Reviewer's report

Title: Managing clinical trials

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Reviewer: Rustam Al-Shahi

Reviewer's report:

This article gives three experienced (in fact, legendary) trial managers' views on their importance to the success of clinical trials. Although there are no trials that I know of to demonstrate the benefit of styles of trial management, the intervention in question has such a large effect that it’s unlikely to require a trial! The authors do cite an analysis of 114 multicentre trials in the second paragraph, but I could not see the reference to the study, which I would have been interested to read. I would be interested in the authors' view on whether their involvement at the trial design stage would be beneficial - my impression is that an experienced trial manager can see problems approaching that far off. In the same vein, I'd be interested in the authors' wish-list of Principal Investigator attributes/approaches, because they undoubtedly have an influence on the success of a trial along with the trial manager. Lastly, I was surprised to find little mention of the impact of the change in research regulation during these trial managers' professional lives, nor any comment on the impact of Research Networks; I'd be interested in their reflections on them.

Level of interest: An article whose findings are important to those with closely related research interests

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