAY 36	15JUN2005	38	64	130	88	0	0	8	72	124	88	-8	-6	-2
		DAY 43	20JUN2005	43	66	130	86	2	0	6	70	120	86	-10	-10	-4
		DAY 50	29JUN2005	52	68	124	80	4	-6	0	76	120	82	-4	-10	-8
		DAY 57	05JUL2005	58	76	124	80	12	-6	0	80	120	80	0	-10	-10
		FINAL			76	124	80	12	-6	0	80	120	80	0	-10	-10
	E0037029	SCREEN	26MAY2005	-11	84	120	88				96	120	94			
		DAY 1	06JUN2005	1	84	128	86				96	130	90			
		BASELINE			84	128	86				96	130	90			
		DAY 15	20JUN2005	15	84	130	86	0	2	0	96	130	90	0	0	0
		DAY 22	27JUN2005	22	86	120	88	2	-8	2	92	138	92	-4	8	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0037029	DAY 29	05JUL2005	30	84	120	86	0	-8	0	92	130	90	-4	0	0
		DAY 36	11JUL2005	36	86	120	84	2	-8	-2	96	130	90	0	0	0
		DAY 43	18JUL2005	43	92	130	88	8	2	2	100	130	90	4	0	0
		DAY 50	26JUL2005	51	76	160	100	-8	32I	14	84	150	110H	-12	20I	20
		DAY 57	02AUG2005	58	88	160	100	4	32I	14	92	150	106H	-4	20I	16
		FINAL			88	160	100	4	32I	14	92	150	106H	-4	20I	16
	E0037031	SCREEN	13JUN2005	-8	59	110	86				68	110	88			
		DAY 1	21JUN2005	1	60	110	80				64	120	88			
		BASELINE			60	110	80				64	120	88			
		DAY 8	30JUN2005	10	58	128	88	-2	18	8	60	130	94	-4	10	6
		DAY 15	07JUL2005	17	60	120	80	0	10	0	64	124	84	0	4	-4
		DAY 22	15JUL2005	25	60	120	80	0	10	0	64	124	84	0	4	-4
		DAY 29	20JUL2005	30	60	120	80	0	10	0	60	120	86	-4	0	-2
		DAY 36	27JUL2005	37	66	120	82	6	10	2	60	120	80	-4	0	-8
		DAY 43	03AUG2005	44	68	110	76	8	0	-4	76	92	70	12	-28D	-18
		DAY 50	11AUG2005	52	64	130	88	4	20I	8	68	126	80	4	6	-8
		DAY 57	19AUG2005	60	64	120	86	4	10	6	68	120	88	4	0	0
		FINAL			64	120	86	4	10	6	68	120	88	4	0	0
	E0039009	SCREEN	30SEP2004	-7	74	110	70				80	110	70			
		DAY 1	07OCT2004	1	74	122	60				88	118	58			
		BASELINE			74	122	60				88	118	58			
		DAY 8	18OCT2004	12	66	130	70	-8	8	10	84	120	80	-4	2	22
		DAY 15	25OCT2004	19	68	110	50L	-6	-12	-10	84	104	68	-4	-14	10
		DAY 22	01NOV2004	26	74	118	76	0	-4	16	78	118	70	-10	0	12
		DAY 36	09NOV2004	34	78	108	60	4	-14	0	84	102	68	-4	-16	10
		DAY 43	17NOV2004	42	62	120	74	-12	-2	14	68	118	70	-20D	0	12
		FINAL			62	120	74	-12	-2	14	68	118	70	-20D	0	12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039010	SCREEN	04OCT2004	-8	64	120	80				70	118	80			
		DAY 1	12OCT2004	1	64	122	78				70	115	70			
		BASELINE			64	122	78				70	115	70			
		DAY 8	20OCT2004	9	80	128	84	16I	6	6	76	112	80	6	-3	10
		DAY 15	28OCT2004	17	72	128	80	8	6	2	78	124	90	8	9	20
		DAY 22	03NOV2004	23	66	120	84	2	-2	6	74	130	90	4	15	20
		DAY 29	10NOV2004	30	76	128	82	12	6	4	80	118	78	10	3	8
		DAY 36	17NOV2004	37	78	120	80	14	-2	2	80	118	90	10	3	20
		DAY 43	24NOV2004	44	80	124	92	16I	2	14	84	118	90	14	3	20
		DAY 50	02DEC2004	52	76	110	70	12	-12	-8	80	110	74	10	-5	4
		DAY 57	08DEC2004	58	80	126	90	16I	4	12	80	120	80	10	5	10
		FINAL			80	126	90	16I	4	12	80	120	80	10	5	10
	E0039019	SCREEN	20DEC2004	-10	60	138	72				78	142	90			
		DAY 1	30DEC2004	1	60	128	80				66	126	70			
		BASELINE			60	128	80				66	126	70			
		DAY 8	05JAN2005	7	64	128	82	4	0	2	68	126	78	2	0	8
		DAY 15	12JAN2005	14	68	118	64	8	-10	-16	78	104	56	12	-22D	-14
		DAY 22	20JAN2005	22	68	122	74	8	-6	-6	70	118	70	4	-8	0
		DAY 29	26JAN2005	28	64	126	76	4	-2	-4	72	128	78	6	2	8
		DAY 36	02FEB2005	35	60	106	64	0	-22D	-16	68	112	68	2	-14	-2
		DAY 43	09FEB2005	42	60	120	70	0	-8	-10	72	126	78	6	0	8
		DAY 50	16FEB2005	49	64	122	80	4	-6	0	70	120	82	4	-6	12
		DAY 57	23FEB2005	56	60	120	78	0	-8	-2	68	122	80	2	-4	10
		FINAL			60	120	78	0	-8	-2	68	122	80	2	-4	10
	E0039023	SCREEN	23MAR2005	-14	68	102	64				72	110	66			
		DAY 1	06APR2005	1	64	98	68				78	104	68			
		BASELINE			64	98	68				78	104	68			
		DAY 8	13APR2005	8	80	112	60	16I	14	-8	84	118	68	6	14	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			SUPINE CHANGE FROM BASELINE			STANDING			STANDING CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0039023	FINAL				80	112	60	16I	14	-8	84	118	68	6	14	0
	E0040001	SCREEN		23JUL2004	-7	67	108	76				83	103	76			
		DAY 1		30JUL2004	1	64	102	72				75	101	76			
		BASELINE				64	102	72				75	101	76			
		DAY 8		06AUG2004	8	81	106	73	17I	4	1	86	110	80	11	9	4
		DAY 15		12AUG2004	14	71	107	74	7	5	2	95	105	83	20I	4	7
		DAY 22		20AUG2004	22	76	113	82	12	11	10	90	110	77	15I	9	1
		DAY 29		27AUG2004	29	74	106	74	10	4	2	96	108	79	21I	7	3
		DAY 36		03SEP2004	36	78	110	78	14	8	6	86	109	85	11	8	9
		DAY 43		10SEP2004	43	78	116	74	14	14	2	84	118	78	9	17	2
		DAY 50		17SEP2004	50	70	110	73	6	8	1	94	123	83	19I	22I	7
		DAY 57		24SEP2004	57	77	108	79	13	6	7	97	98	81	22I	-3	5
		FINAL				77	108	79	13	6	7	97	98	81	22I	-3	5
	E0040002	SCREEN		27JUL2004	-10	78	128	85				84	130	88			
		DAY 1		06AUG2004	1	82	138	82				90	140	88			
		BASELINE				82	138	82				90	140	88			
		DAY 8		12AUG2004	7	85	146	89	3	8	7	90	148	88	0	8	0
		DAY 15		20AUG2004	15	90	145	92	8	7	10	98	150	98	8	10	10
		DAY 22		27AUG2004	22	90	128	75	8	-10	-7	115	134	86	25I	-6	-2
		DAY 29		03SEP2004	29	101	154	92	19I	16	10	107	148	102	17I	8	14
		DAY 36		10SEP2004	36	92	146	86	10	8	4	100	148	90	10	8	2
		FINAL				92	146	86	10	8	4	100	148	90	10	8	2
	E0040003	SCREEN		06AUG2004	-6	61	125	79				70	128	82			
		DAY 1		12AUG2004	1	63	112	68				80	115	70			
		BASELINE				63	112	68				80	115	70			
		DAY 15	*	24AUG2004	13	79	126	73	16I	14	5	79	122	76	-1	7	6
		DAY 15		27AUG2004	16	78	122	68	15I	10	0	86	128	72	6	13	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0040003	DAY 22	02SEP2004	22	78	120	68	15I	8	0	86	126	78	6	11	8
		DAY 29	10SEP2004	30	78	124	70	15I	12	2	82	126	74	2	11	4
		DAY 36	18SEP2004	38	88	116	80	25I	4	12	90	120	81	10	5	11
		DAY 43	24SEP2004	44	74	121	79	11	9	11	77	125	91	-3	10	21
		DAY 50	01OCT2004	51	81	122	77	18I	10	9	78	114	76	-2	-1	6
		DAY 57	08OCT2004	58	74	146	78	11	34I	10	87	120	74	7	5	4
		FINAL			74	146	78	11	34I	10	87	120	74	7	5	4
	E0040006	SCREEN	19AUG2004	-8	68	116	79				72	114	74			
		DAY 1	27AUG2004	1	71	123	70				68	126	88			
		BASELINE			71	123	70				68	126	88			
		DAY 8	02SEP2004	7	88	120	86	17I	-3	16	88	123	88	20I	-3	0
		DAY 15	10SEP2004	15	92	122	86	21I	-1	16	88	126	88	20I	0	0
		DAY 22	17SEP2004	22	73	121	85	2	-2	15	77	124	87	9	-2	-1
		DAY 29	24SEP2004	29	75	123	81	4	0	11	78	125	84	10	-1	-4
		DAY 36	01OCT2004	36	71	117	68	0	-6	-2	73	121	74	5	-5	-14
		DAY 43	08OCT2004	43	95	122	90	24I	-1	20	98	120	87	30I	-6	-1
		DAY 50	18OCT2004	53	74	112	76	3	-11	6	86	119	83	18I	-7	-5
		DAY 57	22OCT2004	57	94	116	81	23I	-7	11	100	111	80	32I	-15	-8
		FINAL			94	116	81	23I	-7	11	100	111	80	32I	-15	-8
	E0040011	SCREEN	23FEB2005	-7	88	130	85				100	140	90			
		DAY 1	02MAR2005	1	94	131	92				94	154	99			
		BASELINE			94	131	92				94	154	99			
		DAY 8	09MAR2005	8	95	130	78	1	-1	-14	129H	128	84	35I	-26D	-15
		DAY 15	16MAR2005	15	90	132	82	-4	1	-10	100	130	89	6	-24D	-10
		DAY 22	23MAR2005	22	88	109	72	-6	-22D	-20D	100	100	68	6	-54D	-31D
		DAY 29	30MAR2005	29	94	118	88	0	-13	-4	105	120	85	11	-34D	-14
		DAY 36	06APR2005	36	105	116	83	11	-15	-9	98	120	90	4	-34D	-9
		DAY 43	13APR2005	43	88	117	78	-6	-14	-14	102	115	84	8	-39D	-15

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0040011	DAY 50	20APR2005	50	90	111	81	-4	-20D	-11	105	104	90	11	-50D	-9
		DAY 57	27APR2005	57	95	116	78	1	-15	-14	109	115	88	15I	-39D	-11
		FINAL			95	116	78	1	-15	-14	109	115	88	15I	-39D	-11
	E0040017	SCREEN	18MAY2005	-7	52	101	64				69	116	73			
		DAY 1	25MAY2005	1	45L	105	61				73	102	68			
		BASELINE			45L	105	61				73	102	68			
		DAY 8	01JUN2005	8	45L	105	62	0	0	1	74	102	66	1	0	-2
		DAY 15	10JUN2005	17	97	97	68	52I	-8	7	90	107	61	17I	5	-7
		DAY 22	17JUN2005	24	66	109	57	21I	4	-4	83	106	79	10	4	11
		DAY 29	24JUN2005	31	84	101	61	39I	-4	0	93	97	68	20I	-5	0
		DAY 36	30JUN2005	37	60	93	58	15I	-12	-3	68	107	70	-5	5	2
		DAY 43	08JUL2005	45	45L	99	57	0	-6	-4	53	97	70	-20D	-5	2
		DAY 50	15JUL2005	52	83	116	86	38I	11	25	83	99	60	10	-3	-8
		DAY 57	22JUL2005	59	82	114	80	37I	9	19	76	100	64	3	-2	-4
		FINAL			82	114	80	37I	9	19	76	100	64	3	-2	-4
	E0040018	SCREEN	20MAY2005	-19	84	130	82				100	130	90			
		DAY 1	08JUN2005	1	84	130	82				100	130	90			
		BASELINE			84	130	82				100	130	90			
		DAY 8	16JUN2005	9	80	130	90	-4	0	8	80	130	80	-20D	0	-10
		DAY 15	22JUN2005	15	82	128	78	-2	-2	-4	100	130	88	0	0	-2
		DAY 22	29JUN2005	22	90	131	84	6	1	2	103	128	90	3	-2	0
		DAY 29	06JUL2005	29	88	130	82	4	0	0	104	128	90	4	-2	0
		DAY 36	12JUL2005	35	86	128	80	2	-2	-2	102	129	90	2	-1	0
		DAY 43	23JUL2005	46	88	128	80	4	-2	-2	102	126	94	2	-4	4
		DAY 50	26JUL2005	49	71	120	76	-13	-10	-6	89	120	78	-11	-10	-12
		DAY 57	03AUG2005	57	74	140	91	-10	10	9	82	145	96	-18D	15	6
		FINAL			74	140	91	-10	10	9	82	145	96	-18D	15	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0041008	SCREEN	02NOV2004	-15	80	112	68				88	118	70			
		DAY 1	17NOV2004	1	60	112	68				88	110	82			
		BASELINE			60	112	68				88	110	82			
		DAY 8	24NOV2004	8	80	108	82	20I	-4	14	88	112	88	0	2	6
		DAY 15	01DEC2004	15	88	106	78	28I	-6	10	120	116	82	32I	6	0
		DAY 22	08DEC2004	22	68	114	72	8	2	4	120	110	76	32I	0	-6
		FINAL			68	114	72	8	2	4	120	110	76	32I	0	-6
	E0041009	SCREEN	04NOV2004	-15	68	118	78				80	116	74			
		DAY 1	19NOV2004	1	68	108	76				76	106	76			
		BASELINE			68	108	76				76	106	76			
		DAY 8	24NOV2004	6	80	126	78	12	18	2	100	126	74	24I	20I	-2
		FINAL			80	126	78	12	18	2	100	126	74	24I	20I	-2
	E0042019	SCREEN	02MAR2005	-14	76	122	70				80	124	82			
		DAY 1	16MAR2005	1	76	122	76				76	120	72			
		BASELINE			76	122	76				76	120	72			
		DAY 8	24MAR2005	9	80	122	74	4	0	-2	76	120	70	0	0	-2
		DAY 15	30MAR2005	15	88	124	78	12	2	2	92	120	84	16I	0	12
		DAY 22	06APR2005	22	88	122	78	12	0	2	82	128	84	6	8	12
		DAY 29	14APR2005	30	80	126	80	4	4	4	80	126	76	4	6	4
		DAY 36	20APR2005	36	88	120	78	12	-2	2	92	120	82	16I	0	10
		DAY 43	27APR2005	43	84	118	80	8	-4	4	88	120	80	12	0	8
		DAY 50	04MAY2005	50	100	126	86	24I	4	10	100	124	80	24I	4	8
		DAY 57	12MAY2005	58	84	118	84	8	-4	8	84	118	80	8	-2	8
		FINAL			84	118	84	8	-4	8	84	118	80	8	-2	8
	E0043001	SCREEN	03AUG2004	-7	62	130	80				64	134	82			
		DAY 1	10AUG2004	1	60	120	68				60	128	84			
		BASELINE			60	120	68				60	128	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0043001	DAY 8	17AUG2004	8	60	124	64	0	4	-4	66	122	82	6	-6	-2
		DAY 15	24AUG2004	15	66	138	74	6	18	6	66	130	72	6	2	-12
		DAY 22	01SEP2004	23	76	130	78	16I	10	10	76	132	76	16I	4	-8
		DAY 29	08SEP2004	30	62	120	80	2	0	12	64	118	78	4	-10	-6
		DAY 36	15SEP2004	37	72	110	70	12	-10	2	74	118	72	14	-10	-12
		FINAL			72	110	70	12	-10	2	74	118	72	14	-10	-12
	E0044005	SCREEN	24FEB2005	-21	68	130	86				68	140	90			
		DAY 1	17MAR2005	1	68	100	76				84	114	86			
		BASELINE			68	100	76				84	114	86			
		DAY 8	22MAR2005	6	76	118	72	8	18	-4	80	114	76	-4	0	-10
		DAY 15	31MAR2005	15	80	116	84	12	16	8	88	118	90	4	4	4
		DAY 22	07APR2005	22	76	124	68	8	24I	-8	100	126	66	16I	12	-20D
		DAY 29	14APR2005	29	88	130	92	20I	30I	16	80	126	84	-4	12	-2
		DAY 36	22APR2005	37	84	118	90	16I	18	14	88	116	92	4	2	6
		DAY 43	28APR2005	43	100	150	88	32I	50I	12	80	158	104	-4	44I	18
		DAY 50	06MAY2005	51	80	116	80	12	16	4	104	114	84	20I	0	-2
		DAY 57	13MAY2005	58	80	126	76	12	26I	0	80	124	84	-4	10	-2
		FINAL			80	126	76	12	26I	0	80	124	84	-4	10	-2
	E0044006	SCREEN	18APR2005	-7	68	122	88				80	126	88			
		DAY 1	25APR2005	1	64	122	68				84	124	70			
		BASELINE			64	122	68				84	124	70			
		DAY 8	02MAY2005	8	72	122	78	8	0	10	84	122	82	0	-2	12
		DAY 15	09MAY2005	15	76	120	84	12	-2	16	92	130	92	8	6	22
		DAY 22	16MAY2005	22	84	132	78	20I	10	10	84	132	82	0	8	12
		DAY 29	23MAY2005	29	76	118	68	12	-4	0	92	128	80	8	4	10
		DAY 36	31MAY2005	37	64	118	86	0	-4	18	72	118	78	-12	-6	8
		DAY 43	06JUN2005	43	72	112	78	8	-10	10	76	118	88	-8	-6	18
		DAY 50	13JUN2005	50	76	116	78	12	-6	10	80	116	82	-4	-8	12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR I)	E0044006	DAY 57	20JUN2005	57	72	116	72	8	-6	4	72	114	68	-12	-10	-2
		FINAL			72	116	72	8	-6	4	72	114	68	-12	-10	-2
	E0046008	SCREEN	12JAN2005	-7	76	140	60				100	110	70			
		DAY 1	19JAN2005	1	72	139	79				95	125	78			
		BASELINE			72	139	79				95	125	78			
		DAY 8	25JAN2005	7	84	133	72	12	-6	-7	128H	100	67	33I	-25D	-11
		DAY 22	07FEB2005	20	76	142	71	4	3	-8	97	118	75	2	-7	-3
		DAY 29	14FEB2005	27	70	133	76	-2	-6	-3	85	134	82	-10	9	4
		DAY 36	21FEB2005	34	75	138	71	3	-1	-8	97	121	76	2	-4	-2
		DAY 43	28FEB2005	41	71	136	72	-1	-3	-7	87	135	77	-8	10	-1
		DAY 50	08MAR2005	49	78	134	74	6	-5	-5	98	119	73	3	-6	-5
		DAY 57	14MAR2005	55	69	136	80	-3	-3	1	79	124	75	-16D	-1	-3
		FINAL			69	136	80	-3	-3	1	79	124	75	-16D	-1	-3
QUETIAPINE 300 MG (BIPOLAR II)	E0004004	SCREEN	14JUL2004	-7	76	110	70				80	104	70			
		DAY 1	21JUL2004	1	78	100	70				76	98	70			
		BASELINE			78	100	70				76	98	70			
		DAY 8	29JUL2004	9	88	106	72	10	6	2	92	102	80	16I	4	10
		DAY 15	05AUG2004	16	88	104	72	10	4	2	96	98	68	20I	0	-2
		DAY 22	11AUG2004	22	88	110	78	10	10	8	96	104	82	20I	6	12
		DAY 29	18AUG2004	29	76	100	70	-2	0	0	88	102	72	12	4	2
		DAY 36	25AUG2004	36	84	106	68	6	6	-2	88	100	64	12	2	-6
		DAY 43	01SEP2004	43	80	108	70	2	8	0	88	100	72	12	2	2
		DAY 50	08SEP2004	50	90	104	74	12	4	4	88	102	78	12	4	8
		DAY 57	15SEP2004	57	80	100	68	2	0	-2	88	106	72	12	8	2
		FINAL			80	100	68	2	0	-2	88	106	72	12	8	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0004025	SCREEN	07FEB2005	-21	72	108	76				76	118	78			
		DAY 1	28FEB2005	1	80	116	80				84	112	80			
		BASELINE			80	116	80				84	112	80			
		DAY 8	07MAR2005	8	88	114	76	8	-2	-4	92	116	80	8	4	0
		DAY 15	14MAR2005	15	84	112	80	4	-4	0	90	118	86	6	6	6
		DAY 22	21MAR2005	22	94	132	72	14	16	-8	84	122	88	0	10	8
		DAY 29	28MAR2005	29	100	128	82	20I	12	2	96	122	80	12	10	0
		DAY 36	06APR2005	38	80	118	82	0	2	2	88	122	86	4	10	6
		DAY 43	14APR2005	46	80	118	82	0	2	2	86	122	84	2	10	4
		DAY 50	21APR2005	53	84	112	70	4	-4	-10	88	116	76	4	4	-4
		DAY 57	25APR2005	57	104	130	80	24I	14	0	116	138	88	32I	26I	8
		FINAL			104	130	80	24I	14	0	116	138	88	32I	26I	8
	E0006016	SCREEN	07OCT2004	-8	65	170	118H				76	168	112H			
		DAY 1	15OCT2004	1	68	140	110H				86	140	106H			
		BASELINE			68	140	110H				86	140	106H			
		DAY 8	22OCT2004	8	80	156	110H	12	16	0	92	160	124H	6	20I	18
		DAY 15	28OCT2004	14	76	138	100	8	-2	-10	82	140	98	-4	0	-8
		DAY 22	03NOV2004	20	70	138	110H	2	-2	0	80	132	108H	-6	-8	2
		DAY 29	15NOV2004	32	78	130	100	10	-10	-10	76	140	106H	-10	0	0
		DAY 43	24NOV2004	41	80	138	94	12	-2	-16	78	140	100	-8	0	-6
		DAY 57	10DEC2004	57	80	138	88	12	-2	-22D	84	136	90	-2	-4	-16
		FINAL			80	138	88	12	-2	-22D	84	136	90	-2	-4	-16
	E0008006	SCREEN	09NOV2004	-29	60	102	68				64	100	66			
		DAY 1	08DEC2004	1	72	96	64				70	100	66			
		BASELINE			72	96	64				70	100	66			
		DAY 8	15DEC2004	8	68	110	70	-4	14	6	74	116	74	4	16	8
		DAY 15	22DEC2004	15	89	119	69	17I	23I	5	98	107	83	28I	7	17

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0008006	DAY 22	28DEC2004	21	88	112	70	16I	16	6	94	102	74	24I	2	8
		DAY 29	05JAN2005	29	90	116	74	18I	20I	10	96	124	80	26I	24I	14
		DAY 36	12JAN2005	36	102	110	71	30I	14	7	67	102	86	-3	2	20
		DAY 43	19JAN2005	43	84	93	65	12	-3	1	80	105	79	10	5	13
		DAY 50	26JAN2005	50	78	118	66	6	22I	2	86	102	70	16I	2	4
		DAY 57	02FEB2005	57	80	101	68	8	5	4	88	100	68	18I	0	2
		FINAL			80	101	68	8	5	4	88	100	68	18I	0	2
	E0008007	SCREEN	12JAN2005	-7	66	105	59				70	108	74			
		DAY 1	19JAN2005	1	70	112	70				86	96	64			
		BASELINE			70	112	70				86	96	64			
		DAY 8	26JAN2005	8	72	104	66	2	-8	-4	88	70L	46L	2	-26D	-18
		FINAL			72	104	66	2	-8	-4	88	70L	46L	2	-26D	-18
	E0010007	SCREEN	02NOV2004	-6	60	120	78				64	122	76			
		DAY 1	08NOV2004	1	76	110	70				80	120	70			
		BASELINE			76	110	70				80	120	70			
		DAY 8	15NOV2004	8	60	135	80	-16D	25I	10	68	142	92	-12	22I	22
		DAY 15	22NOV2004	15	70	138	84	-6	28I	14	86	138	78	6	18	8
		DAY 22	29NOV2004	22	66	132	84	-10	22I	14	70	138	86	-10	18	16
		DAY 29	06DEC2004	29	64	128	74	-12	18	4	68	124	76	-12	4	6
		DAY 36	13DEC2004	36	66	140	80	-10	30I	10	74	134	78	-6	14	8
		DAY 43	20DEC2004	43	68	128	84	-8	18	14	74	122	78	-6	2	8
		DAY 50	28DEC2004	51	66	142	78	-10	32I	8	72	138	86	-8	18	16
		DAY 57	03JAN2005	57	64	124	78	-12	14	8	68	128	80	-12	8	10
		FINAL			64	124	78	-12	14	8	68	128	80	-12	8	10
	E0011001	SCREEN	09JUL2004	-7	76	132	76				76	134	76			
		DAY 1	16JUL2004	1	78	128	74				80	130	76			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0011001	BASELINE			78	128	74				80	130	76			
		DAY 8	26JUL2004	11	62	114	74	-16D	-14	0	66	120	80	-14	-10	4
		DAY 15	30JUL2004	15	72	116	76	-6	-12	2	76	118	74	-4	-12	-2
		DAY 22	06AUG2004	22	68	120	74	-10	-8	0	74	122	76	-6	-8	0
		DAY 29	13AUG2004	29	70	126	76	-8	-2	2	76	128	80	-4	-2	4
		DAY 36	20AUG2004	36	68	124	74	-10	-4	0	72	118	74	-8	-12	-2
		DAY 43	27AUG2004	43	70	112	72	-8	-16	-2	84	108	68	4	-22D	-8
		DAY 50	03SEP2004	50	76	108	78	-2	-20D	4	64	102	78	-16D	-28D	2
		DAY 57	10SEP2004	57	72	116	78	-6	-12	4	82	114	80	2	-16	4
		FINAL			72	116	78	-6	-12	4	82	114	80	2	-16	4
	E0011009	SCREEN	29OCT2004	-7	40L	130	70				38L	126	68			
		DAY 1	05NOV2004	1	38L	128	60				38L	126	60			
		BASELINE			38L	128	60				38L	126	60			
		DAY 8	12NOV2004	8	60	112	62	22I	-16	2	60	110	60	22I	-16	0
		DAY 15	19NOV2004	15	56	128	60	18I	0	0	60	130	62	22I	4	2
		DAY 22	24NOV2004	20	52	128	64	14	0	4	54	128	64	16I	2	4
		DAY 29	03DEC2004	29	54	126	68	16I	-2	8	52	124	64	14	-2	4
		DAY 36	10DEC2004	36	48L	118	72	10	-10	12	48L	112	62	10	-14	2
		DAY 43	17DEC2004	43	56	126	64	18I	-2	4	54	122	60	16I	-4	0
		DAY 50	27DEC2004	53	52	130	70	14	2	10	52	128	64	14	2	4
		DAY 57	30DEC2004	56	54	128	72	16I	0	12	54	126	68	16I	0	8
		FINAL			54	128	72	16I	0	12	54	126	68	16I	0	8
	E0011016	SCREEN	07DEC2004	-9	76	120	72				74	118	70			
		DAY 1	16DEC2004	1	95	108	76				96	120	80			
		BASELINE			95	108	76				96	120	80			
		DAY 8	23DEC2004	8	82	116	76	-13	8	0	82	116	72	-14	-4	-8
		DAY 15	30DEC2004	15	80	118	74	-15D	10	-2	76	116	72	-20D	-4	-8

