Reviewer’s report

Title: Heterogeneity prevails: the state of clinical trial data management in Europe - results of a survey of ECRIN centres

Version: 1 Date: 2 February 2010

Reviewer: Tania Shelby-James

Reviewer’s report:

Major compulsory revisions
1. The surveys had response rates of 47% and 44%. This represents less than ½ the centres and so any conclusions drawn from the survey must be interpreted with caution. The authors make no mention of this poor response rate. At the very least in must be included in the discussion as a limitation of the study. Also many of the statements made in this manuscript may not be valid given that a minority of centres are represented in the results. The authors must address this in the manuscript.

2. Abstract. The abstract should mention the response rate, at present it only states that 80 centres answered but does not say how many were approached. The response rate is needed to allow readers to interpret the statement “Our survey showed that about 90% of centres have a CDMS in routine use.”

3. No mention of ethical approval

4. Results, last paragraph. “Thus, resources and experience to conduct successfully multinational clinical trials using CDMS are available in ECRIN centres”. The authors cannot make this statement given the poor response rate.

5. Discussion 4th paragraph. These are big statements that are difficult to support with the poor response rate. Can it be proven that centres involved in DM answered the survey or at that responding centres were representative of their country. If this is to remain in the final manuscript there must be supporting data included.

6. Conclusion is concise and replicates the discussion. It should include the key points from the survey that will inform the new ECRIN system and the activities that will be undertaken as a result of this work.

Minor essential revisions
1. Titles are missing from all Table and Figures which make interpretation difficult. This is particularly significant for Figure 1 where it is unclear what the numbers below the countries are, are they response rates for Survey 1/Survey 2?

2. Grammer in the background needs to be revised. It does not read well

3. Background, 1st paragraph last sentence. “It has been demonstrated that web-based EDC and CDMS can be employed very successfully in the academic area” Needs some sort of example here to help readers see why there is a
distinction between academic areas and clinical trials in general.

4. The manuscript would benefit from a linking paragraph from the background to the methods statement. This linking statement would include what the manuscript will describe. It currently seems a bit disjointed.

5. Methods. The manuscript states that both surveys were sent to 167 centres. However, it is also stated that survey 2 included new centres from Switzerland and Austria. Does this mean that some of the centres from Survey 1 were not included in Survey 2 to ensure that the same number of surveys were sent both times?

6. Results, 2nd paragraph, 1st sentence “The vast majority of centres/unit conduct DM” This is the first time we see DM, assume it means data management so it should be written as “data management (DM). Also the authors need to make it clear that it only the vast majority of centres that responded to the survey.

7. Results, section entitled “Special cases of use of CDMS by ECRIN centres/units”. This section should be a table. It does not flow well as text and is difficult to follow

8. Discussion, 1st paragraph. I am not sure what this paragraph is stating, no clear discussion point. If it is to remain in the manuscript more clarity about it’s importance is needed.

9. Discussion, 3rd paragraph. “ECRIN centres are using routinely EDC systems for their data collection needs, even though in only a small number of trials per centre”. This was not mentioned in the results section. The discussion should flow from the results so the must be something mentioned in results or else do not include it in the discussion. Also what does this statement mean? Does it show that there is no consistence in data capture within a centre?

10. Discussion, 3rd paragraph mentiones 21 CRF Part 11. This is a FDA guideline. Given that this is a European study it would be better to mention the European guidelines, what they require for CDMS and if the systems identified in the surveys meet those requirements.

Discretionary revisions

1. Results. I would recommend that numbers as well as percentages were included in the manuscript

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

Quality of written English: Needs some language corrections before being published

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