

Java-Based World Wide Web Clinical Trial Data Management

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Background. In most multi-center clinical trials a central coordinating center is responsible for patient registration, randomization and data collection. Traditionally, these processes are accomplished using the telephone, fax and manually filled forms. To allow larger sample sizes, shorter sampling periods and lower unit costs, new methods are needed.¹ Web-based data collection forms are advantageous because they reduce personnel and communication expenses and delays, make a round-the-clock service available, and expand access to data entry sites.² Hitherto, typical efforts to collect such data have used an ordinary client-server or HTML/CGI combination.³ These models are complex, inelegant, and require special programming for the CGI backends. They tend to be awkward to maintain because of the many pieces that must work together, and the special permissions typically required for development and upgrading, which multiply security risks. On the other hand, an object-oriented, Java Database Connectivity (JDBC) solution inherently results in an elegant, coherent, secure, robust and scalable multiplatform interface to essentially any designated SQL-compliant relational database and its inherent processing power.³

System. This communication demonstrates and briefly describes a prototype information technology system for clinical trial data collection for a limited number of end-points of a hypothetical clinical trial. Java user interfaces for health personnel and data managers as well as needed JDBC modules were developed with object-oriented software engineering methodologies. These were constructed as Java applets using Sun's JDK 1.2 and the Integrated Development Environment provided by Borland's JBuilder3 Professional. The resulting interface was user-friendly, and intuitive. It required minimum keystrokes, prevented entry of erroneous and redundant data, validated data at the point of entry and enforced completion. This ensured conformity with the experimental protocol.

Evaluation. The prototypical system was evaluated by Health Informatics students who were given background knowledge of the domain. Evaluators indicated positive responses that included the following: (a) Navigation and data entry were effortless. (b) Immediate feedback was available in case of operator error. (c) Real-time integration of

data was achieved. Initial feedback from clinical trial project coordinators has also been positive.

Implications. The ease of use and efficiency of this platform-independent system alerted us to the huge impact that a more widely applicable system could have on the numerous multi-center clinical trials conducted from a large medical center such as University of Texas-Houston Health Science Center. This has spurred the development of a feasibility and project definition report for a more comprehensive Java-based application.

Conclusion. Our initial experience with the Java-based JDBC/SQL system based on TCP/IP has been positive. It has presented a viable model and demonstrated the ease of Java-based World Wide Web collection and storage of validated clinical trial data to SQL-compliant relational databases. Current technology enables the construction of a generic web-based clinical trial data entry system that can be custom-designed to suit the special needs of a large academic medical center. Such information technology systems will make the management of multi-center clinical trials more efficient and economical.

References

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