Reviewer’s report

Title: Clinical trial data reuse – overcoming complexities in trial design and data sharing

Version: 0 Date: 21 Jun 2019

Reviewer: Michelle Mello

Reviewer’s report:

This well-written manuscript explores a popular topic, clinical trial data sharing, from an atypical perspective, that of the data reuser. Most discussions of facilitating data sharing have focused on the needs and perspectives of data suppliers, so this commentary adds a valuable voice.

My suggestions for strengthening the manuscript are mostly organizational in nature. I found the substantive points interesting and important.

The introduction could be improved by providing a topic sentence and forecast that alerts readers to what the article is going to do and cover.

For the psoriasis example, I would have enjoyed hearing more about how the reported data problem affected the authors' work. It seems like a pretty small issue with a dataset that, apparently, was otherwise OK. Was it in fact significant? Is it indicative of some broader problem with datasets?

More generally, it might be helpful to more explicitly call out that there are 2 different kinds of problems that data reusers encounter that the authors are going to cover. First are problems with the datasets: they might have poor quality data, missing data/fields, or nonstandard ways of reporting key fields. Second is the fact that different trials have different designs and that can make it hard to pool data in a reasonable way. The first problem is theoretically fixable, the second really isn’t. Both require that appropriate metadata be available to help reusers know what they are seeing and how different trials and datatset are or aren't comparable.

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

An article of importance in its field

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Quality of figures
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.

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

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests.

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal
Were you mentored through this peer review?

No