



adverse events processing

Technology Consulting Associates, LLC was recently engaged with a global pharmaceuticals company to design, construct and implement a successful, paperless, low cost solution to adverse events processing. Issues confronting the firm included:

- Manually sifting through Individual Case Safety Reports (ICSRs) and identifying Adverse Events (AEs)
- Meeting regulatory (e.g., 15 day reports) deadline
- Rapid assessment of causality
- Tracking ICSRs and follow-ups from acquisition through reporting

The Drug Safety division of this company needed a more reliable and efficient method of capturing and processing ICSRs. Their mostly paper-based systems and processes had reached operational limits and presented numerous challenges:

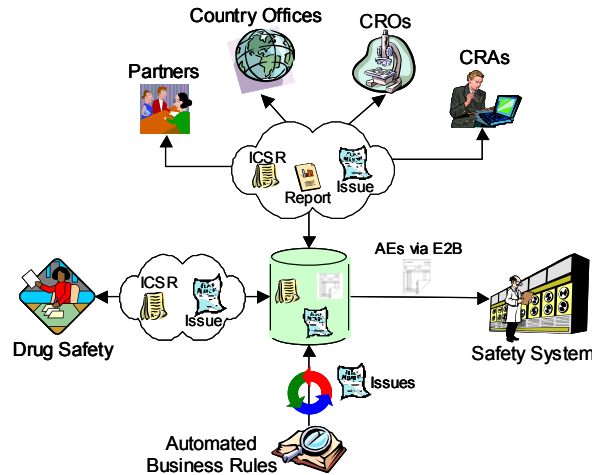
- Existing methods of submitting ICSRs were unreliable allowing for the possibility of lost submissions
- Multiple business processes were required for each different type of ICSR form submitted to drug safety (e.g., firm's form, other company forms, CIOMS I, etc.)
- ICSRs were not tracked until sometime after the initial receipt, thus increasing the possibility for them to be misplaced or difficult to locate
- Every ICSR needed manual review to determine if it met criteria for an Adverse Event
- ICSRs were manually entered into multiple systems which was time consuming and error prone
- Resource levels increased significantly annually to meet demand from increased ICSRs
- The workforce required access to ICSR information from multiple geographical locations which was not supported by the existing systems
- Country offices and other 3rd party organizations did not get timely information about their ICSR submissions
- Redundant tracking systems were required to enable both Drug Safety Office and submitters of ICSRs to track submissions which was costly to maintain and created data synchronization issues

vision

The corporation engaged TCA to rapidly develop a new low cost, efficient, and easily supported web-based system to capture ICSRs electronically from reporting groups worldwide.

The new system developed by TCA captured ICSRs electronically; stored them in an electronic document management (EDMS) repository in E2B format; automatically validated each submission; enabled Drug Safety to triage cases on-line; and then automatically entered them into the firm's safety database.

Operationally, submitters utilize an electronic template to capture ICSRs off-line, and then submit ICSRs on-line to Drug Safety via a high availability web-based system. Submitters, such as country offices, are also able to execute searches and reports via the new system to track the progress of their ICSRs.



The new system automatically validates each ICSR against the firm's business rules to ensure it meets both the FDA's criteria for an AE and the firm's own data standards. Submitters of ICSRs are notified automatically of any issues that need to be resolved. Drug Safety resources are notified on-line of any problems that have not been resolved by submitters in a timely fashion.

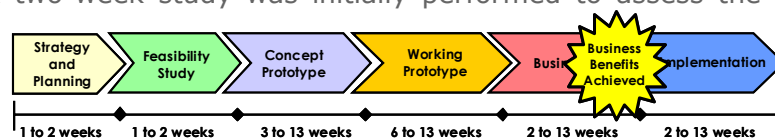
TCA's solution allows Drug Safety to triage cases on-line after they have completed the automated validation process to provide additional metadata and identify any additional information required from the submitter. The solution also automates the costly, time-consuming, and error prone task of manually entering AEs into the firm's safety database. Validated AEs are exported in E2B format from the new electronic document management repository and then imported into the firm's safety system.

The system is 21 CFR Part 11 compliant, supporting both electronic signature and electronic records requirements.

Project Approach

Our consultants worked with the firm's business and IT resources to develop a strategy, business case, and phased approach to implementation that fit their needs. We employed a Rapid Application Development (RAD) methodology to implement the new system.

A two-week study was initially performed to assess the feasibility of



implementing a web-based solution to solve the firm's Drug Safety

business issues. Our consultants quickly learned that most users had access to the corporate network and regularly used current web browsers. In addition, they used Microsoft Word to document ICSRs. We also learned that the firm already had most of the required technology infrastructure: an EDMS was being used in other divisions, and a web infrastructure existed, but needed some upgrades to reliably support high availability access.

Over the next six weeks, we gathered business requirements, developed a concept prototype, and conducted a pilot with one office. Feedback was used to enhance the prototype and a subsequent pilot was conducted with two other offices. Total duration for the first two pilots was 13 weeks.

Following the RAD methodology, a working prototype of the final system was developed over the next 13 weeks. In parallel with system development efforts, we assisted the firm in designing and implementing the high availability web and EDMS infrastructures.

Several countries conducted a business pilot of the system over the next 13 weeks. TCA consultants traveled to each site individually to gather requirements and to conduct on-site training and feedback sessions. In parallel, we worked with functional management within the firm's Drug Safety organization to define/revise associated business processes and to develop business continuity processes, practices and procedures.

Total duration from inception to the completion of the initial production implementation to 15 sites was under 12 months. We were responsible for all system development, validation, and end-user training. In addition, we trained the firm's IT operational staff.

results

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

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

- Have extensive experience within Drug Safety
- 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

value

TCA consultants exceeded the firm's expectations. We were able to deliver the solution on time within scope and on budget. Benefits of this project were:

- On-line processes replaced unreliable paper-based processes with guaranteed delivery methods
- Many manual review and data entry tasks were automated and costs lowered significantly

Technology Consulting Associates

experience

- Compliance is high. In the first three months of use, the firm enjoyed the best compliance statistics since internal drug safety metrics have been kept
- Cost impact included a 5-year NPV EVA¹ for this system over \$6 million, reduced staffing levels required to process AE submissions from suppliers, and the elimination of a \$3 million annual cost for data entry by external vendors
- Reduced overall case processing times by 2 to 4 days
- Partners and CROs now have the option to send safety data electronically to the firm using E2B
- Countries are now able to submit ICSRs during their local business hours and receive feedback within minutes on issues that need to be resolved

¹ Net Present Value Economic Value Added. Accounts for all one-time and on-going costs, and all quantifiable business benefits over a period. Measures investment comparison to the same money invested at a fixed rate of return.