Reviewer’s report

Title: Resource implications of preparing Individual Participant Data from a clinical trial to share with external researchers

Version: 0 Date: 01 May 2017

Reviewer: Frank Rockhold

Reviewer’s report:

Great work by authors to attack this issue. These seem like "typical " trials. Did you intend them to be?

Do you have plans to take a slightly larger sample? Valuable contribution and you now have the skills and process to look at this issue and most will not have the focus and patience to do what you have. Obviously large and more diverse trial set would give robustness to your findings.

Excellent analysis and to put in perspective the total cost is less than the cost of one patient in a typical clinical trial so the marginal cost is quite small and if made a standard part of the analysis plan as you imply would be a small marginal increase. Also, as you have said in your paper this will get more efficient over time reducing further. If you amortize the cost further over the number of reuses the costs seem quite reasonable.

Did you think about the implications of using a common standard such as CDASH and SDTM? This would seem to go along with the efficiency gains you imply when talking about having a common platform.

One thing that does need attention is opportunity costs. If these skilled individuals are doing this work they are nor working on new trials and that could be a cost to research unless we do as you say and shift the burden from the data analysts to the data scientists.

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