

To address today's industry challenges, Aris Global has developed Total Safety™ — a comprehensive, scalable suite of applications designed to meet the broad spectrum of drug safety, pharmacovigilance and risk management needs of pharmaceutical, biotechnology, medical device and contract research organizations (CROs).

The following are real-world success stories from a few of the companies that rely on Total Safety software solutions to implement effective domestic and global pharmacovigilance, clinical safety and risk management programs.

Integrating disparate systems into a centralized, user friendly database

Ranked in the top 20, a leading pharmaceutical giant integrated a multitude of ARISg databases by upgrading to the new user-friendly, web-based version of ARISg. Prior to this upgrade, the databases were managed locally in separate regions and synchronized to the central system only once daily. This absence of real-time, global data visibility increased the company's risk of non-compliance.

The company sought to have a continuously up-to-date, central, secure and controlled system for capturing, tracking, analyzing and reporting all safety data.

By harmonizing and consolidating multiple systems into one, the company strove to decrease costs and increase efficiency and speed.

To fully realize its vision, the company partnered with Aris Global to further develop functionality into ARISg in

order to support the complexity of its business. After a successful testing phase, the pharma implemented ARISg's web-based version and Aris Global's E2B gateway solution, and integrated all of the organization's safety data from numerous independent locations into a centralized database.

Thanks to these solutions, the company has significantly decreased the complexity of its infrastructure by efficiently harmonizing all safety business into a central system that can be accessed at any time by all worldwide locations. This streamlined database environment is one of the greatest benefits for the large pharmaceutical company.

Benefits

- Decreases risk of error and non-compliance by establishing a secure, centralized database
- Increases efficiency and quality of safety data
- Reduces costs associated with maintaining numerous, dispersed databases
- Improves decision making by providing an up-to-date, consolidated view of information

“...the company has significantly decreased the complexity of its infrastructure by efficiently harmonizing all safety business into a central system...”

Streamlining case processing with flexible workflows

A trusted national health authority strives to protect the health of its citizens, and works diligently with health professionals and consumers to collect and assess the adverse reaction reports for an extensive list of post-market products. To ensure it consistently achieves this mission, the company sought to improve its ability to more efficiently and effectively manage all safety information.

The health authority embarked on a search for a comprehensive pharmacovigilance system that would accommodate its growing needs. It was critical that a new system provide a user-friendly interface that would easily handle multiple languages, reduce manual processes and provide extensive search and reporting capabilities. Additionally, the agency needed the ability to centralize multiple product dictionaries into a single company product dictionary.

Ultimately, the health authority proof tested and selected ARISg[™] and agSignals[™] for their ease of use and extensive functionality that addressed their business needs. ARISg is the industry-leading pharmacovigilance and clinical safety system used by more than 300 global companies. agSignals is Aris Global's all-in-one solution for querying, reporting, data mining and signal detection. agSignals can be integrated with any safety system that offers access to regulatory data sets, such as FDA AERS.

Aris Global's professional services team managed the implementation effort, which involved migrating nearly 250,000 cases from the agency's previous system to ARISg. A new workflow, which optimizes the organization's business processes and case-processing requirements, was designed and implemented. Through its use of agSignals, the agency now has access to cleansed FDA AERS data for greater signal detection and comparison.

Thanks to ARISg and agSignals, the national health authority records and processes post-market cases faster and with greater efficiency, and detects signals that may represent potential safety issues that need further investigation. These integrated data mining and detection capabilities gave them access to all the available safety data for better managing risk.

“Thanks to ARISg and agSignals, the national health authority records and processes post-market cases faster and with greater efficiency...”

Benefits

- Streamlines case processing of post-market cases with greater speed and efficiency
- Improves risk management by enabling users to more quickly detect potential safety issues
- Centralizes multiple product dictionaries into a single company product dictionary
- Delivers systems in multiple languages to support its users' native language requirements



Automating adverse event receipt management for efficiency, visibility and compliance

One of the world's leading healthcare companies, with operations in more than 130 countries, implemented Aris Global's agXchange IRT™ to automate and streamline the inbound receipt and triage of adverse event information. In the past, the company used a paper-based tracking system that required employees and affiliates to manually capture, access and distribute all potential safety cases. These processes proved to be cumbersome, costly and prone to error and duplications. The system also made it difficult to obtain end-to-end visibility needed for sound decision making and preventing issues of non-compliance.

With the organization's continuous growth and the industry's ever-expanding set of regulatory requirements, the company wanted a new system that would enable its medical services, call center staff and affiliates to easily collect and enter adverse events directly into a web-based AE form. After the data is checked for possible duplication and then triaged, the AE form would then be imported directly into ARISg, its drug safety database.

The company partnered with Aris Global, and together they defined and tested agXchange IRT against a list of critical requirements. The first phase of implementation is complete, and agXchange IRT is enabling the company to automate the entry of adverse events using forms filled out directly by affiliates, the call center and the central medical services groups. The user-friendliness of the online AE form is helping to speed the efficiency of call center employees and affiliates who submit electronic cases for processing. Comprehensive assessment and triage capabilities are enabling its global medical services staff to assess incoming potential safety items prior to promotion to case processing.

The agXchange IRT module is decreasing the amount of time the organization spends collecting and verifying safety information, and is increasing its ability to report complete and accurate safety information on time. By electronically collecting and processing safety information, the healthcare provider is anticipating that it will achieve significant productivity gains and associated cost savings.

“The agXchange IRT module is decreasing the amount of time the organization spends collecting and verifying safety information...”

Benefits

- Improves the case intake process by incorporating business rules
- Decreases the time spent collecting and verifying safety information
- Provides an electronic audit trail of all cases
- Significantly improves productivity of employees and affiliates

Pharmacovigilance & Safety

Providing a platform to achieve Total Safety, our comprehensive suite of integrated software solutions enables all life sciences organizations, regardless of size, to implement effective domestic and global pharmacovigilance programs in full compliance with international regulations.

ARISg™

Collect, code, assess and report clinical and spontaneous adverse event data in accordance with international guidelines.

ARISj™

Process and report adverse event reports in compliance with Japanese regulations.

agXchange ESM™

Exchange ICSRs, SUSARs, and aggregate reports with authorities and license partners.

agXchange™ IRT/OST

Enter, track and report safety data at local and regional levels in compliance with local processes and regulations.

agComposer™

Prepare, compile and track aggregate and periodic reports, including ASRs, DSURs and PSURs.

agSignals™

Perform in-depth data analysis and signal detection on internal and external data sets, including FDA AERS.

About Aris Global®

For more than 20 years, Aris Global has been a trusted and reliable partner of many of the world's leading pharmaceutical, device, biotechnology and clinical research organizations. More than 300 life sciences companies rely on our innovation and advanced technology solutions in pharmacovigilance & safety, regulatory affairs, clinical research and medical information.

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