

LifeSphere® Safety MultiVigilance

Ensuring Pharmacovigilance Efficiency and Compliance with Advanced Technology

Heightened interest and scrutiny in product safety and risk management by regulators has challenged today's life science organization. Today's marketing authorization holder must have comprehensive pharmacovigilance systems in place to comply with the increasing volume of legislation and changes to transmission formats such as E2B(R3), and to protect patients and product sponsors against risk.

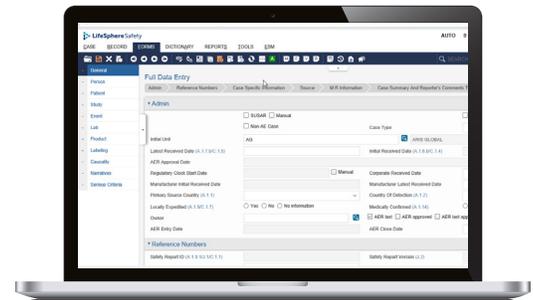
LifeSphere Safety MultiVigilance is the modern, multi-tenant cloud platform for unified safety and case management that delivers full E2B (R3) compliance in support of the pharmaceutical, biotech, medical device and cosmetic industries. Advanced technology, such as artificial intelligence and machine learning, helps automate the repetitive and routine manual tasks in case processing. Our innovative design based on industry standard architecture enables open integration with any third-party system.

Leading the Way for Efficient, Cost-Effective Safety and Case Management

LifeSphere Safety MultiVigilance is designed for efficiency, compliance and cost-effectiveness. The Out-of-the-box configurations are based on industry best practices (ISPs) that were developed in collaboration with members of the industry. The solution offers advanced automation capabilities to add efficiency to case processing. Designed and offered as a multi-tenant, cloud-based and pre-validated solution companies are able to achieve quick deployment when compared to traditional implementations. The upgrade process has been streamlined to minimize the impact of required changes through scheduled upgrades aligned with a SaaS model. This replaces large infrequent, high impact updates with smaller minimally disruptive updates that are regularly scheduled allowing our partners to realize lower total cost of ownership.

Full Pharmacovigilance and Safety Compliance

Full compliance with both E2B(R3) import and export functionalities, as well as with the latest domestic and global safety reporting obligations for drugs, devices, cosmetics, vaccines and biologics, assure companies of full global compliance with regulatory agencies in every region.



Based on industry standard practices and leveraging cognitive computing, LifeSphere Safety MultiVigilance delivers the most complete, mature and proven drug safety software solution available today.

Flexible and Configurable for Company-Specific Processes and SOPs

LifeSphere Safety MultiVigilance can be deployed out-of-the-box or tailored to support company-specific business processes and SOPs.

Automates Case Professing

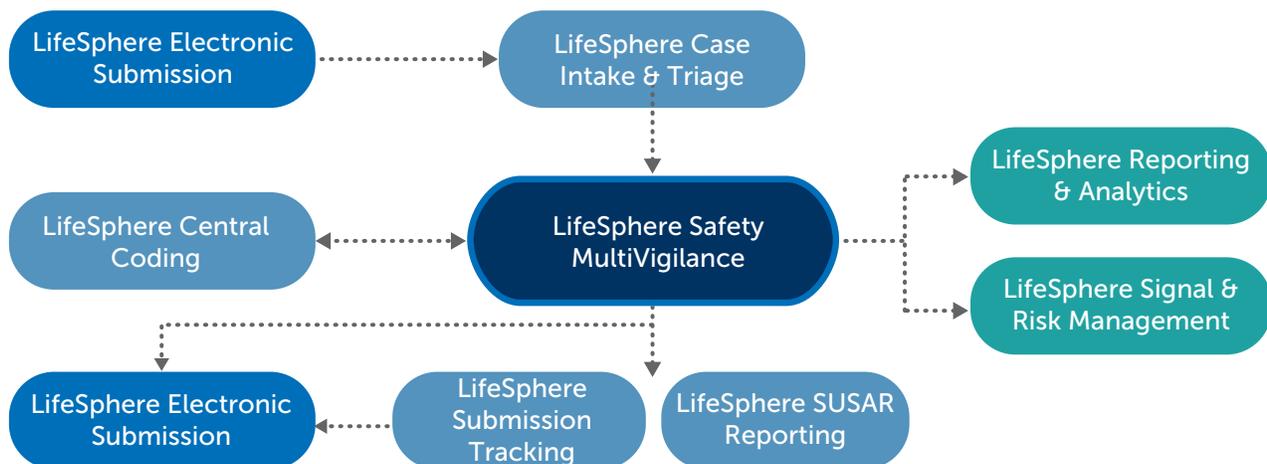
An enhanced user interface with an extensive feature set facilitates the entry, classification, coding and assessment of AE reports in accordance with international standards and guidelines.

Optical Character Recognition is one of the technologies leveraged to deliver seamless, automated data population into fields from any structured data format. Built-in scoring of cases and quality-monitoring mechanisms deliver better control of a service partner’s performance.

Efficient Case Handling

A flexible workflow module routes cases automatically for efficient processing based on company SOPs and policies. Extensive tracking capabilities are provided, and enable a company’s workflow manager to assign to and review cases of individual team members.

A Complete Platform for Anywhere, Anytime Access



Advanced Case Query and Analysis

An advanced query engine supports Boolean logic, case-insensitive and free-text searching, allowing users to easily create complex queries for case retrieval, analysis and reporting. Users can run a variety of operations for case review, batch operations, validations, case updates and report generation. Interactive views represent data in the form of charts or listings for immediate analysis.

Global Adverse Event Reporting

To aid in risk mitigation, a full variety of expedited and aggregate reports aid in global AE reporting. For electronic exchange, support for export and import of E2B files with recipient-based mapping helps comply with local deviations. The solution’s integral distribution server automatically determines reporting responsibilities and timelines depending upon case detail.

ABOUT ARISGLOBAL®

ArisGlobal is a visionary technology company that’s transforming the way today’s most successful life sciences companies develop breakthroughs and bring new products to market. The ArisGlobal LifeSphere® cognitive technology platform integrates machine-learning capabilities to automate the core functions of the product lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy. Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. For more information, visit arisglobal.com or follow ArisGlobal on LinkedIn and Twitter.