Reviewer’s report

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

Version: 0 Date: 16 Jan 2018

Reviewer: M Briel

Reviewer's report:

This manuscript by Treweek et al. on the definition, usefulness, and practical issues with SWATs is timely, informative, clearly written, addresses an important topic, and it contains many useful links. There is not much to criticize. Here are some minor suggestions to further improve the paper:

1. Typo on page 8, line 12/13: "…this is that that the evidence…"

2. Box 1: Under Randomisation - "In some cases randomization may not be appropriate or possible…" - could you give an example for this?

"…and another allocation method can be used but…" - do you have any specific recommendation for this case?

3. Box 1: Under Analysis - Would a sample size calculation for a SWAT make sense to see how many patients/trials will be needed to answer the SWAT question with sufficient statistical power? Do you have any thoughts on Minimum Important Differences for recruitment and/or retention?

4. Title: "Trial Forge Guidance 1…" - As an interested reader I am wondering whether this article is the first in a series of planned articles? If yes, could you add 1-2 sentences briefly explaining to readers the purpose of the series and the content of the following articles of this series?

Matthias Briel

Level of interest
Please indicate how interesting you found the manuscript:

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Acceptable

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All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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