



## electronic adverse events management

The Drug Safety division of a global pharmaceutical and consumer products company with \$32 billion in annual revenues and 90,000 employees needed a reliable and efficient method of capturing and processing adverse events (AEs) electronically from their suppliers.

- Existing submission methods are unreliable and have been cited by the FDA for compliance issues (lost adverse events and late submissions)
- Existing adverse event capture and review business process is paper-based and manual-intensive
- Client has approximately 80 country offices, Clinical Research Organizations, licensing partners, and Clinical Research Associates submitting adverse events
- Merger with another pharmaceutical company requires access to AE information from multiple geographical locations, which current systems and processes do not support
- Redundant tracking systems are required to enable suppliers to track submissions since there is no remote on-line access to a central AE database

The combination of new product launches and the recent merger has resulted in a dramatic increase in the number of adverse events over the past 3 years. Adverse events are currently submitted via fax (20%) and e-mail (80%). Regardless of the submission method used, all adverse events are printed and processed as paper.

AEs submissions are not tracked until numerous paper handoffs are performed. AEs must be manually entered into multiple systems, which is time consuming and error prone. Resource levels have been significantly increased in an effort to keep pace and maintain compliance levels.

### vision

TCA developed a web-based system to capture Adverse Events electronically from suppliers worldwide and store them in an electronic document management repository.

Suppliers fill out an electronic template with AE information and then submit AEs to Drug Safety by logging onto a new web-based system. This system is available via the corporate Intranet 22 hours per day 7 days per week (with 2 hours reserved as a backup window). In addition to being able to submit AEs, suppliers are able to perform searches and run reports, which eliminate the need to maintain local tracking systems.

Each submission is automatically validated to ensure that it meets both the criteria for an Adverse Event and internal data standards. Suppliers are notified immediately of any issues that need resolution with each submission and can track issues via a notification inbox available by the new web-based system.

Within the client's Regulatory Affairs division, on-line case receipt processes have replaced paper-based processes and many of the previous manual tasks have been automated. Cases are now tracked from the moment they are first received. Unreliable submission methods have been replaced with guaranteed delivery methods.

Once the client finishes transitioning to a new AE system, manual data entry will be replaced with automated data entry, which is much faster, cheaper, and eliminates data entry errors.

The new system is 21 CFR Part 11 compliant, supporting both electronic signature and records requirements. Data is automatically extracted from each submission and stored in E2B format, enabling the client to easily support multiple AE forms used internally and ones used by licensing partners.

TCA performed a two-week study to assess the feasibility of developing and implementing a web-based solution. TCA quickly learned that most country offices have access to the corporate intranet, used Netscape or Internet Explorer browsers and used Microsoft Word on the desktop to document AEs. In addition, the client owned and utilized Documentum in other divisions. From an IT operations perspective, the existing web infrastructure needed some upgrades to support high availability systems. The conclusion was that target users would be able to utilize a web-based solution.

TCA employed a Rapid Application Development (RAD) methodology to develop and implement the new web-based system. A prototype was developed within 6 weeks and a proof of concept was conducted with one country office. Feedback from the Proof of Concept was used to enhance the prototype and another pilot was conducted with two country offices. Total duration for the first two pilots was 16 weeks.

Scope and requirements were finalized based on feedback from the initial pilots. Following the RAD methodology, a working prototype of the final system was developed over the next 13 weeks. In parallel with system development efforts, TCA assisted the client in designing and implementing the web infrastructure required to enable 22x7 high availability access (with 2 hours reserved for backups).

Approximately 12 countries piloted the system over the next 6 months. TCA traveled to each country individually to gather requirements and to conduct on-site training and feedback sessions. Feedback was incorporated into the system, with new versions released monthly throughout this pilot period. In parallel with this effort, TCA worked with functional management within the Regulatory Affairs division to define/revise associated business processes and to develop business continuity processes and procedures.

Total duration from inception to initial production rollout was 12 months. TCA was responsible for all system development, validation, and end-user training. In addition, TCA trained all appropriate client IT operational staff.

### results

Production web-based capabilities for managing adverse events resulting in significant operational cost savings and higher levels of compliance.

### value

The project resulted in:

- 5-year NPV EVA<sup>1</sup> for this system is over \$8 million
- Reduced staffing levels required to process AE submissions from suppliers by 20%
- Eliminated \$4 million annual cost for external AE data entry vendors
- Eliminated lost AE submissions from suppliers
- Reduced overall case processing times by 2 to 4 days

The following tools, technologies, and platforms were utilized to develop this solution. The client's existing architectural standards were utilized wherever possible. Unix is the standard database platform; Microsoft Windows NT is the standard web server and application server platform; and Microsoft Windows is the standard desktop platform.

- Microsoft IIS 4.0 (web server),
- Windows NT 4.0 (server O/S),
- Windows 95, 98, 2000, NT 4 (client O/S)
- Microsoft Active Server Pages,
- VBScript,
- Visual Basic 6.0 (application server components),
- Internet Explorer 5.0 and greater
- Netscape Navigator 5.0 and greater
- Oracle 8i,
- Documentum 4i,
- Mercury Interactive (load and performance testing),
- Unix Sun Solaris (Documentum and Oracle),
- NetIQ (monitoring and alerts),
- Cisco Content Services Switch (load balancing and failover)

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<sup>1</sup> 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.