Reviewer’s report

Title: Managing clinical trials

Version: 1 Date: 25 March 2010

Reviewer: John Norrie

Reviewer’s report:

- Minor Essential Revisions
  1. Page 7 2nd line “it’s” should be “its”
  2. Page 12 ‘… as it quickly becomes ‘wallpaper’ – not sure what this meant?

- Discretionary Revisions
  1. Page 1 – the authors state ‘Trials fail because tried and tested systems handed down through apprenticeships have not been documented, evaluated or published to guide new trialists starting out in this important field’ – agreed, this is one dimension of why trials fail, but it would be wrong to create the impression that trials that are well managed will always succeed. Trials still have to be well designed and properly analysed & reported, as well as being well conducted, to succeed.
  2. It would be useful early on to have a paragraph defining what is meant by ‘managing’ a trial. Implicitly, the context presented here seems to be a large, multicentre, (probably publicly funded trial) of long duration in which a single trial manager (see the section ‘A Trial Manager’, page 4) takes responsibility for the smooth running of a single trial, organizing all aspects of authorizations, training, recruitment, progress reporting, closedown, and so on. This is a useful and common model, but it is not the only one – for example, a commercial operation might manage a large portfolio of trials, with these tasks concentrated across trials to individuals or small teams. This will create additional different challenges to the ones discussed here?
  3. Page 5/6 – the section on Project Planning was particular welcome, and had interesting references. It might be worth emphasizing more ‘the ability to constantly review and adapt’, since a trial may well not go to its planned finish. An iDMC (which it should be noted might operate and be managed entirely separately from the rest of the trial management) might recommend the early closure of the trial, which can put a coach and horses through the best laid plans for trial closure.
  4. Page 8 – on several occasions the authors conclude a paragraph by stating e.g. ‘However, how these concepts are applied to trial management is unclear and further observation and evaluation is needed’ – fair enough, this is bound to be true, but perhaps the authors could be more specific and insightful on what e.g. the barriers are to implementing such important methodologies or disciplines to trial management?
5. Page 8 ‘… for example web randomisation may not be practical for … a trial of an emergency intervention’ – wasn’t convinced this was a good example – yes, you can see access to the web may be difficult in some emergency settings, but in others e.g. an ambulance, accessing the web by a mobile phone say may be the only way of effecting a randomisation as near in time as possible to the intervention being given?

6. One issue that was fairly vague was what should be the proper extent of trial management involvement in the trial processes – for example, page 9 the authors mention creation of dummy tables – important task, but should it be included under trial management and/or involve the trial manager? Likewise, design issues – very often the trial management or trial manager is given a design signed and sealed and expected to implement and transact that design – often a hopeless task! So involving trial management issues in the design of the trial seems important; involving them in statistical reporting issues seems less so?

7. Page 10 ‘Every piece of paper that relates to a trial participant should be logged and tracked through the system’ – well, I suppose this is sound advice, but the important antecedent for this is that every single piece of paper is deemed necessary for the trial, and only necessary information is processed (this allowing the trial management to be focused on what is important).

8. Page 10 ‘Using systems that reduce the number of steps required for data entry, for example the use of electronic data capture, can minimize the workload for both investigators and the data management team’ – not sure I would agree with this – yes, in principle, EDC systems can be more efficient – in practice, they need a very high level of clarity and specification before the first randomisation, so really it is the possibly the same workload, just needed sooner, perhaps – and a poorly written / badly implemented EDC will create much more work for the management of the trial.

9. Under the section ‘Publication and Dissemination’ it might be worth discussing authorship for trial management activities – these can go unrewarded when deciding on who has made an important contribution to the trial. This plays into the wider issue of career structure and professional qualifications for those working in trial management.

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. For the record, I know Barbara Ferrell and Sara Kenyon as colleagues on the Advisory Board of the UK Trial
Managers Network. This has not influenced by review in any direction.