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0011016	DAY 22	06JAN2005	22	84	124	76	-11	16	0	80	122	74	-16D	2	-6
		DAY 29	13JAN2005	29	80	120	74	-15D	12	-2	80	118	72	-16D	-2	-8
		DAY 36	20JAN2005	36	78	126	74	-17D	18	-2	78	124	72	-18D	4	-8
		DAY 43	27JAN2005	43	80	124	76	-15D	16	0	80	122	74	-16D	2	-6
		DAY 50	03FEB2005	50	78	122	74	-17D	14	-2	76	120	70	-20D	0	-10
		DAY 57	11FEB2005	58	62	114	58	-33D	6	-18	60	112	52	-36D	-8	-28D
		FINAL			62	114	58	-33D	6	-18	60	112	52	-36D	-8	-28D
	E0013003	SCREEN	02AUG2004	-7	57	130	86				62	122	70			
		DAY 1	09AUG2004	1	60	132	80				60	132	84			
		BASELINE			60	132	80				60	132	84			
		DAY 8	16AUG2004	8	64	128	84	4	-4	4	68	128	82	8	-4	-2
		DAY 15	23AUG2004	15	84	132	88	24I	0	8	92	132	92	32I	0	8
		DAY 22	30AUG2004	22	90	130	80	30I	-2	0	90	130	86	30I	-2	2
		DAY 29	07SEP2004	30	90	138	88	30I	6	8	88	140	90	28I	8	6
		DAY 36	13SEP2004	36	98	118	68	38I	-14	-12	94	120	70	34I	-12	-14
		DAY 43	20SEP2004	43	80	126	78	20I	-6	-2	84	126	80	24I	-6	-4
		DAY 50	27SEP2004	50	80	130	78	20I	-2	-2	78	128	80	18I	-4	-4
		DAY 57	04OCT2004	57	80	118	68	20I	-14	-12	80	120	68	20I	-12	-16
		FINAL			80	118	68	20I	-14	-12	80	120	68	20I	-12	-16
	E0013014	SCREEN	07FEB2005	-7	81	159	89				86	158	101			
		DAY 1	14FEB2005	1	76	157	79				82	155	87			
		BASELINE			76	157	79				82	155	87			
		DAY 8	21FEB2005	8	73	157	89	-3	0	10	77	159	102	-5	4	15
		DAY 15	28FEB2005	15	97	162	102	21I	5	23	94	149	87	12	-6	0
		DAY 22	07MAR2005	22	79	149	87	3	-8	8	79	148	85	-3	-7	-2
		DAY 29	14MAR2005	29	76	146	86	0	-11	7	81	149	89	-1	-6	2
		DAY 36	21MAR2005	36	92	142	97	16I	-15	18	92	154	99	10	-1	12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0013014	DAY 43	28MAR2005	43	76	144	84	0	-13	5	94	134	86	12	-21D	-1
		DAY 50	04APR2005	50	83	133	94	7	-24D	15	93	133	94	11	-22D	7
		DAY 57	11APR2005	57	80	132	91	4	-25D	12	89	135	90	7	-20D	3
		FINAL			80	132	91	4	-25D	12	89	135	90	7	-20D	3
	E0014005	SCREEN	16AUG2004	-14	72	140	82				76	140	84			
		DAY 1	30AUG2004	1	60	128	70				80	126	72			
		BASELINE			60	128	70				80	126	72			
		DAY 8	07SEP2004	9	72	130	80	12	2	10	80	136	80	0	10	8
		DAY 15	14SEP2004	16	68	140	100	8	12	30I	76	136	86	-4	10	14
		FINAL			68	140	100	8	12	30I	76	136	86	-4	10	14
	E0019002	SCREEN	11AUG2004	-27	80	118	78				82	115	74			
		DAY 1	07SEP2004	1	70	112	78				66	110	70			
		BASELINE			70	112	78				66	110	70			
		DAY 8	15SEP2004	9	72	112	80	2	0	2	72	106	68	6	-4	-2
		DAY 15	23SEP2004	17	66	120	78	-4	8	0	70	118	76	4	8	6
		DAY 22	29SEP2004	23	72	118	78	2	6	0	70	118	70	4	8	0
		DAY 29	06OCT2004	30	76	112	76	6	0	-2	74	110	74	8	0	4
		DAY 36	13OCT2004	37	88	118	76	18I	6	-2	82	112	70	16I	2	0
		DAY 43	19OCT2004	43	80	110	70	10	-2	-8	80	108	70	14	-2	0
		DAY 50	28OCT2004	52	88	120	78	18I	8	0	70	118	70	4	8	0
		DAY 57	03NOV2004	58	73	110	70	3	-2	-8	78	112	70	12	2	0
		FINAL			73	110	70	3	-2	-8	78	112	70	12	2	0
	E0019009	SCREEN	06JAN2005	-6	64	118	72				60	116	74			
		DAY 1	12JAN2005	1	68	128	76				72	126	80			
		BASELINE			68	128	76				72	126	80			
		DAY 8	19JAN2005	8	80	118	88	12	-10	12	80	120	86	8	-6	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0019009	DAY 15	26JAN2005	15	80	124	82	12	-4	6	76	122	86	4	-4	6
		DAY 29	07FEB2005	27	80	130	80	12	2	4	76	126	88	4	0	8
		DAY 36	16FEB2005	36	80	122	80	12	-6	4	80	120	80	8	-6	0
		DAY 43	24FEB2005	44	82	124	84	14	-4	8	86	128	82	14	2	2
		DAY 50	02MAR2005	50	80	128	82	12	0	6	86	126	86	14	0	6
		DAY 57	09MAR2005	57	84	120	82	16I	-8	6	80	124	86	8	-2	6
		FINAL			84	120	82	16I	-8	6	80	124	86	8	-2	6
	E0020009	SCREEN	15SEP2004	-13	64	110	70				80	104	80			
		DAY 1	28SEP2004	1	64	104	64				80	108	68			
		BASELINE			64	104	64				80	108	68			
		DAY 8	06OCT2004	9	64	110	64	0	6	0	80	100	78	0	-8	10
		DAY 15	13OCT2004	16	72	112	62	8	8	-2	80	100	78	0	-8	10
		DAY 22	20OCT2004	23	80	104	68	16I	0	4	88	100	72	8	-8	4
		FINAL			80	104	68	16I	0	4	88	100	72	8	-8	4
	E0020020	SCREEN	09NOV2004	-7	66	106	80				66	112	88			
		DAY 1	16NOV2004	1	70	108	70				72	112	80			
		BASELINE			70	108	70				72	112	80			
		DAY 8	23NOV2004	8	84	110	65	14	2	-5	76	100	60	4	-12	-20D
		DAY 15	30NOV2004	15	82	102	82	12	-6	12	86	108	86	14	-4	6
		DAY 22	06DEC2004	21	78	120	80	8	12	10	76	125	75	4	13	-5
		DAY 29	13DEC2004	28	74	118	70	4	10	0	84	120	70	12	8	-10
		DAY 36	20DEC2004	35	88	120	80	18I	12	10	84	120	84	12	8	4
		DAY 43	29DEC2004	44	80	110	60	10	2	-10	86	120	70	14	8	-10
		DAY 50	05JAN2005	51	88	122	60	18I	14	-10	106	122	76	34I	10	-4
		DAY 57	12JAN2005	58	74	119	82	4	11	12	92	112	84	20I	0	4
		FINAL			74	119	82	4	11	12	92	112	84	20I	0	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0020028	SCREEN	09DEC2004	-6	88	120	80				86	123	84			
		DAY 1	15DEC2004	1	100	120	80				100	120	90			
		BASELINE			100	120	80				100	120	90			
		DAY 8	22DEC2004	8	100	120	80	0	0	0	110	120	82	10	0	-8
		DAY 15	30DEC2004	16	90	130	90	-10	10	10	100	140	100	0	20I	10
		DAY 22	06JAN2005	23	88	140	96	-12	20I	16	118	142	100	18I	22I	10
		DAY 29	13JAN2005	30	94	120	90	-6	0	10	104	120	102	4	0	12
		DAY 36	20JAN2005	37	86	140	100	-14	20I	20	92	140	95	-8	20I	5
		DAY 43	27JAN2005	44	100	132	90	0	12	10	102	130	100	2	10	10
		DAY 50	03FEB2005	51	88	130	90	-12	10	10	86	130	90	-14	10	0
		DAY 57	10FEB2005	58	91	130	92	-9	10	12	100	130	98	0	10	8
		FINAL			91	130	92	-9	10	12	100	130	98	0	10	8
	E0020041	SCREEN	01MAR2005	-15	66	110	70				82	120	70			
		DAY 1	16MAR2005	1	66	110	72				82	90L	70			
		BASELINE			66	110	72				82	90L	70			
		DAY 8	23MAR2005	8	80	122	74	14	12	2	108	124	76	26I	34I	6
		DAY 15	31MAR2005	16	60	110	70	-6	0	-2	68	115	70	-14	25I	0
		DAY 22	07APR2005	23	90	100	68	24I	-10	-4	108	102	74	26I	12	4
		DAY 29	14APR2005	30	80	100	70	14	-10	-2	95	100	72	13	10	2
		DAY 36	21APR2005	37	100	110	50L	34I	0	-22D	106	120	50L	24I	30I	-20D
		DAY 43	28APR2005	44	89	100	60	23I	-10	-12	90	100	62	8	10	-8
		FINAL			89	100	60	23I	-10	-12	90	100	62	8	10	-8
	E0021019	SCREEN	14DEC2004	-16	60	112	62				72	100	64			
		DAY 1	30DEC2004	1	63	102	68				72	96	72			
		BASELINE			63	102	68				72	96	72			
		DAY 8	06JAN2005	8	63	90L	68	0	-12	0	81	112	68	9	16	-4
		DAY 15	13JAN2005	15	66	98	60	3	-4	-8	84	102	68	12	6	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0021019	DAY 22	20JAN2005	22	60	92	58	-3	-10	-10	75	94	66	3	-2	-6
		DAY 29	27JAN2005	29	63	98	64	0	-4	-4	78	106	68	6	10	-4
		DAY 43	10FEB2005	43	72	94	64	9	-8	-4	87	108	72	15I	12	0
		DAY 50	17FEB2005	50	66	102	66	3	0	-2	87	122	76	15I	26I	4
		DAY 57	24FEB2005	57	63	118	70	0	16	2	80	108	64	8	12	-8
		FINAL			63	118	70	0	16	2	80	108	64	8	12	-8
	E0025009	SCREEN	04AUG2004	-7	58	128	82				44L	126	80			
		DAY 1	11AUG2004	1	57	138	73				56	136	72			
		BASELINE			57	138	73				56	136	72			
		DAY 8	18AUG2004	8	88	136	86	31I	-2	13	86	135	86	30I	-1	14
		DAY 15	25AUG2004	15	82	138	84	25I	0	11	83	137	84	27I	1	12
		DAY 22	31AUG2004	21	63	131	87	6	-7	14	65	132	88	9	-4	16
		DAY 29	08SEP2004	29	70	128	84	13	-10	11	69	127	83	13	-9	11
		DAY 36	15SEP2004	36	64	116	82	7	-22D	9	65	117	83	9	-19	11
		DAY 43	22SEP2004	43	70	122	84	13	-16	11	68	122	82	12	-14	10
		DAY 50	29SEP2004	50	76	128	82	19I	-10	9	75	126	80	19I	-10	8
		DAY 57	06OCT2004	57	74	126	80	17I	-12	7	75	125	80	19I	-11	8
		FINAL			74	126	80	17I	-12	7	75	125	80	19I	-11	8
	E0025018	SCREEN	07SEP2004	-6	96	136	90				98	130	90			
		DAY 1	13SEP2004	1	90	130	92				92	128	90			
		BASELINE			90	130	92				92	128	90			
		DAY 8	20SEP2004	8	86	134	92	-4	4	0	86	136	90	-6	8	0
		DAY 15	27SEP2004	15	84	130	88	-6	0	-4	82	130	86	-10	2	-4
		DAY 22	04OCT2004	22	96	138	92	6	8	0	96	138	90	4	10	0
		DAY 29	11OCT2004	29	90	130	90	0	0	-2	94	128	90	2	0	0
		DAY 36	18OCT2004	36	100	128	98	10	-2	6	110	138	100	18I	10	10
		DAY 43	25OCT2004	43	90	130	90	0	0	-2	100	132	90	8	4	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0025018	DAY 50	01NOV2004	50	86	126	88	-4	-4	-4	94	130	90	2	2	0
		DAY 57	08NOV2004	57	90	130	90	0	0	-2	90	128	90	-2	0	0
		FINAL			90	130	90	0	0	-2	90	128	90	-2	0	0
	E0025027	SCREEN	02NOV2004	-7	80	104	76				84	100	78			
		DAY 1	09NOV2004	1	82	102	76				83	100	77			
		BASELINE			82	102	76				83	100	77			
		DAY 8	16NOV2004	8	84	100	76	2	-2	0	86	100	78	3	0	1
		DAY 15	23NOV2004	15	84	102	78	2	0	2	82	100	76	-1	0	-1
		DAY 22	30NOV2004	22	80	100	74	-2	-2	-2	82	100	73	-1	0	-4
		DAY 29	07DEC2004	29	77	120	72	-5	18	-4	80	118	72	-3	18	-5
		DAY 36	16DEC2004	38	80	118	72	-2	16	-4	82	116	70	-1	16	-7
		DAY 43	22DEC2004	44	84	112	70	2	10	-6	90	116	76	7	16	-1
		DAY 50	30DEC2004	52	86	113	72	4	11	-4	88	115	74	5	15	-3
		DAY 57	05JAN2005	58	66	123	74	-16D	21I	-2	64	121	71	-19D	21I	-6
		FINAL			66	123	74	-16D	21I	-2	64	121	71	-19D	21I	-6
	E0025029	SCREEN	16NOV2004	-14	61	117	68				64	101	66			
		DAY 1	30NOV2004	1	68	104	67				65	121	78			
		BASELINE			68	104	67				65	121	78			
		DAY 8	07DEC2004	8	60	120	73	-8	16	6	61	118	70	-4	-3	-8
		DAY 15	14DEC2004	15	111	106	72	43I	2	5	105	128	85	40I	7	7
		DAY 22	21DEC2004	22	80	132	88	12	28I	21	110	108	84	45I	-13	6
		DAY 36	04JAN2005	36	76	140	98	8	36I	31I	82	134	94	17I	13	16
		DAY 43	11JAN2005	43	82	110	60	14	6	-7	80	116	70	15I	-5	-8
		DAY 50	18JAN2005	50	76	124	84	8	20I	17	70	120	82	5	-1	4
		DAY 57	25JAN2005	57	79	118	82	11	14	15	76	106	80	11	-15	2
		FINAL			79	118	82	11	14	15	76	106	80	11	-15	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0025039	SCREEN		03FEB2005	-7	58	112	68				66	108	78			
		DAY 1		10FEB2005	1	64	136	68				88	138	92			
		BASELINE				64	136	68				88	138	92			
		DAY 8		18FEB2005	9	84	118	80	20I	-18	12	86	116	82	-2	-22D	-10
		DAY 15		25FEB2005	16	78	122	78	14	-14	10	78	120	76	-10	-18	-16
		DAY 22		04MAR2005	23	84	122	84	20I	-14	16	86	112	84	-2	-26D	-8
		DAY 29		11MAR2005	30	92	138	92	28I	2	24	100	128	90	12	-10	-2
		DAY 36		18MAR2005	37	94	146	76	30I	10	8	96	142	88	8	4	-4
		DAY 43		25MAR2005	44	80	120	78	16I	-16	10	82	118	76	-6	-20D	-16
		DAY 50		01APR2005	51	76	128	72	12	-8	4	96	120	78	8	-18	-14
		FINAL				76	128	72	12	-8	4	96	120	78	8	-18	-14
	E0025042	SCREEN		09FEB2005	-9	70	108	80				82	110	78			
		DAY 1		18FEB2005	1	76	106	76				80	108	82			
		BASELINE				76	106	76				80	108	82			
		DAY 8		25FEB2005	8	80	104	78	4	-2	2	78	100	80	-2	-8	-2
		DAY 15		03MAR2005	14	66	120	76	-10	14	0	84	106	72	4	-2	-10
		DAY 22		11MAR2005	22	68	118	80	-8	12	4	68	114	84	-12	6	2
		DAY 29		18MAR2005	29	74	104	74	-2	-2	-2	88	92	74	8	-16	-8
		DAY 43	*	30MAR2005	41	76	108	74	0	2	-2	76	106	74	-4	-2	-8
		DAY 43		01APR2005	43	80	102	74	4	-4	-2	88	98	70	8	-10	-12
		DAY 57	*	13APR2005	55	88	122	80	12	16	4	96	98	68	16I	-10	-14
		DAY 57		15APR2005	57	68	106	76	-8	0	0	84	94	78	4	-14	-4
		FINAL				68	106	76	-8	0	0	84	94	78	4	-14	-4
	E0026004	SCREEN		16AUG2004	-9	72	116	80				82	126	82			
		DAY 1		25AUG2004	1	72	120	79				78	110	74			
		BASELINE				72	120	79				78	110	74			
		DAY 8		01SEP2004	8	72	120	80	0	0	1	84	122	80	6	12	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0026004	DAY 22	13SEP2004	20	78	100	64	6	-20D	-15	86	106	62	8	-4	-12
		DAY 29	22SEP2004	29	74	102	78	2	-18	-1	78	100	74	0	-10	0
		DAY 36	27SEP2004	34	74	118	78	2	-2	-1	84	122	80	6	12	6
		DAY 43	06OCT2004	43	77	110	80	5	-10	1	85	106	74	7	-4	0
		DAY 50	15OCT2004	52	81	100	60	9	-20D	-19		108	66		-2	-8
		DAY 57	28OCT2004	65	73	100	70	1	-20D	-9	80	106	72	2	-4	-2
		FINAL			73	100	70	1	-20D	-9	80	106	72	2	-4	-2
	E0030008	SCREEN	16AUG2004	-3	56	129	63				80	129	85			
		DAY 1	19AUG2004	1	54	123	77				71	132	82			
		BASELINE			54	123	77				71	132	82			
		DAY 8	26AUG2004	8	72	137	82	18I	14	5	103	133	89	32I	1	7
		DAY 15	02SEP2004	15	79	115	78	25I	-8	1	123H	132	94	52I	0	12
		DAY 22	09SEP2004	22	80	106	74	26I	-17	-3	66	102	82	-5	-30D	0
		DAY 57	13OCT2004	56	64	119	81	10	-4	4	74	129	82	3	-3	0
		FINAL			64	119	81	10	-4	4	74	129	82	3	-3	0
	E0030023	SCREEN	02DEC2004	-7	81	120	75				96	132	90			
		DAY 1	09DEC2004	1	78	122	84				78	120	90			
		BASELINE			78	122	84				78	120	90			
		DAY 8	16DEC2004	8	80	134	81	2	12	-3	93	131	85	15I	11	-5
		FINAL			80	134	81	2	12	-3	93	131	85	15I	11	-5
	E0035007	SCREEN	09AUG2004	-10	60	118	84				60	104	80			
		DAY 1	19AUG2004	1	90	120	86				86	108	80			
		BASELINE			90	120	86				86	108	80			
		DAY 8	24AUG2004	6	64	110	80	-26D	-10	-6	64	104	78	-22D	-4	-2
		DAY 15	02SEP2004	15	70	124	92	-20D	4	6	76	120	90	-10	12	10
		DAY 22	09SEP2004	22	76	122	86	-14	2	0	80	112	86	-6	4	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0035007	DAY 29	16SEP2004	29	84	120	84	-6	0	-2	96	130	88	10	22I	8
		DAY 36	22SEP2004	35	92	112	86	2	-8	0	96	108	82	10	0	2
		DAY 43	28SEP2004	41	70	124	90	-20D	4	4	80	114	80	-6	6	0
		DAY 50	05OCT2004	48	76	122	82	-14	2	-4	80	120	78	-6	12	-2
		DAY 57	13OCT2004	56	74	124	86	-16D	4	0	80	120	80	-6	12	0
		FINAL			74	124	86	-16D	4	0	80	120	80	-6	12	0
	E0035016	SCREEN	24SEP2004	-11	58	90L	60				70	86L	62			
		DAY 1	05OCT2004	1	76	94	60				80	104	60			
		BASELINE			76	94	60				80	104	60			
		DAY 8	12OCT2004	8	76	98	66	0	4	6	76	100	70	-4	-4	10
		DAY 15	19OCT2004	15	64	98	68	-12	4	8	68	92	68	-12	-12	8
		DAY 22	26OCT2004	22	70	104	68	-6	10	8	80	92	68	0	-12	8
		DAY 29	01NOV2004	28	64	90L	60	-12	-4	0	68	94	68	-12	-10	8
		DAY 36	08NOV2004	35	64	90L	60	-12	-4	0	80	90L	58	0	-14	-2
		DAY 43	15NOV2004	42	60	90L	60	-16D	-4	0	60	90L	60	-20D	-14	0
		DAY 50	22NOV2004	49	80	90L	60	4	-4	0	70	96	70	-10	-8	10
		DAY 57	30NOV2004	57	64	98	60	-12	4	0	74	96	60	-6	-8	0
		FINAL			64	98	60	-12	4	0	74	96	60	-6	-8	0
	E0037008	SCREEN	06OCT2004	-6	60	140	100				68	140	102			
		DAY 1	12OCT2004	1	68	150	98				72	150	100			
		BASELINE			68	150	98				72	150	100			
		DAY 8	19OCT2004	8	68	120	88	0	-30D	-10	80	138	94	8	-12	-6
		DAY 15	26OCT2004	15	76	120	86	8	-30D	-12	84	136	96	12	-14	-4
		DAY 22	04NOV2004	24	76	120	90	8	-30D	-8	80	140	98	8	-10	-2
		DAY 29	09NOV2004	29	68	130	90	0	-20D	-8	72	140	94	0	-10	-6
		DAY 36	16NOV2004	36	68	130	90	0	-20D	-8	76	138	96	4	-12	-4
		DAY 43	23NOV2004	43	64	120	84	-4	-30D	-14	76	130	90	4	-20D	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 300 MG (BIPOLAR II)	E0037008	DAY 50	30NOV2004	50	68	120	84	0	-30D	-14	72	130	90	0	-20D	-10
		DAY 57	08DEC2004	58	72	130	86	4	-20D	-12	68	128	90	-4	-22D	-10
		FINAL			72	130	86	4	-20D	-12	68	128	90	-4	-22D	-10
	E0039018	SCREEN	16DEC2004	-26							69	122	84			
		DAY 1	11JAN2005	1	64	120	60				72	100	60			
		BASELINE			64	120	60				72	100	60			
		DAY 8	18JAN2005	8	72	110	60	8	-10	0	84	102	58	12	2	-2
		DAY 15	24JAN2005	14	64	116	66	0	-4	6	72	112	60	0	12	0
		DAY 22	02FEB2005	23	88	104	70	24I	-16	10	88	100	64	16I	0	4
		DAY 29	09FEB2005	30	76	108	68	12	-12	8	76	110	68	4	10	8
		DAY 36	17FEB2005	38	72	116	62	8	-4	2	80	108	70	8	8	10
		DAY 50	28FEB2005	49	74	118	70	10	-2	10	76	116	68	4	16	8
		DAY 57	08MAR2005	57	72	110	64	8	-10	4	76	106	62	4	6	2
		FINAL			72	110	64	8	-10	4	76	106	62	4	6	2
	E0042005	SCREEN	10AUG2004	-23	68	116	84				64	116	84			
		DAY 1	02SEP2004	1	76	106	68				68	110	76			
		BASELINE			76	106	68				68	110	76			
		DAY 8	09SEP2004	8	60	110	70	-16D	4	2	68	110	70	0	0	-6
		DAY 15	16SEP2004	15	76	110	64	0	4	-4	80	118	70	12	8	-6
		DAY 22	23SEP2004	22	84	128	70	8	22I	2	80	124	72	12	14	-4
		DAY 29	30SEP2004	29	80	146	84	4	40I	16	84	134	90	16I	24I	14
		DAY 36	07OCT2004	36	82	134	80	6	28I	12	88	128	84	20I	18	8
		DAY 43	14OCT2004	43	88	124	78	12	18	10	84	120	82	16I	10	6
		DAY 50	21OCT2004	50	98	119	72	22I	13	4	108	125	78	40I	15	2
		DAY 57	28OCT2004	57	84	124	82	8	18	14	76	120	78	8	10	2
		FINAL			84	124	82	8	18	14	76	120	78	8	10	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0001002	SCREEN		28JUL2004	-14	62	110	70				60	102	60			
		DAY 1		11AUG2004	1	72	110	62				68	114	68			
		BASELINE				72	110	62				68	114	68			
		DAY 8		16AUG2004	6	74	112	78	2	2	16	70	110	84	2	-4	16
		DAY 15		23AUG2004	13	90	120	80	18I	10	18	92	116	78	24I	2	10
		DAY 22		30AUG2004	20	84	122	80	12	12	18	84	118	82	16I	4	14
		DAY 29		08SEP2004	29	82	124	82	10	14	20	84	118	78	16I	4	10
		DAY 36		13SEP2004	34	82	118	76	10	8	14	86	108	68	18I	-6	0
		DAY 43	*	20SEP2004	41	84	132	82	12	22I	20	86	120	84	18I	6	16
		DAY 43		24SEP2004	45	94	132	82	22I	22I	20	90	126	80	22I	12	12
		FINAL				94	132	82	22I	22I	20	90	126	80	22I	12	12
	E0001009	SCREEN		03DEC2004	-4	68	110	82				68	106	66			
		DAY 1		07DEC2004	1	68	104	60				68	110	68			
		BASELINE				68	104	60				68	110	68			
		DAY 8		14DEC2004	8	66	110	80	-2	6	20	68	112	78	0	2	10
		DAY 15		21DEC2004	15	68	108	76	0	4	16	68	108	74	0	-2	6
		DAY 22		28DEC2004	22	68	112	70	0	8	10	70	116	70	2	6	2
		DAY 29		04JAN2005	29	70	122	78	2	18	18	70	124	80	2	14	12
		DAY 36		11JAN2005	36	70	114	72	2	10	12	72	110	76	4	0	8
		DAY 43		19JAN2005	44	72	130	78	4	26I	18	74	122	74	6	12	6
		DAY 50		25JAN2005	50	72	122	78	4	18	18	76	116	88	8	6	20
		DAY 57		01FEB2005	57	68	124	88	0	20I	28	72	120	80	4	10	12
		FINAL				68	124	88	0	20I	28	72	120	80	4	10	12
	E0001010	SCREEN		18JAN2005	-27	60	110	70				55	110	65			
		DAY 1		14FEB2005	1	64	110	74				66	110	80			
		BASELINE				64	110	74				66	110	80			
		DAY 8		21FEB2005	8	64	120	78	0	10	4	66	124	80	0	14	0
		DAY 15		01MAR2005	16	78	126	74	14	16	0	80	116	72	14	6	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0001010	DAY 22	08MAR2005	23	78	114	72	14	4	-2	80	120	80	14	10	0
		DAY 29	15MAR2005	30	72	120	80	8	10	6	76	128	84	10	18	4
		DAY 36	22MAR2005	37	80	116	72	16I	6	-2	78	116	74	12	6	-6
		DAY 43	29MAR2005	44	80	110	74	16I	0	0	76	120	84	10	10	4
		DAY 50	05APR2005	51	70	136	80	6	26I	6	72	130	86	6	20I	6
		DAY 57	14APR2005	60	68	124	80	4	14	6	72	116	80	6	6	0
		FINAL			68	124	80	4	14	6	72	116	80	6	6	0
	E0003011	SCREEN	21DEC2004	-10	92	139	96				98	147	102			
		DAY 1	31DEC2004	1	94	147	89				103	136	88			
		BASELINE			94	147	89				103	136	88			
		DAY 8	07JAN2005	8	103	157	99	9	10	10	109	165	105H	6	29I	17
		DAY 15	14JAN2005	15	98	136	90	4	-11	1	103	148	99	0	12	11
		DAY 22	21JAN2005	22	114	163	107H	20I	16	18	109	161	94	6	25I	6
		DAY 29	28JAN2005	29	94	151	94	0	4	5	105	148	86	2	12	-2
		DAY 36	02FEB2005	34	111	147	90	17I	0	1	107	143	90	4	7	2
		DAY 43	11FEB2005	43	101	139	84	7	-8	-5	109	151	80	6	15	-8
		DAY 50	22FEB2005	54	105	170	112H	11	23I	23	103	158	102	0	22I	14
		DAY 57	03MAR2005	63	93	120	83	-1	-27D	-6	98	134	89	-5	-2	1
		FINAL			93	120	83	-1	-27D	-6	98	134	89	-5	-2	1
	E0004009	SCREEN	09AUG2004	-7	56	128	62				64	110	68			
		DAY 1	16AUG2004	1	56	120	60				68	108	70			
		BASELINE			56	120	60				68	108	70			
		DAY 8	23AUG2004	8	60	120	62	4	0	2	72	120	70	4	12	0
		DAY 15	30AUG2004	15	72	118	66	16I	-2	6	80	120	74	12	12	4
		DAY 22	07SEP2004	23	68	118	60	12	-2	0	96	108	58	28I	0	-12
		DAY 29	13SEP2004	29	56	120	60	0	0	0	60	122	68	-8	14	-2
		DAY 36	20SEP2004	36	64	120	76	8	0	16	72	120	80	4	12	10
		FINAL			64	120	76	8	0	16	72	120	80	4	12	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0004012	SCREEN		13SEP2004	-7	48L	140	88				52	150	90			
		DAY 1		20SEP2004	1	56	140	84				52	128	80			
		BASELINE				56	140	84				52	128	80			
		DAY 8		29SEP2004	10	84	140	86	28I	0	2	64	140	88	12	12	8
		DAY 15		04OCT2004	15	64	150	92	8	10	8	68	144	90	16I	16	10
		DAY 22		11OCT2004	22	72	140	80	16I	0	-4	72	132	80	20I	4	0
		DAY 29		19OCT2004	30	56	128	82	0	-12	-2	64	120	80	12	-8	0
		DAY 36		25OCT2004	36	64	150	88	8	10	4	72	158	90	20I	30I	10
		DAY 43		01NOV2004	43	56	150	98	0	10	14	68	144	90	16I	16	10
		DAY 50		08NOV2004	50	76	138	100	20I	-2	16	80	130	98	28I	2	18
		DAY 57		17NOV2004	59	60	128	90	4	-12	6	64	140	86	12	12	6
		FINAL				60	128	90	4	-12	6	64	140	86	12	12	6
	E0004022	SCREEN		12JAN2005	-14	84	130	80				84	122	78			
		DAY 1		26JAN2005	1	88	122	80				84	112	88			
		BASELINE				88	122	80				84	112	88			
		DAY 8		02FEB2005	8	88	118	80	0	-4	0	86	122	84	2	10	-4
		DAY 15		09FEB2005	15	84	110	82	-4	-12	2	78	122	88	-6	10	0
		DAY 22		17FEB2005	23	84	120	80	-4	-2	0	88	118	86	4	6	-2
		DAY 29		23FEB2005	29	88	114	80	0	-8	0	90	110	82	6	-2	-6
		DAY 36		03MAR2005	37	80	120	78	-8	-2	-2	88	116	76	4	4	-12
		DAY 43		10MAR2005	44	90	108	68	2	-14	-12	92	106	70	8	-6	-18
		DAY 57	*	21MAR2005	55	80	128	86	-8	6	6	78	126	88	-6	14	0
		DAY 57		29MAR2005	63	84	118	84	-4	-4	4	100	122	90	16I	10	2
		FINAL				84	118	84	-4	-4	4	100	122	90	16I	10	2
	E0006014	SCREEN		01SEP2004	-6	60	112	70				64	114	72			
		DAY 1		07SEP2004	1	56	112	70				60	126	70			
		BASELINE				56	112	70				60	126	70			
		DAY 8		14SEP2004	8	60	120	72	4	8	2	66	122	80	6	-4	10

