Reviewer's report

Title: Ancillary Study Management Systems: Review of Needs and Options

Version: 1 Date: 20 May 2012

Reviewer: meredith nahm

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Major Comp. Revisions:
- The scenarios were helpful, but from a formal requirements gathering and specification process and for publication, I would expect to see more detailed artifacts such as a use case diagram, functional specifications, static (information model) and dynamic models (activity and state diagram) and a data flow diagram. If the journal supports electronic supplemental information, I would want to see this type of information along with the article.

- For a complimentary system such as that favored in the manuscript, I would expect and want to see a lot more information about interoperability. For example, interface with the CTMS, electronic IRB, and LIMS systems. There are standards available for some of these, and standards are lacking for others. A thorough analysis of where the software can automate workflow through supporting available standards should be a key part of a requirements analysis. An analysis of where standards are lacking and what the research team proposes to do about it, i.e., propose and/or work toward the needed standards, how to fill the gap until the needed standards are available.

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.