Id :	i.m.7c05909efeee17a5dbe42a22aa3896a2
CN :	F339-E05326923
Date :	Tuesday, December 12, 2000 6:41:00 PM GMT
From :	Schilling, Ann E
To :	Moriarity, Sean
Cc :	Tumas, John A
Subject :	FW: Reinstein/Sonnenberg paper
Attachments :	Comparative Efficacy and Tolerability of Quetiapine at High and Low Doses.doc
Custodians :	grpshare

From:
Schilling, Ann E

Sent:
Tuesday, December 12, 2000 3:40 PM

To:
Moriarity, Sean

Cc:
Tumas, John A

Subject:
FW: Reinstein/Sonnenberg paper

EXHIBIT
Reinstein20
11-5-08

Attachments:
Comparative Efficacy and Tolerability of Quetiapine at High and Low Doses.doc

Sean, Can you shed any light on the Reinstein retro trial. I think it was approved sometime last spring.

Thanks

Ann S

-----Original Message-----

From: Tumas, John A

Sent: Tuesday, December 12, 2000 10:11 AM

To: Brecher, Martin; Altman, Charles; Jones, Martin AM (PHMS); Goldstein, Jeffrey M; Richards, Adam B; Holdsworth, Debbie; Mullen, Jamie A; Schilling, Ann E; Gavin, Jim P; Zimmerman, Paul M; Leon, Ann L; Ney, Christine A; Williams-Hughes, Celeste

Cc: Yao, Faith

Subject: Reinstein/Sonnenberg paper

Importance: High

All,

Attached is a preliminary draft of a manuscript by John Sonnenberg, who works with Michael Reinstein. It is based on the IIT they are doing comparing high and low dose quetiapine. Although the basic message sounds favorable, ie there were no safety issues with the high dose (1200 mg) vs the low dose (600 mg) and there appeared to be some improvement in efficacy at the higher dose, I think this data is likely to be criticized.

Firstly, the investigator selected which patients would be in which group. Presumably, the sicker patients got the higher dose, which may explain the small difference in efficacy.

Secondly, safety was based entirely on adverse event reports, and out of 30 patients there were no reports of adverse events - a bit hard to believe, especially at 1200 mg. I don't think this will support any claims of safety.

Dr. Sonnenberg wants to submit an abstract to APA on this data. As the deadline is only a couple of weeks away, please let me know your thoughts on this as soon as you can. Even though it is an IIT, I'm not sure that we can prevent him from submitting this data if he wants to. Perhaps we can help him with some statistical support, as Faith has suggested.

Best regards,

John

cid:CHILKAT-CID-9a244b03-bedf-49ea-bc2f-de6a7fa3bfc2