

LifeSphere® Safety

Transforming Case Processing and Risk Management with Advanced Technology

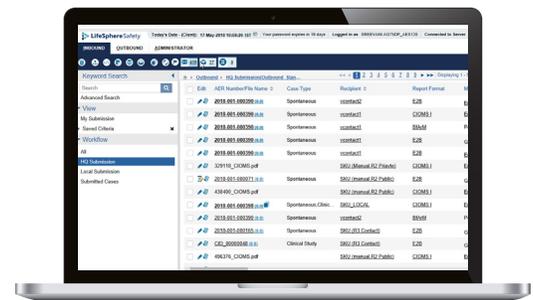
Increased case volumes and complexities are pushing life sciences companies to rethink their processes and technologies.

Technological breakthroughs and large-scale consumer adoption of next-generation platforms are pushing companies toward innovations, such as artificial intelligence. Faced with flat or reduced resources, today's safety department is at a crossroads for how to proceed.

LifeSphere Safety is the multi-tenant, cloud-based platform that leverages industry standards practices, cognitive computing capabilities and single sign-on across its suite of solutions to transform and help implement domestic and global pharmacovigilance and safety, clinical safety and benefit-risk management programs in full E2B (R3) compliance along with other latest regulations from ICH, FDA, EMA, PMDA and SDA, including all regional variations.

Empowering Global Teams with Efficiency and Compliance

LifeSphere Safety offers capabilities that deliver greater efficiency and compliance, covering the full spectrum of safety case processing needs and enhancing the collection, assessment and evaluation of safety data. As a multi-tenant, cloud-based and pre-validated solution, quick deployment is achieved. The streamlined upgradation process minimizes the impact of required changes with upgrade schedule aligned with a SaaS model. Therefore, large, infrequent, and high-impact updates are replaced with smaller, minimally disruptive, regular updates. This change in approach allows our customers to remain compliant with regulations while achieving nimble response to changes in a lower total cost of ownership.



LifeSphere Safety leads the way with an innovative pharmacovigilance software and drug safety platform to transcend all traditional safety data management and reporting processes.

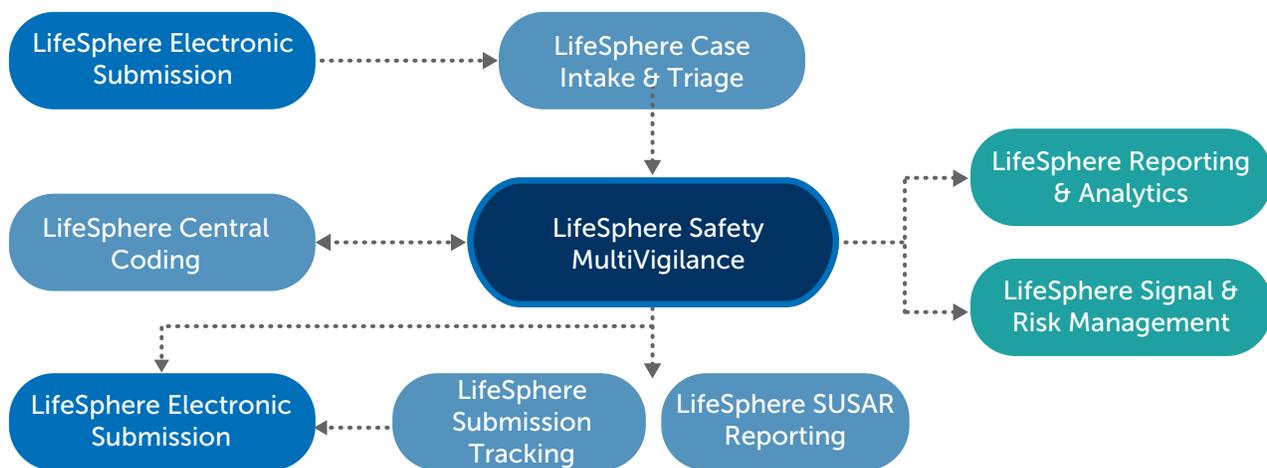
An Integrated Approach

LifeSphere Safety enables easy integration of end-to-end pharmacovigilance processes. The solution has capabilities that span case management, signal and risk management, inbound case receipt and triage, e-case submission, submissions tracking, mobile-based reporting of adverse events, reporting and analytics, centralized coding, automated triage of MAH-applicable E2B (R3) cases and veterinary safety.

Simpler, More Intuitive Process Based on Industry-Standard Best Practices (ISPs)

The solution is based on ArisGlobal's Safety ISP group recommendations. Distribution rules have been developed collaboratively, validated by customers, and implemented as out-of-box features and functionalities to transform clinical safety and pharmacovigilance into a simpler, more intuitive process.

End-to-End Cloud Platform for Safety and Pharmacovigilance



Designed for Productivity and Ease of Use

An improved, responsive user interface simplifies and speeds up the efforts. All fields in data entry screens have been regrouped to better align with typical data entry flow. Users can modify screen layout using our Screen Designer, enabling a configuration that moves with clients as they upgrade to later versions of the suite.

Intelligent process automation and digital technologies such as optical character recognition (OCR) reduce case processing efforts through automated data extraction.

Completely Mobile Enabled

Mobile applications for medical review and field reporting of adverse events streamline workload management.

A Focus on Case Processing Quality

A unified schema across the entire LifeSphere Safety platform suite and smarter validation checks that are aligned with recent regulations, and intelligent workflows with sampling logic for quality control are examples of how we improve case processing quality.

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.