Reviewer’s report

Title: Trial Forge Guidance 1: What is a Study Within A Trial (SWAT)?

Version: 0 Date: 13 Jan 2018

Reviewer: Valerie Smith

Reviewer's report:

This is a well-written paper, describing the concept of SWAT, which will be very beneficial for researchers, and others with interest in improving trial design and conduct. I have a few comments only that you might like to consider:

Page 9; Line 17; in the sentence ending '….with the bespoke PIL compared to a standard PIL.'….for clarity, consider adding at the end of the sentence 'before adapting its use in a future trial.'

Page 9, Line 28; how was the approach to the evaluation coordinated and collaborative? Are you referring to conducting the meta-analysis, or did the various researchers conducting these SWATs come together in some way? It's not entirely clear what the coordinated collaboration actually was?

In the examples of questions that could be addressed in SWATs; third bullet point - is this a 2 stage PIL (rather than a 2-component), i.e. giving short version first, then long, or is this a three arm SWAT? (short, long and standard PIL) - needs a little clarity.

Also fourth bullet point; please explain for the reader what is meant by 'formal site selection questionnaires' - not sure what this means.

Re the possible cost of SWAT; where did the 5-10k figures come from? Is this a cost that you have experienced in your SWAT, or how did you arrive at these figure - needs a little more explanation.

In Box 1; randomisation section. While you acknowledge randomisation is not always necessary; I'm not sure its fair to suggest that this will weaken results. What should be emphasised here is that different designs can be used to address SWAT questions. For example, I know of a SWAT that is addressing one of the PRioRiTy questions exploring motivators and challenges for taking part in a trial - this question is best addressed by qualitative enquiry (interviews); I think this section would benefit from expanding to include the possibility of using diverse designs, including qualitative studies.

Similarly, under the analysis section; need to refer to qualitative analyses and other possible types.
Under the SWAT Repository section; might be good to expand and state the application form for registering a SWAT is accessible on line and provide the precise link.

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