Reviewer's report

Title: Comparison of two data collection processes in clinical studies: Electronic and paper case report forms

Version: 1 Date: 29 July 2013

Reviewer: Adam B Wilcox

Reviewer's report:

This represents original work that is relevant to this field, and addresses an important issue. The authors worked well within the limitations of the study design, which was appropriate given the maturity of research in this field. As always, an RCT would have eliminated some bias issues that were present in the retrospective study and survey, but such an approach would have been inefficient and inappropriate.

Major Compulsory Revisions

The main issue, which should be addressed in the discussion and not by changing the methods or the study, is that some clear potential biases were not noted or explained. Specifically, there were three issues that were not noted.

1. In the selection of the studies, only studies that completed use of eCRFs were used. What about studies that started with eCRFs (the newer approach at the time), and then after difficulties reverted back to pCRFs (the established approach)?

2. The eCRFs were used for larger, multi-center trials, while the pCRFs were used for smaller trials. The difference in length of time until completion, as it was reported, was significant but could have been due to different types of trials being conducted. Investigative studies of rare conditions may take much longer to accrue patients, regardless of the CRF approach. This seems a more-likely explanation for the time difference, especially since the time from last visit of last patient to database freeze was not different.

3. Table 1 shows an interesting characteristic difference in the studies that was not addressed: Median number of variables in the CRF. This seems a very larger difference (1062 v. 396), but it wasn't explained. This supports the hypothesis that the studies are more different than the other factors that may lead to a choice between eCRF and pCRF.

Minor Essential

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.