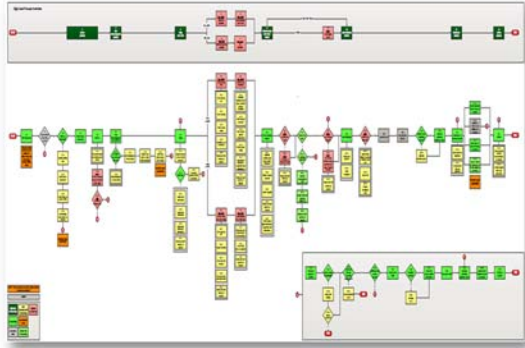


Global - Japan Harmonized PV Business Process



PROBLEM STATEMENT

A large international pharmaceutical company headquartered in Japan was trying to determine whether or not to implement Argus Safety™ to replace ARISg and ARISj.

CHALLENGES

- Reporting being conducted in 3 global regions
- Inconsistent reporting methodologies
- Need to consolidate process for transition to single global integrated drug safety database

SOLUTION

- Documented process
- Future-state, end-to-end globally harmonized business process developed for single case processing and PSUR preparation
- Workshops and training conducted
- Implementation of a globally-aligned single case management process facilitated efficient and consistent data capture, analysis and decision making

PROBLEM STATEMENT

A large international pharmaceutical company headquartered in Japan was trying to determine whether or not to implement Argus Safety™ to replace ARISg and ARISj.

- In their current state, the company employed a global operating model in which pharmacovigilance data, including Individual Case Safety Reports (ICSRs) of all types (i.e., solicited, spontaneous, clinical trial, literature reports, etc.), were collected and processed by four (4) major regional case processing sites located in Japan, Europe and the United States
- Each of these sites possessed different internal resource structures, outsourcing requirements and product reporting requirements
- Three locally installed instances of the safety database were being used across these four major case processing sites
- Each of the four sites possessed its own unique business practices for processing ICSRs. Furthermore, major sites responsible for preparation of Periodic Safety Update Reports (PSURs) had different methods for preparing these reports.

SOLUTION

The company engaged Foresight Group to design robust, harmonized, end-to-end ICSR and PSUR business processes across all four sites that would support the unique requirements and constraints of each of the four major case processing sites. In addition, the company engaged Foresight to conduct Argus Safety™ feature adoption workshops to help analyze whether Argus Safety™ and Argus J could support their desired business model.

Using Foresight's Business Transition Methodology, a discrete process schematic was created for each of the four major case processing sites to outline their 'as is' ICSR business practices. A separate schematic documenting the global PSUR business process was also rendered. Through this exercise, each site's process requirements and processing limitations were documented. Based upon these findings and knowledge of the Argus and industry best practices, two future-state, end-to-end, globally harmonized business processes were developed by Foresight personnel – one for single case processing and one for PSUR preparation.

Foresight resources subsequently conducted multiple workshops with key stakeholders from each of the four major case processing sites. Workshops were conducted in Japan and in the United States. The purpose of these workshops was to confirm understanding of the current business processes and to review and modify the proposed future state processes based upon stakeholder clarification and feedback.



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

Global - Japan Harmonized PV Business Process

SOLUTION (CONTINUED)

During this process, special consideration was paid to integrating Japan's regulatory requirements and translation needs into the globally harmonized ICSR process and addressing the process steps necessitated by use of Argus J.

During the course of the end-to-end process design, an effort was made to fully comprehend the qualifications and capabilities of the staff currently performing ICSR and PSUR pharmacovigilance activities at each of the four major case processing sites.

Once a consensus was reached by the key stakeholders with regard to the globally harmonized ICSR and PSUR business processes, an additional initiative was undertaken by Foresight resources to assess the impact of the future-state processes upon the company's global and major site-level SOPs.

RESULTS ACHIEVED

At the conclusion of the project, Foresight resources were able to successfully gain consensus among the key global stakeholders with regard to a single, harmonized ICSR and PSUR business process to be implemented across the four major case processing sites. Furthermore, previously reluctant major case processing sites recognized the importance of moving toward harmonized PV business processes.

The implementation of this globally-aligned single case management process will facilitate efficient and consistent data capture, analysis and decision making. The ultimate result will facilitate an enhanced signal detection process. Furthermore, leveraging Argus automation and technology will facilitate workflow management and increase operational efficiency.

Foresight resources met all final project deliverable timelines. These deliverables included:

- Business process overview document outlining the future state ICSR and PSUR business processes in narrative detail
- Final ICSR and PSUR future state process schematics
- SOP Impact Analysis
- RACI (Responsible, Accountable, Consulted, Impacted) Matrix
- Quality Management Framework
- Project Governance Model
- Qualitative Return on Investment (ROI) Model

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