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0006014	DAY 15		21SEP2004	15	80	116	72	24I	4	2	82	119	70	22I	-7	0
		DAY 22		28SEP2004	22	64	112	78	8	0	8	80	110	74	20I	-16	4
		DAY 29		05OCT2004	29	78	112	82	22I	0	12	82	110	82	22I	-16	12
		DAY 36		12OCT2004	36	62	126	78	6	14	8	68	126	78	8	0	8
		DAY 43		19OCT2004	43	72	118	68	16I	6	-2	70	120	70	10	-6	0
		DAY 50		26OCT2004	50	74	120	80	18I	8	10	78	120	82	18I	-6	12
		DAY 57		02NOV2004	57	52	108	70	-4	-4	0	60	108	78	0	-18	8
		FINAL				52	108	70	-4	-4	0	60	108	78	0	-18	8
	E0006017	SCREEN		08OCT2004	-7	65	122	82				84	128	88			
		DAY 1		15OCT2004	1	60	116	76				74	120	80			
		BASELINE				60	116	76				74	120	80			
		DAY 8		22OCT2004	8	89	160	120H	29I	44I	44I	94	160	118H	20I	40I	38I
		DAY 15		29OCT2004	15	88	166	110H	28I	50I	34I	96	170	108H	22I	50I	28
		DAY 15	*	01NOV2004	18	86	172	106H	26I	56I	30I	102	178	118H	28I	58I	38I
		FINAL				86	172	106H	26I	56I	30I	102	178	118H	28I	58I	38I
	E0008012	SCREEN		31JAN2005	-7	80	135	88				84	138	90			
		DAY 1		07FEB2005	1	84	140	90				99	136	95			
		BASELINE				84	140	90				99	136	95			
		DAY 8		14FEB2005	8	98	152	100	14	12	10	94	146	74	-5	10	-21D
		DAY 15		21FEB2005	15	92	130	88	8	-10	-2	90	134	86	-9	-2	-9
		FINAL				92	130	88	8	-10	-2	90	134	86	-9	-2	-9
	E0010016	SCREEN		02MAY2005	-3	72	130	96				80	130	100			
		DAY 1		04MAY2005	-1	78	130	92				84	136	104			
		BASELINE				78	130	92				84	136	104			
		DAY 8		11MAY2005	7	84	128	76	6	-2	-16	80	128	84	-4	-8	-20D
		DAY 15		17MAY2005	13	105	120	88	27I	-10	-4	102	106	70	18I	-30D	-34D
		FINAL				105	120	88	27I	-10	-4	102	106	70	18I	-30D	-34D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0011023	SCREEN		02MAR2005	-6	82	138	76				80	136	76			
		DAY 1		08MAR2005	1	80	136	74				82	134	74			
		BASELINE				80	136	74				82	134	74			
		DAY 8		15MAR2005	8	94	130	80	14	-6	6	96	130	84	14	-4	10
		DAY 15		22MAR2005	15	84	140	76	4	4	2	86	138	74	4	4	0
		DAY 22		29MAR2005	22	80	136	74	0	0	0	80	134	74	-2	0	0
		DAY 29		05APR2005	29	82	138	70	2	2	-4	82	136	72	0	2	-2
		DAY 36		12APR2005	36	80	136	76	0	0	2	80	136	76	-2	2	2
		DAY 43		19APR2005	43	82	138	76	2	2	2	84	136	76	2	2	2
		DAY 50		26APR2005	50	84	136	76	4	0	2	82	136	76	0	2	2
		DAY 57		03MAY2005	57	96	138	76	16I	2	2	94	136	76	12	2	2
		FINAL				96	138	76	16I	2	2	94	136	76	12	2	2
	E0012004	SCREEN		23JUL2004	-7	76	128	88				76	130	88			
		DAY 1		30JUL2004	1	82	128	80				82	130	80			
		BASELINE				82	128	80				82	130	80			
		DAY 8		06AUG2004	8	88	148	80	6	20I	0	80	146	92	-2	16	12
		DAY 15		13AUG2004	15	80	144	82	-2	16	2	80	142	88	-2	12	8
		DAY 22		20AUG2004	22	80	136	68	-2	8	-12	80	134	68	-2	4	-12
		DAY 29		27AUG2004	29	84	140	84	2	12	4	88	140	84	6	10	4
		DAY 36		03SEP2004	36	80	144	90	-2	16	10	80	138	86	-2	8	6
		FINAL				80	144	90	-2	16	10	80	138	86	-2	8	6
	E0013008	SCREEN		27OCT2004	-15	62	122	86				60	118	78			
		DAY 1		11NOV2004	1	64	122	72				62	120	76			
		BASELINE				64	122	72				62	120	76			
		DAY 8		17NOV2004	7	60	118	70	-4	-4	-2	64	122	74	2	2	-2
		DAY 8	*	22NOV2004	12	68	127	93	4	5	21	70	127	95	8	7	19
		DAY 15		29NOV2004	19	91	135	88	27I	13	16	99	125	95	37I	5	19
		DAY 29		08DEC2004	28	95	123	83	31I	1	11	95	121	90	33I	1	14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0013008	DAY 36		16DEC2004	36	90	117	86	26I	-5	14	82	131	94	20I	11	18
		DAY 36	*	20DEC2004	40	80	126	94	16I	4	22	80	133	96	18I	13	20
		DAY 50		29DEC2004	49	76	138	88	12	16	16	88	132	92	26I	12	16
		DAY 50	*	03JAN2005	54	98	142	105H	34I	20I	33I	111	142	97	49I	22I	21
		FINAL				98	142	105H	34I	20I	33I	111	142	97	49I	22I	21
	E0013012	SCREEN		17JAN2005	-7	57	131	78				56	133	76			
		DAY 1		24JAN2005	1	76	140	79				72	128	78			
		BASELINE				76	140	79				72	128	78			
		DAY 8		31JAN2005	8	80	138	76	4	-2	-3	81	121	82	9	-7	4
		DAY 15		09FEB2005	17	68	117	79	-8	-23D	0	83	115	77	11	-13	-1
		DAY 22		14FEB2005	22	72	118	82	-4	-22D	3	81	110	79	9	-18	1
		DAY 29		21FEB2005	29	68	137	86	-8	-3	7	68	130	94	-4	2	16
		DAY 36		28FEB2005	36	73	127	95	-3	-13	16	71	125	85	-1	-3	7
		DAY 43		07MAR2005	43	72	131	90	-4	-9	11	81	124	86	9	-4	8
		DAY 50		16MAR2005	52	66	129	78	-10	-11	-1	82	125	88	10	-3	10
		DAY 57		21MAR2005	57	69	123	79	-7	-17	0	81	115	82	9	-13	4
		FINAL				69	123	79	-7	-17	0	81	115	82	9	-13	4
	E0013013	SCREEN		17JAN2005	-14	70	147	102				83	148	108H			
		DAY 1		31JAN2005	1	70	132	87				71	133	100			
		BASELINE				70	132	87				71	133	100			
		DAY 8		07FEB2005	8	76	127	92	6	-5	5	82	164	103	11	31I	3
		DAY 15		16FEB2005	17	88	130	95	18I	-2	8	83	122	108H	12	-11	8
		DAY 22		21FEB2005	22	73	136	104	3	4	17	85	134	106H	14	1	6
		FINAL				73	136	104	3	4	17	85	134	106H	14	1	6
	E0014011	SCREEN		09FEB2005	-8	75	135	90				84	130	93			
		DAY 1		17FEB2005	1	92	138	94				92	128	94			
		BASELINE				92	138	94				92	128	94			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0014011	DAY 8	24FEB2005	8	96	135	94	4	-3	0	88	127	95	-4	-1	1
		DAY 15	03MAR2005	15	106	130	86	14	-8	-8	112	119	90	20I	-9	-4
		DAY 22	10MAR2005	22	90	130	91	-2	-8	-3	104	124	93	12	-4	-1
		DAY 29	17MAR2005	29	90	137	94	-2	-1	0	100	130	95	8	2	1
		DAY 36	23MAR2005	35	96	126	85	4	-12	-9	102	129	88	10	1	-6
		DAY 43	01APR2005	44	88	125	88	-4	-13	-6	96	127	91	4	-1	-3
		DAY 50	07APR2005	50	90	130	88	-2	-8	-6	94	133	92	2	5	-2
		DAY 57	13APR2005	56	92	132	91	0	-6	-3	97	135	94	5	7	0
		FINAL			92	132	91	0	-6	-3	97	135	94	5	7	0
	E0014023	SCREEN	16JUN2005	-7	68	98	78				70	100	81			
		DAY 1	23JUN2005	1	66	99	76				72	102	78			
		BASELINE			66	99	76				72	102	78			
		DAY 8	30JUN2005	8	67	97	75	1	-2	-1	73	100	78	1	-2	0
		DAY 15	07JUL2005	15	70	98	77	4	-1	1	75	101	77	3	-1	-1
		DAY 22	13JUL2005	21	68	98	78	2	-1	2	80	102	80	8	0	2
		DAY 29	22JUL2005	30	76	100	82	10	1	6	78	104	86	6	2	8
		DAY 36	26JUL2005	34	72	102	78	6	3	2	82	102	82	10	0	4
		DAY 43	03AUG2005	42	82	100	79	16I	1	3	84	103	83	12	1	5
		FINAL			82	100	79	16I	1	3	84	103	83	12	1	5
	E0015005	SCREEN	20SEP2004	-7	84	102	80				86	96	74			
		DAY 1	27SEP2004	1	67	100	70				88	98	88			
		BASELINE			67	100	70				88	98	88			
		DAY 8	05OCT2004	9	76	122	84	9	22I	14	86	112	80	-2	14	-8
		DAY 15	11OCT2004	15	60	100	70	-7	0	0	68	98	70	-20D	0	-18
		FINAL			60	100	70	-7	0	0	68	98	70	-20D	0	-18
	E0015006	SCREEN	28SEP2004	-6	76	122	88				80	130	90			
		DAY 1	04OCT2004	1	72	130	80				78	118	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0015006	BASELINE				72	130	80				78	118	80			
		DAY 8		11OCT2004	8	70	128	82	-2	-2	2	82	120	80	4	2	0
		DAY 15		18OCT2004	15	88	130	86	16I	0	6	92	112	86	14	-6	6
		DAY 22		25OCT2004	22	70	132	80	-2	2	0	76	126	82	-2	8	2
		FINAL				70	132	80	-2	2	0	76	126	82	-2	8	2
	E0015012	SCREEN		19JAN2005	-9	74	104	80				80	102	76			
		DAY 1		28JAN2005	1	60	118	72				80	106	88			
		BASELINE				60	118	72				80	106	88			
		DAY 8		03FEB2005	7	84	120	70	24I	2	-2	88	114	72	8	8	-16
		DAY 15		14FEB2005	18	88	110	82	28I	-8	10	86	112	84	6	6	-4
		DAY 22		18FEB2005	22	78	116	70	18I	-2	-2	86	122	82	6	16	-6
		DAY 22	*	22FEB2005	26	82	108	88	22I	-10	16	86	118	88	6	12	0
		DAY 36		02MAR2005	34	82	124	88	22I	6	16	88	108	88	8	2	0
		DAY 50		21MAR2005	53	62	112	70	2	-6	-2	66	108	74	-14	2	-14
		FINAL				62	112	70	2	-6	-2	66	108	74	-14	2	-14
	E0015020	SCREEN		28APR2005	-7	80	138	92				82	128	86			
		DAY 1		05MAY2005	1	70	122	84				72	130	90			
		BASELINE				70	122	84				72	130	90			
		DAY 8		12MAY2005	8	74	136	86	4	14	2	72	140	86	0	10	-4
		DAY 15		19MAY2005	15	76	130	90	6	8	6	70	136	94	-2	6	4
		DAY 22		24MAY2005	20	78	134	88	8	12	4	80	130	86	8	0	-4
		DAY 29		02JUN2005	29	76	136	82	6	14	-2	76	134	86	4	4	-4
		DAY 36		09JUN2005	36	76	134	80	6	12	-4	78	132	82	6	2	-8
		DAY 43		15JUN2005	42	74	146	80	4	24I	-4	76	140	82	4	10	-8
		DAY 50		22JUN2005	49	74	130	80	4	8	-4	78	132	82	6	2	-8
		DAY 57		29JUN2005	56	76	140	88	6	18	4	72	136	90	0	6	0
		FINAL				76	140	88	6	18	4	72	136	90	0	6	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020005	SCREEN		18AUG2004	-28	48L	120	60				48L	120	50L			
		DAY 1		15SEP2004	1	56	112	58				60	110	60			
		BASELINE				56	112	58				60	110	60			
		DAY 8		22SEP2004	8	60	118	70	4	6	12	56	120	60	-4	10	0
		DAY 22	*	04OCT2004	20	60	120	60	4	8	2	60	116	60	0	6	0
		DAY 22		07OCT2004	23	64	126	60	8	14	2	72	120	70	12	10	10
		DAY 29		14OCT2004	30	64	116	60	8	4	2	72	120	70	12	10	10
		DAY 36		21OCT2004	37	60	110	70	4	-2	12	72	110	60	12	0	0
		DAY 43		28OCT2004	44	72	120	76	16I	8	18	80	110	70	20I	0	10
		DAY 50		04NOV2004	51	72	120	75	16I	8	17	84	125	80	24I	15	20
		DAY 57		11NOV2004	58	60	110	80	4	-2	22	66	124	70	6	14	10
		FINAL				60	110	80	4	-2	22	66	124	70	6	14	10
	E0020032	SCREEN		29DEC2004	-12	80	140	80				100	140	84			
		DAY 1		10JAN2005	1	82	120	80				90	130	110H			
		BASELINE				82	120	80				90	130	110H			
		DAY 8		17JAN2005	8	102	120	80	20I	0	0	102	130	100	12	0	-10
		DAY 15		24JAN2005	15	80	125	75	-2	5	-5	84	120	80	-6	-10	-30D
		DAY 22		31JAN2005	22	86	110	70	4	-10	-10	88	110	75	-2	-20D	-35D
		DAY 29		07FEB2005	29	88	125	85	6	5	5	86	120	85	-4	-10	-25D
		FINAL				88	125	85	6	5	5	86	120	85	-4	-10	-25D
	E0020037	SCREEN		01FEB2005	-7	48L	110	62				60	110	74			
		DAY 1		08FEB2005	1	51	100	74				51	100	72			
		BASELINE				51	100	74				51	100	72			
		DAY 8		14FEB2005	7	62	109	70	11	9	-4	74	120	60	23I	20I	-12
		FINAL				62	109	70	11	9	-4	74	120	60	23I	20I	-12
	E0020046	SCREEN		20APR2005	-7	66	120	80				62	118	82			
		DAY 1		27APR2005	1	52	120	84				60	120	94			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0020046	BASELINE			52	120	84				60	120	94			
		DAY 8	04MAY2005	8	74	126	88	22I	6	4	78	132	84	18I	12	-10
		FINAL			74	126	88	22I	6	4	78	132	84	18I	12	-10
	E0020048	SCREEN	09JUN2005	-5	66	119	86				70	120	90			
		DAY 1	14JUN2005	1	70	120	80				80	126	90			
		BASELINE			70	120	80				80	126	90			
		DAY 8	21JUN2005	8	80	128	78	10	8	-2	82	122	84	2	-4	-6
		DAY 15	28JUN2005	15	76	122	72	6	2	-8	104	138	90	24I	12	0
		DAY 22	05JUL2005	22	70	118	76	0	-2	-4	84	119	90	4	-7	0
		DAY 29	12JUL2005	29	80	114	88	10	-6	8	84	128	90	4	2	0
		DAY 36	19JUL2005	36	70	130	90	0	10	10	84	120	88	4	-6	-2
		DAY 43	26JUL2005	43	78	129	84	8	9	4	98	129	100	18I	3	10
		DAY 50	02AUG2005	50	78	132	90	8	12	10	88	134	88	8	8	-2
		DAY 57	09AUG2005	57	76	120	88	6	0	8	86	128	94	6	2	4
		FINAL			76	120	88	6	0	8	86	128	94	6	2	4
	E0021003	SCREEN	26JUL2004	-10	58	116	68				64	118	68			
		DAY 1	05AUG2004	1	56	120	70				66	120	72			
		BASELINE			56	120	70				66	120	72			
		DAY 8	16AUG2004	12	70	118	74	14	-2	4	68	118	78	2	-2	6
		DAY 15	19AUG2004	15	75	112	66	19I	-8	-4	78	114	78	12	-6	6
		DAY 22	25AUG2004	21	66	102	66	10	-18	-4	87	116	84	21I	-4	12
		DAY 29	01SEP2004	28	66	110	70	10	-10	0	81	114	80	15I	-6	8
		DAY 36	08SEP2004	35	69	116	78	13	-4	8	63	116	78	-3	-4	6
		DAY 43	14SEP2004	41	69	112	76	13	-8	6	88	120	78	22I	0	6
		DAY 50	23SEP2004	50	80	116	66	24I	-4	-4	99	108	80	33I	-12	8
		DAY 57	29SEP2004	56	75	118	58	19I	-2	-12	96	110	82	30I	-10	10
		FINAL			75	118	58	19I	-2	-12	96	110	82	30I	-10	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0021005	SCREEN	10AUG2004	-9	66	116	72				72	126	88			
		DAY 1	19AUG2004	1	64	122	74				76	124	84			
		BASELINE			64	122	74				76	124	84			
		DAY 8	26AUG2004	8	75	110	82	11	-12	8	78	122	86	2	-2	2
		DAY 15	02SEP2004	15	72	112	88	8	-10	14	87	116	90	11	-8	6
		DAY 22	09SEP2004	22	81	118	86	17I	-4	12	90	122	90	14	-2	6
		DAY 29	16SEP2004	29	72	126	94	8	4	20	84	126	96	8	2	12
		FINAL			72	126	94	8	4	20	84	126	96	8	2	12
	E0021029	SCREEN	30MAR2005	-7	72	132	90				90	124	92			
		DAY 1	06APR2005	1	69	116	72				72	112	88			
		BASELINE			69	116	72				72	112	88			
		DAY 8	13APR2005	8	98	112	74	29I	-4	2	104	108	84	32I	-4	-4
		DAY 15	21APR2005	16	86	124	88	17I	8	16	105	110	96	33I	-2	8
		DAY 22	28APR2005	23	87	128	74	18I	12	2	93	116	94	21I	4	6
		DAY 29	05MAY2005	30	94	126	82	25I	10	10	110	100	70	38I	-12	-18
		DAY 36	11MAY2005	36	92	106	80	23I	-10	8	103	124	84	31I	12	-4
		DAY 43	19MAY2005	44	94	114	84	25I	-2	12	108	110	96	36I	-2	8
		DAY 50	26MAY2005	51	104	120	94	35I	4	22	120	138	104	48I	26I	16
		DAY 57	03JUN2005	59	96	126	82	27I	10	10	102	126	94	30I	14	6
		FINAL			96	126	82	27I	10	10	102	126	94	30I	14	6
	E0021032	SCREEN	18APR2005	-7	40L	122	84				54	126	84			
		DAY 1	25APR2005	1	48L	102	66				58	104	68			
		BASELINE			48L	102	66				58	104	68			
		DAY 8	04MAY2005	10	57	94	60	9	-8	-6	81	94	72	23I	-10	4
		DAY 15	09MAY2005	15	54	92	60	6	-10	-6	69	108	78	11	4	10
		DAY 22	16MAY2005	22	51	94	62	3	-8	-4	72	106	76	14	2	8
		DAY 29	23MAY2005	29	57	96	68	9	-6	2	78	106	84	20I	2	16
		DAY 36	01JUN2005	38	54	100	62	6	-2	-4	72	98	78	14	-6	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0021032	DAY 43	06JUN2005	43	56	102	64	8	0	-2	66	108	84	8	4	16
		FINAL			56	102	64	8	0	-2	66	108	84	8	4	16
	E0021033	SCREEN	25APR2005	-8	54	122	76				60	118	78			
		DAY 1	03MAY2005	1	54	116	78				54	106	68			
		BASELINE			54	116	78				54	106	68			
		DAY 8	10MAY2005	8	74	112	74	20I	-4	-4	76	108	88	22I	2	20
		DAY 15	17MAY2005	15	77	118	79	23I	2	1	80	130	82	26I	24I	14
		DAY 22	24MAY2005	22	72	134	84	18I	18	6	78	118	88	24I	12	20
		DAY 29	02JUN2005	31	69	112	76	15I	-4	-2	72	126	88	18I	20I	20
		DAY 36	08JUN2005	37	77	120	68	23I	4	-10	77	124	80	23I	18	12
		DAY 43	13JUN2005	42	81	126	76	27I	10	-2	76	126	74	22I	20I	6
		DAY 50	20JUN2005	49	75	114	70	21I	-2	-8	75	118	80	21I	12	12
		DAY 57	29JUN2005	58	70	124	74	16I	8	-4	79	126	72	25I	20I	4
		FINAL			70	124	74	16I	8	-4	79	126	72	25I	20I	4
	E0025024	SCREEN	05OCT2004	-13	69	92	64				71	94	62			
		DAY 1	18OCT2004	1	70	96	66				73	96	60			
		BASELINE			70	96	66				73	96	60			
		DAY 8	25OCT2004	8	72	100	72	2	4	6	74	98	70	1	2	10
		DAY 15	01NOV2004	15	94	115	82	24I	19	16	95	120	86	22I	24I	26
		DAY 22	08NOV2004	22	73	124	77	3	28I	11	92	116	72	19I	20I	12
		DAY 29	15NOV2004	29	91	127	67	21I	31I	1	86	127	74	13	31I	14
		DAY 36	22NOV2004	36	88	128	72	18I	32I	6	89	129	74	16I	33I	14
		DAY 43	29NOV2004	43	82	120	80	12	24I	14	84	119	80	11	23I	20
		DAY 50	06DEC2004	50	72	109	72	2	13	6	74	108	70	1	12	10
		DAY 57	13DEC2004	57	70	100	70	0	4	4	74	100	66	1	4	6
		FINAL			70	100	70	0	4	4	74	100	66	1	4	6
	E0025053	SCREEN	24MAR2005	-26	72	130	80				80	132	92			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0025053	DAY 1	19APR2005	1	88	122	68				92	118	70			
		BASELINE			88	122	68				92	118	70			
		DAY 15	05MAY2005	17	96	114	78	8	-8	10	104	120	96	12	2	26
		DAY 22	12MAY2005	24	88	124	70	0	2	2	90	122	72	-2	4	2
		DAY 29	18MAY2005	30	88	138	78	0	16	10	92	130	80	0	12	10
		DAY 36	24MAY2005	36	81	128	75	-7	6	7	92	122	86	0	4	16
		DAY 43	02JUN2005	45	76	122	72	-12	0	4	80	118	78	-12	0	8
		DAY 50	08JUN2005	51	80	118	78	-8	-4	10	84	118	84	-8	0	14
		DAY 57	15JUN2005	58	86	119	74	-2	-3	6	98	139	85	6	21I	15
		FINAL			86	119	74	-2	-3	6	98	139	85	6	21I	15
	E0025054	SCREEN	31MAR2005	-5	72	166	101				74	167	102			
		DAY 1	05APR2005	1	76	161	98				78	158	97			
		BASELINE			76	161	98				78	158	97			
		DAY 8	15APR2005	11	80	160	97	4	-1	-1	77	158	97	-1	0	0
		DAY 22	26APR2005	22	96	148	104	20I	-13	6	98	148	108H	20I	-10	11
		FINAL			96	148	104	20I	-13	6	98	148	108H	20I	-10	11
	E0025056	SCREEN	26APR2005	-16	92	122	88				110	120	84			
		DAY 1	12MAY2005	1	88	102	82				90	100	82			
		BASELINE			88	102	82				90	100	82			
		DAY 8	17MAY2005	6	72	108	86	-16D	6	4	88	104	88	-2	4	6
		DAY 15	24MAY2005	13	83	117	74	-5	15	-8	58	121	83	-32D	21I	1
		DAY 22	31MAY2005	20	82	104	75	-6	2	-7	106	102	78	16I	2	-4
		DAY 29	07JUN2005	27	74	139	92	-14	37I	10	91	109	64	1	9	-18
		FINAL			74	139	92	-14	37I	10	91	109	64	1	9	-18
	E0025057	SCREEN	26APR2005	-6	68	138	88				72	144	88			
		DAY 1	02MAY2005	1	68	132	68				84	122	84			
		BASELINE			68	132	68				84	122	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0025057	DAY 8	10MAY2005	9	68	138	72	0	6	4	88	128	86	4	6	2
		DAY 15	17MAY2005	16	72	144	74	4	12	6	88	132	86	4	10	2
		DAY 22	24MAY2005	23	85	129	82	17I	-3	14	87	124	84	3	2	0
		DAY 29	31MAY2005	30	78	125	83	10	-7	15	80	126	86	-4	4	2
		DAY 36	07JUN2005	37	76	125	75	8	-7	7	78	127	87	-6	5	3
		DAY 43	13JUN2005	43	86	125	74	18I	-7	6	92	130	89	8	8	5
		DAY 50	21JUN2005	51	84	127	79	16I	-5	11	82	132	86	-2	10	2
		DAY 57	27JUN2005	57	64	125	77	-4	-7	9	81	127	92	-3	5	8
		FINAL			64	125	77	-4	-7	9	81	127	92	-3	5	8
	E0025060	SCREEN	04MAY2005	-15	59	140	96				62	138	94			
		DAY 1	19MAY2005	1	64	142	94				62	140	92			
		BASELINE			64	142	94				62	140	92			
		DAY 8	25MAY2005	7	62	148	98	-2	6	4	64	148	96	2	8	4
		DAY 15	01JUN2005	14	80	138	78	16I	-4	-16	88	132	88	26I	-8	-4
		DAY 22	08JUN2005	21	80	132	82	16I	-10	-12	82	122	84	20I	-18	-8
		DAY 29	15JUN2005	28	80	120	80	16I	-22D	-14	88	118	88	26I	-22D	-4
		DAY 36	22JUN2005	35	84	128	80	20I	-14	-14	88	126	88	26I	-14	-4
		DAY 50	06JUL2005	49	69	126	84	5	-16	-10	84	121	78	22I	-19	-14
		DAY 57	15JUL2005	58	56	117	72	-8	-25D	-22D	72	125	77	10	-15	-15
		FINAL			56	117	72	-8	-25D	-22D	72	125	77	10	-15	-15
	E0025061	SCREEN	12MAY2005	-12	94	124	84				92	120	80			
		DAY 1	24MAY2005	1	92	125	74				102	157	101			
		BASELINE			92	125	74				102	157	101			
		DAY 8	02JUN2005	10	86	130	78	-6	5	4	92	138	84	-10	-19	-17
		DAY 22	15JUN2005	23	95	129	83	3	4	9	94	134	86	-8	-23D	-15
		DAY 36	29JUN2005	37	84	132	78	-8	7	4	86	140	88	-16D	-17	-13
		DAY 43	06JUL2005	44	89	110	66	-3	-15	-8	99	116	82	-3	-41D	-19
		DAY 50	12JUL2005	50	92	118	76	0	-7	2	92	108	84	-10	-49D	-17

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0025061	DAY 57		20JUL2005	58	84	124	68	-8	-1	-6	88	124	70	-14	-33D	-31D
		FINAL				84	124	68	-8	-1	-6	88	124	70	-14	-33D	-31D
	E0026011	SCREEN		03NOV2004	-5	84	110	80				88	106	74			
		DAY 1		08NOV2004	1	73	120	74				84	112	78			
		BASELINE				73	120	74				84	112	78			
		DAY 8		15NOV2004	8	78	130	80	5	10	6	83	126	78	-1	14	0
		DAY 15		22NOV2004	15	75	134	82	2	14	8	84	128	80	0	16	2
		DAY 22		30NOV2004	23	77	130	80	4	10	6	85	134	82	1	22I	4
		DAY 29		06DEC2004	29	78	132	80	5	12	6	84	130	80	0	18	2
		DAY 36		13DEC2004	36	75	130	80	2	10	6	82	126	78	-2	14	0
		DAY 43		22DEC2004	45	79	132	80	6	12	6	86	136	86	2	24I	8
		DAY 57	*	04JAN2005	58	72	122	80	-1	2	6	79	126	82	-5	14	4
		DAY 57		10JAN2005	64	74	124	80	1	4	6	82	128	80	-2	16	2
		FINAL				74	124	80	1	4	6	82	128	80	-2	16	2
	E0027008	SCREEN		02AUG2004	-4	62	110	75				64	112	76			
		DAY 1		06AUG2004	1	64	110	78				66	115	78			
		BASELINE				64	110	78				66	115	78			
		DAY 8		12AUG2004	7	66	120	80	2	10	2	68	122	82	2	7	4
		DAY 15		19AUG2004	14	64	118	78	0	8	0	66	120	80	0	5	2
		DAY 22		26AUG2004	21	66	122	82	2	12	4	68	124	82	2	9	4
		DAY 29		03SEP2004	29	66	120	80	2	10	2	68	122	82	2	7	4
		DAY 36		09SEP2004	35	64	118	82	0	8	4	66	120	84	0	5	6
		DAY 43		16SEP2004	42	62	115	78	-2	5	0	64	118	80	-2	3	2
		DAY 50		23SEP2004	49	68	134	84	4	24I	6	70	135	84	4	20I	6
		DAY 57		01OCT2004	57	66	130	85	2	20I	7	68	132	86	2	17	8
		FINAL				66	130	85	2	20I	7	68	132	86	2	17	8
	E0028001	SCREEN		08JUL2004	-7	72	100	70				84	100	74			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028001	DAY 1	15JUL2004	1	76	100	70				84	110	80			
		BASELINE			76	100	70				84	110	80			
		DAY 8	20JUL2004	6	92	100	70	16I	0	0	96	102	70	12	-8	-10
		DAY 15	29JUL2004	15	84	100	70	8	0	0	88	110	70	4	0	-10
		DAY 22	04AUG2004	21	84	120	80	8	20I	10	88	110	70	4	0	-10
		DAY 29	11AUG2004	28	80	100	60	4	0	-10	84	100	70	0	-10	-10
		DAY 36	18AUG2004	35	84	110	70	8	10	0	88	120	82	4	10	2
		DAY 43	25AUG2004	42	84	100	70	8	0	0	88	110	70	4	0	-10
		DAY 50	01SEP2004	49	76	100	68	0	0	-2	88	100	70	4	-10	-10
		DAY 57	08SEP2004	56	76	100	70	0	0	0	84	100	74	0	-10	-6
		FINAL			76	100	70	0	0	0	84	100	74	0	-10	-6
	E0028002	SCREEN	08JUL2004	-33	68	100	70				72	110	60			
		DAY 1	10AUG2004	1	80	110	70				84	100	80			
		BASELINE			80	110	70				84	100	80			
		DAY 8	17AUG2004	8	80	120	70	0	10	0	84	110	80	0	10	0
		DAY 15	24AUG2004	15	88	110	70	8	0	0	92	110	80	8	10	0
		DAY 22	31AUG2004	22	88	110	80	8	0	10	92	110	82	8	10	2
		DAY 29	07SEP2004	29	84	110	70	4	0	0	84	110	80	0	10	0
		DAY 36	15SEP2004	37	80	100	80	0	-10	10	88	110	80	4	10	0
		DAY 43	22SEP2004	44	80	110	70	0	0	0	88	110	80	4	10	0
		DAY 50	28SEP2004	50	84	120	80	4	10	10	84	120	70	0	20I	-10
		FINAL			84	120	80	4	10	10	84	120	70	0	20I	-10
	E0028004	SCREEN	14JUL2004	-5	80	110	90				80	120	90			
		DAY 1	19JUL2004	1	84	120	90				88	130	80			
		BASELINE			84	120	90				88	130	80			
		DAY 8	26JUL2004	8	88	122	80	4	2	-10	92	122	90	4	-8	10
		DAY 15	02AUG2004	15	88	110	80	4	-10	-10	88	110	74	0	-20D	-6
		DAY 22	09AUG2004	22	84	110	90	0	-10	0	92	120	90	4	-10	10

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT103.SAS
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028004	FINAL			84	110	90	0	-10	0	92	120	90	4	-10	10
	E0028008	SCREEN	05NOV2004	-5	84	110	70				92	110	60			
		DAY 1	10NOV2004	1	88	120	60				92	110	70			
		BASELINE			88	120	60				92	110	70			
		DAY 8	17NOV2004	8	80	110	80	-8	-10	20	92	110	80	0	0	10
		DAY 15	22NOV2004	13	80	110	68	-8	-10	8	96	118	60	4	8	-10
		DAY 22	30NOV2004	21	76	120	70	-12	0	10	84	122	68	-8	12	-2
		DAY 29	08DEC2004	29	76	110	70	-12	-10	10	84	110	70	-8	0	0
		DAY 36	15DEC2004	36	96	110	60	8	-10	0	100	120	60	8	10	-10
		DAY 43	22DEC2004	43	88	120	70	0	0	10	96	124	68	4	14	-2
		DAY 50	28DEC2004	49	88	100	70	0	-20D	10	96	110	70	4	0	0
		DAY 57	05JAN2005	57	88	100	60	0	-20D	0	100	110	68	8	0	-2
		FINAL			88	100	60	0	-20D	0	100	110	68	8	0	-2
	E0028009	SCREEN	18NOV2004	-11	88	110	80				100	120	70			
		DAY 1	29NOV2004	1	96	100	70				100	110	70			
		BASELINE			96	100	70				100	110	70			
		DAY 8	06DEC2004	8	108	104	80	12	4	10	112	102	84	12	-8	14
		DAY 15	16DEC2004	18	88	98	68	-8	-2	-2	104	100	66	4	-10	-4
		DAY 22	20DEC2004	22	104	90L	70	8	-10	0	108	100	60	8	-10	-10
		DAY 29	27DEC2004	29	102	98	62	6	-2	-8	106	98	70	6	-12	0
		DAY 36	03JAN2005	36	88	100	70	-8	0	0	96	100	70	-4	-10	0
		DAY 43	10JAN2005	43	88	90L	60	-8	-10	-10	96	80L	60	-4	-30D	-10
		DAY 50	17JAN2005	50	96	90L	70	0	-10	0	100	90L	60	0	-20D	-10
		DAY 57	24JAN2005	57	100	100	70	4	0	0	104	100	70	4	-10	0
		FINAL			100	100	70	4	0	0	104	100	70	4	-10	0
	E0028013	SCREEN	15FEB2005	-6	80	100	60				92	100	70			
		DAY 1	21FEB2005	1	84	100	70				92	100	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0028013	BASELINE			84	100	70				92	100	80			
		DAY 8	28FEB2005	8	88	110	70	4	10	0	96	120	78	4	20I	-2
		DAY 15	08MAR2005	16	88	100	70	4	0	0	96	104	80	4	4	0
		DAY 22	14MAR2005	22	104	110	70	20I	10	0	108	120	80	16I	20I	0
		DAY 29	21MAR2005	29	92	100	60	8	0	-10	100	100	80	8	0	0
		DAY 57	20APR2005	59	108	100	70	24I	0	0	112	110	80	20I	10	0
		FINAL			108	100	70	24I	0	0	112	110	80	20I	10	0
	E0028016	SCREEN	24FEB2005	-7	72	110	80				76	110	80			
		DAY 1	03MAR2005	1	84	110	90				84	120	80			
		BASELINE			84	110	90				84	120	80			
		DAY 8	10MAR2005	8	80	110	70	-4	0	-20D	88	110	80	4	-10	0
		DAY 15	17MAR2005	15	72	100	70	-12	-10	-20D	80	90L	70	-4	-30D	-10
		DAY 22	24MAR2005	22	76	110	70	-8	0	-20D	92	114	80	8	-6	0
		DAY 29	31MAR2005	29	84	100	60	0	-10	-30D	96	100	70	12	-20D	-10
		DAY 36	07APR2005	36	72	110	80	-12	0	-10	80	110	90	-4	-10	10
		DAY 43	14APR2005	43	84	120	80	0	10	-10	84	110	80	0	-10	0
		DAY 50	21APR2005	50	72	108	80	-12	-2	-10	78	108	80	-6	-12	0
		DAY 57	27APR2005	56	88	120	70	4	10	-20D	92	110	80	8	-10	0
		FINAL			88	120	70	4	10	-20D	92	110	80	8	-10	0
	E0028017	SCREEN	09MAY2005	-7	80	110	80				88	120	90			
		DAY 1	16MAY2005	1	88	120	70				88	110	80			
		BASELINE			88	120	70				88	110	80			
		DAY 8	24MAY2005	9	84	100	80	-4	-20D	10	88	100	70	0	-10	-10
		DAY 15	31MAY2005	16	92	100	80	4	-20D	10	108	110	80	20I	0	0
		FINAL			92	100	80	4	-20D	10	108	110	80	20I	0	0
	E0030010	SCREEN	23AUG2004	-7	61	137	84				72	141	92			
		DAY 1	30AUG2004	1	62	159	94				76	148	98			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030010	BASELINE			62	159	94				76	148	98			
		DAY 8	07SEP2004	9	75	131	79	13	-28D	-15	88	128	88	12	-20D	-10
		DAY 15	13SEP2004	15	75	135	78	13	-24D	-16	80	127	80	4	-21D	-18
		DAY 22	20SEP2004	22	72	131	85	10	-28D	-9	80	127	91	4	-21D	-7
		DAY 29	27SEP2004	29	66	170	92	4	11	-2	121H	142	103	45I	-6	5
		DAY 36	04OCT2004	36	72	136	85	10	-23D	-9	86	114	87	10	-34D	-11
		DAY 43	11OCT2004	43	75	133	81	13	-26D	-13	81	152	85	5	4	-13
		DAY 50	18OCT2004	50	80	133	80	18I	-26D	-14	96	125	85	20I	-23D	-13
		DAY 57	25OCT2004	57	76	136	86	14	-23D	-8	95	144	107H	19I	-4	9
		FINAL			76	136	86	14	-23D	-8	95	144	107H	19I	-4	9
	E0030015	SCREEN	04OCT2004	-7	66	138	73				82	125	76			
		DAY 1	11OCT2004	1	76	128	82				96	132	86			
		BASELINE			76	128	82				96	132	86			
		DAY 8	21OCT2004	11	68	124	76	-8	-4	-6	96	122	84	0	-10	-2
		DAY 15	26OCT2004	16	89	135	79	13	7	-3	111	133	107H	15I	1	21
		DAY 22	05NOV2004	26	97	151	87	21I	23I	5	111	164	93	15I	32I	7
		DAY 29	10NOV2004	31	84	126	82	8	-2	0	96	120	84	0	-12	-2
		DAY 36	17NOV2004	38	80	124	76	4	-4	-6	88	118	80	-8	-14	-6
		DAY 43	23NOV2004	44	76	124	72	0	-4	-10	88	134	84	-8	2	-2
		DAY 57	10DEC2004	61	89	129	78	13	1	-4	101	149	96	5	17	10
		FINAL			89	129	78	13	1	-4	101	149	96	5	17	10
	E0030018	SCREEN	09NOV2004	-8	60	129	84				64	136	85			
		DAY 1	17NOV2004	1	62	138	86				61	140	70			
		BASELINE			62	138	86				61	140	70			
		DAY 8	24NOV2004	8	83	150	78	21I	12	-8	88	144	94	27I	4	24
		DAY 15	30NOV2004	14	96	149	76	34I	11	-10	103	150	93	42I	10	23
		DAY 22	08DEC2004	22	74	147	86	12	9	0	86	181H	109H	25I	41I	39I
		DAY 29	15DEC2004	29	98	151	79	36I	13	-7	117	143	82	56I	3	12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0030018	DAY 36	23DEC2004	37	80	140	98	18I	2	12	88	144	100	27I	4	30I
		DAY 43	30DEC2004	44	65	156	90	3	18	4	74	144	90	13	4	20
		FINAL			65	156	90	3	18	4	74	144	90	13	4	20
	E0030036	SCREEN	26MAY2005	-7	69	164	91				84	157	97			
		DAY 1	02JUN2005	1	60	132	80				72	140	88			
		BASELINE			60	132	80				72	140	88			
		DAY 8	10JUN2005	9	74	159	101	14	27I	21	88	144	113H	16I	4	25
		FINAL			74	159	101	14	27I	21	88	144	113H	16I	4	25
	E0032010	SCREEN	01MAR2005	-7	70	130	84				80	125	82			
		DAY 1	08MAR2005	1	78	140	85				82	125	84			
		BASELINE			78	140	85				82	125	84			
		DAY 8	17MAR2005	10	68	130	82	-10	-10	-3	72	125	80	-10	0	-4
		DAY 15	24MAR2005	17	76	120	85	-2	-20D	0	83	130	80	1	5	-4
		FINAL			76	120	85	-2	-20D	0	83	130	80	1	5	-4
	E0032012	SCREEN	14JUN2005	-8	60	108	79				62	105	74			
		DAY 1	22JUN2005	1	70	114	70				72	110	74			
		BASELINE			70	114	70				72	110	74			
		DAY 8	28JUN2005	7	78	112	76	8	-2	6	90	114	80	18I	4	6
		DAY 15	05JUL2005	14	72	120	74	2	6	4	78	118	70	6	8	-4
		DAY 22	13JUL2005	22	68	120	70	-2	6	0	74	116	70	2	6	-4
		DAY 29	22JUL2005	31	74	118	72	4	4	2	78	116	76	6	6	2
		DAY 36	29JUL2005	38	74	132	84	4	18	14	78	130	82	6	20I	8
		DAY 43	03AUG2005	43	70	116	74	0	2	4	74	112	74	2	2	0
		DAY 50	10AUG2005	50	68	120	74	-2	6	4	76	110	74	4	0	0
		DAY 57	17AUG2005	57	80	132	72	10	18	2	84	128	76	12	18	2
		FINAL			80	132	72	10	18	2	84	128	76	12	18	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0032014	SCREEN	16JUN2005	-6	69	102	70				72	110	82			
		DAY 1	22JUN2005	1	70	100	70				73	105	75			
		BASELINE			70	100	70				73	105	75			
		DAY 8	30JUN2005	9	88	108	72	18I	8	2	91	110	84	18I	5	9
		DAY 15	06JUL2005	15	76	107	73	6	7	3	76	110	80	3	5	5
		DAY 22	13JUL2005	22	74	110	72	4	10	2	76	110	80	3	5	5
		DAY 29	20JUL2005	29	92	126	76	22I	26I	6	112	130	80	39I	25I	5
		DAY 36	27JUL2005	36	84	100	68	14	0	-2	88	110	70	15I	5	-5
		DAY 43	02AUG2005	42	88	110	80	18I	10	10	88	110	80	15I	5	5
		DAY 50	10AUG2005	50	88	110	88	18I	10	18	86	110	75	13	5	0
		DAY 57	17AUG2005	57	84	104	78	14	4	8	93	108	80	20I	3	5
		FINAL			84	104	78	14	4	8	93	108	80	20I	3	5
	E0033008	SCREEN	24NOV2004	-15	60	110	72				58	116	76			
		DAY 1	09DEC2004	1	64	120	74				60	116	70			
		BASELINE			64	120	74				60	116	70			
		DAY 8	15DEC2004	7	66	110	80	2	-10	6	68	116	80	8	0	10
		DAY 15	21DEC2004	13	70	118	72	6	-2	-2	72	116	70	12	0	0
		DAY 22	29DEC2004	21	70	118	80	6	-2	6	74	118	82	14	2	12
		DAY 29	06JAN2005	29	64	98	70	0	-22D	-4	66	100	70	6	-16	0
		DAY 36	13JAN2005	36	74	100	68	10	-20D	-6	70	102	70	10	-14	0
		DAY 43	20JAN2005	43	68	102	80	4	-18	6	70	108	76	10	-8	6
		DAY 50	27JAN2005	50	68	100	80	4	-20D	6	70	106	80	10	-10	10
		DAY 57	03FEB2005	57	72	120	86	8	0	12	70	118	82	10	2	12
		FINAL			72	120	86	8	0	12	70	118	82	10	2	12
	E0034005	SCREEN	29NOV2004	-14	84	130	80				80	128	82			
		DAY 1	13DEC2004	1	80	118	78				82	120	76			
		BASELINE			80	118	78				82	120	76			
		DAY 8	20DEC2004	8	78	116	82	-2	-2	4	82	118	86	0	-2	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0034005	DAY 15		27DEC2004	15	76	118	82	-4	0	4	82	116	86	0	-4	10
		DAY 22		03JAN2005	22	76	120	80	-4	2	2	84	140	82	2	20I	6
		DAY 29		10JAN2005	29	84	118	74	4	0	-4	88	116	84	6	-4	8
		DAY 36		17JAN2005	36	88	140	110H	8	22I	32I	88	138	100	6	18	24
		DAY 36	*	21JAN2005	40	84	138	92	4	20I	14	88	130	92	6	10	16
		FINAL				84	138	92	4	20I	14	88	130	92	6	10	16
	E0035026	SCREEN		20DEC2004	-8	80	120	80				80	120	80			
		DAY 1		27DEC2004	-1	72	112	74				76	118	80			
		BASELINE				72	112	74				76	118	80			
		DAY 8		04JAN2005	8	76	120	80	4	8	6	60	118	80	-16D	0	0
		DAY 15		11JAN2005	15	60	100	70	-12	-12	-4	65	110	80	-11	-8	0
		DAY 22		17JAN2005	21	100	140	80	28I	28I	6	100	130	80	24I	12	0
		DAY 29		24JAN2005	28	80	140	80	8	28I	6	90	140	76	14	22I	-4
		FINAL				80	140	80	8	28I	6	90	140	76	14	22I	-4
	E0035030	SCREEN		07MAR2005	-9	60	114	76				64	118	72			
		DAY 1		15MAR2005	-1	64	110	70				68	120	76			
		BASELINE				64	110	70				68	120	76			
		DAY 8		21MAR2005	6	68	118	68	4	8	-2	74	110	78	6	-10	2
		DAY 15		28MAR2005	13	70	120	70	6	10	0	65	113	72	-3	-7	-4
		DAY 22		04APR2005	20	84	120	70	20I	10	0	80	120	65	12	0	-11
		FINAL				84	120	70	20I	10	0	80	120	65	12	0	-11
	E0038004	SCREEN		02NOV2004	-9	70	110	80				78	116	78			
		DAY 1		11NOV2004	1	80	110	76				76	112	80			
		BASELINE				80	110	76				76	112	80			
		DAY 8		19NOV2004	9	80	120	78	0	10	2	80	116	80	4	4	0
		DAY 15		23NOV2004	13	90	115	80	10	5	4	96	110	75	20I	-2	-5
		DAY 22		02DEC2004	22	92	118	82	12	8	6	90	110	78	14	-2	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0038004	DAY 29		09DEC2004	29	88	120	86	8	10	10	84	124	80	8	12	0
		DAY 36		16DEC2004	36	100	130	80	20I	20I	4	94	126	88	18I	14	8
		DAY 43		23DEC2004	43	90	118	80	10	8	4	92	115	78	16I	3	-2
		DAY 50		30DEC2004	50	86	116	78	6	6	2	84	116	76	8	4	-4
		DAY 57		07JAN2005	58	77	126	80	-3	16	4	80	121	80	4	9	0
		FINAL				77	126	80	-3	16	4	80	121	80	4	9	0
	E0039002	SCREEN		10AUG2004	-21	64	108	60				78	94	60			
		DAY 1		31AUG2004	1	58	108	60				60	92	70			
		BASELINE				58	108	60				60	92	70			
		DAY 8		07SEP2004	8	68	108	64	10	0	4	88	100	70	28I	8	0
		DAY 15		14SEP2004	15	76	110	60	18I	2	0	88	98	60	28I	6	-10
		DAY 22		21SEP2004	22	88	110	58	30I	2	-2	92	110	58	32I	18	-12
		DAY 29		28SEP2004	29	78	102	60	20I	-6	0	88	94	56	28I	2	-14
		DAY 36		05OCT2004	36	76	110	64	18I	2	4	80	108	62	20I	16	-8
		DAY 43		12OCT2004	43	80	110	70	22I	2	10	80	102	70	20I	10	0
		DAY 50		20OCT2004	51	74	100	64	16I	-8	4	82	98	60	22I	6	-10
		DAY 57		28OCT2004	59	68	110	74	10	2	14	70	104	70	10	12	0
		FINAL				68	110	74	10	2	14	70	104	70	10	12	0
	E0039007	SCREEN		15SEP2004	-15	62	100	60				68	96	50L			
		DAY 1		30SEP2004	1	76	108	50L				84	90L	60			
		BASELINE				76	108	50L				84	90L	60			
		DAY 8		07OCT2004	8	76	110	58	0	2	8	88	98	52	4	8	-8
		DAY 15		13OCT2004	14	96	120	68	20I	12	18	88	114	60	4	24I	0
		DAY 22		20OCT2004	21	88	122	62	12	14	12	94	102	52	10	12	-8
		DAY 29		28OCT2004	29	98	108	68	22I	0	18	104	100	60	20I	10	0
		DAY 36		08NOV2004	40	96	104	60	20I	-4	10	102	100	60	18I	10	0
		DAY 43		15NOV2004	47	86	110	60	10	2	10	98	102	64	14	12	4
		DAY 57	*	24NOV2004	56	88	102	64	12	-6	14	100	98	58	16I	8	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0039007	DAY 57	01DEC2004	63	98	110	64	22I	2	14	104	100	60	20I	10	0
		FINAL			98	110	64	22I	2	14	104	100	60	20I	10	0
	E0039013	SCREEN	22NOV2004	-24	68	124	88				70	118	80			
		DAY 1	16DEC2004	1	64	138	90				70	132	80			
		BASELINE			64	138	90				70	132	80			
		DAY 8	23DEC2004	8	80	120	84	16I	-18	-6	84	126	86	14	-6	6
		DAY 22	04JAN2005	20	76	132	74	12	-6	-16	80	130	94	10	-2	14
		FINAL			76	132	74	12	-6	-16	80	130	94	10	-2	14
	E0039022	SCREEN	15MAR2005	-7	72	118	68				84	110	72			
		DAY 1	22MAR2005	1	80	108	70				84	106	70			
		BASELINE			80	108	70				84	106	70			
		DAY 8	29MAR2005	8	84	100	60	4	-8	-10	100	104	78	16I	-2	8
		DAY 15	05APR2005	15	84	104	66	4	-4	-4	80	106	70	-4	0	0
		DAY 22	12APR2005	22	84	102	60	4	-6	-10	88	106	72	4	0	2
		DAY 29	19APR2005	29	80	98	62	0	-10	-8	84	100	64	0	-6	-6
		DAY 36	26APR2005	36	80	102	64	0	-6	-6	80	104	68	-4	-2	-2
		DAY 43	03MAY2005	43	80	102	70	0	-6	0	84	100	74	0	-6	4
		DAY 50	10MAY2005	50	84	108	70	4	0	0	88	104	72	4	-2	2
		DAY 57	18MAY2005	58	82	110	68	2	2	-2	84	110	70	0	4	0
		FINAL			82	110	68	2	2	-2	84	110	70	0	4	0
	E0040019	SCREEN	01JUN2005	-6	76	122	80				78	126	84			
		DAY 1	07JUN2005	1	76	122	80				78	126	84			
		BASELINE			76	122	80				78	126	84			
		DAY 8	14JUN2005	8	91	128	81	15I	6	1	100	131	97	22I	5	13
		DAY 15	21JUN2005	15	88	126	82	12	4	2	104	132	90	26I	6	6
		DAY 22	28JUN2005	22	82	126	83	6	4	3	91	140	88	13	14	4
		DAY 29	05JUL2005	29	80	124	88	4	2	8	98	138	90	20I	12	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE			SUPINE CHANGE FROM BASELINE			STANDING			STANDING CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0040019	DAY 36		14JUL2005	38	86	130	80	10	8	0	97	138	86	19I	12	2
		DAY 43		21JUL2005	45	82	130	84	6	8	4	99	132	88	21I	6	4
		DAY 50		28JUL2005	52	84	130	84	8	8	4	98	136	78	20I	10	-6
		DAY 57		04AUG2005	59	74	132	84	-2	10	4	78	136	88	0	10	4
		FINAL				74	132	84	-2	10	4	78	136	88	0	10	4
	E0041006	SCREEN		19OCT2004	-10	52	124	72				56	118	74			
		DAY 1		29OCT2004	1	56	106	70				72	102	78			
		BASELINE				56	106	70				72	102	78			
		DAY 8		05NOV2004	8	52	110	72	-4	4	2	68	108	72	-4	6	-6
		DAY 15		12NOV2004	15	64	108	74	8	2	4	84	108	82	12	6	4
		DAY 22		19NOV2004	22	60	102	72	4	-4	2	64	106	76	-8	4	-2
		DAY 22	*	23NOV2004	26	72	108	70	16I	2	0	72	104	68	0	2	-10
		DAY 36		02DEC2004	35	76	108	68	20I	2	-2	84	102	76	12	0	-2
		DAY 43		10DEC2004	43	68	106	62	12	0	-8	76	102	76	4	0	-2
		DAY 50		17DEC2004	50	64	104	68	8	-2	-2	68	110	76	-4	8	-2
		DAY 50	*	21DEC2004	54	60	108	66	4	2	-4	60	102	68	-12	0	-10
		FINAL				60	108	66	4	2	-4	60	102	68	-12	0	-10
	E0042008	SCREEN		26AUG2004	-7	64	114	82				60	116	80			
		DAY 1		02SEP2004	1	72	130	78				88	126	82			
		BASELINE				72	130	78				88	126	82			
		DAY 8		09SEP2004	8	68	130	82	-4	0	4	76	120	78	-12	-6	-4
		DAY 15		16SEP2004	15	84	132	74	12	2	-4	88	128	76	0	2	-6
		DAY 22		23SEP2004	22	88	132	84	16I	2	6	92	120	72	4	-6	-10
		DAY 29		30SEP2004	29	92	128	76	20I	-2	-2	100	120	72	12	-6	-10
		DAY 36		07OCT2004	36	92	134	86	20I	4	8	92	138	80	4	12	-2
		DAY 43		14OCT2004	43	92	138	76	20I	8	-2	88	136	80	0	10	-2
		DAY 50		21OCT2004	50	80	122	78	8	-8	0	92	119	72	4	-7	-10
		DAY 57		28OCT2004	57	88	122	86	16I	-8	8	96	114	78	8	-12	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0042008	FINAL			88	122	86	16I	-8	8	96	114	78	8	-12	-4
	E0042009	SCREEN	21SEP2004	-7	82	124	78				74	122	84			
		DAY 1	28SEP2004	1	84	124	80				80	120	76			
		BASELINE			84	124	80				80	120	76			
		DAY 8	05OCT2004	8	100	150	96	16I	26I	16	92	140	92	12	20I	16
		DAY 15	12OCT2004	15	84	146	94	0	22I	14	88	140	98	8	20I	22
		DAY 22	19OCT2004	22	80	136	90	-4	12	10	76	134	86	-4	14	10
		DAY 29	26OCT2004	29	76	122	84	-8	-2	4	80	116	80	0	-4	4
		DAY 36	02NOV2004	36	84	122	86	0	-2	6	82	114	82	2	-6	6
		DAY 43	09NOV2004	43	86	128	86	2	4	6	88	122	84	8	2	8
		DAY 50	16NOV2004	50	80	134	88	-4	10	8	76	136	84	-4	16	8
		DAY 57	22NOV2004	56	80	126	88	-4	2	8	80	124	82	0	4	6
		FINAL			80	126	88	-4	2	8	80	124	82	0	4	6
	E0042020	SCREEN	28MAR2005	-14	72	132	84				72	124	78			
		DAY 1	11APR2005	1	72	124	70				84	122	76			
		BASELINE			72	124	70				84	122	76			
		DAY 8	18APR2005	8	88	128	98	16I	4	28	84	136	94	0	14	18
		FINAL			88	128	98	16I	4	28	84	136	94	0	14	18
	E0042021	SCREEN	30MAR2005	-14	68	110	70				68	110	70			
		DAY 1	13APR2005	1	68	114	70				68	120	76			
		BASELINE			68	114	70				68	120	76			
		DAY 8	20APR2005	8	64	102	70	-4	-12	0	64	98	74	-4	-22D	-2
		FINAL			64	102	70	-4	-12	0	64	98	74	-4	-22D	-2
	E0042023	SCREEN	27APR2005	-19	84	134	84				88	134	86			
		DAY 1	16MAY2005	1	80	118	76				84	126	84			
		BASELINE			80	118	76				84	126	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0042023	DAY 8	23MAY2005	8	82	120	80	2	2	4	90	120	85	6	-6	1
		DAY 15	31MAY2005	16	80	120	80	0	2	4	96	120	85	12	-6	1
		DAY 22	09JUN2005	25	96	120	70	16I	2	-6	96	125	80	12	-1	-4
		DAY 29	13JUN2005	29	76	126	72	-4	8	-4	80	120	70	-4	-6	-14
		DAY 36	20JUN2005	36	64	100	62	-16D	-18	-14	66	110	60	-18D	-16	-24D
		DAY 43	27JUN2005	43	88	110	85	8	-8	9	92	120	90	8	-6	6
		DAY 50	06JUL2005	52	84	120	75	4	2	-1	88	130	85	4	4	1
		DAY 57	13JUL2005	59	88	130	90	8	12	14	80	140	88	-4	14	4
		FINAL			88	130	90	8	12	14	80	140	88	-4	14	4
	E0044001	SCREEN	14OCT2004	-26	84	126	72				88	124	74			
		DAY 1	09NOV2004	1	88	124	72				88	118	76			
		BASELINE			88	124	72				88	118	76			
		DAY 8	18NOV2004	10	84	124	76	-4	0	4	80	122	80	-8	4	4
		DAY 15	26NOV2004	18	72	120	78	-16D	-4	6	72	120	72	-16D	2	-4
		DAY 22	03DEC2004	25	88	116	70	0	-8	-2	78	120	72	-10	2	-4
		DAY 29	09DEC2004	31	60	110	70	-28D	-14	-2	66	110	76	-22D	-8	0
		DAY 36	17DEC2004	39	62	112	68	-26D	-12	-4	62	108	76	-26D	-10	0
		DAY 43	23DEC2004	45	68	112	70	-20D	-12	-2	64	110	74	-24D	-8	-2
		DAY 50	30DEC2004	52	96	116	60	8	-8	-12	104	124	74	16I	6	-2
		DAY 57	06JAN2005	59	84	112	68	-4	-12	-4	80	110	68	-8	-8	-8
		FINAL			84	112	68	-4	-12	-4	80	110	68	-8	-8	-8
	E0044002	SCREEN	26OCT2004	-23	76	112	66				60	106	62			
		DAY 1	18NOV2004	1	60	104	68				68	102	62			
		BASELINE			60	104	68				68	102	62			
		DAY 8	24NOV2004	7	68	102	58	8	-2	-10	78	98	60	10	-4	-2
		DAY 15	02DEC2004	15	76	112	78	16I	8	10	84	114	76	16I	12	14
		DAY 22	08DEC2004	21	80	102	58	20I	-2	-10	84	108	62	16I	6	0
		DAY 29	15DEC2004	28	68	102	58	8	-2	-10	72	102	58	4	0	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0044002	DAY 36	22DEC2004	35	80	108	78	20I	4	10	84	102	76	16I	0	14
		DAY 43	29DEC2004	42	76	110	76	16I	6	8	72	110	78	4	8	16
		DAY 50	06JAN2005	50	88	112	78	28I	8	10	88	120	78	20I	18	16
		DAY 57	13JAN2005	57	72	102	62	12	-2	-6	88	112	58	20I	10	-4
		FINAL			72	102	62	12	-2	-6	88	112	58	20I	10	-4
	E0045003	SCREEN	08FEB2005	-17	92	130	90				92	140	90			
		DAY 1	24FEB2005	-1	86	140	90				82	136	82			
		BASELINE			86	140	90				82	136	82			
		DAY 8	04MAR2005	8	80	158	85	-6	18	-5	80	130	65	-2	-6	-17
		DAY 15	11MAR2005	15	112	132	92	26I	-8	2	112	120	90	30I	-16	8
		FINAL			112	132	92	26I	-8	2	112	120	90	30I	-16	8
	E0046002	SCREEN	15NOV2004	-7	69	118	78				72	114	82			
		DAY 1	22NOV2004	1	70	122	78				80	122	78			
		BASELINE			70	122	78				80	122	78			
		DAY 8	29NOV2004	8	81	121	78	11	-1	0	92	117	77	12	-5	-1
		DAY 15	06DEC2004	15	97	128	88	27I	6	10	95	124	86	15I	2	8
		DAY 22	14DEC2004	23	92	124	82	22I	2	4	110	119	81	30I	-3	3
		DAY 29	22DEC2004	31	84	126	86	14	4	8	96	119	78	16I	-3	0
		DAY 36	27DEC2004	36	88	126	80	18I	4	2	100	120	90	20I	-2	12
		DAY 43	03JAN2005	43	75	126	80	5	4	2	89	126	89	9	4	11
		DAY 50	10JAN2005	50	81	126	82	11	4	4	88	124	84	8	2	6
		DAY 57	18JAN2005	58	83	133	86	13	11	8	88	121	82	8	-1	4
		FINAL			83	133	86	13	11	8	88	121	82	8	-1	4
	E0046004	SCREEN	17NOV2004	-15	68	132	90				84	129	83			
		DAY 1	02DEC2004	1	61	130	83				77	124	84			
		BASELINE			61	130	83				77	124	84			
		DAY 8	09DEC2004	8	99	126	84	38I	-4	1	115	132	86	38I	8	2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR I)	E0046004	DAY 15		16DEC2004	15	80	126	78	19I	-4	-5	105	110	78	28I	-14	-6
		DAY 22		22DEC2004	21	90	148	93	29I	18	10	104	124	82	27I	0	-2
		DAY 29		29DEC2004	28	86	129	86	25I	-1	3	100	112	76	23I	-12	-8
		DAY 36		05JAN2005	35	89	136	83	28I	6	0	102	128	80	25I	4	-4
		DAY 43		12JAN2005	42	97	137	83	36I	7	0	105	128	76	28I	4	-8
		DAY 50		19JAN2005	49	88	143	85	27I	13	2	96	125	87	19I	1	3
		DAY 50	*	24JAN2005	54	88	110	78	27I	-20D	-5	80	110	78	3	-14	-6
		FINAL				88	110	78	27I	-20D	-5	80	110	78	3	-14	-6
QUETIAPINE 600 MG (BIPOLAR II)	E0004006	SCREEN		22JUL2004	-7	64	130	88				64	132	88			
		DAY 1		29JUL2004	1	64	120	88				72	110	80			
		BASELINE				64	120	88				72	110	80			
		DAY 8		04AUG2004	7	56	120	90	-8	0	2	72	116	90	0	6	10
		DAY 22		18AUG2004	21	64	128	78	0	8	-10	60	122	88	-12	12	8
		DAY 29		26AUG2004	29	68	120	80	4	0	-8	78	122	88	6	12	8
		DAY 36		02SEP2004	36	68	114	80	4	-6	-8	80	120	86	8	10	6
		DAY 43		09SEP2004	43	76	120	76	12	0	-12	88	110	70	16I	0	-10
		DAY 50		16SEP2004	50	60	116	78	-4	-4	-10	64	104	72	-8	-6	-8
		DAY 57		23SEP2004	57	68	112	74	4	-8	-14	80	120	82	8	10	2
		FINAL				68	112	74	4	-8	-14	80	120	82	8	10	2
	E0004014	SCREEN		05OCT2004	-7	48L	120	80				60	116	74			
		DAY 1		12OCT2004	1	56	112	72				60	108	66			
		BASELINE				56	112	72				60	108	66			
		DAY 8		20OCT2004	9	68	110	78	12	-2	6	76	114	82	16I	6	16
		FINAL				68	110	78	12	-2	6	76	114	82	16I	6	16

