Reviewer’s report

Title: What are the main inefficiencies in trial conduct: a survey of UKCRC registered clinical trials units in the UK

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Reviewer: Ana Terleira

Reviewer’s report:

This article is the result of a survey carried out in 2013 to identify inefficiencies during what the investigators consider the two key processes in a clinical trial development:

1) From the award of the grant to the first participant inclusion and 2) from the first participant to the final report of results. Respondents were asked to list, in their opinion, the three top inefficiencies in both processes. There was also a free space where they could explain why they thought those were important, if desired. Thus, it is presumed that the survey did not have closed-ended questions and the answers must be subject to the authors’ interpretation and classification. This approach is more subject to biases than if the survey had contained closed-ended questions. Therefore, it leads to a subjective interpretation and the analysis will be more likely to have inaccuracies.

Within the 45 units registered in 2013, only 25 answered the survey and, from them, there were only 43 respondents. In the discussion hold by the authors, they consider this response rate lower than expected. It cannot be drawn from the results if the distribution of those 43 respondents was more or less homogeneous among units or some units contributed more than others. In the latter case, the inefficiencies of those units would be overestimated in the survey.

Most of the article includes the original texts of the respondents. Therefore, the reader is able to interpret the responses in a different way to the one carried out by the authors. For example, inefficiencies regarding the CRF design are included in the two key processes mentioned above. However, the CRF design is expected to be finished when the first participant is included and, from this reviewer's point of view, it shouldn't be registered as "inefficiency" from the inclusion of the first participant to the final report of results, as the authors did. Other responses could also be related to processes of a research in general more than in relation to the unit in which the respondent was included, for example the biases in the publication. In other cases, the responses were unclear, as the authors said in the discussion. Moreover, it is also discussed if the units perform research with medical drugs or not, which can also have a big influence in the inefficiencies described in the survey. I agree with the authors that, from a regulatory and administrative point of view, a clinical trial carried out with medical drugs is not the same as an observational study. Therefore, this issue can influence the responses.

From 2013 until now a new clinical trial regulation has been implemented (EU 536/2014) and many regulatory authorities have implemented changes in their policy of research studies to improve efficiency and reduce the time of approval. At this time, due to the remarkable
legislative changes, the study performed in 2013 could be obsolete and inefficiencies could be different. Taking into account the responses in this article, the authors could use this study as a pilot study and design a new one with close-ended questions not subject to interpretation and including the latest regulatory developments.

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