Reviewer's report

Title: Processes to Manage Analyses and Publications in a Phase 3 Multicenter Randomized Clinical Trial

Version: 2 Date: 26 March 2014

Reviewer: Sean Grant

Reviewer's report:

I thank the authors for their thoughtful responses to reviewer comments, and for their revisions to the original manuscript.

The only minor essential revision that I still request is for the authors to explicitly incorporate in the manuscript the following information from their cover letter, as I think it would be helpful for the readers to know:

"There were 75 manuscripts, one of which was not published. Figure 1 includes 43 manuscripts, 33 with analyses conducted at the DCC and 10 with analyses conducted elsewhere under a data use agreement. We chose to present statistics only for the 33 analyzed at the DCC. Although all of the procedures were in place, we did not formally track the first 32 publications because they were being analyzed at a time when the workload was relatively light because the final study results were not available for analysis. One of these 32 was the primary results manuscript. We did not include this manuscript in the statistics because of the constraints imposed by the wait for the final data lock."

I appreciate the author providing the peer-reviewers and editorial staff with this information, though I think readers should explicitly see somewhere in the Methods/Results of this manuscript such information on how the sample of publications was selected for analysis from the population of 74 study publications, as well as a line or two in the Discussion about potential risks of selection biases on the data presented in Figures 1 and 3.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.