

FACT SHEET
.....

LifeSphere Safety™

KEY BENEFITS

- Built-in industry best practices streamline deployment and implementation
- Cognitive computing capabilities and single sign-on across the suite and responsive user interface speed case processing
- Compliance dashboard eases monitoring
- Unified schema across the suite streamlines functionality
- Multi-tenant, cloud-based solution insulates against changing regulations and maintenance costs

Drug safety departments in life sciences companies are being asked to do more with less, without compromising quality or compliance. With case volumes and complexities increasing, organizations can no longer rely on a “same as we did last year” approach to handle today’s complex safety challenges. Supporting the demands of an increased workload with flat or reduced resources requires companies to look for an approach that can help automate case processing tasks so focus can be applied to proactive activities like signal detection and benefit-risk management.

LifeSphere Safety™: Improving Efficiency and Lowering Total Cost of Ownership

LifeSphere Safety is the multi-tenant, SaaS-based clinical safety and pharmacovigilance (PV) platform that leverages industry-standard processes to help organizations implement effective domestic and global pharmacovigilance, clinical safety and benefit/risk management programs in full E2B(R3) compliance with the latest regulations from ICH, FDA, EMA and PMDA, including all regional variations. As a cloud-based and fully validated solution, upgrades are never required to meet any current regulatory requirements, helping to lower your total cost of ownership.

The LifeSphere Safety suite covers the full spectrum of safety case needs and enhances the collection, assessment and evaluation of safety data.

LifeSphere Safety Database	Market-Leading Global Adverse Event Management
LifeSphere Signal and Risk Management	End-to-End Safety Intelligence
LifeSphere Intake and Triage	Vendor-Agnostic Inbound Case Receipt and Triage
LifeSphere Electronic Safety Submissions	Electronic Safety Messaging Exchange System
LifeSphere Submissions Tracking	Outbound Safety Submissions Tracking
LifeSphere Reporting and Analytics	Out-of-the-Box Reporting and Analytics
LifeSphere Central Coding	Centralized Coding
LifeSphere Vet Safety	Veterinary Safety Reporting

An Innovative Solution Suite

LifeSphere Safety is designed to help safety and pharmacovigilance teams succeed:

Rapid Deployment and Lower TCO

LifeSphere Safety is a SaaS-enabled and pre-validated solution on ArisGlobal's secure cloud platform, enabling quick deployment, lower total cost of ownership, easy upgrades, and inexpensive fine-tuning to facilitate quick reactions to changing regulations.

Optimized to Reflect Industry Standard Practices

ArisGlobal's Safety ISP group recommendations, including distribution rules, have been developed collaboratively, validated by customers, and implemented as out-of-the box features and functionalities to transform safety and pharmacovigilance into a **simpler, more intuitive process**.

Designed for Improved Productivity and Ease of Use

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

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

A Focus on Quality

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

Completely Mobile Enabled

ArisGlobal provides **mobile applications** for medical review and work load management.

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.