

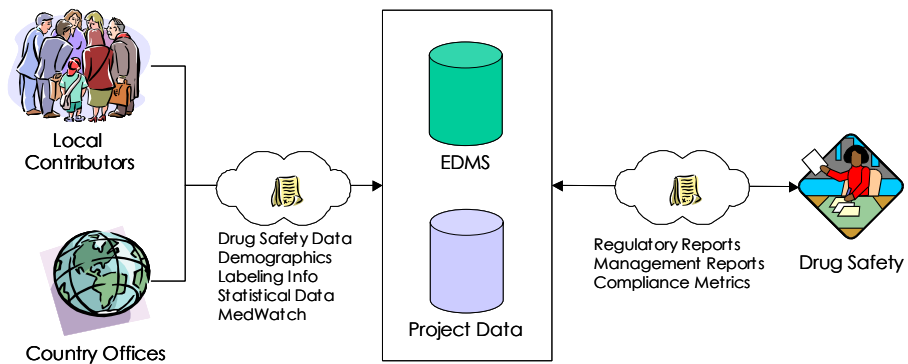
regulatory reporting

At a large global pharmaceutical company, the Drug Safety Reporting division needed a more efficient method of managing creation and publishing of aggregate reports to the FDA and other global regulatory agencies (i.e., NDA Periodic, IND Annual, and PSUR Reports).

- Over 200 regulatory reports were prepared by this group annually, with the number steadily increasing over time
- Compilation, review, and publication of reports was an entirely paper-based endeavor, with some reports having as many as 10,000 pages
- Managers were overwhelmed with task and resource management to ensure reports were submitted in a timely manner; progress versus plan was not easily known
- Report preparation often spanned several months as information was gathered from contributors at various worldwide locations
- Report preparers spent a disproportionate amount of time on report creation mechanics versus ensuring high quality report content

vision

TCA was engaged by the firm to develop an on-line process to replace the existing paper-based reporting process. The solution implemented by TCA leverages existing off-the-shelf project management and electronic document management (EDMS) technologies to reduce development costs and enable rapid deployment of the new solution.



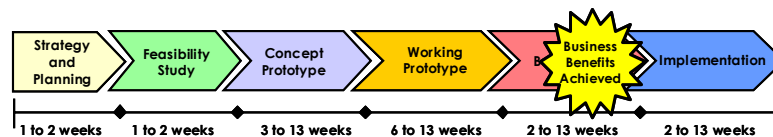
Project management software was used to schedule and track completion of report tasks. Templates were setup to allow quick creation of a report timeline, and redundant steps were automated to ease the report coordinator's responsibilities.

Adobe PDF rendering tools were used to compile reports electronically, and an EDMS was deployed to store them. Reports are now available on-line via the corporate Intranet, thus eliminating printing and reducing time and cost to distribute reports.

The new solution includes many new features to improve the productivity of report authors and to streamline the report creation process. Report authors now:

- Solicit contributions electronically rather than by hard copy, which also reduces scanning costs
- Initiate the creation process by generating a report "shell" and supporting documents based on predefined templates
- Generate reports using output from various electronic sources
- Share and version documents
- Use workflow functions to approve documents
- Track report creation progress against plan
- Identify resource bottlenecks
- Publish and distribute reports electronically

Project Approach: TCA employed a Rapid Application Development



(RAD) methodology in developing and implementing the new system. TCA was engaged initially for a three-week period to review and refine the requirements, perform an evaluation of applicable software products, assess the existing infrastructure capabilities, and create a project plan. The project approach and software products were presented to the firm's steering committee for approval.

Design sessions were conducted with future users of the system to review configuration and interface options of the off-the-shelf application components. A concept prototype was delivered for user comments within 6 weeks of the project start. Feedback from the concept prototype was incorporated into the system and a working prototype was developed over the next 10 weeks.

Several small-scale business pilots were run within the user community using a production-ready version of the application to gather feedback and ensure the application met the requirements of disparate reporting groups. Over the next few months, refinements were added to the application and it was deployed for production use 16 weeks after the initial pilot.

Total duration from steering committee approval to initial production rollout was 32 weeks. TCA was responsible for all software selection, system development, validation, and end-user training. In addition, TCA trained all client desk-side support and operational staff.

results

TCA's RAD methodology produces tangible results quickly; places a premium on time to market; ensures realization of measurable business benefits; and breaks down and defines projects into discrete manageable phases with predictable costs.

Technology Consulting Associates

experience

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

- Have extensive experience within Drug Safety
- Have extensive 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

value

The solution implemented by TCA provides the firm's Drug Safety Reporting group with a new on-line, electronic report creation and distribution process. The system provides the firm with many business benefits.

- Users are now able to better measure their ability to generate and submit reports that adhere to regulatory timelines
- The time required to create a regulatory report was reduced by eliminating error-prone duplication and pagination steps
- Project/process management was centralized, thus providing metrics and compliance statistics across reports
- The new electronic repository for reports eliminates the need to store millions of pages in hard-copy format
- Contributions are solicited electronically, rather than by hard copy, which eliminates scanning time and cost
- Printing and shipping costs are expected to decline as reports are submitted electronically
- A foundation was created for future electronic submissions to regulatory agencies