

Title: Decision Support Methodology: Implementation on a Clinical Trial

Authors: Rebecca Wilgus, RN MSN; Brian McCourt, CCDM; John Snapp; Hans Tillmann, MD; Michael Bangert, ASQ CQA, MA

Background Clinical research projects require frequent monitoring and complex algorithms for changes to therapeutic modalities guided by diagnostic tests and procedures. Industry trends toward more frequent subject assessments and robust monitoring during premarket clinical evaluations make current methods of manual processing by multidisciplinary teams increasingly difficult to sustain.

Methods The Duke Clinical Research Institute's (DCRI) Data Management and Clinical Research Informatics teams implemented a decision-support infrastructure for a large ($N \geq 1000$) international infectious disease study. This infrastructure was designed to aggregate data from multiple sources, generate computer-assisted treatment recommendations for qualifying laboratory results, and create visit records within a Web-based electronic data capture (EDC) system. The system then produced reports that were used for a wide array of essential tasks, including monitoring and management of treatment decisions that were communicated to investigators by the Clinical Operations team, management of quality-control processes by the Data Management team, and management of numerous logistical and operational functions. The system was also used by the monitoring physician to identify cases, display laboratory and clinical data required to perform reviews, and record treatment decisions.

Results To date, greater than 17,000 laboratory result records have been aggregated, 4000 computer-assisted treatment recommendations rendered, and 3800 site-notification forms created and sent to sites using the system. The decision-support system adds valuable functionality by allowing near-real-time, quantifiable tracking of: results received; computer-assisted treatment recommendations generated; medical decisions rendered; notifications sent to and received by sites; late, missing, or anomalous laboratory results; and progress reporting. The system also enhances treatment efficacy and patient safety by allowing site personnel to closely manage subject exposure to study medication and helps ensure consistent application of protocol-specified treatments. The system reduces but does not eliminate the risk of treatment decision errors, which was further managed by additional quality control processing. Finally, the reviewer reported great value in being able to access the monitoring system and the information needed to render treatment decisions via the Internet.

Discussion Implementing this system imparted a number of significant lessons, including the importance of: 1) incorporating carefully specified metadata into processes such as data status reporting and management of laboratory result changes; 2) embedding decision-support logic within treatment algorithms; 3) requiring clinician review and approval of all changes to logic and processes; 4) additional human review of all treatment recommendations before distributing site notifications; 5) creating and carefully monitoring quality-control processes, and 6) resisting pressures to rush through project planning and system validation. Additionally, we realized considerable value in designing system flexibility sufficient to accommodate changes to the study protocol. Future considerations include evaluating time and cost savings, the extent of quality improvement, and ease of adapting data for secondary uses. In conclusion, we found that

properly implemented technology-assisted decision-support systems can add value to clinical research infrastructure. Future development plans include faster, more flexible decision support for upcoming projects. The success of this project, together with the experience gained, has positioned our teams to meet the increasing demands of industry-funded clinical research.