Reviewer’s report

Title: How should Individual Participant Data (IPD) from publicly funded clinical trials be shared?

Version: 0 Date: 24 Sep 2015

Reviewer: David Moher

Reviewer’s report:

The authors report developing guidance on how individual participant data (IPD) should be shared from publicly funded clinical trials. The authors report a classic series of methods to achieve their guidance: examination of the literature to ascertain ‘what's out there' (phase 1); a web based survey of UK registered clinical trial units (phase 2); and a 1-day meeting in London in November 2014 (phase 3).

I enjoyed reading the paper. The question posed by the authors is important, particularly in light of the global effort to ramp up data sharing. While I appreciate the paper is about 'how' to share data, I wonder whether the authors should add a few sentences as to 'why' data share, in their introduction? A nice recent example could be the paroxetine papers published in the BMJ (Le Noury et al. BMJ 2015;351:h4320). Similarly, would mentioning something about reproducibility be worth including in the introduction? It is the source of much dialogue, for example, the recent paper by the Open Science Forum (Open Science Collaboration. Psychology. Estimating the reproducibility of psychological science. Science 2015; 28; 349: aac4716).

I was glad to read that academia and the pharmaceutical industry were both involved.

I found the paper more silent on issues pertaining to implementation. It is very nice to read that some important organizations have endorsed the guidance. However, like everything else in life, won't there be some barriers to implementing the guidance at local clinical trial centres? Do the authors have any guidance for minimizing the barriers to implementation and notions of what might facilitate such implementation? I think a section on this issue would be helpful to readers wanting to implement the guidance.

Although SPIRIT is mentioned in box 2, do the authors think the SPIRIT group should update their guidance to accommodate their guidance for data sharing? Is this an implementation issue? Similarly, while SPIRIT is likely relevant to consider - getting the trial organized for data sharing as it is being planned, does the present guidance have any implication for CONSORT? Should this be mentioned in this paper?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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

Acceptable

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