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0010011	SCREEN	27JAN2005	-7	82	126	84				82	122	80			
		DAY 1	03FEB2005	1	84	128	88				86	128	90			
		BASELINE			84	128	88				86	128	90			
		DAY 8	10FEB2005	8	78	132	90	-6	4	2	64	134	88	-22D	6	-2
		DAY 22	23FEB2005	21	78	120	88	-6	-8	0	88	118	88	2	-10	-2
		FINAL			78	120	88	-6	-8	0	88	118	88	2	-10	-2
	E0010015	SCREEN	16FEB2005	-7	66	140	82				80	120	80			
		DAY 1	23FEB2005	1	74	120	78				90	120	74			
		BASELINE			74	120	78				90	120	74			
		DAY 8	03MAR2005	9	84	128	88	10	8	10	78	124	92	-12	4	18
		DAY 15	10MAR2005	16	92	126	92	18I	6	14	86	124	90	-4	4	16
		DAY 22	17MAR2005	23	96	116	82	22I	-4	4	76	120	80	-14	0	6
		DAY 29	24MAR2005	30	86	126	84	12	6	6	90	130	88	0	10	14
		DAY 36	31MAR2005	37	82	124	92	8	4	14	90	124	88	0	4	14
		DAY 43	07APR2005	44	88	118	88	14	-2	10	84	124	86	-6	4	12
		DAY 50	14APR2005	51	76	118	88	2	-2	10	88	116	86	-2	-4	12
		DAY 57	21APR2005	58	88	128	70	14	8	-8	76	118	74	-14	-2	0
		FINAL			88	128	70	14	8	-8	76	118	74	-14	-2	0
	E0011004	SCREEN	04AUG2004	-13	56	100	60				64	104	62			
		DAY 1	17AUG2004	1	70	106	72				72	100	72			
		BASELINE			70	106	72				72	100	72			
		DAY 8	25AUG2004	9	64	106	72	-6	0	0	80	106	76	8	6	4
		DAY 15	31AUG2004	15	80	105	71	10	-1	-1	84	104	72	12	4	0
		DAY 22	07SEP2004	22	72	118	80	2	12	8	80	110	78	8	10	6
		DAY 29	14SEP2004	29	84	100	64	14	-6	-8	90	106	70	18I	6	-2
		DAY 36	24SEP2004	39	80	98	68	10	-8	-4	84	98	64	12	-2	-8
		DAY 43	29SEP2004	44	88	106	60	18I	0	-12	90	110	60	18I	10	-12

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0011004	DAY 50	05OCT2004	50	82	112	70	12	6	-2	86	104	70	14	4	-2
		DAY 57	18OCT2004	63	78	104	64	8	-2	-8	80	104	60	8	4	-12
		FINAL			78	104	64	8	-2	-8	80	104	60	8	4	-12
	E0011018	SCREEN	03JAN2005	-7	66	106	64				64	104	62			
		DAY 1	10JAN2005	1	70	108	66				68	106	60			
		BASELINE			70	108	66				68	106	60			
		DAY 8	17JAN2005	8	68	130	72	-2	22I	6	68	126	70	0	20I	10
		DAY 15	24JAN2005	15	72	126	74	2	18	8	70	120	72	2	14	12
		DAY 22	01FEB2005	23	70	118	76	0	10	10	68	116	74	0	10	14
		DAY 29	09FEB2005	31	68	124	76	-2	16	10	64	120	74	-4	14	14
		DAY 36	16FEB2005	38	54	117	58	-16D	9	-8	54	114	54	-14	8	-6
		FINAL			54	117	58	-16D	9	-8	54	114	54	-14	8	-6
	E0012002	SCREEN	20JUL2004	-28	80	114	68				80	114	64			
		DAY 1	17AUG2004	1	80	120	82				80	116	80			
		BASELINE			80	120	82				80	116	80			
		DAY 8	24AUG2004	8	84	116	80	4	-4	-2	88	114	76	8	-2	-4
		DAY 15	31AUG2004	15	82	114	76	2	-6	-6	82	112	70	2	-4	-10
		DAY 22	07SEP2004	22	80	126	74	0	6	-8	80	120	70	0	4	-10
		DAY 29	14SEP2004	29	80	118	80	0	-2	-2	80	116	76	0	0	-4
		DAY 36	21SEP2004	36	78	122	82	-2	2	0	82	120	80	2	4	0
		DAY 43	27SEP2004	42	74	120	78	-6	0	-4	79	124	82	-1	8	2
		DAY 50	04OCT2004	49	73	128	80	-7	8	-2	78	130	78	-2	14	-2
		DAY 57	11OCT2004	56	64	130	78	-16D	10	-4	68	126	80	-12	10	0
		FINAL			64	130	78	-16D	10	-4	68	126	80	-12	10	0
	E0012014	SCREEN	05OCT2004	-7	68	138	84				70	134	82			
		DAY 1	12OCT2004	1	72	134	86				62	138	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0012014	BASELINE				72	134	86				62	138	80			
		DAY 8		19OCT2004	8	70	128	80	-2	-6	-6	68	130	82	6	-8	2
		DAY 15		25OCT2004	14	66	120	80	-6	-14	-6	69	126	82	7	-12	2
		DAY 22		01NOV2004	21	68	124	86	-4	-10	0	68	128	80	6	-10	0
		DAY 29		10NOV2004	30	68	120	72	-4	-14	-14	68	118	70	6	-20D	-10
		DAY 36		18NOV2004	38	64	128	80	-8	-6	-6	62	130	84	0	-8	4
		DAY 43		24NOV2004	44	62	130	82	-10	-4	-4	64	134	82	2	-4	2
		DAY 50		01DEC2004	51	66	132	78	-6	-2	-8	64	132	80	2	-6	0
		DAY 57		08DEC2004	58	60	128	78	-12	-6	-8	62	130	80	0	-8	0
		FINAL				60	128	78	-12	-6	-8	62	130	80	0	-8	0
	E0014009	SCREEN		18NOV2004	-21	60	100	60				76	100	70			
		DAY 1		09DEC2004	1	66	110	68				80	110	74			
		BASELINE				66	110	68				80	110	74			
		DAY 8		15DEC2004	7	78	118	70	12	8	2	95	120	79	15I	10	5
		DAY 15		22DEC2004	14	60	117	64	-6	7	-4	75	112	70	-5	2	-4
		DAY 15	*	27DEC2004	19	64	115	70	-2	5	2	78	110	70	-2	0	-4
		FINAL				64	115	70	-2	5	2	78	110	70	-2	0	-4
	E0019005	SCREEN		10NOV2004	-19	78	120	84				76	116	80			
		DAY 1		29NOV2004	1	64	164	106H				76	152	108H			
		BASELINE				64	164	106H				76	152	108H			
		DAY 8		06DEC2004	8	76	142	108H	12	-22D	2	80	140	100	4	-12	-8
		DAY 15		13DEC2004	15	80	130	90	16I	-34D	-16	80	128	86	4	-24D	-22D
		DAY 22		22DEC2004	24	70	120	90	6	-44D	-16	72	118	90	-4	-34D	-18
		DAY 29		27DEC2004	29	80	125	90	16I	-39D	-16	80	122	88	4	-30D	-20D
		DAY 36		04JAN2005	37	68	136	90	4	-28D	-16	80	130	90	4	-22D	-18
		DAY 43		10JAN2005	43	68	150	88	4	-14	-18	70	148	88	-6	-4	-20D
		DAY 50		18JAN2005	51	68	138	100	4	-26D	-6	80	138	98	4	-14	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0019005	DAY 57	24JAN2005	57	80	130	88	16I	-34D	-18	88	130	90	12	-22D	-18
		FINAL			80	130	88	16I	-34D	-18	88	130	90	12	-22D	-18
	E0020021	SCREEN	09NOV2004	-14	64	130	86				64	120	80			
		DAY 1	23NOV2004	1	74	109	78				90	110	88			
		BASELINE			74	109	78				90	110	88			
		DAY 8	02DEC2004	10	78	130	90	4	21I	12	88	130	85	-2	20I	-3
		DAY 15	07DEC2004	15	88	130	100	14	21I	22	89	130	100	-1	20I	12
		DAY 22	14DEC2004	22	80	120	90	6	11	12	88	130	90	-2	20I	2
		DAY 29	21DEC2004	29	82	120	80	8	11	2	92	122	90	2	12	2
		DAY 36	30DEC2004	38	92	120	80	18I	11	2	89	120	90	-1	10	2
		DAY 43	04JAN2005	43	100	130	98	26I	21I	20	108	130	92	18I	20I	4
		DAY 50	11JAN2005	50	88	124	90	14	15	12	100	124	98	10	14	10
		DAY 57	18JAN2005	57	78	140	93	4	31I	15	94	140	100	4	30I	12
		FINAL			78	140	93	4	31I	15	94	140	100	4	30I	12
	E0020040	SCREEN	11FEB2005	-7	66	120	80				92	120	100			
		DAY 1	18FEB2005	1	84	134	92				98	140	100			
		BASELINE			84	134	92				98	140	100			
		DAY 8	24FEB2005	7	100	132	94	16I	-2	2	104	150	106H	6	10	6
		DAY 15	03MAR2005	14	96	150	100	12	16	8	98	150	95	0	10	-5
		DAY 22	10MAR2005	21	88	140	95	4	6	3	86	145	100	-12	5	0
		DAY 29	17MAR2005	28	84	140	90	0	6	-2	84	145	95	-14	5	-5
		DAY 36	24MAR2005	35	92	110	90	8	-24D	-2	100	114	90	2	-26D	-10
		DAY 43	31MAR2005	42	88	130	96	4	-4	4	100	130	102	2	-10	2
		DAY 50	07APR2005	49	94	120	96	10	-14	4	100	120	98	2	-20D	-2
		DAY 57	14APR2005	56	96	140	106H	12	6	14	102	160	110H	4	20I	10
		FINAL			96	140	106H	12	6	14	102	160	110H	4	20I	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0025002	SCREEN	14JUL2004	-34	82	108	72				82	108	74			
		DAY 1	17AUG2004	1	79	111	73				74	99	53			
		BASELINE			79	111	73				74	99	53			
		DAY 8	24AUG2004	8	89	99	71	10	-12	-2	89	98	70	15I	-1	17
		FINAL			89	99	71	10	-12	-2	89	98	70	15I	-1	17
	E0025003	SCREEN	19JUL2004	-8	80	140	88				82	140	87			
		DAY 1	27JUL2004	1	97	130	89				98	130	88			
		BASELINE			97	130	89				98	130	88			
		DAY 8	02AUG2004	7	88	132	84	-9	2	-5	86	132	86	-12	2	-2
		DAY 15	09AUG2004	14	91	138	87	-6	8	-2	92	139	88	-6	9	0
		DAY 22	16AUG2004	21	82	135	80	-15D	5	-9	84	134	82	-14	4	-6
		FINAL			82	135	80	-15D	5	-9	84	134	82	-14	4	-6
	E0025014	SCREEN	23AUG2004	-9	90	130	88				90	128	80			
		DAY 1	01SEP2004	1	84	101	78				84	100	78			
		BASELINE			84	101	78				84	100	78			
		DAY 8	07SEP2004	7	82	104	78	-2	3	0	83	102	78	-1	2	0
		DAY 15	13SEP2004	13	78	133	80	-6	32I	2	79	129	79	-5	29I	1
		DAY 22	20SEP2004	20	84	121	79	0	20I	1	83	120	80	-1	20I	2
		DAY 29	27SEP2004	27	86	120	80	2	19	2	84	122	80	0	22I	2
		DAY 36	04OCT2004	34	82	122	82	-2	21I	4	81	121	81	-3	21I	3
		DAY 43	11OCT2004	41	78	120	82	-6	19	4	77	118	81	-7	18	3
		DAY 50	18OCT2004	48	74	123	82	-10	22I	4	75	121	80	-9	21I	2
		DAY 57	25OCT2004	55	72	120	80	-12	19	2	74	119	80	-10	19	2
		FINAL			72	120	80	-12	19	2	74	119	80	-10	19	2
	E0025017	SCREEN	02SEP2004	-12	75	140	80				76	138	79			
		DAY 1	14SEP2004	1	70	116	66				91	110	74			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0025017	BASELINE			70	116	66				91	110	74			
		DAY 8	22SEP2004	9	82	105	70	12	-11	4	100	109	74	9	-1	0
		DAY 15	29SEP2004	16	82	101	66	12	-15	0	104	106	73	13	-4	-1
		DAY 29	13OCT2004	30	76	108	76	6	-8	10	76	118	78	-15D	8	4
		DAY 36	20OCT2004	37	76	98	67	6	-18	1	102	111	78	11	1	4
		DAY 43	27OCT2004	44	88	110	66	18I	-6	0	107	138	96	16I	28I	22
		DAY 57	09NOV2004	57	74	132	89	4	16	23	81	132	88	-10	22I	14
		FINAL			74	132	89	4	16	23	81	132	88	-10	22I	14
	E0025022	SCREEN	04OCT2004	-28	60	118	80				62	126	86			
		DAY 1	01NOV2004	1	69	128	80				70	126	80			
		BASELINE			69	128	80				70	126	80			
		DAY 8	08NOV2004	8	72	124	82	3	-4	2	74	126	84	4	0	4
		DAY 15	15NOV2004	15	78	120	80	9	-8	0	76	124	82	6	-2	2
		DAY 22	23NOV2004	23	80	122	82	11	-6	2	82	120	79	12	-6	-1
		DAY 29	29NOV2004	29	88	126	84	19I	-2	4	88	124	82	18I	-2	2
		DAY 36	08DEC2004	38	84	120	82	15I	-8	2	86	118	80	16I	-8	0
		DAY 43	15DEC2004	45	86	122	84	17I	-6	4	88	120	80	18I	-6	0
		DAY 50	20DEC2004	50	84	120	78	15I	-8	-2	86	118	76	16I	-8	-4
		DAY 57	29DEC2004	59	86	124	78	17I	-4	-2	88	122	78	18I	-4	-2
		FINAL			86	124	78	17I	-4	-2	88	122	78	18I	-4	-2
	E0025030	SCREEN	15DEC2004	-6	84	109	72				86	110	74			
		DAY 1	21DEC2004	1	84	113	71				89	114	81			
		BASELINE			84	113	71				89	114	81			
		DAY 8	28DEC2004	8	82	110	74	-2	-3	3	84	108	74	-5	-6	-7
		DAY 15	05JAN2005	16	86	114	76	2	1	5	88	112	74	-1	-2	-7
		DAY 22	11JAN2005	22	82	118	77	-2	5	6	86	116	75	-3	2	-6
		DAY 29	19JAN2005	30	84	120	82	0	7	11	85	119	80	-4	5	-1

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0025030	DAY 36	25JAN2005	36	82	124	80	-2	11	9	84	120	78	-5	6	-3
		DAY 43	01FEB2005	43	87	133	75	3	20I	4	97	135	81	8	21I	0
		DAY 50	08FEB2005	50	82	138	80	-2	25I	9	95	151	93	6	37I	12
		DAY 57	15FEB2005	57	88	132	88	4	19	17	89	130	87	0	16	6
		FINAL			88	132	88	4	19	17	89	130	87	0	16	6
	E0025036	SCREEN	21JAN2005	-5	54	104	70				79	118	82			
		DAY 1	26JAN2005	1	60	104	60				76	108	88			
		BASELINE			60	104	60				76	108	88			
		DAY 8	02FEB2005	8	56	112	52	-4	8	-8	83	113	73	7	5	-15
		DAY 15	09FEB2005	15	62	118	82	2	14	22	80	112	82	4	4	-6
		DAY 22	15FEB2005	21	80	112	84	20I	8	24	96	106	80	20I	-2	-8
		DAY 29	23FEB2005	29	84	124	80	24I	20I	20	100	122	90	24I	14	2
		DAY 36	02MAR2005	36	70	111	78	10	7	18	72	120	84	-4	12	-4
		DAY 43	09MAR2005	43	62	124	78	2	20I	18	92	141	92	16I	33I	4
		DAY 50	16MAR2005	50	72	106	80	12	2	20	88	109	82	12	1	-6
		DAY 57	24MAR2005	58	68	114	82	8	10	22	96	104	86	20I	-4	-2
		FINAL			68	114	82	8	10	22	96	104	86	20I	-4	-2
	E0025045	SCREEN	18FEB2005	-10	74	122	68				88	118	78			
		DAY 1	28FEB2005	1	76	120	81				78	118	79			
		BASELINE			76	120	81				78	118	79			
		DAY 8	07MAR2005	8	82	124	72	6	4	-9	100	122	78	22I	4	-1
		DAY 15	15MAR2005	16	70	98	53	-6	-22D	-28D	81	120	72	3	2	-7
		FINAL			70	98	53	-6	-22D	-28D	81	120	72	3	2	-7
	E0025050	SCREEN	03MAR2005	-5	74	108	74				74	102	80			
		DAY 1	08MAR2005	1	70	120	80				80	114	84			
		BASELINE			70	120	80				80	114	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0025050	DAY 8	14MAR2005	7	76	112	80	6	-8	0	72	100	78	-8	-14	-6
		DAY 15	21MAR2005	14	76	118	82	6	-2	2	92	94	80	12	-20D	-4
		DAY 22	28MAR2005	21	74	120	80	4	0	0	76	118	78	-4	4	-6
		DAY 29	04APR2005	28	68	124	84	-2	4	4	72	106	80	-8	-8	-4
		DAY 36	11APR2005	35	80	118	84	10	-2	4	84	114	90	4	0	6
		DAY 43	18APR2005	42	68	114	78	-2	-6	-2	88	106	78	8	-8	-6
		DAY 50	26APR2005	50	69	118	82	-1	-2	2	68	112	78	-12	-2	-6
		FINAL			69	118	82	-1	-2	2	68	112	78	-12	-2	-6
	E0026009	SCREEN	08OCT2004	-12	61	135	88				70	138	86			
		DAY 1	20OCT2004	1	70	140	88				80	138	88			
		BASELINE			70	140	88				80	138	88			
		DAY 8	27OCT2004	8	84	138	86	14	-2	-2	88	138	88	8	0	0
		DAY 15	05NOV2004	17	85	140	88	15I	0	0	89	136	88	9	-2	0
		DAY 22	12NOV2004	24	84	138	86	14	-2	-2	93	136	86	13	-2	-2
		DAY 29	17NOV2004	29	78	138	86	8	-2	-2	88	140	88	8	2	0
		DAY 36	23NOV2004	35	84	138	88	14	-2	0	87	138	86	7	0	-2
		DAY 43	03DEC2004	45	80	136	88	10	-4	0	84	140	90	4	2	2
		DAY 50	10DEC2004	52	83	138	86	13	-2	-2	88	132	84	8	-6	-4
		DAY 57	17DEC2004	59	82	138	90	12	-2	2	87	136	88	7	-2	0
		FINAL			82	138	90	12	-2	2	87	136	88	7	-2	0
	E0026017	SCREEN	03NOV2004	-8	73	118	80				81	110	70			
		DAY 1	11NOV2004	1	66	100	70				73	94	70			
		BASELINE			66	100	70				73	94	70			
		DAY 8	17NOV2004	7	72	110	72	6	10	2	78	104	70	5	10	0
		DAY 15	23NOV2004	13	71	104	70	5	4	0	80	100	68	7	6	-2
		DAY 22	01DEC2004	21	70	106	74	4	6	4	77	102	70	4	8	0
		DAY 29	13DEC2004	33	71	110	64	5	10	-6	78	120	68	5	26I	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0026017	DAY 36	20DEC2004	40	80	102	62	14	2	-8	85	110	60	12	16	-10
		DAY 43	23DEC2004	43	76	104	60	10	4	-10	84	112	62	11	18	-8
		DAY 50	03JAN2005	54	72	110	70	6	10	0	79	102	64	6	8	-6
		DAY 57	07JAN2005	58	71	100	64	5	0	-6	83	106	66	10	12	-4
		FINAL			71	100	64	5	0	-6	83	106	66	10	12	-4
	E0029007	SCREEN	22OCT2004	-7	66	110	76				72	112	72			
		DAY 1	29OCT2004	1	72	121	72				76	108	70			
		BASELINE			72	121	72				76	108	70			
		DAY 8	05NOV2004	8	66	110	80	-6	-11	8	78	112	74	2	4	4
		DAY 15	15NOV2004	18	94	128	88	22I	7	16	100	120	86	24I	12	16
		FINAL			94	128	88	22I	7	16	100	120	86	24I	12	16
	E0030002	SCREEN	15JUL2004	-6	55	153	80				62	161	82			
		DAY 1	21JUL2004	1	68	152	82				78	150	88			
		BASELINE			68	152	82				78	150	88			
		DAY 8	28JUL2004	8	58	170	80	-10	18	-2	62	162	90	-16D	12	2
		DAY 15	04AUG2004	15	54	206H	94	-14	54I	12	66	203H	91	-12	53I	3
		FINAL			54	206H	94	-14	54I	12	66	203H	91	-12	53I	3
	E0030003	SCREEN	03AUG2004	-16	74	112	78				89	101	76			
		DAY 1	19AUG2004	1	80	120	91				93	98	74			
		BASELINE			80	120	91				93	98	74			
		DAY 8	26AUG2004	8	80	116	83	0	-4	-8	90	106	82	-3	8	8
		DAY 15	03SEP2004	16	74	121	86	-6	1	-5	82	108	86	-11	10	12
		DAY 22	08SEP2004	21	77	107	77	-3	-13	-14	86	108	82	-7	10	8
		DAY 29	16SEP2004	29	80	102	71	0	-18	-20D	86	95	71	-7	-3	-3
		DAY 36	24SEP2004	37	70	107	81	-10	-13	-10	76	104	79	-17D	6	5
		DAY 43	30SEP2004	43	86	132	90	6	12	-1	90	119	93	-3	21I	19

