

"...(CATMOD) of the SAS system with a model including effects for treatment and investigator."

(6) pg 14: I will note that the original sample size calculations called for 300 patients and this was determined apriori. The 275 was a modified number.

7 - not reflected in final paper

(7) We did not compute confidence intervals for the data. Since these are not presented, I would remove reference to them from the text and from Table 4. Also, why does Table 4 not include any of the 8 depression-related variables? I find it odd that only the 'secondary' variables are presented. Without figures or the table, this gives the reader no reference, other than the text, to this data.

(8) Why is there only a graph for % patients in remission? I would suggest that we might want to have graphs for all depression-related efficacy variables.

(9) Due to time constraints, I have not confirmed any numbers with our source tables. I will look at these as I have time. I assume some QC was done to confirm these numbers(?).

Regards,
rosemary.

My secretary compared the values reported in the tables to the approved Q/C version of the report. Some minor corrections are needed. I will send these via regular mail.

I do not have Dr. Keller's E-mail address, so I will send via regular mail.

Jim

ROSEMARY OAKES

05-Mar-1999 18:00

Sr. Statistician: Biostatistics & Data Sciences - Phase IV DART UP:
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To: James P McCafferty

cc:

Subject: PAR329 - Rosemary's comments on manuscript

Jim:

Here are my comments on the PAR329 manuscript:

- (1) pg 3, 11: It is not clear from the manuscript which variable was primary for the study. As it reads, the reader might imply there are 8 primary variables. Can we either specify which was primary (as determined by sample size calculations) or refer to these variables as 'depression-related variables.'
- (2) pg 3/4, 11: Please clarify the primary timepoint of interest (i.e., study endpoint--last observation carried forward). It's not too clear to me from these paragraphs.
- (3) pg 4, 16, 18: There are questions about statistical significance here. We did not perform statistical tests to compare the reasons for withdrawal. The study was not designed for such tests and we usually try to keep the additional tests performed to a minimum.
- (4) pg 11, 15: There were 150 screen failures--so the number of patients screened could be considered as $150+275=425$. Keep in mind this is only those patients of whom we have a record on the database.
- (5) pg 13/14: In the statistical methods section, please revised the 1st two sentences of the 1st paragraph to the following sentence. (Note, the text represented by the ... can remain the same.)

"Changes from baseline to endpoint in the ... implemented using the general linear models (GLM) procedure of the SAS system with a model including effects for treatment and investigator."

Please add the following text to the end of the 3rd sentence of the paragraph.

This fact noted by GSK staff in Mar '99, but not acted on for Jul 99 submission to JAMA

*then doesn't appear in final version & deleted later
Is it kept.*

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