Unknown

From: Repp, Edward

Sent: Thursday, February 19, 2004 5:54 PM

To: Gonzalez, John P; X:Seth, Aruna (External); Campbell, Denise; Brown, Donna; X:Casparro, Donna (External); Goldstein, Jeffrey M; Stening, Göran K; Hess, William; Jones, Martin AM (Seroquel); Lloyd (Washington), Lisa M; Hagger, Lynn; X:Brady, Max (External); Mullen, Jamie A; Ney, Christine A; Nordell-Friberg, Sarah; Olbrich, Richard; Paulsson, Björn; Sayce, Rod; Daniels, Stephanie; 'Svarvar, Patrick'; Swalley, Jeffrey S; Tumas, John A; Vågerö, Mårten; Williams-Hughes, Celeste

Subject: RE: Trial 104 Manuscript Ghaemi as co-author

Team,

I vote for "NOT" giving the raw data. If that's the only path forward, I'd suggest dropping Dr. Ghaemi as an author.

An alternative would be for a member or two (clinical and statistical) to walk through the hardcopy data with Dr. Ghaemi and address any of his questions.

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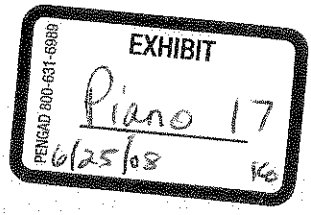

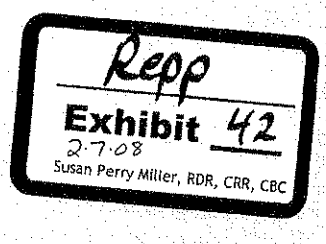

-----Original Message-----
From: Gonzalez, John P
Sent: Thursday, February 19, 2004 6:23 AM
To: Aruna Seth (E-mail); Campbell, Denise; Donna Brown (E-mail); Donna Casparro (E-mail); Goldstein, Jeffrey M; Göran K Stening (E-mail); Hess, William; Jones, Martin AM (Seroquel); Lloyd (Washington), Lisa M; Lynn Hagger (E-mail); 'Max Brady (E-mail) ' (E-mail); Mullen, Jamie A; Ney, Christine A; Nordell-Friberg, Sarah; Olbrich, Richard; Paulsson, Björn; Repp, Edward; Rod Sayce (E-mail); Stephanie Daniels (E-mail); Svarvar, Patrick; Swalley, Jeffrey S; Tumas, John A; Vågerö, Mårten; Williams-Hughes, Celeste
Subject: Trial 104 Manuscript Ghaemi as co-author

Dear All

As you are aware trial 104 main paper is authored by Roger MacIntyre and he had requested Nassir Ghaemi be second author. Please note the draft of the paper is well advanced having already had Roger's comments back. The response to this invitation from Ghaemi is included below.
In summary, he is asking to see the raw data so that he can analyse them himself or if not, 'uninterpreted data' and access to our statisticians. All of this will introduce significant delays to the manuscript and likely to lead to re-interpretation of the study results. So as a team we need to decide if we wish to have Ghaemi as co-author under his conditions and the resultant delays or whether we decline in the interests of getting this published ASAP. For those of you that have worked with him before, you might want to comment on ease of working with him and what is the likely outcome here.

Look forward to any comments/views on this

Regards
John

-----Original Message-----
From: X:Casparro, Donna (External)
Sent: Wednesday, 18 February, 2004 17:06
To: Gonzalez, John P
Subject: Note from Ghaemi/reply from McIntyre re: T104 mss

Thanks Nassir
I certainly respect this position. Oviously I cant answer some of these questions as it is AZ data. I value your input
Be in touch
Roger

"Ghaemi, S.Nassir" wrote:

> Thank you Donna. Indeed Roger and I had spoken about this. I take co-authoring as a serious scientific matter, not as one of signing on to the work of others. I will describe here what I mentioned to him: To participate, I would need access to the data. I would prefer this to be access to the raw data. If they are in a SAS file, they can be emailed to me in Excel. We will then import them into our statistical software. If AstraZeneca is not willing to send me the raw data, then the next best thing is to send me the uninterpreted data, ie, means, medians, and ranges on everything. Further, depending on specific issues in the manuscript, if I do not receive the raw data, I may need to interact with AZ statisticians about specific regression models. So if AZ is not willing to send the raw data, then they would need to know that my involvement would require more work on the part of some of their statisticians. All this is a basic prerequisite for my involvement. I understand that you have been working on a draft, but my involvement and reanalysis of the data would mean that we would not be near a final draft in a matter of weeks. And, I may request rather extensive rewriting of the draft if the basic data reanalysis does not agree with the way the current draft is presented. Finally, I will remove myself as an author if my recommendations are resisted based on marketing grounds, so it is probably best to get this issue to the front at the start so as to avoid any time lost for me as well as for you. I understand that my requests exceed those of most investigators. But I feel strongly that we as investigators must make sure that studies are published in an unbiased and objective way. Many companies do not do the things I have requested above for co-authors; if that is the case, I could not be involved. I hope you and AstraZeneca understand that these requests are all in the spirit of scientific integrity. Sincerely Nassir Ghaemi