

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. NIH Center for Information Technology (CIT), in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), 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. CSIS is currently being used in over ten studies with hundreds of patients and over 200 eCRFs.

CIMS Platform

Clinical Informatics and Management System (CIMS) is a centralized clinical data management and analysis system that assists clinical investigators in managing their protocols as well as patient and research data in a framework with integrated disparate data sources. The CIMS platform consists of three key modules:

1. Protocol Tracking and Management System (PTMS)
2. Clinical Study Informatics System (CSIS)
3. Data Integration and Analysis System

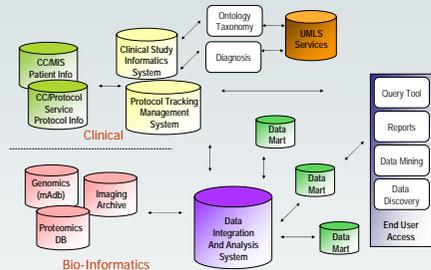


Figure 1: CIMS Data Architecture

Clinical Workflows

The goal of CSIS is to facilitate the clinical data management, simplify analysis that will lead to proper clinical care, treatment, and decision-making and share data with other collaborators.



Key Features:

- Form Designer/Versioning
- Patient Registry
- Study Plan
- Ad-hoc Query Engine
- Custom Reports
- Form Library



Figure 2: A web-based interface allows the users to access the system from anywhere.

Form Designer

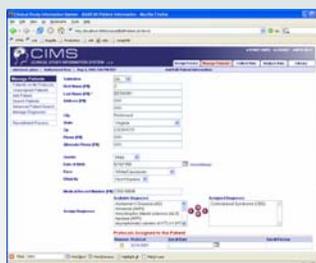
CSIS enables investigators to design forms using a browser. The form is built using extensible markup language (XML) and then rendered to HTML through extensible style-sheet language (XSL). Users can also group forms into a single form. This is useful in when collecting data for a battery of tests. The form library provides standard and shareable forms from all existing protocols that users can adapt and adopt for their own use.



Figure 3: The system allows the users render electronic forms in both simple and grid layouts.

Patient Registry

Patient Coordinators can set up a recruitment process for new subjects and normal volunteers across multiple protocols. Recruits with qualified diagnosis can be assigned or transferred to one or more protocols.



Study Plan

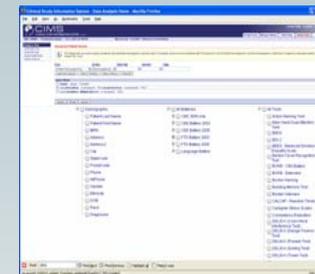
Investigators can design a study or treatment plan to efficiently manage their study. The study plan provides a roadmap for the clinical staff. It consists of a series of study events. Each study event contains required forms that need to be completed. The study plan interface uses Asynchronous JavaScript and XML (AJAX) technology to provide fast, highly-interactive, user experience.



Ad Hoc Query Engine

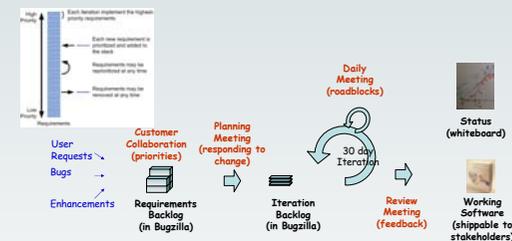
The system provides an ad hoc retrieval of parameter-centric data. Users can build and run ad hoc query based on the patient demographics data and/or a Boolean combination of clinical parameters from the collection forms. For example:

Identify female patients between the ages of 40 and 70 who have been diagnosed with the Frontotemporal Dementia (FTD) and have a raw visual scan score greater than 100 in the DELIS-K Trail Making Test.



Agile Development Process

The development team uses a highly-collaborative Agile Development process to quickly deliver highest-value features requested by the end users. The overall design of the system organically evolves with each small cycle (30 days).



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.

Clinical Study Informatics System	
Number of protocols	10
Number of patients	300+
Number of case report forms	200+

Protocol Tracking Management System	
Number of protocols	250+
Number of users	700+
Number of principal investigators	60

References

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