Reviewer’s report

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

Version: 1 Date: 23 May 2012

Reviewer: Wenle Zhao

Reviewer’s report:

Major Compulsory Revisions:
1. The manuscript discussed the information management system requirements for ancillary study management. This topic is of high importance in medical researches.

2. Based on the contents of the manuscript, I had the impression that a computerized database system has been developed and implemented for the management of actual ancillary studies. However, throughout the article, no information on the design of architecture structure of such system was shared with the readers. The scenarios and requirements discussed in this manuscript are important for the planning of the ASMS. But they are far from sufficient.

3. It is unclear that the ASMS mentioned in this article is a computerized database information system, like those well-known Clinical Trial Management System (CTMS) or Electronic Data Capture (EDC) system with Graphical User Interfaces (GUI), a computerized program, or a standardized operation procedure (SOP)?

4. If the ASMS has been actually developed, I feel it will be necessary to provide key design features to the readers, and also answer the questions the author challenged existing alternatives (described in pages from 9 to 12). For example, how to link to existing CTMS? How to work with on-going studies? How to avoid redundant data capture activities on regulatory document, clinical data, study progress data? How to manage user accounts, user access permission? How to protect data safety and integrity? How to control data transfer from the primary CTMS based on IC status for the ancillary study? Who is responsible for data queries raised from ancillary study investigators? How to handle data error when the primary study data is locked?

5. A CTMS is a comprehensive information management system. It could cover many aspects of clinical trial managements. The challenges caused by unique requirements for ancillary studies may not necessary overweight the burden of creating a new information management system to cover the basic common requirements of clinical studies (both clinical trials and ancillary studies).

6. The author listed Excel, SAS as project and data management tools as alternatives to the proposed ASMS. In clinical research practice, Excel spread sheets and SAS programs can’t be considered at the same level as a centralized, usually web-based, information system like CTMS. They are not on the same levels regarding of functionality scopes, reliability, and data safety.
7. The readers may want to know the proposed ASMS is developed in what platform? Is it a Excel Spreadsheet manually managed by an investigator or it is an information management system with a 3-tire structure?

Minor Essential Revisions:
1. Missing page numbers.
2. Confusing numbering of sections and paragraphs.

**Level of interest:** An article of limited interest

**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.