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0030003	DAY 50	07OCT2004	50	77	108	77	-3	-12	-14	90	117	74	-3	19	0
		DAY 57	12OCT2004	55	64	101	68	-16D	-19	-23D	80	85L	62	-13	-13	-12
		FINAL			64	101	68	-16D	-19	-23D	80	85L	62	-13	-13	-12
	E0030024	SCREEN	07DEC2004	-7	59	110	71				74	120	86			
		DAY 1	14DEC2004	1	57	106	68				70	121	74			
		BASELINE			57	106	68				70	121	74			
		DAY 8	21DEC2004	8	70	113	69	13	7	1	88	132	82	18I	11	8
		DAY 15	28DEC2004	15	78	121	69	21I	15	1	88	119	76	18I	-2	2
		DAY 22	05JAN2005	23	68	122	68	11	16	0	88	110	70	18I	-11	-4
		DAY 43	25JAN2005	43	56	110	78	-1	4	10	72	118	78	2	-3	4
		FINAL			56	110	78	-1	4	10	72	118	78	2	-3	4
	E0035018	SCREEN	11OCT2004	-7	60	102	70				62	100	70			
		DAY 1	18OCT2004	1	60	108	70				60	106	70			
		BASELINE			60	108	70				60	106	70			
		DAY 8	25OCT2004	8	68	118	82	8	10	12	68	120	80	8	14	10
		DAY 15	01NOV2004	15	68	120	70	8	12	0	80	110	60	20I	4	-10
		DAY 22	08NOV2004	22	80	98	60	20I	-10	-10	88	105	68	28I	-1	-2
		DAY 29	15NOV2004	29	76	94	60	16I	-14	-10	76	96	60	16I	-10	-10
		DAY 36	22NOV2004	36	80	96	70	20I	-12	0	80	98	60	20I	-8	-10
		DAY 43	30NOV2004	44	66	110	80	6	2	10	76	104	74	16I	-2	4
		DAY 50	09DEC2004	53	66	122	80	6	14	10	70	120	70	10	14	0
		DAY 57	17DEC2004	61	66	122	80	6	14	10	70	120	70	10	14	0
		FINAL			66	122	80	6	14	10	70	120	70	10	14	0
	E0036003	SCREEN	20JAN2005	-6	84	118	64				90	116	64			
		DAY 1	26JAN2005	1	80	142	82				80	136	84			
		BASELINE			80	142	82				80	136	84			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0036003	DAY 8		02FEB2005	8	100	142	90	20I	0	8	100	118	80	20I	-18	-4
		DAY 15		09FEB2005	15	96	116	82	16I	-26D	0	100	122	84	20I	-14	0
		DAY 22		16FEB2005	22	100	118	80	20I	-24D	-2	100	128	88	20I	-8	4
		DAY 29		23FEB2005	29	88	148	90	8	6	8	92	128	86	12	-8	2
		DAY 36		02MAR2005	36	96	138	86	16I	-4	4	92	132	80	12	-4	-4
		DAY 43		09MAR2005	43	100	122	78	20I	-20D	-4	100	118	88	20I	-18	4
		DAY 50		15MAR2005	49	96	138	82	16I	-4	0	100	136	78	20I	0	-6
		DAY 57		23MAR2005	57	100	142	88	20I	0	6	104	138	92	24I	2	8
		FINAL				100	142	88	20I	0	6	104	138	92	24I	2	8
	E0036005	SCREEN		08FEB2005	-7	76	110	76				84	110	76			
		DAY 1		15FEB2005	1	80	122	80				88	118	80			
		BASELINE				80	122	80				88	118	80			
		DAY 8		22FEB2005	8	100	116	78	20I	-6	-2	92	116	82	4	-2	2
		DAY 15		02MAR2005	16	100	118	80	20I	-4	0	92	114	76	4	-4	-4
		DAY 22		09MAR2005	23	100	110	80	20I	-12	0	92	106	80	4	-12	0
		DAY 29		15MAR2005	29	80	116	84	0	-6	4	84	116	86	-4	-2	6
		DAY 36		22MAR2005	36	76	108	78	-4	-14	-2	72	98	80	-16D	-20D	0
		DAY 43		29MAR2005	43	72	106	82	-8	-16	2	76	98	88	-12	-20D	8
		DAY 50		05APR2005	50	76	98	78	-4	-24D	-2	72	102	84	-16D	-16	4
		DAY 57		12APR2005	57	104	112	76	24I	-10	-4	108	116	76	20I	-2	-4
		FINAL				104	112	76	24I	-10	-4	108	116	76	20I	-2	-4
	E0036007	DAY 1	*	18MAR2005	1												
		DAY 1		18MAR2005	1	84	136	80				88	118	78			
		BASELINE				84	136	80				88	118	78			
		BASELINE															
		DAY 8		29MAR2005	12	72	118	82	-12	-18	2	72	132	82	-16D	14	4
		FINAL				72	118	82	-12	-18	2	72	132	82	-16D	14	4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0037020	SCREEN	08MAR2005	-7	72	140	100				72	150	110H			
		DAY 1	15MAR2005	1	76	150	100				80	150	102			
		BASELINE			76	150	100				80	150	102			
		DAY 8	22MAR2005	8	76	148	100	0	-2	0	84	150	110H	4	0	8
		DAY 15	29MAR2005	15	80	140	100	4	-10	0	84	142	110H	4	-8	8
		DAY 22	07APR2005	24	72	130	90	-4	-20D	-10	84	132	100	4	-18	-2
		DAY 29	12APR2005	29	84	140	100	8	-10	0	92	138	96	12	-12	-6
		DAY 36	20APR2005	37	80	120	90	4	-30D	-10	96	110	88	16I	-40D	-14
		DAY 43	26APR2005	43	80	130	100	4	-20D	0	92	120	98	12	-30D	-4
		DAY 50	03MAY2005	50	80	140	100	4	-10	0	82	136	102	2	-14	0
		DAY 57	10MAY2005	57	80	130	90	4	-20D	-10	108	120	100	28I	-30D	-2
		FINAL			80	130	90	4	-20D	-10	108	120	100	28I	-30D	-2
	E0042014	SCREEN	15DEC2004	-14	72	144	98				78	144	92			
		DAY 1	29DEC2004	1	80	152	104				80	146	110H			
		BASELINE			80	152	104				80	146	110H			
		DAY 8	05JAN2005	8	76	158	104	-4	6	0	76	156	110H	-4	10	0
		DAY 15	12JAN2005	15	76	146	102	-4	-6	-2	80	144	106H	0	-2	-4
		DAY 22	19JAN2005	22	80	144	110H	0	-8	6	88	140	106H	8	-6	-4
		DAY 29	26JAN2005	29	84	142	94	4	-10	-10	80	138	96	0	-8	-14
		DAY 36	02FEB2005	36	88	146	96	8	-6	-8	84	142	90	4	-4	-20D
		DAY 43	10FEB2005	44	80	130	88	0	-22D	-16	84	126	86	4	-20D	-24D
		DAY 50	16FEB2005	50	76	132	90	-4	-20D	-14	80	130	94	0	-16	-16
		DAY 57	21FEB2005	55	78	134	96	-2	-18	-8	84	136	100	4	-10	-10
		FINAL			78	134	96	-2	-18	-8	84	136	100	4	-10	-10
	E0043003	SCREEN	29NOV2004	-4	85	120	70				78	118	70			
		DAY 1	03DEC2004	1	88	132	78				94	124	72			
		BASELINE			88	132	78				94	124	72			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0043003	DAY 8	10DEC2004	8	69	120	80	-19D	-12	2	70	122	80	-24D	-2	8
		DAY 15	17DEC2004	15	72	122	70	-16D	-10	-8	70	120	70	-24D	-4	-2
		DAY 22	23DEC2004	21	72	128	72	-16D	-4	-6	74	130	72	-20D	6	0
		DAY 29	29DEC2004	27	84	122	88	-4	-10	10	96	120	82	2	-4	10
		DAY 36	06JAN2005	35	76	120	78	-12	-12	0	76	120	80	-18D	-4	8
		DAY 43	13JAN2005	42	70	120	70	-18D	-12	-8	72	122	70	-22D	-2	-2
		DAY 50	20JAN2005	49	76	132	78	-12	0	0	88	128	70	-6	4	-2
		DAY 57	27JAN2005	56	72	110	70	-16D	-22D	-8	74	120	70	-20D	-4	-2
		FINAL			72	110	70	-16D	-22D	-8	74	120	70	-20D	-4	-2
	E0046001	SCREEN	03NOV2004	-7	76	120	78				84	130	82			
		DAY 1	10NOV2004	1	80	130	76				88	130	80			
		BASELINE			80	130	76				88	130	80			
		DAY 8	17NOV2004	8	73	132	72	-7	2	-4	85	126	74	-3	-4	-6
		DAY 15	24NOV2004	15	72	113	80	-8	-17	4	93	121	89	5	-9	9
		DAY 22	01DEC2004	22	100	143	89	20I	13	13	122H	131	88	34I	1	8
		DAY 29	08DEC2004	29	79	126	86	-1	-4	10	92	133	96	4	3	16
		DAY 36	14DEC2004	35	89	123	81	9	-7	5	94	125	86	6	-5	6
		DAY 43	22DEC2004	43	88	132	90	8	2	14	103	136	97	15I	6	17
		DAY 50	29DEC2004	50	92	126	78	12	-4	2	100	124	82	12	-6	2
		DAY 57	05JAN2005	57	84	118	64	4	-12	-12	100	114	64	12	-16	-16
		FINAL			84	118	64	4	-12	-12	100	114	64	12	-16	-16
	E0046007	SCREEN	21DEC2004	-14	68	154	90				72	170	90			
		DAY 1	04JAN2005	1	63	147	87				73	162	90			
		BASELINE			63	147	87				73	162	90			
		DAY 8	11JAN2005	8	81	144	85	18I	-3	-2	103	154	84	30I	-8	-6
		DAY 15	18JAN2005	15	75	166	82	12	19	-5	86	169	98	13	7	8
		DAY 22	25JAN2005	22	76	142	87	13	-5	0	99	135	91	26I	-27D	1

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
QUETIAPINE 600 MG (BIPOLAR II)	E0046007	DAY 29	01FEB2005	29	72	153	87	9	6	0	86	141	93	13	-21D	3
		DAY 36	08FEB2005	36	84	142	80	21I	-5	-7	96	131	86	23I	-31D	-4
		DAY 43	15FEB2005	43	87	142	81	24I	-5	-6	103	131	88	30I	-31D	-2
		DAY 50	22FEB2005	50	84	127	73	21I	-20D	-14	100	122	82	27I	-40D	-8
		DAY 57	28FEB2005	56	80	157	97	17I	10	10	95	156	95	22I	-6	5
		FINAL			80	157	97	17I	10	10	95	156	95	22I	-6	5
	E0046011	SCREEN	01FEB2005	-8	73	136	88				96	138	96			
		DAY 1	09FEB2005	1	73	128	80				93	136	87			
		BASELINE			73	128	80				93	136	87			
		DAY 8	16FEB2005	8	66	120	78	-7	-8	-2	90	114	82	-3	-22D	-5
		DAY 15	23FEB2005	15	72	138	77	-1	10	-3	105	146	84	12	10	-3
		DAY 22	02MAR2005	22	65	118	77	-8	-10	-3	88	141	85	-5	5	-2
		DAY 29	10MAR2005	30	65	113	77	-8	-15	-3	86	120	79	-7	-16	-8
		DAY 36	16MAR2005	36	75	127	83	2	-1	3	98	145	89	5	9	2
		DAY 43	22MAR2005	42	60	130	80	-13	2	0	80	120	80	-13	-16	-7
		DAY 50	30MAR2005	50	69	131	87	-4	3	7	83	141	84	-10	5	-3
		DAY 57	06APR2005	57	72	132	80	-1	4	0	82	126	82	-11	-10	-5
		FINAL			72	132	80	-1	4	0	82	126	82	-11	-10	-5
PLACEBO (BIPOLAR I)	E0001013	SCREEN	28APR2005	-7	68	120	96				84	136	100			
		DAY 1	05MAY2005	1	72	160	100				80	148	104			
		BASELINE			72	160	100				80	148	104			
		DAY 8	12MAY2005	8	70	140	92	-2	-20D	-8	76	140	90	-4	-8	-14
		DAY 15	19MAY2005	15	64	146	90	-8	-14	-10	84	128	90	4	-20D	-14
		DAY 29	02JUN2005	29	72	136	90	0	-24D	-10	76	118	80	-4	-30D	-24D
		FINAL			72	136	90	0	-24D	-10	76	118	80	-4	-30D	-24D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0004007	SCREEN	27JUL2004	-7	64	98	78				72	102	80			
		DAY 1	03AUG2004	1	64	106	78				72	102	78			
		BASELINE			64	106	78				72	102	78			
		DAY 8	10AUG2004	8	64	108	66	0	2	-12	76	102	78	4	0	0
		DAY 15	17AUG2004	15	68	110	70	4	4	-8	76	108	74	4	6	-4
		DAY 22	24AUG2004	22	80	114	80	16I	8	2	84	110	82	12	8	4
		DAY 29	31AUG2004	29	68	108	78	4	2	0	72	110	84	0	8	6
		DAY 36	10SEP2004	39	70	108	68	6	2	-10	72	108	76	0	6	-2
		DAY 43	14SEP2004	43	70	112	72	6	6	-6	78	116	78	6	14	0
		DAY 50	21SEP2004	50	76	112	80	12	6	2	76	112	80	4	10	2
		DAY 57	29SEP2004	58	76	102	78	12	-4	0	80	106	72	8	4	-6
		FINAL			76	102	78	12	-4	0	80	106	72	8	4	-6
	E0004008	SCREEN	04AUG2004	-7	56	100	68				60	102	72			
		DAY 1	11AUG2004	1	60	92	62				70	96	68			
		BASELINE			60	92	62				70	96	68			
		DAY 8	18AUG2004	8	60	92	58	0	0	-4	68	92	56	-2	-4	-12
		DAY 15	25AUG2004	15	72	90L	60	12	-2	-2	76	92	68	6	-4	0
		DAY 22	01SEP2004	22	68	90L	62	8	-2	0	76	94	64	6	-2	-4
		DAY 29	08SEP2004	29	72	100	68	12	8	6	80	98	70	10	2	2
		DAY 36	15SEP2004	36	76	92	72	16I	0	10	80	90L	68	10	-6	0
		DAY 43	22SEP2004	43	64	94	66	4	2	4	76	90L	62	6	-6	-6
		DAY 50	29SEP2004	50	76	92	68	16I	0	6	80	94	70	10	-2	2
		DAY 57	06OCT2004	57	72	100	70	12	8	8	80	96	68	10	0	0
		FINAL			72	100	70	12	8	8	80	96	68	10	0	0
	E0004010	SCREEN	11AUG2004	-15	68	114	78				72	112	80			
		DAY 1	26AUG2004	1	80	118	80				84	126	82			
		BASELINE			80	118	80				84	126	82			
		DAY 8	02SEP2004	8	76	130	82	-4	12	2	80	132	88	-4	6	6
		DAY 15	09SEP2004	15	72	120	76	-8	2	-4	80	112	80	-4	-14	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0004010	DAY 22		16SEP2004	22	80	108	68	0	-10	-12	84	110	68	0	-16	-14
		DAY 29		22SEP2004	28	72	110	78	-8	-8	-2	84	112	70	0	-14	-12
		DAY 36		29SEP2004	35	80	110	70	0	-8	-10	92	100	72	8	-26D	-10
		DAY 43		06OCT2004	42	60	110	80	-20D	-8	0	78	100	70	-6	-26D	-12
		DAY 50		13OCT2004	49	72	102	74	-8	-16	-6	76	100	80	-8	-26D	-2
		DAY 57		20OCT2004	56	80	120	72	0	2	-8	76	114	80	-8	-12	-2
		FINAL				80	120	72	0	2	-8	76	114	80	-8	-12	-2
	E0004018	SCREEN		13DEC2004	-7	56	122	88				60	120	82			
		DAY 1		20DEC2004	1	68	120	82				68	120	80			
		BASELINE				68	120	82				68	120	80			
		DAY 8		28DEC2004	9	72	104	80	4	-16	-2	80	116	82	12	-4	2
		DAY 15		04JAN2005	16	64	128	82	-4	8	0	68	130	88	0	10	8
		DAY 22		10JAN2005	22	72	122	80	4	2	-2	76	120	88	8	0	8
		DAY 29		20JAN2005	32	72	120	76	4	0	-6	80	112	80	12	-8	0
		DAY 36		24JAN2005	36	64	124	76	-4	4	-6	80	122	82	12	2	2
		DAY 43		31JAN2005	43	72	120	80	4	0	-2	88	122	86	20I	2	6
		DAY 50		07FEB2005	50	64	120	86	-4	0	4	80	116	82	12	-4	2
		DAY 57		14FEB2005	57	72	118	88	4	-2	6	80	120	90	12	0	10
		FINAL				72	118	88	4	-2	6	80	120	90	12	0	10
	E0006004	SCREEN		02AUG2004	-7	66	108	70				74	110	80			
		DAY 1		09AUG2004	1	64	100	70				80	110	76			
		BASELINE				64	100	70				80	110	76			
		DAY 8		17AUG2004	9	80	106	70	16I	6	0	88	102	78	8	-8	2
		DAY 15		24AUG2004	16	80	104	76	16I	4	6	68	102	64	-12	-8	-12
		DAY 22		02SEP2004	25	78	110	68	14	10	-2	84	102	84	4	-8	8
		DAY 29		09SEP2004	32	64	110	80	0	10	10	68	108	82	-12	-2	6
		DAY 36		16SEP2004	39	64	98	62	0	-2	-8	74	102	70	-6	-8	-6
		DAY 43		23SEP2004	46	80	104	68	16I	4	-2	84	108	78	4	-2	2
		DAY 43	*	24SEP2004	47	64	98	70	0	-2	0	70	100	70	-10	-10	-6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0006004	FINAL			64	98	70	0	-2	0	70	100	70	-10	-10	-6
	E0006010	SCREEN	12AUG2004	-6	60	130	90				72	130	90			
		DAY 1	18AUG2004	1	64	132	88				72	130	90			
		BASELINE			64	132	88				72	130	90			
		DAY 8	25AUG2004	8	78	122	74	14	-10	-14	74	128	76	2	-2	-14
		DAY 15	01SEP2004	15	76	132	76	12	0	-12	88	122	80	16I	-8	-10
		DAY 22	08SEP2004	22	70	118	76	6	-14	-12	74	110	80	2	-20D	-10
		DAY 29	15SEP2004	29	84	110	72	20I	-22D	-16	88	110	74	16I	-20D	-16
		DAY 36	22SEP2004	36	74	120	68	10	-12	-20D	82	116	78	10	-14	-12
		DAY 43	29SEP2004	43	62	110	72	-2	-22D	-16	70	110	70	-2	-20D	-20D
		DAY 50	06OCT2004	50	80	140	76	16I	8	-12	84	136	76	12	6	-14
		DAY 57	13OCT2004	57	62	112	76	-2	-20D	-12	76	116	76	4	-14	-14
		FINAL			62	112	76	-2	-20D	-12	76	116	76	4	-14	-14
	E0006019	SCREEN	17NOV2004	-7	68	124	82				72	130	88			
		DAY 1	24NOV2004	1	84	118	80				80	124	84			
		BASELINE			84	118	80				80	124	84			
		DAY 8	01DEC2004	8	80	118	82	-4	0	2	88	120	84	8	-4	0
		DAY 15	08DEC2004	15	88	120	98	4	2	18	84	118	98	4	-6	14
		DAY 22	15DEC2004	22	88	128	104	4	10	24	88	126	98	8	2	14
		DAY 29	22DEC2004	29	80	138	102	-4	20I	22	76	136	102	-4	12	18
		DAY 36	29DEC2004	36	103	140	80	19I	22I	0	108	152	96	28I	28I	12
		DAY 43	07JAN2005	45	83	106	78	-1	-12	-2	84	120	100	4	-4	16
		DAY 50	12JAN2005	50	82	122	70	-2	4	-10	84	132	108H	4	8	24
		DAY 57	19JAN2005	57	84	138	108H	0	20I	28	88	140	108H	8	16	24
		FINAL			84	138	108H	0	20I	28	88	140	108H	8	16	24
	E0006021	SCREEN	31MAR2005	-7	78	126	84				86	134	86			
		DAY 1	07APR2005	1	72	130	82				80	120	74			
		BASELINE			72	130	82				80	120	74			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0006021	DAY 8	13APR2005	7	80	130	90	8	0	8	88	132	86	8	12	12
		DAY 15	20APR2005	14	70	130	86	-2	0	4	80	126	82	0	6	8
		DAY 22	27APR2005	21	76	130	84	4	0	2	82	126	82	2	6	8
		DAY 29	04MAY2005	28	74	117	80	2	-13	-2	76	122	80	-4	2	6
		DAY 36	11MAY2005	35	88	118	94	16I	-12	12	92	110	96	12	-10	22
		DAY 43	18MAY2005	42	80	126	82	8	-4	0	86	130	84	6	10	10
		DAY 50	25MAY2005	49	76	130	96	4	0	14	84	132	98	4	12	24
		FINAL			76	130	96	4	0	14	84	132	98	4	12	24
	E0008004	SCREEN	28SEP2004	-21	68	100	64				70	102	66			
		DAY 1	19OCT2004	1	72	104	68				76	100	66			
		BASELINE			72	104	68				76	100	66			
		DAY 8	26OCT2004	8	70	106	70	-2	2	2	78	110	72	2	10	6
		DAY 15	02NOV2004	15	70	124	72	-2	20I	4	74	122	68	-2	22I	2
		DAY 50	08DEC2004	51	80	118	70	8	14	2	84	126	74	8	26I	8
		FINAL			80	118	70	8	14	2	84	126	74	8	26I	8
	E0008011	SCREEN	26JAN2005	-7	82	108	70				76	106	68			
		DAY 1	02FEB2005	1	78	112	72				80	108	68			
		BASELINE			78	112	72				80	108	68			
		DAY 8	09FEB2005	8	80	126	80	2	14	8	98	116	80	18I	8	12
		DAY 15	16FEB2005	15	76	104	78	-2	-8	6	80	114	86	0	6	18
		DAY 22	23FEB2005	22	78	122	80	0	10	8	82	118	78	2	10	10
		DAY 29	02MAR2005	29	74	112	70	-4	0	-2	78	108	68	-2	0	0
		DAY 36	09MAR2005	36	70	116	78	-8	4	6	74	110	68	-6	2	0
		DAY 43	15MAR2005	42	82	106	68	4	-6	-4	86	102	64	6	-6	-4
		FINAL			82	106	68	4	-6	-4	86	102	64	6	-6	-4
	E0012026	SCREEN	08JUN2005	-7	72	124	68				74	128	72			
		DAY 1	15JUN2005	1	92	124	78				92	118	80			
		BASELINE			92	124	78				92	118	80			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0012026	DAY 8	22JUN2005	8	83	120	95	-9	-4	17	75	126	78	-17D	8	-2
		DAY 15	29JUN2005	15	78	112	70	-14	-12	-8	78	118	74	-14	0	-6
		DAY 22	06JUL2005	22	80	116	74	-12	-8	-4	82	116	76	-10	-2	-4
		DAY 29	13JUL2005	29	72	112	74	-20D	-12	-4	74	114	74	-18D	-4	-6
		DAY 36	20JUL2005	36	84	110	70	-8	-14	-8	88	108	74	-4	-10	-6
		DAY 43	27JUL2005	43	80	118	72	-12	-6	-6	82	118	74	-10	0	-6
		DAY 50	01AUG2005	48	80	120	74	-12	-4	-4	84	118	72	-8	0	-8
		DAY 57	10AUG2005	57	78	124	78	-14	0	0	80	126	78	-12	8	-2
		FINAL			78	124	78	-14	0	0	80	126	78	-12	8	-2
	E0013004	SCREEN	23AUG2004	-7	68	120	76				70	120	78			
		DAY 1	30AUG2004	1	64	118	70				64	120	70			
		BASELINE			64	118	70				64	120	70			
		DAY 8	07SEP2004	9	76	122	84	12	4	14	68	118	68	4	-2	-2
		DAY 15	13SEP2004	15	80	116	68	16I	-2	-2	76	118	70	12	-2	0
		DAY 22	20SEP2004	22	80	132	86	16I	14	16	84	126	92	20I	6	22
		DAY 29	27SEP2004	29	68	118	76	4	0	6	70	120	80	6	0	10
		DAY 36	04OCT2004	36	88	122	84	24I	4	14	96	126	88	32I	6	18
		DAY 43	11OCT2004	43	68	118	88	4	0	18	72	116	84	8	-4	14
		DAY 50	18OCT2004	50	72	120	80	8	2	10	80	122	84	16I	2	14
		DAY 57	27OCT2004	59	70	122	78	6	4	8	72	120	80	8	0	10
		FINAL			70	122	78	6	4	8	72	120	80	8	0	10
	E0013015	SCREEN	09MAY2005	-7	83	113	78				91	108	83			
		DAY 1	16MAY2005	1	93	114	79				92	115	82			
		BASELINE			93	114	79				92	115	82			
		DAY 8	23MAY2005	8	80	108	78	-13	-6	-1	80	107	79	-12	-8	-3
		DAY 15	01JUN2005	17	75	116	85	-18D	2	6	80	113	75	-12	-2	-7
		DAY 22	08JUN2005	24	75	116	85	-18D	2	6	80	113	75	-12	-2	-7
		DAY 29	16JUN2005	32	70	118	83	-23D	4	4	70	116	85	-22D	1	3
		DAY 43	29JUN2005	45	58	129	83	-35D	15	4	53	114	82	-39D	-1	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0013015	FINAL			58	129	83	-35D	15	4	53	114	82	-39D	-1	0
	E0015007	SCREEN	12OCT2004	-6	64	114	84				64	112	80			
		DAY 1	18OCT2004	1	68	124	86				70	120	86			
		BASELINE			68	124	86				70	120	86			
		DAY 8	25OCT2004	8	80	136	90	12	12	4	84	128	88	14	8	2
		DAY 15	01NOV2004	15	76	128	86	8	4	0	72	124	82	2	4	-4
		DAY 22	08NOV2004	22	78	122	88	10	-2	2	82	120	88	12	0	2
		DAY 29	15NOV2004	29	80	130	90	12	6	4	86	126	86	16I	6	0
		DAY 36	22NOV2004	36	76	128	92	8	4	6	80	122	80	10	2	-6
		DAY 43	29NOV2004	43	72	152	102	4	28I	16	76	142	102	6	22I	16
		DAY 50	06DEC2004	50	64	156	102	-4	32I	16	76	142	102	6	22I	16
		DAY 57	13DEC2004	57	62	142	104	-6	18	18	68	136	104	-2	16	18
		FINAL			62	142	104	-6	18	18	68	136	104	-2	16	18
	E0015018	SCREEN	08MAR2005	-7	62	108	84				68	100	80			
		DAY 1	15MAR2005	1	68	132	90				72	126	88			
		BASELINE			68	132	90				72	126	88			
		DAY 8	22MAR2005	8	66	126	82	-2	-6	-8	68	124	80	-4	-2	-8
		DAY 15	30MAR2005	16	68	114	82	0	-18	-8	72	108	74	0	-18	-14
		DAY 22	06APR2005	23	68	132	94	0	0	4	70	136	90	-2	10	2
		DAY 29	12APR2005	29	64	114	86	-4	-18	-4	64	112	82	-8	-14	-6
		DAY 36	19APR2005	36	66	112	78	-2	-20D	-12	68	114	80	-4	-12	-8
		DAY 43	26APR2005	43	64	118	76	-4	-14	-14	68	116	76	-4	-10	-12
		DAY 50	03MAY2005	50	66	122	78	-2	-10	-12	68	120	78	-4	-6	-10
		DAY 57	13MAY2005	60	74	128	78	6	-4	-12	72	128	74	0	2	-14
		FINAL			74	128	78	6	-4	-12	72	128	74	0	2	-14
	E0018003	SCREEN	22NOV2004	-14	105	129	62				105	132	68			
		DAY 1	06DEC2004	1	96	114	64				107	115	68			
		BASELINE			96	114	64				107	115	68			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0018003	DAY 8	14DEC2004	9	87	121	63	-9	7	-1	102	127	76	-5	12	8
		DAY 15	21DEC2004	16	84	120	70	-12	6	6	100	124	80	-7	9	12
		DAY 22	28DEC2004	23	83	129	63	-13	15	-1	93	139	64	-14	24I	-4
		DAY 29	04JAN2005	30	81	114	63	-15D	0	-1	94	135	80	-13	20I	12
		DAY 36	11JAN2005	37	102	134	66	6	20I	2	115	123	72	8	8	4
		DAY 43	20JAN2005	46	98	135	76	2	21I	12	108	134	77	1	19	9
		DAY 50	27JAN2005	53	111	148	76	15I	34I	12	127H	147	74	20I	32I	6
		DAY 57	03FEB2005	60	84	126	69	-12	12	5	89	114	79	-18D	-1	11
		FINAL			84	126	69	-12	12	5	89	114	79	-18D	-1	11
	E0020007	SCREEN	26AUG2004	-12	64	120	70				64	118	70			
		DAY 1	07SEP2004	1	72	110	60				68	108	70			
		BASELINE			72	110	60				68	108	70			
		DAY 8	14SEP2004	8	80	110	60	8	0	0	72	106	68	4	-2	-2
		DAY 15	23SEP2004	17	68	112	60	-4	2	0	72	110	68	4	2	-2
		DAY 29	08OCT2004	32	76	100	68	4	-10	8	86	100	70	18I	-8	0
		DAY 36	14OCT2004	38	72	108	60	0	-2	0	80	102	64	12	-6	-6
		DAY 43	19OCT2004	43	84	110	80	12	0	20	92	102	80	24I	-6	10
		DAY 50	28OCT2004	52	86	100	69	14	-10	9	98	104	72	30I	-4	2
		DAY 57	04NOV2004	59	88	130	70	16I	20I	10	92	140	85	24I	32I	15
		FINAL			88	130	70	16I	20I	10	92	140	85	24I	32I	15
	E0020008	SCREEN	01SEP2004	-12	80	140	80				84	140	90			
		DAY 1	13SEP2004	1	88	135	80				80	138	80			
		BASELINE			88	135	80				80	138	80			
		DAY 8	22SEP2004	10	72	140	70	-16D	5	-10	76	136	80	-4	-2	0
		DAY 15	27SEP2004	15	80	142	80	-8	7	0	84	140	78	4	2	-2
		DAY 22	04OCT2004	22	64	140	80	-24D	5	0	72	138	80	-8	0	0
		DAY 29	13OCT2004	31	68	138	80	-20D	3	0	80	134	80	0	-4	0
		DAY 43	25OCT2004	43	76	150	94	-12	15	14	80	140	100	0	2	20
		DAY 50	01NOV2004	50	76	145	70	-12	10	-10	86	120	70	6	-18	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0020008	DAY 57	10NOV2004	59	72	130	100	-16D	-5	20	88	132	110H	8	-6	30I
		FINAL			72	130	100	-16D	-5	20	88	132	110H	8	-6	30I
	E0020024	SCREEN	22NOV2004	-9	62	108	76				84	120	72			
		DAY 1	01DEC2004	1	68	122	78				80	124	80			
		BASELINE			68	122	78				80	124	80			
		DAY 8	08DEC2004	8	68	120	90	0	-2	12	60	120	80	-20D	-4	0
		DAY 15	15DEC2004	15	66	110	68	-2	-12	-10	84	120	80	4	-4	0
		DAY 22	22DEC2004	22	62	102	80	-6	-20D	2	84	102	80	4	-22D	0
		DAY 29	29DEC2004	29	68	122	80	0	0	2	96	130	92	16I	6	12
		DAY 36	05JAN2005	36	68	110	78	0	-12	0	88	110	80	8	-14	0
		DAY 43	12JAN2005	43	72	111	90	4	-11	12	92	110	90	12	-14	10
		DAY 50	19JAN2005	50	66	100	70	-2	-22D	-8	94	120	80	14	-4	0
		DAY 57	26JAN2005	57	72	102	70	4	-20D	-8	74	102	84	-6	-22D	4
		FINAL			72	102	70	4	-20D	-8	74	102	84	-6	-22D	4
	E0020036	SCREEN	28JAN2005	-10	58	136	80				58	120	90			
		DAY 1	07FEB2005	1	54	130	90				58	132	102			
		BASELINE			54	130	90				58	132	102			
		DAY 8	16FEB2005	10	62	120	82	8	-10	-8	60	130	90	2	-2	-12
		DAY 15	23FEB2005	17	66	130	84	12	0	-6	66	132	90	8	0	-12
		DAY 22	02MAR2005	24	60	120	90	6	-10	0	64	140	98	6	8	-4
		DAY 29	09MAR2005	31	54	140	102	0	10	12	60	130	104	2	-2	2
		DAY 36	14MAR2005	36	60	126	82	6	-4	-8	64	130	90	6	-2	-12
		DAY 43	21MAR2005	43	60	126	92	6	-4	2	64	126	98	6	-6	-4
		DAY 50	30MAR2005	52	64	111	90	10	-19	0	64	124	94	6	-8	-8
		DAY 57	06APR2005	59	72	110	82	18I	-20D	-8	72	119	92	14	-13	-10
		FINAL			72	110	82	18I	-20D	-8	72	119	92	14	-13	-10
	E0020045	SCREEN	18APR2005	-9	56	98	80				60	98	82			
		DAY 1	27APR2005	1	68	90L	70				84	90L	76			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0020045	BASELINE			68	90L	70				84	90L	76			
		DAY 8	03MAY2005	7	70	100	70	2	10	0	80	114	80	-4	24I	4
		DAY 15	11MAY2005	15	66	104	72	-2	14	2	76	111	82	-8	21I	6
		DAY 22	18MAY2005	22	62	120	76	-6	30I	6	68	120	82	-16D	30I	6
		DAY 29	25MAY2005	29	66	106	72	-2	16	2	78	100	76	-6	10	0
		DAY 36	01JUN2005	36	80	110	76	12	20I	6	84	110	70	0	20I	-6
		FINAL			80	110	76	12	20I	6	84	110	70	0	20I	-6
	E0021030	SCREEN	05APR2005	-8	54	126	90				72	134	94			
		DAY 1	13APR2005	1	63	116	74				75	112	86			
		BASELINE			63	116	74				75	112	86			
		DAY 8	19APR2005	7	69	116	74	6	0	0	72	122	92	-3	10	6
		DAY 15	27APR2005	15	68	112	84	5	-4	10	76	122	90	1	10	4
		DAY 22	04MAY2005	22	72	116	74	9	0	0	93	110	86	18I	-2	0
		DAY 29	09MAY2005	27	63	124	76	0	8	2	72	120	82	-3	8	-4
		DAY 36	18MAY2005	36	69	118	74	6	2	0	72	112	82	-3	0	-4
		DAY 43	25MAY2005	43	69	134	82	6	18	8	72	122	90	-3	10	4
		DAY 50	01JUN2005	50	72	108	66	9	-8	-8	78	124	88	3	12	2
		DAY 57	08JUN2005	57	72	110	90	9	-6	16	96	118	96	21I	6	10
		FINAL			72	110	90	9	-6	16	96	118	96	21I	6	10
	E0024001	SCREEN	26JUL2004	-7	64	136	84				68	134	90			
		DAY 1	02AUG2004	1	84	132	84				92	136	88			
		BASELINE			84	132	84				92	136	88			
		DAY 8	09AUG2004	8	72	138	84	-12	6	0	84	140	88	-8	4	0
		DAY 15	18AUG2004	17	76	136	86	-8	4	2	84	136	84	-8	0	-4
		DAY 22	23AUG2004	22	72	140	92	-12	8	8	80	132	92	-12	-4	4
		DAY 29	30AUG2004	29	86	140	82	2	8	-2	92	140	80	0	4	-8
		DAY 36	07SEP2004	37	72	142	88	-12	10	4	88	144	94	-4	8	6
		DAY 43	14SEP2004	44	72	140	82	-12	8	-2	80	140	86	-12	4	-2
		DAY 50	20SEP2004	50	60	140	92	-24D	8	8	72	132	94	-20D	-4	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0024001	DAY 57	28SEP2004	58	84	138	88	0	6	4	72	126	86	-20D	-10	-2
		FINAL			84	138	88	0	6	4	72	126	86	-20D	-10	-2
	E0024004	SCREEN	09NOV2004	-7	84	130	98				82	130	94			
		DAY 1	16NOV2004	1	88	144	92				96	138	94			
		BASELINE			88	144	92				96	138	94			
		DAY 8	23NOV2004	8	80	128	92	-8	-16	0	72	126	96	-24D	-12	2
		DAY 15	30NOV2004	15	88	132	96	0	-12	4	84	130	92	-12	-8	-2
		DAY 22	06DEC2004	21	88	136	96	0	-8	4	84	134	92	-12	-4	-2
		DAY 29	13DEC2004	28	88	132	96	0	-12	4	80	126	88	-16D	-12	-6
		DAY 36	20DEC2004	35	88	138	92	0	-6	0	80	132	92	-16D	-6	-2
		DAY 43	28DEC2004	43	82	136	84	-6	-8	-8	84	130	86	-12	-8	-8
		DAY 50	03JAN2005	49	76	128	82	-12	-16	-10	72	122	86	-24D	-16	-8
		DAY 57	10JAN2005	56	80	122	88	-8	-22D	-4	72	118	90	-24D	-20D	-4
		FINAL			80	122	88	-8	-22D	-4	72	118	90	-24D	-20D	-4
	E0024009	SCREEN	09FEB2005	-6	60	118	78				64	116	74			
		DAY 1	15FEB2005	1	68	124	86				80	118	88			
		BASELINE			68	124	86				80	118	88			
		DAY 8	22FEB2005	8	78	110	78	10	-14	-8	80	118	82	0	0	-6
		DAY 15	01MAR2005	15	68	124	94	0	0	8	76	122	92	-4	4	4
		DAY 22	08MAR2005	22	72	118	80	4	-6	-6	80	116	78	0	-2	-10
		DAY 29	15MAR2005	29	60	112	72	-8	-12	-14	64	110	72	-16D	-8	-16
		DAY 36	22MAR2005	36	64	118	86	-4	-6	0	80	116	86	0	-2	-2
		DAY 43	29MAR2005	43	72	124	82	4	0	-4	76	118	78	-4	0	-10
		DAY 50	05APR2005	50	84	138	88	16I	14	2	72	124	84	-8	6	-4
		DAY 57	26APR2005	71	72	124	84	4	0	-2	84	122	88	4	4	0
		FINAL			72	124	84	4	0	-2	84	122	88	4	4	0
	E0025023	SCREEN	05OCT2004	-7	78	117	80				91	132	86			
		DAY 1	12OCT2004	1	87	116	76				80	123	85			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0025023	BASELINE			87	116	76				80	123	85			
		DAY 8	19OCT2004	8	84	109	72	-3	-7	-4	82	138	80	2	15	-5
		DAY 15	26OCT2004	15	92	129	68	5	13	-8	99	117	76	19I	-6	-9
		DAY 22	02NOV2004	22	76	125	73	-11	9	-3	92	146	80	12	23I	-5
		DAY 29	09NOV2004	29	71	129	87	-16D	13	11	91	148	89	11	25I	4
		DAY 36	15NOV2004	35	89	117	75	2	1	-1	88	116	78	8	-7	-7
		DAY 43	23NOV2004	43	87	105	71	0	-11	-5	85	127	84	5	4	-1
		DAY 50	30NOV2004	50	84	97	60	-3	-19	-16	92	115	69	12	-8	-16
		DAY 57	07DEC2004	57	87	135	88	0	19	12	88	130	86	8	7	1
		FINAL			87	135	88	0	19	12	88	130	86	8	7	1
	E0025026	SCREEN	07OCT2004	-6	80	104	70				84	106	70			
		DAY 1	13OCT2004	1	84	108	76				88	108	78			
		BASELINE			84	108	76				88	108	78			
		DAY 8	20OCT2004	8	88	106	76	4	-2	0	84	107	68	-4	-1	-10
		DAY 15	27OCT2004	15	65	124	86	-19D	16	10	74	120	86	-14	12	8
		DAY 22	03NOV2004	22	68	120	80	-16D	12	4	74	120	74	-14	12	-4
		DAY 29	10NOV2004	29	74	112	78	-10	4	2	78	116	80	-10	8	2
		DAY 36	17NOV2004	36	76	118	80	-8	10	4	78	116	76	-10	8	-2
		DAY 43	23NOV2004	42	80	110	78	-4	2	2	84	114	80	-4	6	2
		DAY 50	01DEC2004	50	70	118	74	-14	10	-2	72	110	70	-16D	2	-8
		DAY 57	08DEC2004	57	68	122	78	-16D	14	2	74	118	76	-14	10	-2
		FINAL			68	122	78	-16D	14	2	74	118	76	-14	10	-2
	E0025046	SCREEN	24FEB2005	-8	69	122	84				78	118	84			
		DAY 1	04MAR2005	1	70	116	80				72	118	82			
		BASELINE			70	116	80				72	118	82			
		DAY 8	14MAR2005	11	83	129	80	13	13	0	72	118	82	0	0	0
		DAY 36	07APR2005	35	88	118	72	18I	2	-8	116	104	74	44I	-14	-8
		FINAL			88	118	72	18I	2	-8	116	104	74	44I	-14	-8

