Tools for Clinical Trials Management: Handling the Norm and the Outliers

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While planning for the newly funded University of Washington Institute of Translational Health Sciences (ITHS) the informatics core has begun to assess the information management needs of ITHS investigators with relatively small scale datasets, who generally do not have the funds to purchase expensive commercial systems. Our preliminary conclusion from this effort is that the majority of investigators are engaged in relatively standard clinical trials, the data from which can be organized into a common schema such as the CDISC Operational Data Model (ODM), and for which a number of software tools have been developed. However, a minority of investigators has non-standard data management needs; hence no single schema will handle these needs. These users present a difficult problem since custom development can be prohibitively expensive.

In order to address these two types of users   we are undertaking a survey of existing tools, many of which have been presented at this expo in past years. We have also developed our own tools as part of earlier funded work, and are assessing their usefulness in the context of the requirements of ITHS users. In this presentation we will demonstrate two of these tools: 1) the UW WebTrials system for managing standard clinical trials, and 2) the Customized Electronic Laboratory Online (CELO) toolkit for rapidly creating web-based database management systems that require non-standard data models.

WebTrials is a secure, web-based data management system built with the Microsoft ASP.NET platform, using a Microsoft SQL Server backend. WebTrials provides tools for electronic modeling of research protocols; tracking of research subjects;   collection and management of research data via electronic case report forms; and role-based security. Investigators and study team members can login to the system and view reports about their protocol, their subjects, and their data, as well as update the status of protocol tasks and enter or download research data.

CELO is an open source application, written in Perl and built as a middle layer over a MySQL database. The middle layer allows the database developer to use a browser to create a database schema and web front end with little or no need for programming. The end-user then enters data and queries using the generated front end.

These systems have been used as part of a pilot project to manage two types of data for a single ITHS investigator, co-author Anne Stevens, who is studying the effect of maternal cells on the subsequent onset of auto-immune disorders. De-identified data from these studies will be used to demonstrate the features of the two systems.

In our current work we are evaluating the usefulness of these two systems for Dr. Stevens, with the goal of using the result of this evaluation as a basis for our survey of other existing tools.