



electronic clinical imaging processing system implementation

The client was a \$36 billion manufacturer and distributor of pharmaceutical products, with more than 12,000 researchers on three continents.

With Phase 3B trials burdened by millions of pages annually of Casebook Report Forms (CRFs), the manual process was causing 2-week delays in imaging with commensurate 2-3 week delays in data entry. The existing process and tools had no provision for reconciling Data Clarification Forms (DCFs), producing acceptable operational reports, or tracking documents from study design to their archive. Scanning costs were approaching \$5 per page, overnight shipping costs had surpassed \$1 million annually, and the resulting regulatory review prior to submission had stretched to weeks from days.

vision

The solution was to upgrade the imaging resources to allow automatic scanning and indexing of CRF pages from any global operations center or service provider equipped with system-compliant TELEform™ technology. Data entry went from manual to a semi-automated process using a tool that displayed CRF forms as images and allowed data entry directly into Oracle Clinical™. A global business process was developed and deployed.

Business processes were validated with 19 user groups, representing 1000+ end users. TCA deployed a Conference Room Pilot facility for process validation, user orientation, training content development and user training. We also developed a global standard specification for installing the system in corporate Data Operations Centers (DOCs), report specifications for the Pharmaceuticals Group and an approach for Load-Stress Testing. In the future, the system will be expanded to DOCs in Sydney, Madrid, Freiburg GE, Latin America, Africa, the Middle East and Canada.

results

Standard processes enabled by automation for scanning and imaging casebook report forms

value

Bottom Line benefits - Imaging costs have dropped from \$4.72 per page to under \$2 per page. Overnight shipping cost reductions have not been measured, but are expected to drop 70-80% as data entry can now be accomplished from a scanned image. It is no longer necessary to copy and ship casebooks to an operations center for scanning.

Improved service - The imaging Service Level Agreement was adjusted from 10 to 3 business days. Current metrics show that images are in the repository in less than 24 hours after receipt of casebooks in an operations center. The data entry Service Level Agreement was adjusted from 15 to 3 business days.

The Service Level Agreement for Index / Bookmark, Data, Medical and Safety Review processes is expected to drop to below 3 days from the previous process which often took 90 days.