The Design and Implementation of a Fully Automated Adverse Event Reporting System

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Background

The reporting of serious adverse events (SAE) is an essential part of conducting a clinical trial. The reporting process is complex because there are a number of individuals involved with every report (e.g., P.I.'s, CRA's, DSMB reviewers), a large amount of detailed information (e.g., toxicities, grades, attributions) that must be accurately submitted, and a multi-step procedure of reviews and approvals that must be strictly followed. The individuals involved must be able to communicate with each other to revise the report data at all steps of the process. There must also be a complete audit trail of all report transactions. And, the whole process must occur within a one or two day time frame. The end product of the process is a signed text document. Traditional paper-based systems for reporting SAE's require significant effort of all individuals involved to provide accurate, timely reports. At Thomas Jefferson University we have designed and implemented a fully automated adverse event reporting system to provide accurate reports in a timely manner, with a complete audit trail of report events, in a manner that minimizes the effort required of all those involved.

Methods

This SAE reporting system was built onto a previously developed clinical trial computer repository for all clinical research at Jefferson. This repository maintains all details of clinical trials, having more than 90 data elements. This repository is integrated with patient trial registration systems for certain departments, and both trial and patient information can be automatically transferred to the SAE reporting system.

The automated SAE process utilizes CTEP codes for specifying the adverse event. The initiator of the SAE report uses web-based forms to enter the report, with all entries stored in a database table. The report is communicated by automatically generated emails to the required individuals for review and approval. The Principal Investigator, upon receiving email notice of an SAE, can review the report and either sign it or email questions and/or modifications back to the submitter . Once a report is signed by the P.I., the SAE reviewers follow a similar process for the Data Safety and Monitoring process. Database timestamp entries log all steps of the process, from generation to final review and acceptance. All required signatures are electronically obtained. All report displays are generated "on the fly" as Adobe™ PDF files from the database entries.

Evaluation Program

The system was implemented University-wide in July, 2006. We will evaluate its efficiency from our audit trail data after six months of operation. We anticipate that the timestamp data from the audit logs will show consistently acceptably-short time intervals for each step of the reporting process.

Next Steps

The difficulty of designing and implementing an automated adverse event reporting system derives more from its multifaceted workflow, than from its data model. We intend to assist other sites in developing such systems by sharing the workflow and data models we created for our system. We will also facilitate the development of similar systems by sharing the software techniques which fulfilled the design requirements. The Jefferson SAE reporting system will soon be exported to member hospitals in the Jefferson Cancer network, located in the greater Philadelphia metropolitan area.

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