



DOCUMENT MANAGEMENT, AUTHORING, REVIEW AND TRACKING SYSTEM (Docu-MART)

CHALLENGE/SITUATION

The process of bringing a drug from bench to bedside is weighed down by regulatory burdens, evolving standards, and administrative roadblocks. Inadequate communication, ineffective group coordination, challenging integration of heterogeneous inputs, and difficulties with knowledge retrieval can result in not only delayed administrative movement, but also slower drug development. The process itself - from the initial draft to site and sponsor review to the final version - can take over 50 weeks. The need for new drug treatments in order to alleviate patient care is as constant as ever; what is also needed, then, is an advanced system that would stimulate protocol authoring and trim the protocol development process.

APPROACH

In order to address the challenge, CTIS needed to develop an automated tool that would expedite the authoring, reviewing, tracking, and approval of clinical trial study documents. The system needed to be simple, easy to use, and adaptable to client needs. It needed to accelerate the protocol authoring processes by reducing time-consuming administrative burdens, thus increasing productivity and efficiency. The goal was to create such an interoperable tool that would allow for an expedited process, one that resulted in faster research and development, earlier drug treatment disclosure, and quicker patient care.

SOLUTION

Docu-MART is a tool that utilizes both desktop and web-based components to assist with the authoring, reviewing, and tracking of clinical trial protocol documents. The Docu-MART suite includes the Authoring Tool, Publish Management, Review & Commenting, Tracking & Correspondence, Scientific Library, and Web Services modules. It is built upon common use of enterprise vocabularies (EVS), common data elements (CDEs), and the mission of the Structure Protocol Representation specific interest group (SIG), thus sustaining compliancy and consistency within an organization. All of the modules include interoperability, Document Lifecycle Management and Workflow, Version Comparison, Enterprise Library, CDE & cloud-based computing, such as caGrid from cancer Biomedical Informatics Grid (caBIG ®) compliance, and alerts, and notifications.

This allows for a highly scalable, robust, configurable, and customizable tool that will meet the business needs and requirements of all stakeholders. It enables the user to create and capture information directly to the Docu-MART repository; use information from disparate sources and to make it available to the application; and deliver information to any medium (web or mobile). It allows for business re-engineering, organization realignment, and workflow streamline.

BENEFITS

Docu-MART facilitates collaborative protocol development; reduces administrative burdens; improves communication; optimizes efficiency; improves document tracking; allows for independent use of sub-applications to support electronic document development/review; enhances online review and commenting capabilities; expands access to larger Investigator base; streamlines protocol submissions; enhances protocol review process; reduces approval time; and increases activation of clinical trials. Docu-MART is Clinical Data Interchange Standards Consortium (CDISC) compliance and is caBIG ® Bronze Certified.

- Decreases the processing time (Letter Of Intent to Activation) by 175% from 550 days (2000) to 200 days (2005)
- Increase in the number of protocols by 283% from 3,000 (2000) to 11,500 (2005)