Reviewer’s report

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

Version: 1 Date: 27 January 2014

Reviewer: Lang’o Odondi

Reviewer’s report:

The authors provide an interesting review of the HALT-C trial with the aim of guiding collaborators through the publication process for multicentre trials. However, the article would have greater impact if the authors provided a more comprehensive literature review to motivate the research problem.

I would recommend publication subject to two minor essential revisions:
1. An expansion of the review/motivation provided in paragraph 1 would make a more compelling case for the need of a streamlined guideline for clinical trial process.

2. A restructure of the article into two distinct parts: first providing general points to consider for inclusion in a trial process guideline followed by the authors’ HALT-C as a specific case. By so doing, trialists would avoid trying to generalise some of the ‘potentially contentious’ items outlined in the HALT-C case study.

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:

NONE