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0025055	SCREEN	18APR2005	-10	78	130	78				80	124	84			
		DAY 1	28APR2005	1	78	128	68				106	130	88			
		BASELINE			78	128	68				106	130	88			
		DAY 8	05MAY2005	8	88	128	80	10	0	12	110	110	84	4	-20D	-4
		DAY 15	12MAY2005	15	80	120	84	2	-8	16	84	112	78	-22D	-18	-10
		DAY 22	19MAY2005	22	88	124	80	10	-4	12	96	120	80	-10	-10	-8
		DAY 29	26MAY2005	29	90	118	80	12	-10	12	98	112	82	-8	-18	-6
		DAY 36	02JUN2005	36	94	132	70	16I	4	2	98	130	76	-8	0	-12
		DAY 43	09JUN2005	43	96	126	80	18I	-2	12	98	110	78	-8	-20D	-10
		DAY 50	17JUN2005	51	89	115	69	11	-13	1	108	113	78	2	-17	-10
		DAY 57	23JUN2005	57	84	112	68	6	-16	0	92	118	82	-14	-12	-6
		FINAL			84	112	68	6	-16	0	92	118	82	-14	-12	-6
	E0026010	SCREEN	15OCT2004	-10	71	132	80				80	118	78			
		DAY 1	25OCT2004	1	70	126	76				79	120	76			
		BASELINE			70	126	76				79	120	76			
		DAY 8	03NOV2004	10	83	120	60	13	-6	-16	88	122	60	9	2	-16
		DAY 15	10NOV2004	17	77	116	77	7	-10	1	80	110	70	1	-10	-6
		DAY 22	17NOV2004	24	72	110	70	2	-16	-6	78	114	74	-1	-6	-2
		DAY 29	23NOV2004	30	70	106	70	0	-20D	-6	76	100	70	-3	-20D	-6
		DAY 36	01DEC2004	38	71	102	72	1	-24D	-4	80	96	74	1	-24D	-2
		DAY 43	08DEC2004	45	72	120	80	2	-6	4	81	112	76	2	-8	0
		DAY 50	15DEC2004	52	80	116	80	10	-10	4	85	110	80	6	-10	4
		DAY 57	23DEC2004	60	73	108	74	3	-18	-2	78	114	78	-1	-6	2
		FINAL			73	108	74	3	-18	-2	78	114	78	-1	-6	2
	E0026024	SCREEN	30MAR2005	-12	62	122	80				66	116	78			
		DAY 1	11APR2005	1	66	110	70				71	104	72			
		BASELINE			66	110	70				71	104	72			
		DAY 8	18APR2005	8	64	110	74	-2	0	4	67	112	76	-4	8	4
		DAY 15	25APR2005	15	66	106	70	0	-4	0	77	116	66	6	12	-6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0026024	DAY 22		02MAY2005	22	65	96	62	-1	-14	-8	75	104	68	4	0	-4
		DAY 29		09MAY2005	29	64	96	60	-2	-14	-10	72	100	70	1	-4	-2
		DAY 36		16MAY2005	36	67	92	60	1	-18	-10	73	98	64	2	-6	-8
		DAY 43		23MAY2005	43	62	92	60	-4	-18	-10	70	98	68	-1	-6	-4
		DAY 43	*	27MAY2005	47	60	90L	64	-6	-20D	-6	67	100	70	-4	-4	-2
		DAY 50		31MAY2005	51	65	94	62	-1	-16	-8	66	96	66	-5	-8	-6
		FINAL				65	94	62	-1	-16	-8	66	96	66	-5	-8	-6
	E0027021	SCREEN		23MAY2005	-8	72	140	88				74	142	90			
		DAY 1		31MAY2005	1	74	145	90				76	148	92			
		BASELINE				74	145	90				76	148	92			
		DAY 8		07JUN2005	8	76	142	92	2	-3	2	78	144	94	2	-4	2
		DAY 15		15JUN2005	16	70	124	88	-4	-21D	-2	70	126	88	-6	-22D	-4
		DAY 22		21JUN2005	22	72	140	92	-2	-5	2	74	142	94	-2	-6	2
		DAY 29		29JUN2005	30	68	132	89	-6	-13	-1	70	134	90	-6	-14	-2
		DAY 36		06JUL2005	37	68	130	90	-6	-15	0	72	132	90	-4	-16	-2
		DAY 43		14JUL2005	45	68	135	88	-6	-10	-2	70	136	88	-6	-12	-4
		DAY 50		22JUL2005	53	72	128	80	-2	-17	-10	74	128	78	-2	-20D	-14
		DAY 57		27JUL2005	58	76	128	78	2	-17	-12	78	130	80	2	-18	-12
		FINAL				76	128	78	2	-17	-12	78	130	80	2	-18	-12
	E0028006	SCREEN		20JUL2004	-8	88	130	90				88	140	90			
		DAY 1		28JUL2004	1	88	120	90				88	118	94			
		BASELINE				88	120	90				88	118	94			
		DAY 8		04AUG2004	8	84	120	80	-4	0	-10	88	122	80	0	4	-14
		DAY 15		11AUG2004	15	88	120	80	0	0	-10	92	110	70	4	-8	-24D
		DAY 22		18AUG2004	22	80	120	80	-8	0	-10	84	130	90	-4	12	-4
		DAY 29		25AUG2004	29	76	110	80	-12	-10	-10	84	110	80	-4	-8	-14
		DAY 36		01SEP2004	36	80	120	80	-8	0	-10	80	110	90	-8	-8	-4
		DAY 43		08SEP2004	43	80	120	80	-8	0	-10	88	120	80	0	2	-14
		DAY 50		15SEP2004	50	76	110	80	-12	-10	-10	80	110	80	-8	-8	-14

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0028006	DAY 57	22SEP2004	57	76	120	80	-12	0	-10	76	110	80	-12	-8	-14
		FINAL			76	120	80	-12	0	-10	76	110	80	-12	-8	-14
	E0028014	SCREEN	18FEB2005	-7	76	140	100				80	148	100			
		DAY 1	25FEB2005	1	88	130	90				92	138	98			
		BASELINE			88	130	90				92	138	98			
		DAY 8	04MAR2005	8	72	136	90	-16D	6	0	88	138	92	-4	0	-6
		DAY 15	11MAR2005	15	84	150	100	-4	20I	10	84	150	90	-8	12	-8
		DAY 22	18MAR2005	22	76	120	80	-12	-10	-10	80	118	80	-12	-20D	-18
		DAY 29	25MAR2005	29	68	110	80	-20D	-20D	-10	76	120	80	-16D	-18	-18
		DAY 36	31MAR2005	35	88	120	80	0	-10	-10	92	120	80	0	-18	-18
		DAY 43	08APR2005	43	80	130	70	-8	0	-20D	80	120	80	-12	-18	-18
		DAY 50	14APR2005	49	76	120	90	-12	-10	0	80	122	98	-12	-16	0
		DAY 57	21APR2005	56	80	120	80	-8	-10	-10	88	130	90	-4	-8	-8
		FINAL			80	120	80	-8	-10	-10	88	130	90	-4	-8	-8
	E0029010	SCREEN	22DEC2004	-8	78	138	84				72	132	82			
		DAY 1	30DEC2004	1	76	136	80				78	130	80			
		BASELINE			76	136	80				78	130	80			
		DAY 8	07JAN2005	9	74	92	72	-2	-44D	-8	90	98	76	12	-32D	-4
		DAY 15	12JAN2005	14	76	120	80	0	-16	0	88	127	92	10	-3	12
		DAY 22	21JAN2005	23	74	126	78	-2	-10	-2	82	120	84	4	-10	4
		DAY 29	28JAN2005	30	84	120	74	8	-16	-6	78	122	75	0	-8	-5
		DAY 36	04FEB2005	37	80	138	88	4	2	8	80	138	88	2	8	8
		DAY 43	11FEB2005	44	88	136	85	12	0	5	82	130	86	4	0	6
		DAY 50	17FEB2005	50	84	120	70	8	-16	-10	86	130	80	8	0	0
		DAY 57	25FEB2005	58	84	138	88	8	2	8	78	132	78	0	2	-2
		FINAL			84	138	88	8	2	8	78	132	78	0	2	-2
	E0029011	SCREEN	04FEB2005	-7	66	120	88				78	123	90			
		DAY 1	11FEB2005	1	72	118	70				78	120	74			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0029011	BASELINE			72	118	70				78	120	74			
		DAY 8	18FEB2005	8	88	122	68	16I	4	-2	92	110	78	14	-10	4
		DAY 15	25FEB2005	15	72	114	60	0	-4	-10	84	100	78	6	-20D	4
		DAY 22	04MAR2005	22	88	141	84	16I	23I	14	78	138	80	0	18	6
		DAY 29	11MAR2005	29	86	122	80	14	4	10	78	124	76	0	4	2
		DAY 36	18MAR2005	36	72	132	78	0	14	8	78	128	74	0	8	0
		DAY 43	25MAR2005	43	78	130	80	6	12	10	78	132	84	0	12	10
		DAY 50	01APR2005	50	70	126	86	-2	8	16	84	130	84	6	10	10
		DAY 57	08APR2005	57	84	129	77	12	11	7	91	119	78	13	-1	4
		FINAL			84	129	77	12	11	7	91	119	78	13	-1	4
	E0030011	SCREEN	25AUG2004	-5	67	135	71				83	123	79			
		DAY 1	30AUG2004	1	93	138	80				109	127	81			
		BASELINE			93	138	80				109	127	81			
		DAY 8	07SEP2004	9	78	150	70	-15D	12	-10	106	144	93	-3	17	12
		DAY 15	13SEP2004	15	88	157	80	-5	19	0	103	119	76	-6	-8	-5
		DAY 22	20SEP2004	22	94	155	81	1	17	1	98	137	75	-11	10	-6
		DAY 29	27SEP2004	29	84	122	76	-9	-16	-4	87	125	75	-22D	-2	-6
		DAY 36	04OCT2004	36	81	147	74	-12	9	-6	95	121	70	-14	-6	-11
		DAY 43	11OCT2004	43	82	149	76	-11	11	-4	100	145	67	-9	18	-14
		DAY 50	18OCT2004	50	89	152	89	-4	14	9	91	143	68	-18D	16	-13
		DAY 57	25OCT2004	57	60	152	66	-33D	14	-14	79	160	79	-30D	33I	-2
		FINAL			60	152	66	-33D	14	-14	79	160	79	-30D	33I	-2
	E0030020	SCREEN	17NOV2004	-7	76	158	81				92	190H	97			
		DAY 1	24NOV2004	1	84	171	95				93	159	103			
		BASELINE			84	171	95				93	159	103			
		DAY 8	01DEC2004	8	85	162	88	1	-9	-7	94	171	102	1	12	-1
		DAY 15	08DEC2004	15	80	150	88	-4	-21D	-7	92	160	92	-1	1	-11
		DAY 22	15DEC2004	22	88	148	88	4	-23D	-7	100	142	90	7	-17	-13
		DAY 29	22DEC2004	29	80	144	98	-4	-27D	3	88	158	100	-5	-1	-3

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0030020	DAY 36	29DEC2004	36	79	137	78	-5	-34D	-17	86	152	90	-7	-7	-13
		DAY 43	05JAN2005	43	79	173	89	-5	2	-6	84	168	92	-9	9	-11
		DAY 50	12JAN2005	50	82	158	92	-2	-13	-3	88	168	104	-5	9	1
		DAY 57	19JAN2005	57	96	160	98	12	-11	3	104	180H	102	11	21I	-1
		FINAL			96	160	98	12	-11	3	104	180H	102	11	21I	-1
	E0030021	SCREEN	18NOV2004	-5	64	143	93				74	127	95			
		DAY 1	23NOV2004	1	64	140	96				86	124	82			
		BASELINE			64	140	96				86	124	82			
		DAY 8	01DEC2004	9	76	130	90	12	-10	-6	86	116	90	0	-8	8
		DAY 15	08DEC2004	16	65	137	95	1	-3	-1	80	135	99	-6	11	17
		DAY 22	15DEC2004	23	66	151	95	2	11	-1	74	138	103	-12	14	21
		DAY 29	22DEC2004	30	62	134	91	-2	-6	-5	78	121	97	-8	-3	15
		DAY 36	29DEC2004	37	68	145	94	4	5	-2	82	129	91	-4	5	9
		DAY 43	05JAN2005	44	71	161	97	7	21I	1	93	167	88	7	43I	6
		DAY 50	12JAN2005	51	66	139	89	2	-1	-7	83	137	94	-3	13	12
		DAY 57	19JAN2005	58	65	142	89	1	2	-7	83	131	92	-3	7	10
		FINAL			65	142	89	1	2	-7	83	131	92	-3	7	10
	E0030031	SCREEN	01MAR2005	-7	48L	137	89				60	132	95			
		DAY 1	08MAR2005	1	60	145	81				76	127	89			
		BASELINE			60	145	81				76	127	89			
		DAY 8	15MAR2005	8	60	119	77	0	-26D	-4	65	126	86	-11	-1	-3
		DAY 15	22MAR2005	15	50	123	76	-10	-22D	-5	68	138	92	-8	11	3
		DAY 22	29MAR2005	22	60	115	86	0	-30D	5	74	131	92	-2	4	3
		DAY 29	05APR2005	29	63	121	78	3	-24D	-3	80	138	87	4	11	-2
		DAY 36	12APR2005	36	56	122	80	-4	-23D	-1	77	123	86	1	-4	-3
		DAY 43	19APR2005	43	54	134	91	-6	-11	10	62	150	94	-14	23I	5
		DAY 50	26APR2005	50	72	112	78	12	-33D	-3	88	120	80	12	-7	-9
		DAY 57	03MAY2005	57	64	120	78	4	-25D	-3	72	112	80	-4	-15	-9
		FINAL			64	120	78	4	-25D	-3	72	112	80	-4	-15	-9

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0030034	SCREEN	03MAY2005	-7	64	128	84				72	122	82			
		DAY 1	10MAY2005	1	60	108	72				72	110	80			
		BASELINE			60	108	72				72	110	80			
		DAY 8	17MAY2005	8	64	124	70	4	16	-2	76	122	78	4	12	-2
		DAY 15	25MAY2005	16	76	136	69	16I	28I	-3	102	142	74	30I	32I	-6
		DAY 22	01JUN2005	23	60	124	72	0	16	0	88	122	80	16I	12	0
		DAY 29	08JUN2005	30	69	121	67	9	13	-5	97	133	71	25I	23I	-9
		DAY 36	15JUN2005	37	60	144	72	0	36I	0	76	144	66	4	34I	-14
		DAY 43	22JUN2005	44	59	139	69	-1	31I	-3	78	131	82	6	21I	2
		DAY 50	29JUN2005	51	64	142	71	4	34I	-1	89	135	85	17I	25I	5
		DAY 57	06JUL2005	58	62	142	72	2	34I	0	96	130	76	24I	20I	-4
		FINAL			62	142	72	2	34I	0	96	130	76	24I	20I	-4
	E0032003	SCREEN	29DEC2004	-7	68	128	90				70	105	88			
		DAY 1	05JAN2005	1	80	110	83				86	95	75			
		BASELINE			80	110	83				86	95	75			
		DAY 8	12JAN2005	8	80	134	88	0	24I	5	92	118	86	6	23I	11
		DAY 15	19JAN2005	15	80	124	90	0	14	7	84	128	92	-2	33I	17
		DAY 22	26JAN2005	22	76	128	90	-4	18	7	78	132	86	-8	37I	11
		DAY 29	03FEB2005	30	86	120	90	6	10	7	83	110	88	-3	15	13
		DAY 36	09FEB2005	36	88	124	82	8	14	-1	89	119	80	3	24I	5
		DAY 43	16FEB2005	43	88	120	84	8	10	1	86	102	80	0	7	5
		DAY 50	23FEB2005	50	68	110	80	-12	0	-3	72	107	81	-14	12	6
		DAY 57	01MAR2005	56	69	115	84	-11	5	1	72	107	88	-14	12	13
		FINAL			69	115	84	-11	5	1	72	107	88	-14	12	13
	E0033003	SCREEN	19AUG2004	-7	58	118	68				60	114	68			
		DAY 1	26AUG2004	1	60	102	78				68	106	80			
		BASELINE			60	102	78				68	106	80			
		DAY 8	02SEP2004	8	64	100	76	4	-2	-2	66	102	78	-2	-4	-2
		DAY 15	08SEP2004	14	86	96	68	26I	-6	-10	82	96	74	14	-10	-6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0033003	DAY 22		15SEP2004	21	60	112	80	0	10	2	64	114	82	-4	8	2
		DAY 29		22SEP2004	28	66	90L	70	6	-12	-8	66	94	76	-2	-12	-4
		DAY 36		29SEP2004	35	58	100	80	-2	-2	2	60	102	80	-8	-4	0
		DAY 43		06OCT2004	42	80	96	60	20I	-6	-18	82	102	64	14	-4	-16
		DAY 50		13OCT2004	49	68	92	70	8	-10	-8	72	100	76	4	-6	-4
		DAY 57		20OCT2004	56	66	100	70	6	-2	-8	68	98	74	0	-8	-6
		FINAL				66	100	70	6	-2	-8	68	98	74	0	-8	-6
	E0033009	SCREEN		01DEC2004	-8	80	120	88				84	122	88			
		DAY 1		09DEC2004	1	76	130	88				68	134	86			
		BASELINE				76	130	88				68	134	86			
		DAY 8		15DEC2004	7	76	128	90	0	-2	2	72	128	88	4	-6	2
		DAY 15		21DEC2004	13	58	116	88	-18D	-14	0	66	120	88	-2	-14	2
		DAY 22		29DEC2004	21	74	138	100	-2	8	12	86	140	102	18I	6	16
		DAY 29		06JAN2005	29	70	138	98	-6	8	10	74	136	98	6	2	12
		DAY 36		13JAN2005	36	80	130	90	4	0	2	74	130	90	6	-4	4
		DAY 43		20JAN2005	43	82	122	90	6	-8	2	84	120	90	16I	-14	4
		DAY 50		27JAN2005	50	76	130	94	0	0	6	78	128	94	10	-6	8
		DAY 57		03FEB2005	57	78	136	84	2	6	-4	80	136	84	12	2	-2
		FINAL				78	136	84	2	6	-4	80	136	84	12	2	-2
	E0033010	SCREEN		03JAN2005	-3	68	92	60				68	88L	64			
		DAY 1		06JAN2005	1	68	80L	60				66	84L	64			
		BASELINE				68	80L	60				66	84L	64			
		DAY 8		13JAN2005	8	58	84L	60	-10	4	0	56	88L	68	-10	4	4
		DAY 15		21JAN2005	16	66	98	70	-2	18	10	64	96	76	-2	12	12
		DAY 22		26JAN2005	21	76	94	70	8	14	10	74	98	70	8	14	6
		DAY 22	*	31JAN2005	26	64	90L	64	-4	10	4	66	94	70	0	10	6
		DAY 29		07FEB2005	33	58	90L	62	-10	10	2	58	90L	72	-8	6	8
		DAY 43		15FEB2005	41	80	90L	62	12	10	2	76	96	72	10	12	8
		DAY 50		23FEB2005	49	86	100	68	18I	20I	8	84	102	70	18I	18	6

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0033010	DAY 57	02MAR2005	56	60	90L	62	-8	10	2	58	88L	62	-8	4	-2
		FINAL			60	90L	62	-8	10	2	58	88L	62	-8	4	-2
	E0033011	SCREEN	10JAN2005	-8	64	100	78				64	102	74			
		DAY 1	18JAN2005	1	88	100	86				86	104	86			
		BASELINE			88	100	86				86	104	86			
		DAY 8	25JAN2005	8	68	90L	72	-20D	-10	-14	66	92	72	-20D	-12	-14
		DAY 15	01FEB2005	15	70	104	80	-18D	4	-6	72	102	82	-14	-2	-4
		DAY 22	08FEB2005	22	58	94	70	-30D	-6	-16	60	90L	72	-26D	-14	-14
		DAY 29	14FEB2005	28	60	102	70	-28D	2	-16	58	100	66	-28D	-4	-20D
		DAY 36	21FEB2005	35	64	108	86	-24D	8	0	60	106	80	-26D	2	-6
		DAY 43	28FEB2005	42	68	100	80	-20D	0	-6	70	98	76	-16D	-6	-10
		DAY 50	07MAR2005	49	56	90L	72	-32D	-10	-14	60	94	74	-26D	-10	-12
		DAY 57	14MAR2005	56	74	98	70	-14	-2	-16	72	102	68	-14	-2	-18
		FINAL			74	98	70	-14	-2	-16	72	102	68	-14	-2	-18
	E0033014	SCREEN	21FEB2005	-7	72	148	96				76	130	92			
		DAY 1	28FEB2005	1	72	112	72				78	118	76			
		BASELINE			72	112	72				78	118	76			
		DAY 8	07MAR2005	8	80	138	90	8	26I	18	78	136	90	0	18	14
		DAY 15	14MAR2005	15	78	110	68	6	-2	-4	76	118	70	-2	0	-6
		DAY 22	21MAR2005	22	80	110	78	8	-2	6	78	118	80	0	0	4
		DAY 29	28MAR2005	29	78	130	70	6	18	-2	80	126	70	2	8	-6
		DAY 36	06APR2005	38	76	128	70	4	16	-2	74	126	84	-4	8	8
		DAY 43	13APR2005	45	84	136	98	12	24I	26	84	140	98	6	22I	22
		DAY 50	18APR2005	50	68	114	72	-4	2	0	72	116	78	-6	-2	2
		DAY 57	25APR2005	57	78	150	98	6	38I	26	80	150	100	2	32I	24
		FINAL			78	150	98	6	38I	26	80	150	100	2	32I	24
	E0033016	SCREEN	14MAR2005	-14	78	104	76				80	106	74			
		DAY 1	28MAR2005	1	74	108	78				76	106	74			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0033016	BASELINE			74	108	78				76	106	74			
		DAY 8	06APR2005	10	70	104	76	-4	-4	-2	72	110	80	-4	4	6
		DAY 15	11APR2005	15	74	110	74	0	2	-4	90	116	74	14	10	0
		DAY 22	18APR2005	22	74	102	76	0	-6	-2	70	104	76	-6	-2	2
		DAY 29	26APR2005	30	84	108	74	10	0	-4	88	112	78	12	6	4
		DAY 36	02MAY2005	36	74	112	78	0	4	0	78	114	80	2	8	6
		DAY 43	10MAY2005	44	78	118	76	4	10	-2	74	116	80	-2	10	6
		DAY 50	17MAY2005	51	72	112	78	-2	4	0	76	118	82	0	12	8
		DAY 57	24MAY2005	58	88	130	82	14	22I	4	92	130	84	16I	24I	10
		FINAL			88	130	82	14	22I	4	92	130	84	16I	24I	10
	E0034013	SCREEN	27MAY2005	-7	76	128	82				84	130	84			
		DAY 1	03JUN2005	1	68	130	68				72	132	74			
		BASELINE			68	130	68				72	132	74			
		DAY 8	10JUN2005	8	70	124	80	2	-6	12	74	122	84	2	-10	10
		DAY 15	16JUN2005	14	72	120	82	4	-10	14	78	118	86	6	-14	12
		DAY 22	24JUN2005	22	74	118	78	6	-12	10	80	122	82	8	-10	8
		DAY 29	01JUL2005	29	78	120	80	10	-10	12	84	124	80	12	-8	6
		DAY 36	08JUL2005	36	82	126	78	14	-4	10	88	120	84	16I	-12	10
		DAY 43	15JUL2005	43	80	122	82	12	-8	14	84	124	80	12	-8	6
		DAY 50	22JUL2005	50	80	128	82	12	-2	14	78	124	86	6	-8	12
		DAY 57	01AUG2005	60	78	126	78	10	-4	10	88	124	82	16I	-8	8
		FINAL			78	126	78	10	-4	10	88	124	82	16I	-8	8
	E0035003	SCREEN	28JUL2004	-7	62	112	70				78	106	72			
		DAY 1	04AUG2004	1	64	108	78				80	110	80			
		BASELINE			64	108	78				80	110	80			
		DAY 8	11AUG2004	8	60	120	80	-4	12	2	72	110	78	-8	0	-2
		DAY 15	18AUG2004	15	80	104	70	16I	-4	-8	84	102	68	4	-8	-12
		DAY 22	24AUG2004	21	88	116	72	24I	8	-6	92	108	68	12	-2	-12
		DAY 29	02SEP2004	30	67	108	63	3	0	-15	76	112	70	-4	2	-10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0035003	DAY 36	08SEP2004	36	68	100	72	4	-8	-6	84	104	68	4	-6	-12
		DAY 43	15SEP2004	43	76	118	80	12	10	2	80	108	70	0	-2	-10
		DAY 50	22SEP2004	50	64	120	74	0	12	-4	80	110	78	0	0	-2
		DAY 57	30SEP2004	58	72	118	70	8	10	-8	80	110	68	0	0	-12
		FINAL			72	118	70	8	10	-8	80	110	68	0	0	-12
	E0035010	SCREEN	12AUG2004	-11	84	128	70				92	130	80			
		DAY 1	23AUG2004	1	84	120	68				96	120	80			
		BASELINE			84	120	68				96	120	80			
		DAY 8	01SEP2004	10	72	128	74	-12	8	6	100	118	78	4	-2	-2
		DAY 15	07SEP2004	16	80	122	78	-4	2	10	100	120	82	4	0	2
		DAY 22	16SEP2004	25	88	126	70	4	6	2	100	120	76	4	0	-4
		DAY 29	22SEP2004	31	60	138	80	-24D	18	12	72	130	80	-24D	10	0
		DAY 36	01OCT2004	40	92	122	70	8	2	2	96	130	72	0	10	-8
		DAY 43	08OCT2004	47	70	124	80	-14	4	12	80	112	80	-16D	-8	0
		DAY 50	12OCT2004	51	76	122	72	-8	2	4	96	120	80	0	0	0
		DAY 57	18OCT2004	57	62	120	72	-22D	0	4	80	120	78	-16D	0	-2
		FINAL			62	120	72	-22D	0	4	80	120	78	-16D	0	-2
	E0037011	SCREEN	26OCT2004	-7	56	90L	70				64	102	76			
		DAY 1	02NOV2004	1	76	128	80				84	110	80			
		BASELINE			76	128	80				84	110	80			
		DAY 8	10NOV2004	9	80	116	80	4	-12	0	68	110	80	-16D	0	0
		DAY 15	17NOV2004	16	72	102	70	-4	-26D	-10	72	118	78	-12	8	-2
		DAY 29	03DEC2004	32	76	110	80	0	-18	0	76	108	80	-8	-2	0
		DAY 36	08DEC2004	37	72	100	70	-4	-28D	-10	84	110	82	0	0	2
		DAY 43	15DEC2004	44	72	100	72	-4	-28D	-8	76	118	80	-8	8	0
		DAY 57	12JAN2005	72	76	98	80	0	-30D	0	76	100	80	-8	-10	0
		FINAL			76	98	80	0	-30D	0	76	100	80	-8	-10	0
	E0039008	SCREEN	29SEP2004	-7	64	110	64				68	100	60			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0039008	DAY 1	06OCT2004	1	60	100	50L				76	90L	50L			
		BASELINE			60	100	50L				76	90L	50L			
		DAY 8	13OCT2004	8	60	110	90	0	10	40I	68	98	64	-8	8	14
		DAY 15	21OCT2004	16	54	120	80	-6	20I	30I	68	98	64	-8	8	14
		DAY 22	27OCT2004	22	62	110	72	2	10	22	74	98	70	-2	8	20
		DAY 29	04NOV2004	30	60	112	68	0	12	18	66	100	62	-10	10	12
		DAY 36	10NOV2004	36	68	110	90	8	10	40I	68	110	80	-8	20I	30I
		FINAL			68	110	90	8	10	40I	68	110	80	-8	20I	30I
	E0039014	SCREEN	23NOV2004	-14	64	108	60				70	100	68			
		DAY 1	07DEC2004	1	78	110	60				82	110	70			
		BASELINE			78	110	60				82	110	70			
		DAY 8	14DEC2004	8	100	112	70	22I	2	10	107	106	80	25I	-4	10
		DAY 15	21DEC2004	15	88	100	60	10	-10	0	102	88L	60	20I	-22D	-10
		DAY 29	03JAN2005	28	80	120	78	2	10	18	84	110	68	2	0	-2
		FINAL			80	120	78	2	10	18	84	110	68	2	0	-2
	E0039015	SCREEN	30NOV2004	-13	64	110	60				66	98	60			
		DAY 1	13DEC2004	1	64	110	64				72	102	74			
		BASELINE			64	110	64				72	102	74			
		DAY 8	21DEC2004	9	64	110	70	0	0	6	68	98	70	-4	-4	-4
		DAY 15	30DEC2004	18	64	118	60	0	8	-4	78	98	60	6	-4	-14
		DAY 22	06JAN2005	25	64	110	60	0	0	-4	76	104	70	4	2	-4
		DAY 29	13JAN2005	32	58	104	60	-6	-6	-4	78	98	60	6	-4	-14
		DAY 36	19JAN2005	38	76	102	64	12	-8	0	80	108	70	8	6	-4
		DAY 43	24JAN2005	43	64	108	60	0	-2	-4	68	108	64	-4	6	-10
		DAY 50	31JAN2005	50	50	100	40L	-14	-10	-24D	58	100	48L	-14	-2	-26D
		DAY 57	07FEB2005	57	60	96	60	-4	-14	-4	60	98	60	-12	-4	-14
		FINAL			60	96	60	-4	-14	-4	60	98	60	-12	-4	-14
	E0040004	SCREEN	06AUG2004	-6	48L	114	63				44L	120	66			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0040004	DAY 1	12AUG2004	1	50	118	64				55	126	67			
		BASELINE			50	118	64				55	126	67			
		DAY 8	20AUG2004	9	49L	134	68	-1	16	4	55	138	78	0	12	11
		DAY 15	25AUG2004	14	52	124	68	2	6	4	83	131	88	28I	5	21
		DAY 22	31AUG2004	20	59	123	76	9	5	12	75	135	86	20I	9	19
		FINAL			59	123	76	9	5	12	75	135	86	20I	9	19
	E0040009	SCREEN	21JAN2005	-5	88	125	80				98	124	90			
		DAY 1	26JAN2005	1	90	125	86				98	123	85			
		BASELINE			90	125	86				98	123	85			
		DAY 8	02FEB2005	8	98	126	80	8	1	-6	100	124	90	2	1	5
		DAY 15	09FEB2005	15	83	122	89	-7	-3	3	98	120	80	0	-3	-5
		DAY 22	16FEB2005	22	80	112	64	-10	-13	-22D	95	110	62	-3	-13	-23D
		DAY 29	23FEB2005	29	82	114	66	-8	-11	-20D	98	112	68	0	-11	-17
		DAY 36	02MAR2005	36	90	126	81	0	1	-5	96	130	88	-2	7	3
		DAY 43	09MAR2005	43	80	112	64	-10	-13	-22D	94	110	72	-4	-13	-13
		DAY 50	16MAR2005	50	70	114	68	-20D	-11	-18	92	112	72	-6	-11	-13
		DAY 57	23MAR2005	57	80	120	72	-10	-5	-14	92	118	70	-6	-5	-15
		FINAL			80	120	72	-10	-5	-14	92	118	70	-6	-5	-15
	E0040010	SCREEN	26JAN2005	-7	81	113	78				82	130	78			
		DAY 1	02FEB2005	1	98	115	80				100	120	98			
		BASELINE			98	115	80				100	120	98			
		DAY 8	09FEB2005	8	81	125	82	-17D	10	2	96	145	96	-4	25I	-2
		DAY 22	22FEB2005	21	95	120	78	-3	5	-2	106	139	82	6	19	-16
		DAY 29	02MAR2005	29	82	127	84	-16D	12	4	100	146	94	0	26I	-4
		DAY 36	09MAR2005	36	87	123	77	-11	8	-3	94	110	74	-6	-10	-24D
		DAY 43	16MAR2005	43	91	136	85	-7	21I	5	101	135	90	1	15	-8
		DAY 50	23MAR2005	50	108	128	82	10	13	2	115	128	81	15I	8	-17
		DAY 57	30MAR2005	57	91	145	99	-7	30I	19	106	144	99	6	24I	1
		FINAL			91	145	99	-7	30I	19	106	144	99	6	24I	1

