Author's response to reviews

Title: Managing clinical trials

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Author's response to reviews: see over
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Editors-in-Chief
Trials Journal

Dear Sirs

Re: MS: 1169504634350937 - Managing clinical trials

Thank you for providing reviewer’s comments for the above manuscript. Below is our point-by-point response. The revised manuscript has now been submitted. We look forward to hearing that the manuscript is going forward for publication.

Reviewer: Rustam Al-Shahi

This reviewer highlighted the omission of a reference number which has now been included.

The authors also share the view that trial managers should be involved in the development phase of a trial but more often than not the development phase is unfunded and therefore employing the services of a trial manager early on is not an option. In the new climate where Clinical Trials Units are becoming the only way trials will be funded, it is more likely that there will be ‘core’ trial managers or portfolio managers who would be involved at every stage. The authors have addressed this in the revised manuscript.

The reviewer was also surprised at the lack of mention of the impact of regulation of clinical trials. The authors felt that this topic has been discussed in many other forums and was not central to the overall topic being discussed here which is the crucial need for a trial manager, and trial management, to manage all aspects of the conduct of trials including complying with the regulations.

Reviewer: John Norrie

The reviewer noted some minor errors which have been addressed in the revised manuscript.

1 The authors had made the assumption that the paper was discussing trials which had gone through a critical peer review and had secured funding therefore were well designed and would be properly analysed and reported. For clarity the authors have tried to make this point clear in the revised manuscript.
2 The authors felt that the section on project management clearly defines what is meant by managing a trial. The authors recognise that a commercial operation or a large Clinical Trials Unit with a big portfolio faces different challenges to a single trial but the basic principles which we have tried to describe are the foundation of all trials no matter how big, how small or how complicated.

3 The authors have expended on this point

4 The authors have expanded on how it might be difficult to provide evidence for the need for trial management.

5 The authors felt that an emergency setting was a fair example of thinking about the practicalities of the method of randomisation.

6 This highlights the point made by Rustam Al-Shahi and the authors have dealt with his point.

7 The authors have inserted the word ‘essential’ which reflects the regulations that call for the logging and retention of essential documents.

8 The authors have acknowledged the need for planning and training if EDC is to be used.

9 The reviewer makes a very valid point. The authors have expended on the section on publication and dissemination as outlined by the reviewer.

Yours sincerely

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