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: 4 February 2010

Reviewer: Rebecca Kush

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Major Compulsory Revisions - none recommended

Minor Essential Revisions
a) This is a ‘nit’ but there is use of 'less then' in line 6 on p. 8 and then 'less than' on the same page in line 7. These should be consistent and 'less than' is probably the better one to choose.

b) Page 12, there is a reference to a system being 'FDA compliant'. Rather than state this (since FDA does not test or certify systems), it would be better to use the phrases such as on p. 12 (e.g. validated to meet FDA requirements or something like that).

c) The sentence in the Conclusion "But we identified as the most important task for clinical research centers to improve the quality management of CDMS..." is not well-written and difficult to understand. This same concept was introduced in the body of the manuscript in a clearer way. This sentence should probably be reworded to make a better transition between the need for data standards (data exchange as well as increased quality of data) and the message intended in this sentence, especially in a conclusion. The abstract reads well.

Discretionary Revisions
a) It may be appropriate or helpful to have a few sentences in the discussion around the move to encourage EHR adoption (i.e. the future beyond EDC) and the need to have CDMS that will also support such data collection methods in the future. This is all the more reason to encourage the use of clinical research standards in heterogenous CDMS that may receive such data. It will also improve quality (especially without data re-entry).

b) This is an article that I hope will be extremely helpful in helping disparate, heterogeneous academic centers to realize the importance of data exchange and standards in this new era. This will contribute to the streamlining of clinical research and therefore improve healthcare. I don't believe that these values come across in the way that the article is written. Perhaps a few sentences around this vision would bring a broader readership.

Level of interest: An article of importance in its field
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.