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0040012	SCREEN		11MAR2005	-10	88	128	84				100	120	80			
		DAY 1		21MAR2005	1	88	126	84				99	122	78			
		BASELINE				88	126	84				99	122	78			
		DAY 8		28MAR2005	8	101	119	76	13	-7	-8	115	120	72	16I	-2	-6
		FINAL				101	119	76	13	-7	-8	115	120	72	16I	-2	-6
	E0040013	SCREEN		25MAR2005	-7	72	104	64				89	110	88			
		DAY 1		01APR2005	1	89	130	82				81	131	84			
		BASELINE				89	130	82				81	131	84			
		DAY 8		08APR2005	8	73	122	67	-16D	-8	-15	83	109	83	2	-22D	-1
		DAY 15		15APR2005	15	76	129	83	-13	-1	1	85	110	88	4	-21D	4
		DAY 22		22APR2005	22	82	120	78	-7	-10	-4	88	116	74	7	-15	-10
		DAY 29		29APR2005	29	83	123	81	-6	-7	-1	85	126	98	4	-5	14
		DAY 36		06MAY2005	36	84	121	76	-5	-9	-6	102	114	73	21I	-17	-11
		DAY 43		11MAY2005	41	82	124	80	-7	-6	-2	84	122	84	3	-9	0
		DAY 50		20MAY2005	50	76	109	69	-13	-21D	-13	107	103	78	26I	-28D	-6
		DAY 57		27MAY2005	57	71	113	77	-18D	-17	-5	73	111	82	-8	-20D	-2
		FINAL				71	113	77	-18D	-17	-5	73	111	82	-8	-20D	-2
	E0040016	SCREEN		17MAY2005	-3	76	110	70				87	108	76			
		DAY 1		20MAY2005	1	74	108	70				85	107	74			
		BASELINE				74	108	70				85	107	74			
		DAY 8		27MAY2005	8	74	112	72	0	4	2	90	106	74	5	-1	0
		DAY 8	*	31MAY2005	12	70	92	54	-4	-16	-16	104	96	67	19I	-11	-7
		DAY 15		07JUN2005	19	70	99	66	-4	-9	-4	79	107	75	-6	0	1
		DAY 22		14JUN2005	26	74	98	62	0	-10	-8	93	104	70	8	-3	-4
		DAY 36		23JUN2005	35	88	106	74	14	-2	4	93	120	82	8	13	8
		DAY 36	*	28JUN2005	40	77	106	69	3	-2	-1	94	102	72	9	-5	-2
		DAY 50		07JUL2005	49	72	104	68	-2	-4	-2	82	100	74	-3	-7	0
		DAY 57		15JUL2005	57	70	113	74	-4	5	4	76	124	83	-9	17	9
		FINAL				70	113	74	-4	5	4	76	124	83	-9	17	9

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0041004	SCREEN	30AUG2004	-23	60	120	80				68	124	86			
		DAY 1	22SEP2004	1	60	108	80				64	110	84			
		BASELINE			60	108	80				64	110	84			
		DAY 8	29SEP2004	8	60	120	84	0	12	4	64	120	78	0	10	-6
		DAY 15	06OCT2004	15	60	108	60	0	0	-20D	62	112	72	-2	2	-12
		DAY 22	13OCT2004	22	64	112	82	4	4	2	84	110	90	20I	0	6
		DAY 29	21OCT2004	30	64	118	82	4	10	2	68	114	80	4	4	-4
		DAY 36	27OCT2004	36	64	118	80	4	10	0	84	120	78	20I	10	-6
		DAY 43	03NOV2004	43	64	112	82	4	4	2	76	116	82	12	6	-2
		DAY 50	10NOV2004	50	56	114	84	-4	6	4	76	118	86	12	8	2
		DAY 57	17NOV2004	57	64	118	84	4	10	4	96	124	88	32I	14	4
		FINAL			64	118	84	4	10	4	96	124	88	32I	14	4
	E0041007	SCREEN	28OCT2004	-22	48L	112	80				52	106	84			
		DAY 1	19NOV2004	1	60	110	78				76	100	78			
		BASELINE			60	110	78				76	100	78			
		DAY 8	24NOV2004	6	68	118	72	8	8	-6	88	116	76	12	16	-2
		DAY 15	03DEC2004	15	56	112	76	-4	2	-2	68	108	80	-8	8	2
		DAY 22	09DEC2004	21	68	120	66	8	10	-12	72	110	76	-4	10	-2
		DAY 29	17DEC2004	29	56	132	80	-4	22I	2	56	122	76	-20D	22I	-2
		DAY 36	22DEC2004	34	92	120	72	32I	10	-6	114	102	72	38I	2	-6
		DAY 43	30DEC2004	42	68	114	80	8	4	2	72	110	78	-4	10	0
		FINAL			68	114	80	8	4	2	72	110	78	-4	10	0
	E0041015	SCREEN	24MAR2005	-8	48L	120	66				60	130	78			
		DAY 1	01APR2005	1	60	128	68				80	124	74			
		BASELINE			60	128	68				80	124	74			
		DAY 8	07APR2005	7	48L	132	84	-12	4	16	60	130	78	-20D	6	4
		DAY 15	15APR2005	15	60	122	68	0	-6	0	60	130	82	-20D	6	8
		DAY 22	22APR2005	22	60	138	66	0	10	-2	76	132	72	-4	8	-2
		DAY 29	29APR2005	29	60	120	60	0	-8	-8	76	112	72	-4	-12	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0041015	DAY 36	06MAY2005	36	52	110	66	-8	-18	-2	64	120	82	-16D	-4	8
		FINAL			52	110	66	-8	-18	-2	64	120	82	-16D	-4	8
	E0042006	SCREEN	11AUG2004	-8	60	110	68				56	114	74			
		DAY 1	19AUG2004	1	84	124	60				100	114	66			
		BASELINE			84	124	60				100	114	66			
		DAY 8	25AUG2004	7	64	100	64	-20D	-24D	4	72	90L	56	-28D	-24D	-10
		DAY 15	02SEP2004	15	72	104	56	-12	-20D	-4	72	100	60	-28D	-14	-6
		DAY 22	09SEP2004	22	60	102	76	-24D	-22D	16	60	100	70	-40D	-14	4
		DAY 29	16SEP2004	29	64	102	56	-20D	-22D	-4	72	104	60	-28D	-10	-6
		DAY 36	23SEP2004	36	68	100	60	-16D	-24D	0	70	106	74	-30D	-8	8
		DAY 43	30SEP2004	43	76	104	50L	-8	-20D	-10	80	108	68	-20D	-6	2
		DAY 50	08OCT2004	51	80	114	62	-4	-10	2	80	110	74	-20D	-4	8
		DAY 57	14OCT2004	57	78	102	64	-6	-22D	4	78	96	66	-22D	-18	0
		FINAL			78	102	64	-6	-22D	4	78	96	66	-22D	-18	0
	E0042024	SCREEN	15JUN2005	-7	56	116	84				56	116	78			
		DAY 1	22JUN2005	1	64	100	60				72	95	70			
		BASELINE			64	100	60				72	95	70			
		DAY 8	29JUN2005	8	56	116	70	-8	16	10	56	112	68	-16D	17	-2
		DAY 15	06JUL2005	15	60	120	70	-4	20I	10	60	110	65	-12	15	-5
		DAY 22	13JUL2005	22	62	110	70	-2	10	10	80	100	70	8	5	0
		DAY 29	20JUL2005	29	72	124	78	8	24I	18	76	126	74	4	31I	4
		DAY 36	27JUL2005	36	56	118	70	-8	18	10	64	122	70	-8	27I	0
		DAY 43	03AUG2005	43	60	100	70	-4	0	10	64	100	65	-8	5	-5
		DAY 50	10AUG2005	50	60	114	76	-4	14	16	60	100	60	-12	5	-10
		DAY 57	18AUG2005	58	68	94	60	4	-6	0	68	98	56	-4	3	-14
		FINAL			68	94	60	4	-6	0	68	98	56	-4	3	-14
	E0044004	SCREEN	27JAN2005	-21	64	102	58				72	106	60			
		DAY 1	17FEB2005	1	72	102	50L				76	106	52			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0044004	BASELINE				72	102	50L				76	106	52			
		DAY 8		24FEB2005	8	56	98	66	-16D	-4	16	66	106	68	-10	0	16
		DAY 15		03MAR2005	15	70	102	60	-2	0	10	64	102	58	-12	-4	6
		DAY 22		10MAR2005	22	56	104	58	-16D	2	8	60	106	60	-16D	0	8
		DAY 29		17MAR2005	29	56	100	62	-16D	-2	12	68	102	62	-8	-4	10
		DAY 29	*	21MAR2005	33	60	100	76	-12	-2	26	60	112	78	-16D	6	26
		DAY 43		30MAR2005	42	68	102	62	-4	0	12	72	106	62	-4	0	10
		DAY 50		06APR2005	49	80	108	68	8	6	18	84	112	70	8	6	18
		DAY 57		14APR2005	57	64	110	90	-8	8	40I	80	120	88	4	14	36I
		FINAL				64	110	90	-8	8	40I	80	120	88	4	14	36I
	E0046006	SCREEN		16DEC2004	-27	54	120	70				80	128	74			
		DAY 1		12JAN2005	1	56	110	70				72	124	70			
		BASELINE				56	110	70				72	124	70			
		DAY 8		19JAN2005	8	66	103	64	10	-7	-6	87	119	77	15I	-5	7
		DAY 15		26JAN2005	15	53	104	67	-3	-6	-3	61	110	72	-11	-14	2
		DAY 22		02FEB2005	22	65	112	73	9	2	3	79	109	78	7	-15	8
		DAY 29		10FEB2005	30	68	112	68	12	2	-2	72	124	80	0	0	10
		DAY 36		16FEB2005	36	60	104	58	4	-6	-12	72	110	60	0	-14	-10
		DAY 43		23FEB2005	43	54	107	69	-2	-3	-1	65	110	74	-7	-14	4
		DAY 50		02MAR2005	50	66	111	67	10	1	-3	79	117	74	7	-7	4
		DAY 57		09MAR2005	57	71	113	69	15I	3	-1	83	114	77	11	-10	7
		FINAL				71	113	69	15I	3	-1	83	114	77	11	-10	7
	E0046010	SCREEN		01FEB2005	-7	75	120	81				87	113	76			
		DAY 1		08FEB2005	1	59	113	75				76	124	84			
		BASELINE				59	113	75				76	124	84			
		DAY 8		15FEB2005	8	58	109	73	-1	-4	-2	70	114	77	-6	-10	-7
		DAY 15		22FEB2005	15	69	108	67	10	-5	-8	76	110	77	0	-14	-7
		DAY 22		01MAR2005	22	76	111	69	17I	-2	-6	78	120	79	2	-4	-5
		DAY 29		08MAR2005	29	68	112	75	9	-1	0	82	122	81	6	-2	-3

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0046010	DAY 36	15MAR2005	36	73	122	73	14	9	-2	83	124	77	7	0	-7
		DAY 43	22MAR2005	43	60	121	85	1	8	10	74	115	71	-2	-9	-13
		DAY 50	28MAR2005	49	71	126	66	12	13	-9	77	124	72	1	0	-12
		DAY 57	05APR2005	57	68	110	66	9	-3	-9	72	110	58	-4	-14	-26D
		FINAL			68	110	66	9	-3	-9	72	110	58	-4	-14	-26D
	E0046016	SCREEN	11MAY2005	-7	56	112	80				73	110	72			
		DAY 1	18MAY2005	1	60	116	64				64	120	80			
		BASELINE			60	116	64				64	120	80			
		DAY 8	24MAY2005	7	60	138	70	0	22I	6	76	123	62	12	3	-18
		DAY 15	31MAY2005	14	76	145	76	16I	29I	12	86	134	73	22I	14	-7
		DAY 22	07JUN2005	21	63	137	66	3	21I	2	84	128	76	20I	8	-4
		DAY 29	14JUN2005	28	52	135	76	-8	19	12	67	133	81	3	13	1
		DAY 36	21JUN2005	35	54	121	58	-6	5	-6	82	121	72	18I	1	-8
		DAY 43	28JUN2005	42	70	127	72	10	11	8	70	128	61	6	8	-19
		DAY 50	05JUL2005	49	54	137	70	-6	21I	6	75	125	71	11	5	-9
		DAY 57	12JUL2005	56	60	112	70	0	-4	6	64	110	74	0	-10	-6
		FINAL			60	112	70	0	-4	6	64	110	74	0	-10	-6
	E0046017	SCREEN	12MAY2005	-11	60	110	62				80	108	80			
		DAY 1	23MAY2005	1	59	115	75				61	120	84			
		BASELINE			59	115	75				61	120	84			
		DAY 8	31MAY2005	9	60	106	69	1	-9	-6	74	108	82	13	-12	-2
		DAY 15	07JUN2005	16	70	111	70	11	-4	-5	79	109	79	18I	-11	-5
		DAY 22	13JUN2005	22	72	110	73	13	-5	-2	81	112	80	20I	-8	-4
		DAY 29	20JUN2005	29	88	118	77	29I	3	2	76	118	93	15I	-2	9
		DAY 36	27JUN2005	36	55	109	72	-4	-6	-3	74	126	85	13	6	1
		DAY 43	06JUL2005	45	71	113	71	12	-2	-4	77	116	80	16I	-4	-4
		DAY 50	11JUL2005	50	63	98	78	4	-17	3	68	112	79	7	-8	-5
		DAY 57	18JUL2005	57	75	111	74	16I	-4	-1	88	115	80	27I	-5	-4
		FINAL			75	111	74	16I	-4	-1	88	115	80	27I	-5	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR I)	E0046019	SCREEN		02JUN2005	-7	76	112	90				80	120	100			
		DAY 1		09JUN2005	1	80	120	76				76	122	100			
		BASELINE				80	120	76				76	122	100			
		DAY 8		16JUN2005	8	85	133	87	5	13	11	112	133	98	36I	11	-2
		DAY 15		23JUN2005	15	99	136	89	19I	16	13	126H	127	99	50I	5	-1
		DAY 22		30JUN2005	22	74	130	78	-6	10	2	93	126	84	17I	4	-16
		DAY 29		07JUL2005	29	66	124	66	-14	4	-10	87	126	81	11	4	-19
		DAY 36		14JUL2005	36	70	117	67	-10	-3	-9	85	121	75	9	-1	-25D
		DAY 43		21JUL2005	43	78	123	75	-2	3	-1	101	124	78	25I	2	-22D
		DAY 50		28JUL2005	50	83	133	76	3	13	0	102	138	84	26I	16	-16
		DAY 50	*	01AUG2005	54	64	123	75	-16D	3	-1	75	126	85	-1	4	-15
		FINAL				64	123	75	-16D	3	-1	75	126	85	-1	4	-15
PLACEBO (BIPOLAR II)	E0010010	SCREEN		24JAN2005	-4	61	106	70				74	92	64			
		DAY 1		28JAN2005	1	66	114	70				62	114	60			
		BASELINE				66	114	70				62	114	60			
		DAY 8		04FEB2005	8	68	110	64	2	-4	-6	68	112	68	6	-2	8
		DAY 15		11FEB2005	15	70	108	60	4	-6	-10	68	110	64	6	-4	4
		DAY 22		18FEB2005	22	78	108	60	12	-6	-10	68	104	72	6	-10	12
		DAY 29		28FEB2005	32	70	116	72	4	2	2	74	110	66	12	-4	6
		DAY 36		04MAR2005	36	74	110	70	8	-4	0	68	108	74	6	-6	14
		DAY 43		14MAR2005	46	68	108	64	2	-6	-6	88	106	60	26I	-8	0
		DAY 50		18MAR2005	50	84	100	62	18I	-14	-8	84	104	64	22I	-10	4
		DAY 57		24MAR2005	56	70	100	64	4	-14	-6	76	110	60	14	-4	0
		FINAL				70	100	64	4	-14	-6	76	110	60	14	-4	0
	E0011002	SCREEN		15JUL2004	-12	66	124	76				68	126	74			
		DAY 1		27JUL2004	1	62	110	78				68	112	78			
		BASELINE				62	110	78				68	112	78			

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0011002	DAY 8		03AUG2004	8	68	120	74	6	10	-4	72	124	78	4	12	0
		DAY 15		10AUG2004	15	74	122	76	12	12	-2	78	126	80	10	14	2
		DAY 22		17AUG2004	22	72	120	78	10	10	0	74	120	74	6	8	-4
		DAY 29		24AUG2004	29	80	110	80	18I	0	2	82	115	80	14	3	2
		DAY 36		31AUG2004	36	76	118	78	14	8	0	80	120	76	12	8	-2
		DAY 43		07SEP2004	43	68	110	80	6	0	2	78	120	84	10	8	6
		DAY 50		14SEP2004	50	76	108	74	14	-2	-4	84	106	78	16I	-6	0
		DAY 57		23SEP2004	59	84	118	80	22I	8	2	90	112	78	22I	0	0
		FINAL				84	118	80	22I	8	2	90	112	78	22I	0	0
	E0011019	SCREEN		12JAN2005	-7	88	126	76				86	124	74			
		DAY 1		19JAN2005	1	86	128	74				84	126	72			
		BASELINE				86	128	74				84	126	72			
		DAY 8		26JAN2005	8	80	124	74	-6	-4	0	78	122	74	-6	-4	2
		DAY 15		03FEB2005	16	82	130	76	-4	2	2	80	128	74	-4	2	2
		DAY 22		09FEB2005	22	86	122	74	0	-6	0	88	126	74	4	0	2
		DAY 29		18FEB2005	31	78	124	76	-8	-4	2	76	122	74	-8	-4	2
		DAY 43	*	28FEB2005	41	76	126	74	-10	-2	0	76	124	74	-8	-2	2
		DAY 43		03MAR2005	44	78	122	76	-8	-6	2	78	120	74	-6	-6	2
		DAY 50		09MAR2005	50	70	124	72	-16D	-4	-2	68	118	67	-16D	-8	-5
		DAY 57		16MAR2005	57	78	120	74	-8	-8	0	76	118	70	-8	-8	-2
		FINAL				78	120	74	-8	-8	0	76	118	70	-8	-8	-2
	E0012008	SCREEN		16AUG2004	-9	78	118	78				78	112	78			
		DAY 1		25AUG2004	1	84	114	74				88	114	74			
		BASELINE				84	114	74				88	114	74			
		DAY 8		01SEP2004	8	84	134	80	0	20I	6	84	130	84	-4	16	10
		DAY 15		08SEP2004	15	84	124	70	0	10	-4	84	118	70	-4	4	-4
		DAY 22		13SEP2004	20	88	116	68	4	2	-6	96	104	60	8	-10	-14
		DAY 29		22SEP2004	29	88	120	80	4	6	6	88	116	80	0	2	6

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT103.SAS
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE	DAY	SUPINE						STANDING					
									CHANGE FROM BASELINE						CHANGE FROM BASELINE		
						PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0012008	DAY 36		29SEP2004	36	84	118	78	0	4	4	72	120	80	-16D	6	6
		DAY 43		08OCT2004	45	78	124	84	-6	10	10	80	118	84	-8	4	10
		DAY 50		13OCT2004	50	76	120	82	-8	6	8	78	124	84	-10	10	10
		DAY 57		19OCT2004	56	70	116	76	-14	2	2	72	118	72	-16D	4	-2
		FINAL				70	116	76	-14	2	2	72	118	72	-16D	4	-2
	E0013011	SCREEN		08NOV2004	-7	69	130	72				76	142	80			
		DAY 1		15NOV2004	1	74	117	82				72	114	83			
		BASELINE				74	117	82				72	114	83			
		DAY 8		22NOV2004	8	70	114	74	-4	-3	-8	80	110	76	8	-4	-7
		DAY 15		29NOV2004	15	70	120	71	-4	3	-11	89	118	73	17I	4	-10
		DAY 22		06DEC2004	22	72	126	74	-2	9	-8	70	122	74	-2	8	-9
		DAY 29		13DEC2004	29	91	114	81	17I	-3	-1	93	114	78	21I	0	-5
		DAY 36		20DEC2004	36	108	123	82	34I	6	0	98	130	86	26I	16	3
		DAY 43		27DEC2004	43	88	136	91	14	19	9	103	120	93	31I	6	10
		DAY 50		03JAN2005	50	99	128	76	25I	11	-6	99	130	87	27I	16	4
		DAY 57		10JAN2005	57	84	107	77	10	-10	-5	86	110	82	14	-4	-1
		FINAL				84	107	77	10	-10	-5	86	110	82	14	-4	-1
	E0020019	SCREEN		02NOV2004	-14	64	115	75				68	118	80			
		DAY 1		16NOV2004	1	64	100	80				68	111	84			
		BASELINE				64	100	80				68	111	84			
		DAY 8		23NOV2004	8	64	120	80	0	20I	0	86	112	70	18I	1	-14
		DAY 15		29NOV2004	14	32L	100	70	-32D	0	-10	64	117	70	-4	6	-14
		DAY 22		06DEC2004	21	70	100	82	6	0	2	60	100	80	-8	-11	-4
		DAY 22	*	09DEC2004	24	42L	110	82	-22D	10	2	66	110	90	-2	-1	6
		DAY 43		28DEC2004	43	62	104	88	-2	4	8	88	110	84	20I	-1	0
		DAY 50		04JAN2005	50	61	100	80	-3	0	0	64	100	80	-4	-11	-4
		DAY 57		11JAN2005	57	66	111	80	2	11	0	66	112	82	-2	1	-2
		FINAL				66	111	80	2	11	0	66	112	82	-2	1	-2

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0020026	SCREEN	08DEC2004	-8	56	110	70				60	115	70			
		DAY 1	16DEC2004	1	62	112	76				64	120	70			
		BASELINE			62	112	76				64	120	70			
		DAY 8	23DEC2004	8	54	90L	70	-8	-22D	-6	70	100	80	6	-20D	10
		DAY 15	30DEC2004	15	64	95	70	2	-17	-6	66	100	60	2	-20D	-10
		DAY 22	06JAN2005	22	60	100	60	-2	-12	-16	62	95	60	-2	-25D	-10
		DAY 29	13JAN2005	29	52	110	70	-10	-2	-6	60	100	70	-4	-20D	0
		DAY 36	20JAN2005	36	64	102	70	2	-10	-6	72	110	80	8	-10	10
		DAY 43	27JAN2005	43	64	115	75	2	3	-1	74	115	75	10	-5	5
		DAY 50	03FEB2005	50	60	110	70	-2	-2	-6	64	110	70	0	-10	0
		DAY 57	10FEB2005	57	54	104	64	-8	-8	-12	60	100	70	-4	-20D	0
		FINAL			54	104	64	-8	-8	-12	60	100	70	-4	-20D	0
	E0020029	SCREEN	14DEC2004	-7	68	130	90				76	135	90			
		DAY 1	21DEC2004	1	72	120	90				82	130	96			
		BASELINE			72	120	90				82	130	96			
		DAY 8	28DEC2004	8	103	134	96	31I	14	6	102	140	90	20I	10	-6
		DAY 15	04JAN2005	15	70	138	102	-2	18	12	84	136	89	2	6	-7
		DAY 22	11JAN2005	22	70	112	82	-2	-8	-8	62	120	90	-20D	-10	-6
		DAY 29	18JAN2005	29	80	120	80	8	0	-10	78	120	92	-4	-10	-4
		DAY 36	25JAN2005	36	76	115	80	4	-5	-10	80	120	85	-2	-10	-11
		DAY 43	01FEB2005	43	78	110	70	6	-10	-20D	80	105	80	-2	-25D	-16
		DAY 50	08FEB2005	50	74	120	75	2	0	-15	78	125	80	-4	-5	-16
		DAY 57	15FEB2005	57	81	111	80	9	-9	-10	80	112	82	-2	-18	-14
		FINAL			81	111	80	9	-9	-10	80	112	82	-2	-18	-14
	E0020030	SCREEN	16DEC2004	-19	64	130	80				66	130	90			
		DAY 1	04JAN2005	1	70	130	80				89	111	82			
		BASELINE			70	130	80				89	111	82			
		DAY 8	11JAN2005	8	70	138	80	0	8	0	82	130	92	-7	19	10

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0020030	DAY 15	18JAN2005	15	70	120	88	0	-10	8	78	120	80	-11	9	-2
		DAY 22	25JAN2005	22	68	120	85	-2	-10	5	74	120	80	-15D	9	-2
		DAY 29	01FEB2005	29	64	110	80	-6	-20D	0	70	108	80	-19D	-3	-2
		DAY 36	09FEB2005	37	70	110	70	0	-20D	-10	80	110	78	-9	-1	-4
		DAY 43	15FEB2005	43	70	122	78	0	-8	-2	88	120	84	-1	9	2
		DAY 50	22FEB2005	50	70	106	80	0	-24D	0	80	108	84	-9	-3	2
		DAY 57	01MAR2005	57	66	110	84	-4	-20D	4	72	119	84	-17D	8	2
		FINAL			66	110	84	-4	-20D	4	72	119	84	-17D	8	2
	E0020034	SCREEN	10JAN2005	-7	68	110	70				82	100	70			
		DAY 1	17JAN2005	1	54	92	70				64	100	80			
		BASELINE			54	92	70				64	100	80			
		DAY 8	24JAN2005	8	62	95	70	8	3	0	66	100	70	2	0	-10
		DAY 15	31JAN2005	15	60	100	70	6	8	0	62	95	60	-2	-5	-20D
		DAY 22	07FEB2005	22	62	90L	65	8	-2	-5	64	100	60	0	0	-20D
		DAY 29	14FEB2005	29	68	110	80	14	18	10	72	109	80	8	9	0
		DAY 36	21FEB2005	36	72	104	70	18I	12	0	82	100	70	18I	0	-10
		DAY 43	28FEB2005	43	68	110	80	14	18	10	68	105	80	4	5	0
		DAY 50	07MAR2005	50	64	110	80	10	18	10	72	102	90	8	2	10
		DAY 57	14MAR2005	57	80	90L	70	26I	-2	0	78	100	70	14	0	-10
		FINAL			80	90L	70	26I	-2	0	78	100	70	14	0	-10
	E0020035	SCREEN	20JAN2005	-7	50	110	78				48L	140	98			
		DAY 1	27JAN2005	1	56	130	75				60	130	80			
		BASELINE			56	130	75				60	130	80			
		DAY 8	03FEB2005	8	60	120	80	4	-10	5	66	124	82	6	-6	2
		DAY 15	10FEB2005	15	72	118	76	16I	-12	1	80	120	80	20I	-10	0
		DAY 22	17FEB2005	22	74	120	80	18I	-10	5	70	118	78	10	-12	-2
		DAY 29	24FEB2005	29	80	140	80	24I	10	5	80	120	80	20I	-10	0
		DAY 36	03MAR2005	36	84	120	70	28I	-10	-5	80	130	80	20I	0	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0020035	DAY 43	10MAR2005	43	78	120	70	22I	-10	-5	84	120	80	24I	-10	0
		DAY 50	17MAR2005	50	78	118	80	22I	-12	5	82	120	82	22I	-10	2
		DAY 57	24MAR2005	57	84	118	80	28I	-12	5	88	120	80	28I	-10	0
		FINAL			84	118	80	28I	-12	5	88	120	80	28I	-10	0
	E0021015	SCREEN	03NOV2004	-7	57	120	72				72	114	86			
		DAY 1	10NOV2004	1	54	114	70				72	108	88			
		BASELINE			54	114	70				72	108	88			
		DAY 8	17NOV2004	8	63	112	70	9	-2	0	81	116	88	9	8	0
		DAY 15	26NOV2004	17	66	116	72	12	2	2	69	102	86	-3	-6	-2
		DAY 22	01DEC2004	22	66	110	74	12	-4	4	72	130	88	0	22I	0
		DAY 29	08DEC2004	29	66	104	68	12	-10	-2	78	110	84	6	2	-4
		DAY 36	14DEC2004	35	70	98	68	16I	-16	-2	80	122	82	8	14	-6
		DAY 43	21DEC2004	42	63	106	64	9	-8	-6	81	108	78	9	0	-10
		DAY 50	29DEC2004	50	72	109	64	18I	-5	-6	93	104	74	21I	-4	-14
		DAY 57	05JAN2005	57	66	118	76	12	4	6	87	108	84	15I	0	-4
		FINAL			66	118	76	12	4	6	87	108	84	15I	0	-4
	E0025001	SCREEN	13JUL2004	-6	72	100	64				78	102	66			
		DAY 1	19JUL2004	1	87	117	80				84	114	76			
		BASELINE			87	117	80				84	114	76			
		DAY 8	27JUL2004	9	63	104	64	-24D	-13	-16	85	114	73	1	0	-3
		DAY 15	05AUG2004	18	65	94	64	-22D	-23D	-16	109	104	66	25I	-10	-10
		DAY 22	12AUG2004	25	64	110	60	-23D	-7	-20D	74	110	70	-10	-4	-6
		DAY 29	19AUG2004	32	69	94	60	-18D	-23D	-20D	97	132	74	13	18	-2
		DAY 36	25AUG2004	38	73	90L	57	-14	-27D	-23D	64	110	80	-20D	-4	4
		DAY 43	02SEP2004	46	81	112	64	-6	-5	-16	102	133	89	18I	19	13
		DAY 50	09SEP2004	53	56	115	72	-31D	-2	-8	69	114	79	-15D	0	3
		DAY 57	22SEP2004	66	80	118	80	-7	1	0	82	116	76	-2	2	0
		FINAL			80	118	80	-7	1	0	82	116	76	-2	2	0

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0025008	SCREEN	28JUL2004	-7	88	94	61				93	103	70			
		DAY 1	04AUG2004	1	88	110	76				86	111	76			
		BASELINE			88	110	76				86	111	76			
		DAY 8	10AUG2004	7	88	118	74	0	8	-2	86	116	73	0	5	-3
		DAY 15	18AUG2004	15	84	110	76	-4	0	0	86	112	76	0	1	0
		DAY 22	24AUG2004	21	93	103	64	5	-7	-12	105	109	62	19I	-2	-14
		DAY 29	31AUG2004	28	80	104	72	-8	-6	-4	82	105	72	-4	-6	-4
		DAY 36	08SEP2004	36	84	106	78	-4	-4	2	84	105	77	-2	-6	1
		DAY 43	15SEP2004	43	86	99	64	-2	-11	-12	87	100	66	1	-11	-10
		DAY 50	22SEP2004	50	79	100	80	-9	-10	4	78	99	81	-8	-12	5
		DAY 57	28SEP2004	56	85	128	77	-3	18	1	88	126	77	2	15	1
		FINAL			85	128	77	-3	18	1	88	126	77	2	15	1
	E0025013	SCREEN	19AUG2004	-7	80	122	80				84	118	78			
		DAY 1	26AUG2004	1	84	106	66				82	104	65			
		BASELINE			84	106	66				82	104	65			
		DAY 8	02SEP2004	8	78	117	80	-6	11	14	80	116	79	-2	12	14
		DAY 15	09SEP2004	15	79	123	82	-5	17	16	80	122	80	-2	18	15
		DAY 22	16SEP2004	22	82	122	82	-2	16	16	83	120	81	1	16	16
		DAY 29	27SEP2004	33	86	128	82	2	22I	16	85	126	80	3	22I	15
		DAY 36	01OCT2004	37	88	126	82	4	20I	16	86	125	82	4	21I	17
		DAY 43	07OCT2004	43	86	128	82	2	22I	16	84	126	80	2	22I	15
		DAY 50	13OCT2004	49	84	126	80	0	20I	14	86	125	80	4	21I	15
		DAY 57	21OCT2004	57	84	126	84	0	20I	18	84	130	84	2	26I	19
		FINAL			84	126	84	0	20I	18	84	130	84	2	26I	19
	E0025041	SCREEN	08FEB2005	-6	80	156	92				92	132	102			
		DAY 1	14FEB2005	1	92	158	88				84	132	110H			
		BASELINE			92	158	88				84	132	110H			
		DAY 8	24FEB2005	11	64	138	86	-28D	-20D	-2	72	129	86	-12	-3	-24D

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0025041	DAY 15	03MAR2005	18	68	120	90	-24D	-38D	2	80	114	98	-4	-18	-12
		DAY 29	14MAR2005	29	68	134	84	-24D	-24D	-4	88	112	88	4	-20D	-22D
		DAY 36	24MAR2005	39	68	144	94	-24D	-14	6	81	122	92	-3	-10	-18
		FINAL			68	144	94	-24D	-14	6	81	122	92	-3	-10	-18
	E0025049	SCREEN	01MAR2005	-7	80	128	92				92	128	98			
		DAY 1	08MAR2005	1	84	138	86				88	124	89			
		BASELINE			84	138	86				88	124	89			
		DAY 8	15MAR2005	8	90	134	84	6	-4	-2	108	126	92	20I	2	3
		DAY 15	23MAR2005	16	84	128	84	0	-10	-2	88	116	88	0	-8	-1
		DAY 22	30MAR2005	23	80	131	85	-4	-7	-1	78	129	89	-10	5	0
		DAY 29	04APR2005	28	76	138	96	-8	0	10	88	136	98	0	12	9
		FINAL			76	138	96	-8	0	10	88	136	98	0	12	9
	E0026002	SCREEN	28JUL2004	-12	66	132	80				72	126	74			
		DAY 1	09AUG2004	1	72	124	80				84	116	70			
		BASELINE			72	124	80				84	116	70			
		DAY 8	16AUG2004	8	74	124	74	2	0	-6	82	118	70	-2	2	0
		DAY 15	23AUG2004	15	82	138	80	10	14	0	86	132	78	2	16	8
		DAY 22	30AUG2004	22	84	134	80	12	10	0	88	130	74	4	14	4
		DAY 29	08SEP2004	31	72	130	80	0	6	0	84	136	80	0	20I	10
		FINAL			72	130	80	0	6	0	84	136	80	0	20I	10
	E0026013	SCREEN	25OCT2004	-7	74	126	70				78	120	74			
		DAY 1	01NOV2004	1	69	124	78				80	116	80			
		BASELINE			69	124	78				80	116	80			
		DAY 8	08NOV2004	8	72	120	80	3	-4	2	78	112	74	-2	-4	-6
		DAY 15	15NOV2004	15	70	124	80	1	0	2	73	122	72	-7	6	-8
		DAY 22	22NOV2004	22	71	120	70	2	-4	-8	78	116	68	-2	0	-12
		DAY 29	01DEC2004	31	68	122	70	-1	-2	-8	72	122	76	-8	6	-4

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0026013	DAY 36	06DEC2004	36	78	136	80	9	12	2	82	134	78	2	18	-2
		DAY 43	15DEC2004	45	70	134	76	1	10	-2	80	126	72	0	10	-8
		DAY 50	20DEC2004	50	71	134	80	2	10	2	79	136	74	-1	20I	-6
		DAY 57	27DEC2004	57	67	124	78	-2	0	0	84	126	74	4	10	-6
		FINAL			67	124	78	-2	0	0	84	126	74	4	10	-6
	E0028007	SCREEN	26JUL2004	-7	80	100	70				84	110	80			
		DAY 1	02AUG2004	1	96	110	70				100	110	80			
		BASELINE			96	110	70				100	110	80			
		DAY 8	09AUG2004	8	88	100	70	-8	-10	0	92	110	80	-8	0	0
		DAY 15	16AUG2004	15	88	110	80	-8	0	10	92	110	80	-8	0	0
		DAY 22	23AUG2004	22	88	110	80	-8	0	10	92	110	80	-8	0	0
		DAY 29	30AUG2004	29	76	120	80	-20D	10	10	84	110	80	-16D	0	0
		DAY 36	07SEP2004	37	96	100	80	0	-10	10	104	100	82	4	-10	2
		DAY 43	13SEP2004	43	100	100	78	4	-10	8	100	100	80	0	-10	0
		DAY 50	20SEP2004	50	88	100	80	-8	-10	10	92	110	80	-8	0	0
		DAY 57	27SEP2004	57	84	110	70	-12	0	0	84	110	80	-16D	0	0
		FINAL			84	110	70	-12	0	0	84	110	80	-16D	0	0
	E0030014	SCREEN	16SEP2004	-7	57	130	78				88	143	90			
		DAY 1	23SEP2004	1	70	130	78				93	139	86			
		BASELINE			70	130	78				93	139	86			
		DAY 8	30SEP2004	8	56	121	72	-14	-9	-6	93	124	88	0	-15	2
		DAY 15	07OCT2004	15	62	121	65	-8	-9	-13	109	126	95	16I	-13	9
		DAY 22	14OCT2004	22	57	130	71	-13	0	-7	108	130	90	15I	-9	4
		DAY 29	21OCT2004	29	64	122	78	-6	-8	0	88	118	80	-5	-21D	-6
		DAY 36	26OCT2004	34	60	118	76	-10	-12	-2	88	120	80	-5	-19	-6
		DAY 43	04NOV2004	43	62	138	71	-8	8	-7	105	147	87	12	8	1
		DAY 50	11NOV2004	50	72	138	78	2	8	0	90	136	86	-3	-3	0
		DAY 57	18NOV2004	57	59	127	69	-11	-3	-9	91	120	85	-2	-19	-1

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
L: Potentially Clinically Important low. H: Potentially Clinically Important high.

