



casebook report forms

For a large global pharmaceutical company, the Clinical Research Division needed a cost efficient and streamlined method for managing Casebook Report Forms (CRFs).

- Phase 3B and Phase 4 trials generated casebooks consisting of millions of pages of CRFs, which had to be manually processed
- The existing 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)
- Casebooks had to be pulled from paper archives and rescanned for incorporation into section 12 of Supplemental New Drug Applications (sNDAs)
- There was no method of producing acceptable operational reports or tracking documents from design to archive
- CRFs were often copied numerous times with no process of accounting for outstanding pages or means for reconciling changes made during clinical review with original pages
- Scanning costs were approaching \$5 per page
- Overnight shipping costs had surpassed \$1 million annually
- Regulatory review prior to submission had stretched from days to weeks
- Deployment of the existing solution was difficult due to poor deployment processes
- The existing system was not scaleable to meet increased demand

vision

TCA was selected to optimize the existing solution architecture and business processes, and to manage the implementation of a revised solution for their largest division.

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 was changed from manual entry using copies of CRF pages to a semi-automated data entry tool that allows data entry directly from a displayed image into Oracle Clinical™.

Our consultants addressed the existing deployment and control issues by developing a standard specification for installing the system in global data operations centers.

We optimized the solution architecture via load-stress testing to determine the limitations of the system and to enhance the system to meet performance and capacity requirements.

Project Approach: TCA partnered with the firm and led the development of a project plan to address implementation across two

Technology Consulting Associates

experience

major divisions of the corporation including end users in five business units and subsidiaries.

The project was broken into two phases:

- In Phase 1, TCA validated new business processes 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
- In Phase 2, TCA defined business requirements, functional specifications and delivered user training

To ensure that the system could scale to meet increased demand over the next 3 years, TCA developed an approach for load-stress testing and defined the operations architecture required to support the revised system.

TCA managed the implementation for the largest division by providing a project manager, business and technical analysts, report specialists and a change manager.

results

Implementation of a pilot; validation of requirements and architecture; planning for future phase implementation, while managing the current

value

TCA's RAD methodology produced tangible results quickly; decreased time to market; ensured measurable business benefits; and broke down projects into discrete manageable phases with predictable costs.

TCA was selected because of our unique blend of industry experience, IT knowledge, and our ability to deliver results quickly. TCA professionals:

- Have experience within Clinical Data Management
- Have experience within Drug Safety
- Have knowledge of regulatory reporting
- Understand the FDA's 21 CFR Part 11 regulations
- Understand E2B data standards
- Are certified EDMS solution providers
- Deliver end-to-end consulting services
- Leave behind and invest their knowledge in your staff