Author’s response to reviews

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

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We would like to thank both reviewers for their comments and useful suggestions.

We have amended the abstract and removed the words 'open' and 'openly'. The abstract now reads as follows:

There are many acknowledged benefits for the reuse of clinical trial data; from independent verification of published results to the evaluation of new hypotheses. However, the reuse of shared clinical trial data is not without obstacles. Here we present some of the issues and lessons learned from our own experiences in accessing and analysing trial data, specifically where we aim to combine and pool data from multiple different trials. In addition to issues around missing annotation and incomplete datasets, we identify trial design complexity as a potential hurdle that may complicate downstream analyses. We address potential solutions and emphasise the need for benefits of transparent sharing and analysis of participant-level clinical trial data with appropriate risk mitigation, a matter important to efficient clinical research.