A Web-Based, Meta-Data Drive, Clinical Research Platform for Managing Multiple Clinical Research Studies

Huey Cheung, MS[a], Shaohua A. Wang, PhD[a], Yang Fann, PhD[b], Barg Upender, MS[a], Sarada Chinatala, MS[a], Adam Frazin, MS[a], Wen Nie, MS[a], and Calvin Johnson, PhD[a]

[a]Center for Information Technology, National Institutes of Health, Bethesda, MD
[b]National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, MD

Abstract:

Clinical studies are very dynamic in nature; new sets of clinical parameters are introduced with each clinical protocol. This poses a great challenge in building an adaptable informatics platform to support evolving clinical research needs. Center for Information Technology (CIT) at the National Institutes of Health (NIH), in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS, NIH), has developed a web-based Clinical Study Information System (CSIS) to support efficient management of clinical data that would improve the quality and timeliness of conducting clinical research. CSIS allows Principal Investigators (PI) to design new electronic Case Report Forms (eCRF) using a Form Designer. A patient registry module enables the study coordinators to recruit and screen new subjects. Most importantly, an ad-hoc query engine allows investigators to stratify patient groups and export data by specifying arbitrarily complex criteria without having to learn database syntax.

Descriptions:

The goal of CSIS is to facilitate the clinical data management process and allow clinicians to use clinical information for analysis that will lead to proper clinical care, treatment, and decision-making. The tasks that are necessary in designing and managing a clinical study include the following: (1) designing electronic case report form (eCRF) design, (2) recruiting and managing patient, (3) collecting data, and (4) analyzing and reporting data.

A fundamental requirement of CSIS is the collection of arbitrary clinical parameters over many protocols. Given the highly diverse nature of these clinical parameters, this requirement is difficult to meet with traditional database model. The Entity-Attribute-Value (EAV) data model has proved to be flexible and adaptable for changes, it was adopted for the CSIS database. Using the EAV model, users can define any number of new clinical parameters without having to change the underlying physical database structure or the user interface.

In Summary, CSIS facilitates the tracking of patient enrollment, scheduling patient visits, generating eCRFs for clinical data collection, and reporting on relevant clinical activities and events through ad hoc reports and queries. CSIS is currently being used in 10 protocols, supporting over 300 patients and 200 eCRFs.