Reviewer’s report

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

Version: Date: 9 January 2014

Reviewer: Sheila Turner

Reviewer’s report:

Major Compulsory Revisions

1. Is the question posed by the authors new and well defined?

The six goals of the work as described on page 6 are important, and the reasons for doing this work are clearly described. What is not present is a positioning of this work within the current literature. The authors do not tell us if a similar approach has been used previously for other large multi-centred studies. Essentially we are not told if this is new, which is very important. The references cited relate to authorship, but not to the complex overall strategy for co-ordinating publications, as described in this study. If there is no other study of this sort it would be very important to state that, or if there has been similar work, to place this study within that context.

Minor Essential Revisions

1) The legend for Figure 2 states “The shaded portions are for the 36 publications that used only baseline or lead-in phase data and hatched portions are for the 38 publications using data from the randomized phase of the HALT-C trial”. In my copy the bars appear in two shades of grey, none are hatched. I think the next sentence also contains a typing error(s). “The yYear represent the number of years from the start of the study”.

Discretionary Revisions

1) Are the discussion and conclusions well balanced and adequately supported by the data?

The discussion and conclusions are supported by the data, however, although the authors state that “collaborating researchers accepted readily” and “conflicts among investigators over authorship participation and order were avoided” they also state that “the processes did not always work optimally”. I think that the discussion would benefit from some more details about the aspects which did not work quite so well. This would add balance, and provide useful information for others wishing to adopt this approach to publication process.

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