



Top 40 Argus Implementation & Data Migration

PROBLEM STATEMENT

At a large pharmaceutical global company, the drug safety department needed to switch safety databases from a system that was becoming obsolescent. They required a move to a supported & standard platform instead of maintaining a custom and unsupported platform, due to associated risks & IT strategy. Switching to a mature industry standard platform would allow them to implement best practices, and profit off a product roadmap and evolutions rather than 'in-house patching'. Some of the issues the company faced were:

- A disjointed case management process that required multiple reconciliation steps leading to below average case processing efficiency
- No single common system to support local affiliate case management
- A separate document management system which was inconvenient when a user wanted to view or attach associated documents
- Case quality issues that had led to the implementation of expensive additional quality control checks
- A separate submission and compliance system which had led to complicated submission compliance reports
- A relatively new case processing outsource partner who was having to work hard to match their internal systems to the requirements of the client
- A high cost of ownership to maintain many compliant systems to support drug safety

SOLUTION

Foresight was engaged to perform the following services over about fifteen (15) months:

- The case management process was redesigned with the support of the out-source partner to take advantage of the functionality offered by the new solution.
- A single global process was designed and implemented. Redundant process steps were removed or merged into other steps. The case quality approach was redefined and integrated into the system.
- All affiliates (except Japan) received access to Argus affiliate removing the need for a local system and reconciliation activities. All submissions (central and local) were able to be created from one system
- A series of measures (process and system) was implemented to maintain the privacy of individual data. If required by regulation, private data would only be available in the country of origin
- A large data migration was performed using Foresight's proven methodology and the Foresight® Data Migration Engine to migrate cases from the legacy system to the new Argus Safety™ system

CHALLENGES

- AE case management was out-sourced, so changes had to be done in co-operation with the out-sourcing partner
- Simultaneously targeting best in class efficiency and high levels of case quality
- Affiliates had no prior safety system experience
- Solution needed to meet international data privacy regulations for patients and reporters
- Complex analytical report requirements of medical team to monitor safety, not available in standard application
- The company had no existing Argus skills and required a solution for managing the system in the long term

SOLUTION

- Close partnership with outsourcing partner
- Re-define process to meet both quality and efficiency expectations
- Both process and technology solutions devised to address privacy requirements
- Development of custom reports
- Outsourced incident management and service requests



About Foresight

Foresight Group International AG is a global provider of drug safety and risk management professional services and solutions.

With over 200 employees in North America, Europe, Japan and India — we are the largest professional services firm in the world focused exclusively on drug safety and risk management.

Foresight provides all of our core services in both English and Japanese, including service desk for our managed services.

To learn more about Foresight, visit www.foresightgroup.com.

Core Services

- Hosting and Managed Services
- PV Process Design & Optimization
- Safety System Implementation
- Custom Reporting
- Signal Management
- Risk Management
- Inspection Readiness & Response
- Benchmarking and Analytics

Our People

- Experienced (average 8+ yrs.)
- PV process & systems experts
- Program managers
- Analysts and architects
- Developers and testers
- Many from industry
- Bi-lingual English & Japanese
- Local knowledge, globally

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SOLUTION (CONTINUED)

- Twenty plus custom reports were developed to cover specific requirements such as advanced medical analysis, global compliance & affiliate operational reporting
- Foresight and the out-sourced case processing partner signed a five-year contract to provide Incident Management & Application Management

RESULTS ACHIEVED

- A single global process that included more than two dozen affiliates was designed and implemented
- The system successfully went live on-time and on budget
- 250,000 cases were successfully migrated into Argus from the legacy database
- More than 700,000 case documents were migrated from the legacy document management system and linked to individual cases in Argus
- 24 custom reports were developed to support the business process, one report contained more than 300 database fields, and another had numerous sub-reports
- Client was targeting a 20% productivity improvement from the project, after the process and system redesign the productivity increase was estimated by the client at 60%

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