Reviewers report

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

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Reviewer: Philip Payne

Reviewers report:

This report describes a set of information needs related to the design and utilization of what the authors describe as “Ancillary Study Management Systems” (ASMS)—which is defined in this particular report as being as informatics platforms that facilitates the secondary use of data for investigational purposes, where such data are to be derived from the primary or synthesized data generated during the course of other studies or programs of research. At a high level, the rationale for why such systems are needed is both interesting and novel, and is well stated by the authors. Furthermore, the authors provide a well-articulated set of information needs related to their focus area, thus supporting the generalizability and extensibility of their work. This reviewer believes that this report will ultimately be of great interest to the clinical research informatics community, but does have a number of deficiencies that should be addressed prior to publication, as follows:

Major Compulsory Revisions:
• While the authors describe a succinct and at a surface level, rational set of information needs related to the design and use of ASMS, the report does not provide any details concerning how such information needs were systemically defined, verified, or validated. Such methodological rigor would greatly enhance the impact of this submission.
• In the review of pertinent background materials that contributed to the authors understanding of the field of clinical research informatics, especially as it pertains to the design and functionality of clinical research management systems or equivalent informatics platforms, a significant number of notable reports from authors such as Chung, Embi, Richesson, Payne, Weng, and others is omitted. A more comprehensive set of references should be included in this review.
• While the authors present their information needs as distinct functional requirements, there appears to be an underlying conceptual model for the design and use of ASMS that is implicitly being used to inform such analyses and discourse. This model should be formalized, and reported, as an organizing framework for the information needs. This would likely involve some type of visual representation of that conceptual model.

Minor Compulsory Revisions:
• Figure captions could be extended to provide comprehensive descriptions of the purpose of such visuals and describing key, salient features.
• It is not clear if the term “Ancillary Study Management Systems” is widely used by the CRI community. The derivation, definition, and use of this term should be explained more clearly in the manuscript.

Discretionary Revisions:
None

**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