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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0030014	FINAL			59	127	69	-11	-3	-9	91	120	85	-2	-19	-1
	E0030017	SCREEN	09NOV2004	-8	83	110	87				95	143	84			
		DAY 1	17NOV2004	1	103	116	69				115	115	66			
		BASELINE			103	116	69				115	115	66			
		DAY 8	24NOV2004	8	86	127	75	-17D	11	6	102	106	83	-13	-9	17
		DAY 15	30NOV2004	14	92	132	78	-11	16	9	120	118	70	5	3	4
		DAY 22	07DEC2004	21	93	128	74	-10	12	5	106	130	75	-9	15	9
		DAY 29	14DEC2004	28	77	141	76	-26D	25I	7	95	113	85	-20D	-2	19
		DAY 36	22DEC2004	36	88	120	78	-15D	4	9	100	122	80	-15D	7	14
		DAY 43	29DEC2004	43	85	115	65	-18D	-1	-4	101	129	79	-14	14	13
		FINAL			85	115	65	-18D	-1	-4	101	129	79	-14	14	13
	E0030022	SCREEN	29NOV2004	-9	52	121	78				61	131	84			
		DAY 1	08DEC2004	1	58	133	69				60	150	89			
		BASELINE			58	133	69				60	150	89			
		DAY 8	16DEC2004	9	58	118	82	0	-15	13	64	130	80	4	-20D	-9
		DAY 15	23DEC2004	16	53	132	79	-5	-1	10	62	147	95	2	-3	6
		DAY 22	30DEC2004	23	64	139	75	6	6	6	68	142	83	8	-8	-6
		DAY 29	06JAN2005	30	76	136	85	18I	3	16	79	137	84	19I	-13	-5
		DAY 36	13JAN2005	37	66	129	83	8	-4	14	68	145	87	8	-5	-2
		DAY 43	20JAN2005	44	59	117	77	1	-16	8	64	128	76	4	-22D	-13
		DAY 50	26JAN2005	50	58	137	85	0	4	16	62	148	83	2	-2	-6
		DAY 57	01FEB2005	56	52	120	70	-6	-13	1	59	147	90	-1	-3	1
		FINAL			52	120	70	-6	-13	1	59	147	90	-1	-3	1
	E0030028	SCREEN	10FEB2005	-7	70	112	67				77	118	77			
		DAY 1	17FEB2005	1	74	115	68				90	107	72			
		BASELINE			74	115	68				90	107	72			
		DAY 8	24FEB2005	8	83	115	72	9	0	4	102	120	82	12	13	10

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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/VIT103.SAS
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0030028	DAY 15	04MAR2005	16	62	112	70	-12	-3	2	76	120	68	-14	13	-4
		DAY 22	10MAR2005	22	71	113	66	-3	-2	-2	88	109	71	-2	2	-1
		DAY 29	17MAR2005	29	70	90L	66	-4	-25D	-2	90	100	68	0	-7	-4
		DAY 36	23MAR2005	35	80	118	73	6	3	5	108	110	77	18I	3	5
		DAY 43	30MAR2005	42	94	115	62	20I	0	-6	103	92	77	13	-15	5
		DAY 50	06APR2005	49	72	120	78	-2	5	10	80	122	80	-10	15	8
		DAY 57	13APR2005	56	72	106	65	-2	-9	-3	86	121	72	-4	14	0
		FINAL			72	106	65	-2	-9	-3	86	121	72	-4	14	0
	E0037003	SCREEN	31AUG2004	-21	72	125	90				72	135	90			
		DAY 1	21SEP2004	1	88	112	80				84	110	82			
		BASELINE			88	112	80				84	110	82			
		DAY 8	28SEP2004	8	78	122	82	-10	10	2	82	120	80	-2	10	-2
		DAY 15	05OCT2004	15	82	120	82	-6	8	2	80	118	80	-4	8	-2
		DAY 22	12OCT2004	22	92	120	80	4	8	0	100	110	84	16I	0	2
		DAY 29	19OCT2004	29	88	110	76	0	-2	-4	100	100	74	16I	-10	-8
		DAY 36	26OCT2004	36	88	114	82	0	2	2	92	110	78	8	0	-4
		DAY 43	02NOV2004	43	82	112	76	-6	0	-4	84	106	78	0	-4	-4
		DAY 50	09NOV2004	50	84	102	80	-4	-10	0	92	110	80	8	0	-2
		DAY 57	16NOV2004	57	76	120	80	-12	8	0	96	118	84	12	8	2
		FINAL			76	120	80	-12	8	0	96	118	84	12	8	2
	E0037018	SCREEN	24FEB2005	-18	56	100	72				64	116	72			
		DAY 1	14MAR2005	1	60	120	78				66	128	76			
		BASELINE			60	120	78				66	128	76			
		DAY 15	30MAR2005	17	56	106	70	-4	-14	-8	64	114	72	-2	-14	-4
		DAY 22	06APR2005	24	60	100	70	0	-20D	-8	70	118	72	4	-10	-4
		DAY 29	13APR2005	31	56	100	68	-4	-20D	-10	60	120	74	-6	-8	-2
		DAY 36	20APR2005	38	60	110	66	0	-10	-12	76	106	74	10	-22D	-2
		DAY 43	27APR2005	45	68	112	70	8	-8	-8	72	102	68	6	-26D	-8

* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0037018	DAY 50	04MAY2005	52	60	110	70	0	-10	-8	68	110	76	2	-18	0
		DAY 57	16MAY2005	64	64	108	70	4	-12	-8	68	106	76	2	-22D	0
		FINAL			64	108	70	4	-12	-8	68	106	76	2	-22D	0
	E0038001	SCREEN	01JUL2004	-7	60	115	80				64	115	80			
		DAY 1	08JUL2004	1	74	120	70				76	122	90			
		BASELINE			74	120	70				76	122	90			
		DAY 8	15JUL2004	8	74	120	70	0	0	0	80	114	70	4	-8	-20D
		DAY 15	22JUL2004	15	64	120	70	-10	0	0	66	122	80	-10	0	-10
		DAY 22	29JUL2004	22	66	118	80	-8	-2	10	72	118	80	-4	-4	-10
		DAY 29	06AUG2004	30	72	122	80	-2	2	10	80	118	84	4	-4	-6
		DAY 36	12AUG2004	36	58	120	76	-16D	0	6	68	118	78	-8	-4	-12
		FINAL			58	120	76	-16D	0	6	68	118	78	-8	-4	-12
	E0039011	SCREEN	18OCT2004	-8	58	110	60				62	108	66			
		DAY 1	26OCT2004	1	56	102	70				62	98	60			
		BASELINE			56	102	70				62	98	60			
		DAY 8	02NOV2004	8	58	108	60	2	6	-10	64	98	60	2	0	0
		DAY 15	09NOV2004	15	70	100	62	14	-2	-8	70	94	60	8	-4	0
		DAY 22	16NOV2004	22	72	92	54	16I	-10	-16	68	90L	60	6	-8	0
		DAY 29	24NOV2004	30	60	98	64	4	-4	-6	62	90L	60	0	-8	0
		DAY 36	01DEC2004	37	64	108	70	8	6	0	68	98	62	6	0	2
		DAY 43	08DEC2004	44	72	98	62	16I	-4	-8	88	100	80	26I	2	20
		DAY 50	14DEC2004	50	64	118	60	8	16	-10	70	100	70	8	2	10
		DAY 57	22DEC2004	58	64	100	52	8	-2	-18	72	92	56	10	-6	-4
		FINAL			64	100	52	8	-2	-18	72	92	56	10	-6	-4
	E0041013	SCREEN	28DEC2004	-8	72	112	64				80	106	68			
		DAY 1	05JAN2005	1	64	106	58				88	96	64			
		BASELINE			64	106	58				88	96	64			

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I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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Table 11.3.8.2.1.2 Vital Signs - Potentially Clinically Important Change from Baseline

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE	DAY	SUPINE						STANDING					
								CHANGE FROM BASELINE						CHANGE FROM BASELINE		
					PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA	PULSE	SYS	DIA
PLACEBO (BIPOLAR II)	E0041013	DAY 8	12JAN2005	8	88	108	60	24I	2	2	108	108	64	20I	12	0
		DAY 15	19JAN2005	15	92	106	66	28I	0	8	100	110	68	12	14	4
		DAY 22	27JAN2005	23	80	112	68	16I	6	10	84	108	68	-4	12	4
		DAY 29	02FEB2005	29	60	110	70	-4	4	12	80	110	74	-8	14	10
		DAY 36	10FEB2005	37	84	116	78	20I	10	20	96	112	80	8	16	16
		DAY 43	16FEB2005	43	84	108	70	20I	2	12	100	104	74	12	8	10
		DAY 50	23FEB2005	50	84	110	76	20I	4	18	104	100	74	16I	4	10
		DAY 57	02MAR2005	57	68	110	68	4	4	10	84	112	72	-4	16	8
		FINAL			68	110	68	4	4	10	84	112	72	-4	16	8

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SYS: Systolic blood pressure DIA: Diastolic blood pressure.
I: Potentially Clinically Important increase. D: Potentially Clinically Important decrease.
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GENERATED: 17NOV2005 13:53:15 iceadmn3

Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS HEART RATE	PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 300 MG (BIPOLAR I)	E0001005	BASELINE	15SEP2004/16:36	-5	51	135	88	487	460 H	
	E0003010	BASELINE	08DEC2004/14:53	-8	63	143	85	385	391	
		FINAL	11JAN2005/11:09	27	78	141	79	330	360	15 I
	E0003012	BASELINE	15MAR2005/9:39	-24	55	188	73	416	404	
		FINAL	07JUN2005/8:11	61	75	187	71	374	402	20 I
	E0004029	BASELINE	14APR2005/12:25	-14	72	167	91	377	400	
		FINAL	23JUN2005/15:22	57	79	173	82	414	455 H	7
	E0006007	BASELINE	05AUG2004/16:05	-7	46 L	154	73	460	420	
		FINAL	21OCT2004/12:51	71	75	156	81	401	432	29 I
	E0008010	BASELINE	24JAN2005/11:48	-7	58	140	72	422	417	
		FINAL	07FEB2005/13:16	8	69	145	86	436	457 H	11
	E0013009	BASELINE	01NOV2004/12:05	-7	65	128	87	394	405	
		FINAL	05JAN2005/15:26	59	82	135	90	377	419	17 I
	E0015008	BASELINE	08DEC2004/11:57	-7	59	150	93	376	374	
		FINAL	03JAN2005/14:36	20	76	150	98	353	381	17 I
	E0019013	BASELINE	16MAR2005/16:46	-15	57	166	86	397	391	
		FINAL	26APR2005/8:34	27	46 L	172	86	433	396	-11
	E0019015	BASELINE	09JUN2005/11:30	-11	45 L	193	96	432	393	
		FINAL	27JUL2005/14:59	38	61	166	83	400	401	16 I

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG101.SAS
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 300 MG (BIPOLAR I)	E0020044	BASELINE	13APR2005/12:30	-7	59	167	82	415	412	
		FINAL	15JUN2005/8:18	57	74	175	77	422	452 H	15 I
	E0021016	BASELINE	04NOV2004/14:00	-6	55	196	98	371	360	
		FINAL	06JAN2005/8:57	58	55	215 H	81	371	359	0
	E0021022	BASELINE	18JAN2005/16:42	-9	86	146	91	357	402	
		FINAL	22MAR2005/9:29	55	65	144	92	384	394	-21 D
	E0025020	BASELINE	10SEP2004/13:30	-6	69	145	87	384	401	
		FINAL	09NOV2004/11:41	55	84	145	86	369	413	15 I
	E0026021	BASELINE	02FEB2005/17:30	-7	96	132	90	360	421	
		FINAL	07APR2005/16:01	58	72	132	93	385	409	-24 D
	E0028011	BASELINE	31JAN2005/15:39	-7	69	150	79	358	375	
		FINAL	04APR2005/10:09	57	85	127	77	349	392	16 I
	E0029009	BASELINE	17NOV2004/8:57	-7	74	156	77	380	408	
		FINAL	04MAR2005/11:26	101	94	125	72	335	388	20 I
	E0030009	BASELINE	18AUG2004/10:47	-6	75	159	69	349	376	
		FINAL	21OCT2004/12:04	59	94	144	82	311	362	19 I
	E0030038	BASELINE	15JUN2005/9:54	-7	66	184	77	386	397	
		FINAL	16AUG2005/10:03	56	85	184	82	341	382	19 I
	E0032008	BASELINE *	10FEB2005/14:55	-47	81	158	82	347	384	
		BASELINE	22MAR2005/13:21	-7	104	168	77	325	391	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG101.SAS
GENERATED: 17NOV2005 13:48:49 iceadmn3

Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE
					HEART RATE	PR	QRS	QT	FRIDERICIA QTC	HEART RATE
QUETIAPINE 300 MG (BIPOLAR I)	E0032008	FINAL	20APR2005/4:05	23	81	169	86	354	391	-23 D
	E0033015	BASELINE	28FEB2005/14:22	-14	72	131	83	376	400	
		FINAL	09MAY2005/13:51	57	91	149	85	344	396	19 I
	E0033017	BASELINE	17MAR2005/16:18	-13	56	147	88	418	409	
		FINAL	23MAY2005/9:39	55	71	155	78	399	421	15 I
	E0033019	BASELINE	16MAY2005/12:34	-8	54	193	163 H	478	462 H	
	E0040003	BASELINE	06AUG2004/13:00	-6	56	136	87	424	413	
		FINAL	08OCT2004/18:23	58	74	142	89	385	414	18 I
	E0040006	BASELINE	19AUG2004/17:51	-8	66	130	83	422	435	
		FINAL	22OCT2004/18:09	57	83	161	85	348	388	17 I
	E0040017	BASELINE	18MAY2005/16:14	-7	60	161	82	416	417	
		FINAL	22JUL2005/13:23	59	40 L	141	99	445	390	-20 D

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
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GENERATED: 17NOV2005 13:48:49 iceadmn3

Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	HEART RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 300 MG (BIPOLAR II)	E0004025	BASELINE		07FEB2005/14:27	-21	70	124	78	353	370	
		FINAL		25APR2005/10:31	57	109	122	76	337	411	39 I
	E0006016	BASELINE		07OCT2004/11:03	-8	67	187	99	385	400	
		FINAL		10DEC2004/8:57	57	52	195	105	410	392	-15 D
	E0008006	BASELINE	*	09NOV2004/18:22	-29	60		90	387	386	
		BASELINE	*	09NOV2004/18:22	-29		121				
		BASELINE		07DEC2004/13:36	-1	68	155	88	394	409	
		FINAL		02FEB2005/12:28	57	84	157	81	340	380	16 I
	E0010007	FINAL	*	15NOV2004/18:25	8	62	209	121 H	407	410	
		FINAL		03JAN2005/14:47	57	60	207	125 H	405	406	
	E0010009	BASELINE		18JAN2005/18:19	-7	83	250 H	81	369	411	
	E0011009	BASELINE		29OCT2004/12:39	-7	46 L	162	81	473	433	
		FINAL		30DEC2004/15:02	56	63	200	80	423	429	17 I
	E0011016	BASELINE		07DEC2004/12:26	-9	76	130	75	377	408	
		FINAL		11FEB2005/11:20	58	105	142	90	357	430	29 I
	E0011017	BASELINE		16DEC2004/9:50	-12	66	170	84	396	408	
		FINAL		22FEB2005/10:00	57	86	162	85	359	405	20 I
	E0013003	BASELINE		02AUG2004/11:03	-7	57	137	82	415	409	
		FINAL		04OCT2004/13:52	57	80	144	85	359	395	23 I
	E0019002	BASELINE		11AUG2004/11:05	-27	69	150	85	392	410	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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L: Lower than lower limit of normal range.
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SOURCE DOCUMENT: /CSRE/PROD/SEROQUEL/D1447C00135/SP/PROG/TLF/ECG101.SAS
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS				CHANGE FROM BASELINE
						PR	QRS	QT	FRIDERICIA QTC	HEART RATE
QUETIAPINE 300 MG (BIPOLAR II)	E0019002	FINAL	03NOV2004/12:15	58	85	166	85	357	400	16 I
	E0019009	BASELINE	06JAN2005/12:00	-6	58	165	90	369	365	
		FINAL	09MAR2005/14:17	57	73	176	86	347	370	15 I
	E0025009	BASELINE	04AUG2004/11:01	-7	45 L	244 H	93	424	385	
	E0034011	BASELINE	22APR2005/10:56	-11	55	188	84	513 H	498 H	
		FINAL	28JUN2005/10:59	57	53	189	86	531 H	511 H	-2
	E0035007	BASELINE	09AUG2004/10:58	-10	61	137	95	405	407	
		FINAL	13OCT2004/8:39	56	88	136	85	364	414	27 I
	E0036002	BASELINE	10JAN2005/11:12	-2	75	140	90	348	375	
		FINAL	04FEB2005/9:52	24	60	149	86	395	395	-15 D
	E0037007	BASELINE	08OCT2004/11:08	-10	78	162	67	369	403	
		FINAL	16DEC2004/13:00	60	61	201	83	399	401	-17 D
	E0037021	BASELINE	14MAR2005/10:34	-8	67	228 H	85	382	397	
		FINAL	07APR2005/9:31	17	57	217 H	105	412	405	-10
	E0042005	BASELINE	10AUG2004/14:59	-23	60	154	89	377	376	
		FINAL	28OCT2004/16:35	57	79	158	77	341	374	19 I

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	HEART RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0001002	BASELINE	*	28JUL2004/15:47	-14	47 L	157	98	444	409	
		BASELINE		11AUG2004/13:56	1	46 L	133	103	441	403	
		FINAL		24SEP2004/12:54	45	107	149	95	357	432	61 I
	E0004009	BASELINE		09AUG2004/10:12	-7	49 L	122	96	419	392	
	E0006017	BASELINE		08OCT2004/10:09	-7	66	142	88	436	450 H	
		FINAL		01NOV2004/9:28	18	81	126	84	400	441	15 I
	E0010016	BASELINE		02MAY2005/14:31	-3	91	151	75	347	399	
		FINAL		17MAY2005/10:34	13	106	149	71	325	392	15 I
	E0013008	BASELINE		27OCT2004/9:45	-15	72	167	93	409	435	
		FINAL		03JAN2005/14:09	54	99	179	77	353	418	27 I
	E0014013	BASELINE		21FEB2005/16:15	-7	62	162	94	393	398	
		FINAL		27APR2005/12:08	59	83	152	79	360	400	21 I
	E0014023	BASELINE		16JUN2005/14:08	-7	62	150	74	405	409	
		FINAL		03AUG2005/15:07	42	78	145	88	380	415	16 I
	E0020005	BASELINE		18AUG2004/11:52	-28	41 L	178	110	435	383	
		FINAL		11NOV2004/10:09	58	58	174	83	368	363	17 I
	E0021003	BASELINE		26JUL2004/12:34	-10	66	231 H	95	422	435	
		FINAL		29SEP2004/14:19	56	77		83	360	392	11
		FINAL	*	29SEP2004/14:19	56		215 H				
	E0021032	BASELINE		18APR2005/11:15	-7	40 L	188	106	532 H	463 H	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS				CHANGE FROM BASELINE
						PR	QRS	QT	FRIDERICIA QTC	HEART RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0025053	BASELINE	31MAR2005/10:15	-19	66	135	95	386	398	
		FINAL	15JUN2005/15:47	58	83	142	93	379	423	17 I
	E0025057	BASELINE	26APR2005/17:29	-6	49 L	151	99	445	415	
		FINAL	27JUN2005/12:06	57	64	177	92	388	397	15 I
	E0025061	BASELINE	12MAY2005/15:48	-12	98	153	95	327	385	
		FINAL	20JUL2005/13:55	58	75	152	85	361	389	-23 D
	E0027001	BASELINE	09JUL2004/11:13	-21	61	121	71	408	410	
		FINAL	06AUG2004/11:08	8	82	113	77	350	389	21 I
	E0027003	BASELINE	21JUL2004/9:22	-19	65	157	91	372	383	
		FINAL	04OCT2004/9:21	57	83	158	91	355	395	18 I
	E0027008	BASELINE	02AUG2004/9:29	-4	65	180	90	377	388	
		FINAL	01OCT2004/10:07	57	93	188	98	325	376	28 I
	E0027009	BASELINE	23AUG2004/9:34	-3	81	168	86	328	363	
		FINAL	21OCT2004/12:28	57	102	162	76	301	359	21 I
	E0028001	BASELINE	08JUL2004/11:06	-7	54	154	77	409	395	
		FINAL	08SEP2004/9:27	56	72	164	83	380	404	18 I
	E0030005	BASELINE	09AUG2004/12:44	-10	82	130	86	377	419	
		FINAL	26AUG2004/13:07	8	65	136	79	383	392	-17 D
	E0030015	BASELINE	04OCT2004/10:11	-7	71	154	105	393	416	
		FINAL	10DEC2004/11:26	61	92	155	92	352	405	21 I

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS PR	INTERVALS QRS	INTERVALS QT	INTERVALS FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0032010	BASELINE	01MAR2005/15:12	-7	75	231 H	82	351	378	
		FINAL	24MAR2005/12:25	17	73	214 H	75	355	379	-2
	E0032012	BASELINE	13JUN2005/23:35	-9	50	141	104	412	389	
		FINAL	17AUG2005/22:35	57	68	142	102	395	412	18 I
	E0032014	BASELINE	19JUN2005/22:15	-3	77	134	82	378	411	
		FINAL	17AUG2005/5:02	57	96	128	76	332	388	19 I
	E0033008	BASELINE	24NOV2004/12:33	-15	63	141	83	401	408	
		FINAL	03FEB2005/11:45	57	100	176	84	311	369	37 I
	E0034001	BASELINE	03SEP2004/12:46	-13	58	184	89	414	409	
		FINAL	11NOV2004/9:14	57	85	168	87	368	414	27 I
	E0034005	BASELINE	29NOV2004/9:52	-14	61	188	97	404	405	
		FINAL	21JAN2005/12:03	40	100	183	85	341	405	39 I
	E0035030	BASELINE	07MAR2005/17:19	-9	48 L	131	92	435	405	
	E0038004	BASELINE	02NOV2004/14:57	-9	63	136	82	367	374	
		FINAL	07JAN2005/14:08	58	91	153	76	367	421	28 I
	E0039007	BASELINE	15SEP2004/13:12	-15	56	131	74	413	403	
		FINAL	01DEC2004/10:43	63	96	127	83	334	391	40 I
	E0042020	BASELINE	28MAR2005/10:51	-14	68	148	82	384	400	
		FINAL	18APR2005/11:23	8	90	152	73	344	395	22 I

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	HEART RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 600 MG (BIPOLAR I)	E0046004	BASELINE		17NOV2004/12:53	-15	73	154	83	387	414	
		FINAL		24JAN2005/9:32	54	88	173	85	376	428	15 I
	E0046012	BASELINE		08FEB2005/11:54	-7	45 L	191	97	456	414	
		FINAL		21FEB2005/11:41	7	83	185	122 H	340	382	38 I
		FINAL	*	16MAR2005/15:23	30	47 L	205	112	478	442	2

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS PR	INTERVALS QRS	INTERVALS QT	INTERVALS FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 600 MG (BIPOLAR II)	E0004014	BASELINE	05OCT2004/16:36	-7	47 L	133	87	441	406	
		FINAL	20OCT2004/10:37	9	67	129	79	373	388	20 I
	E0011004	BASELINE	04AUG2004/11:10	-13	62	138	89	400	405	
		FINAL	18OCT2004/12:59	63	80	144	82	348	382	18 I
	E0012002	BASELINE	20JUL2004/14:00	-28	66	175	97	395	408	
		FINAL	11OCT2004/10:11	56	86	166	94	373	420	20 I
	E0020040	BASELINE	11FEB2005/11:09	-7	67	175	81	385	400	
		FINAL	14APR2005/13:57	56	98	176	78	329	387	31 I
	E0025022	BASELINE	04OCT2004/16:29	-28	66	185	85	393	407	
		FINAL	29DEC2004/17:31	59	96	168	77	332	388	30 I
	E0025032	BASELINE	30DEC2004/16:54	-11	75	149	86	376	404	
		FINAL	13JAN2005/14:22	4	54	158	82	425	411	-21 D
	E0026009	BASELINE	08OCT2004/11:46	-12	61	231 H	82	372	375	
		FINAL	17DEC2004/10:37	59	85	203	102	368	413	24 I
	E0030002	BASELINE	15JUL2004/10:21	-6	58	289 H	98	424	421	
	E0035018	BASELINE	11OCT2004/11:49	-7	58	166	75	374	371	
		FINAL	17DEC2004/11:46	61	75	160	77	360	388	17 I
	E0036007	BASELINE	14MAR2005/9:36	-4	73	202	93	365	389	
		FINAL *	29MAR2005/8:50	12	109	188	95	330	403	36 I
		FINAL	29MAR2005/8:51	12	109	187	86	332	406	36 I

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS PR	INTERVALS QRS	INTERVALS QT	INTERVALS FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
QUETIAPINE 600 MG (BIPOLAR II)	E0037020	BASELINE	08MAR2005/13:53	-7	72	189	80	343	364	
		FINAL	10MAY2005/11:40	57	88	175	85	314	356	16 I
	E0043003	BASELINE	30NOV2004/12:23	-3	87	177	96	328	371	
		FINAL	27JAN2005/10:44	56	70	184	79	369	389	-17 D
	E0046011	BASELINE	01FEB2005/17:52	-8	82	175	81	357	396	
		FINAL	06APR2005/11:05	57	65	182	89	385	395	-17 D

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT		DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE
						HEART RATE	PR	QRS	QT	FRIDERICIA QTC	HEART RATE
PLACEBO (BIPOLAR I)	E0001013	BASELINE		28APR2005/10:42	-7	62	151	95	443	448	
		FINAL		02JUN2005/10:41	29	69	150	119	432	452 H	7
	E0003008	BASELINE		21OCT2004/13:52	-19	45 L	182	91	469	425	
		FINAL		01DEC2004/18:33	23	68	172	90	388	405	23 I
	E0006003	BASELINE		02AUG2004/10:53	-7	44 L	160	96	434	392	
		FINAL		16AUG2004/8:44	8	39 L	167	96	453	393	-5
	E0008011	BASELINE		26JAN2005/11:11	-7	63	157	88	379	386	
		FINAL		15MAR2005/13:05	42	82	157	96	366	406	19 I
	E0012012	BASELINE		23SEP2004/12:58	-7	66	155	89	377	390	
		FINAL		04OCT2004/12:35	5	51	159	93	436	413	-15 D
	E0012016	BASELINE		25OCT2004/16:11	-8	81	186	98	362	399	
		FINAL		30DEC2004/9:34	59	63	185	90	415	423	-18 D
	E0012026	BASELINE		08JUN2005/11:49	-7	77	227 H	85	376	409	
		FINAL		10AUG2005/10:24	57	80	220 H	86	370	407	3
	E0014021	BASELINE		28APR2005/14:19	-6	58	110	94	408	403	
		FINAL		30JUN2005/12:25	58	73	119	85	386	412	15 I
	E0015018	BASELINE		08MAR2005/14:46	-7	62	177	84	381	385	
		FINAL	*	13MAY2005/9:30	60	80	166	77	381	419	18 I
		FINAL	*	13MAY2005/9:32	60	74	166	83	383	411	12
		FINAL		13MAY2005/9:39	60	77	157	83	383	416	15 I
	E0020007	BASELINE		26AUG2004/14:47	-12	59	148	93	422	420	

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS PR	QRS	QT	FRIDERICIA QTC	CHANGE FROM BASELINE HEART RATE
PLACEBO (BIPOLAR I)	E0020007	FINAL	04NOV2004/15:20	59	89	149	87	351	400	30 I
	E0020036	BASELINE	28JAN2005/11:57	-10	58	149	86	369	364	
		FINAL	06APR2005/11:21	59	47 L	171	98	424	390	-11
	E0021004	BASELINE	04AUG2004/16:50	-14	44 L	179	98	428	384	
	E0021007	BASELINE	08SEP2004/18:16	-9	48 L	149	86	439	406	
	E0021030	BASELINE	05APR2005/13:50	-8	55	190	98	410	397	
		FINAL	08JUN2005/10:31	57	71	204	93	430	454 H	16 I
	E0025007	BASELINE	27JUL2004/13:53	-22	111	157	98	330	405	
		FINAL	15SEP2004/13:49	29	91	151	126 H	346	398	-20 D
	E0025046	BASELINE	28FEB2005/16:24	-4	65	189	84	393	403	
		FINAL	07APR2005/15:05	35	82	168	89	358	398	17 I
	E0026024	BASELINE	30MAR2005/11:41	-12	50	157	88	419	393	
		FINAL	31MAY2005/10:23	51	69	157	96	382	401	19 I
	E0030011	BASELINE	25AUG2004/12:11	-5	58	169	77	391	387	
		FINAL	25OCT2004/11:15	57	78	167	78	381	416	20 I
	E0032005	BASELINE	02FEB2005/16:30	-7	49 L	136	87	450	422	
		FINAL	05APR2005/15:29	56	42 L	146	96	466	413	-7
	E0033002	BASELINE	02JUL2004/13:03	-11	54	157	98	439	424	
		FINAL	07SEP2004/10:00	57	49 L	156	97	439	410	-5

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	INTERVALS				CHANGE FROM BASELINE
					HEART RATE	PR	QRS	QT	FRIDERICIA QTC	HEART RATE
PLACEBO (BIPOLAR I)	E0033003	BASELINE	19AUG2004/11:44	-7	46 L	168	87	416	382	
		FINAL	20OCT2004/9:36	56	72	149	75	349	370	26 I
	E0033013	BASELINE	21JAN2005/8:14	-10	88	145	91	362	411	
		FINAL	01MAR2005/16:44	30	68	142	90	401	417	-20 D
	E0033014	BASELINE	21FEB2005/16:03	-7	82	213 H	126 H	348	386	
		FINAL	25APR2005/13:24	57	77	208	132 H	354	385	-5
	E0034013	BASELINE	27MAY2005/11:59	-7	62	152	100	388	392	
		FINAL	01AUG2005/11:38	60	102	150	107	345	411	40 I
	E0034015	BASELINE	31MAY2005/12:50	-21	55	151	95	441	429	
		FINAL	29JUL2005/13:48	39	70	148	96	407	430	15 I
	E0035003	BASELINE	28JUL2004/12:11	-7	53	137	93	406	390	
		FINAL	01OCT2004/15:59	59	86	146	74	350	395	33 I
	E0035010	BASELINE	12AUG2004/14:41	-11	70	134	84	393	413	
		FINAL	18OCT2004/9:47	57	49 L	155	97	443	413	-21 D
	E0037010	BASELINE	01NOV2004/11:08	-7	98	144	81	353	415	
		FINAL	13DEC2004/17:38	36	62	144	84	408	411	-36 D
	E0037011	BASELINE	26OCT2004/11:20	-7	53	169	82	402	385	
		FINAL	12JAN2005/14:02	72	76	138	85	356	384	23 I
	E0040004	BASELINE	06AUG2004/17:07	-6	44 L	153	83	500 H	451 H	
	E0040012	BASELINE	11MAR2005/17:00	-10	76	127	103	387	419	

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS				CHANGE FROM BASELINE
						PR	QRS	QT	FRIDERICIA QTC	HEART RATE
PLACEBO (BIPOLAR I)	E0040012	FINAL	28MAR2005/16:12	8	101	117	106	347	412	25 I
	E0041007	BASELINE	28OCT2004/12:50	-22	56	158	91	462	450 H	
	E0042024	BASELINE	15JUN2005/16:22	-7	51	174	74	455	431	
		FINAL	18AUG2005/12:10	58	43 L	187	73	484	433	-8
	E0044004	BASELINE	27JAN2005/15:39	-21	54	157	92	399	386	
		FINAL	14APR2005/10:34	57	80	172	89	368	405	26 I
	E0046019	BASELINE	02JUN2005/10:53	-7	88	188	95	357	407	
		FINAL	01AUG2005/17:06	54	59	189	94	396	394	-29 D

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

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Table 11.3.8.2.2 ECGS - Potentially Clinically Important

TREATMENT (BIPOLAR DIAGNOSIS)	SUBJECT CODE	WINDOWED VISIT	DATE/TIME	DAY	HEART RATE	INTERVALS				CHANGE FROM BASELINE
						PR	QRS	QT	FRIDERICIA QTC	HEART RATE
PLACEBO (BIPOLAR II)	E0008005	BASELINE	11OCT2004/10:48	-8	60	219 H	86	415	416	
	E0010003	BASELINE	09AUG2004/18:17	-3	67	153	86	389	403	
		FINAL	19AUG2004/17:51	8	92	162	81	328	378	25 I
	E0011002	BASELINE	15JUL2004/12:07	-12	69	155	86	369	386	
		FINAL	23SEP2004/10:41	59	84	149	82	342	383	15 I
	E0020029	BASELINE	14DEC2004/12:41	-7	66	161	82	407	420	
		FINAL	15FEB2005/9:48	57	82	169	78	377	419	16 I
	E0025008	BASELINE	28JUL2004/16:44	-7	85	125	91	341	382	
		FINAL	28SEP2004/14:01	56	68	138	90	365	381	-17 D
	E0025019	FINAL	16NOV2004/14:53	65	47 L	179	93	459	424	
	E0037018	BASELINE	24FEB2005/10:57	-18	49 L	158	90	437	409	
		FINAL	16MAY2005/14:58	64	67	144	84	382	396	18 I
	E0038003	BASELINE	19AUG2004/14:50	-14	67	122	83	392	407	
		FINAL	28OCT2004/12:01	57	86	129	77	341	385	19 I
	E0039011	BASELINE	18OCT2004/18:24	-8	54	138	77	415	400	
		FINAL	22DEC2004/9:35	58	74	146	78	374	400	20 I
	E0041012	BASELINE	29NOV2004/15:44	-14	73	102	98	392	419	
		FINAL	20DEC2004/14:40	8	91	112	90	354	407	18 I

SUBJECTS E0011014, E0022008 AND E0025021 WERE RANDOMIZED BUT DID NOT RECEIVE STUDY TREATMENT.
* VISITS OUTSIDE OF ACCEPTABLE WINDOW ARE NOT USED IN ANALYSIS.
L: Lower than lower limit of normal range.
H: Higher than upper limit of normal range.
I: Potentially Clinically Important increase.
D: Potentially Clinically Important decrease.

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12. APPENDICES