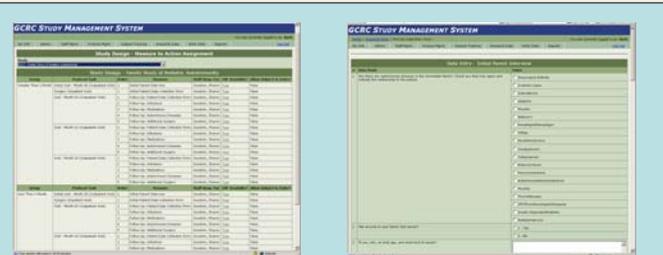


1. INTRODUCTION. An initial assessment by the informatics core of the newly funded Institute of Translational and Health Sciences (ITHS) suggests that the majority of investigators are engaged in relatively standard clinical trials, the data from which can be organized into a common schema such as the CDISC Operational Data Model (ODM). However, the data from a minority of investigators require custom schemata. We describe WebTrial and CELO, two tools we are developing to meet the needs of these different types of users.

2. A SPECIFIC EXAMPLE. Co-author Anne Stevens studies the role of maternal cells in autoimmune diseases such as lupus and scleroderma. In these studies serial blood samples are obtained at intervals from patients and relatives. Aliquots of these samples are frozen, then removed in batches for experimental analyses, correlating laboratory data with clinical data. The blood draws can be modeled using standard clinical trials data management tools (the norm). However, an inventory database of the sample aliquots requires a custom schema (the outlier).

3. HANDLING THE NORM. WebTrial is a secure, web-based clinical trials management system built with the Microsoft ASP.NET platform, using a Microsoft SQL Server backend.



The fixed WebTrial schema models study protocols (Left), consisting of groups, protocol tasks, measures, and case report forms (Right).

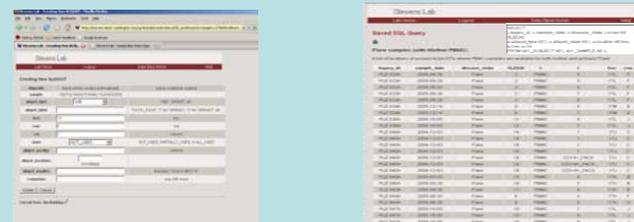


Saved reports can be accessed, as for example, all measures for a given patient (Left). All study data can be exported in the CDISC ODM format for data sharing (Right).

4. HANDLING THE OUTLIERS. CELO is an open source web-based data management toolkit, written in Perl and built as a middle layer over a MySQL database.



The middle layer allows the developer to use a web browser to create a custom database schema, in this case an inventory of ALIQUOTS (Left) from blood SAMPLES (Right).



The end-user then enters data (Left) and queries using the generated front end. Queries can be simple or arbitrary saved SQL (Right).

5. CONCLUSIONS. There is a need for software tools to manage both standard clinical trials and custom data. WebTrial and CELO are designed to meet both these kinds of needs. This evaluation process and these tools represent grounded use cases in our on-going efforts to utilize structured evaluation/feedback cycles to support clinical research through design, implementation and refinement.