Reviewer's report

Title: Risk proportionate clinical trial monitoring: an example approach from a non-commercial trials unit

Version: 2 Date: 27 June 2013

Reviewer: Lehana Thabane

Reviewer's report:

Abstract:
• Results and Conclusion section needs to provide clear description of the results. For example, it is unclear from the abstract what method was used in the example and why.
• What are the take-home messages about which method is appropriate and under what conditions

Background:
• The purpose of the paper addressed in the last sentence of this section needs to includes descriptions of all available methods with relevant empirical data to support their applications.
• Also include the pros and cons of all available methods.

Rest of the Paper:
• How many trials have used these particular methods of monitoring?
• What lessons can be generalized to similar settings?
• What makes unique about his unit and what make it a good example to share. How is the unit fit to be a model template?
• What are the inherent costs of the various methods being discussed?
• The first method (central monitoring) provides detailed descriptions of activities, but analogous descriptions are not provided under the second method (on-site monitoring). This makes it difficult to compare the two methods. More detailed description is needed for on-site monitoring

Conclusions:
• How does the experience of the unit compare to the CTTI project recommendations?
• What lessons can be shared based on the Unit's experiences of monitoring different trials?
• It would be best to make empirical recommendations

Level of interest: An article of importance in its field
Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests'