CASE STUDY

ELECTRONIC TRIAL MASTER FILE SYSTEM – IMPROVED EFFICIENCY, INCREASED ACCURACY, AND REDUCED RISKS

BUSINESS CHALLENGES

Our client, an international clinical research organization (CRO) within a leading health management company, was using physical folders to store and manage critical paper study documents while conducting clinical trials for their various pharmaceutical sponsors. Trial documentation was accessible from three regional centers, but often, documents were dispersed in local duplicate "shadow" files. If a study team member or auditor needed to view a study's documentation, they had to travel to one of the regional centers or request copies. Because of the distributed nature of clinical trials, their physical storage system faced many challenges that became unmanageable, increased risks of ensuring access to current document versions, and was costly to package and deliver completed study files back to sponsors.

The client sought to replace their existing paper-based Trial Master File (TMF) with an electronic TMF Document Management solution to achieve the following benefits:

- Improve efficiency and productivity of daily operations;
- Reduce the risk associated with managing, tracking and archiving large volumes of paper;
- Reduce overall exposure resulting from audits;
- Provide quick and reliable access to required documentation throughout the project lifecycle;
- Create a single document repository that is concurrently available to all business units to eliminate "shadow" file usage.

Their desired solution was a validated, easily accessible, web-based Document Management platform organized in a standard but customizable hierarchy with secure document submittal via scanning, email and import. The client also wanted the platform to be easily expandable in the future to include Asia Pacific regions and support electronic medical authoring and submissions.

THE ARBORSYS SOLUTION

ArborSys collaborated with the client's key business and IT representatives to design, develop, and implement an enterprise-wide document management system that met the client's clinical trial documentation storage needs across their research and statistical organizations globally. ArborSys conducted requirements gathering and business process workshops with each global business area responsible for project management, field monitoring, regulatory affairs, data management, quality assurance, and document storage to document and standardize their study lifecycle processes. The design was verified interactively with the client via system prototyping and reviews. The system included a customized User Interface (UI) and was customized to ingest study email and attachments directly to specific studies and export searchable text-based PDF documents from the scanning application via their metadata. After the development and validation of the system was completed, ArborSys developed classroom and computer-based training materials and worked interactively with the client to deliver the training globally to key users.

EMC Documentum's content management repository and WebTop UI was configured and customized along with EMC's Business Process Services (BPS) to provide email integration. Captiva InputAccel was customized to support scanning and integration of scanned documents into the repository.

The ArborSys team was engaged to:

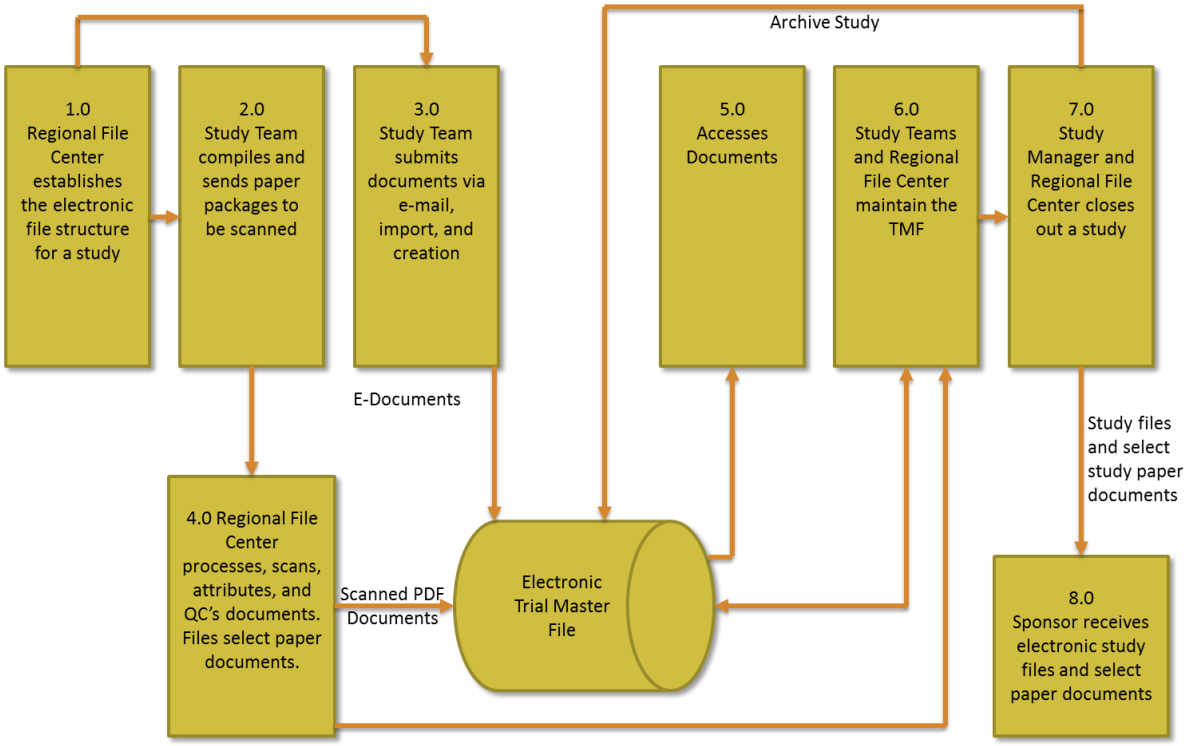
- Conduct requirements gathering/verification and business process workshops;
- Develop and document the business, functional, and technology requirements;
- Develop the "To Be" business process diagrams and the detailed 21 CFR Part 11 compliant system design;
- Prototype a UI design to facilitate the client's functionality and usability assessment;
- Design, configure, and develop the custom application;
- Perform integration testing and support client validation testing and implementation;
- Develop classroom and computer-based training materials and conduct training for key super users across all global regions;
- Perform technical, administrative, and product knowledge transfer.

Functionality included:

- UI customizations to the WebTop application;
- Integration between Documentum and Captiva InputAccel to scan by study file types, attribute documents based on variable study structures, and automatically store documents in the repository as text-based searchable documents in PDF format;
- Integration between Documentum and MS Outlook using EMC BPS to automatically import emails into specific studies;

- Integrations to the client Clinical Trial Portal (CTP) to allow portal users access to TMF documents, as well as store documents within the TMF that had been uploaded by the sites and study teams through the portal
- An expandable architecture that allowed modular expansion for future growth.

The following diagram illustrates the process flow for the electronic TMF system:



VALUE DELIVERED

Our team was able to design and deliver a solution that met the clients' current needs and supported their future initiatives. The electronic TMF solution provided a standardized yet global platform for the management of all clinical trials that:

- Improved the efficiency and reliability of document retrieval for all business units from a single clinical trial master documentation source from study start-up to closure and archiving;
- Maximized performance of daily operations;
- Integrated document submittal via scanning, email, and import;
- Increased compliance across the organization via facilitation of timely document submittal and access by regulatory groups.

The implemented architecture was expandable to support incremental scanning and document storage to additional Asia Pacific regions, and provided a flexible foundation for future authoring and submissions functionality.