

FACT SHEET  
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# LifeSphere Safety MultiVigilance™ (ARISc)

## KEY BENEFITS

- The only pharmacovigilance and safety compliance solution with an in-built Chinese interface on the market
- Provides full compliance with ICH E2B(R3) import and export functionalities
- Single global database supporting the drug safety requirements of multiple regions with multilingual capabilities, including English, Chinese, Japanese and French
- Provides international safety reports for clinical and post-marketing surveillance
- Built with standardized inputs referred to as industry standard practices (ISP) to harmonize deployment and streamline upgrades
- Out-of-the-box support for literature management
- Accurately generates any kind of report such as line listings for easy evaluation of the risk-benefit profile including Chinese line listings
- Chinese MedDRA coding is enabled
- Lowers cost of ownership through multi-tenancy, cloud-based computing
- Automates case processing and report distribution with flexible workflows
- Compliance with all upcoming Chinese regulatory changes already planned in upcoming versions

## Full Pharmacovigilance and Safety Compliance

LifeSphere Safety MultiVigilance™ is a comprehensive adverse event management system, designed to give all life sciences companies the means to establish effective clinical safety and pharmacovigilance programs. It is a market-leading system with over 200 installations worldwide, and serving these multi-tenant cloud customers through a comprehensive platform.

LifeSphere Safety MultiVigilance offers full compliance with global safety reporting obligations for drugs, devices, cosmetics, vaccines, and biologics. This includes requirements from ICH, CFDA, FDA, EMA, CMDA, PMDA and other regulatory authorities, and all regional variations. Full compliance with both E2B(R3) import and export functionalities and complete testing undertaken with EMA for the same, gives clients confidence that they can adhere to current and upcoming regulations. The system has the electronic submission capabilities to various health authorities including CFDA. The cloud-based computing ensures the system stays up to date with all regulatory changes and developments, eliminating the need for costly and time-consuming upgrades.

The system manages reports from all potential sources, including spontaneous, literature for post-marketing safety and SUSARs and other significant events in clinical trials, with extensive support for blinded trials.

A highly configurable, intuitive pharmacovigilance system, LifeSphere Safety MultiVigilance can be deployed out-of-the-box or can be tailored to support company-specific business processes and SOPs. Seamless integration with any case management processing system is enabled through open architecture. The system leverages an enhanced user interface that supports an extensive feature set to facilitate the entry, classification, coding and assessment of adverse event reports. Chinese representation of all field labels increases the speed of data entry and built-in scoring of cases facilitates better monitoring of the quality.

## Case Handling/Workflow

The advanced workflow module allows users to route cases automatically for efficient processing. Incoming cases can be automatically placed in the appropriate workflow, and routed based on company SOPs and policies. Users are able to track who is responsible for specific actions and monitor response timeframes for all key activities such as data entry, assessment, coding and reporting for full compliance. For larger case processing teams, LifeSphere Safety MultiVigilance allows a workflow manager to assign cases to individual team members and review the activities of each individual.

## Localization

The complete user interface is available in Chinese to make it easier for users to enter and assess cases. Its multilingual capabilities allow the corresponding English translation of cases

to fulfill international reporting requirements. As a single global database, LifeSphere Safety MultiVigilance eliminates the need for double data entry, reducing time spent on translation and enhancing the management and reporting of safety cases.

Adverse events can be coded with Chinese MedDRA, allowing users to work in their native language to promote accuracy and precision in assigning codes. Interoperability between English and Chinese MedDRA is provided to make it easy to share data internationally.

## Case Querying and Analysis

LifeSphere Safety MultiVigilance provides an advanced query engine that allows users to easily create complex queries for case retrieval, analysis and reporting. It also allows users to search all LifeSphere Safety MultiVigilance fields using Boolean logic and supports case-insensitive, free-text searches. Support for the published MedDRA SMQs is also provided. Once a search is executed, it is possible to perform a variety of operations, such as case review, and to run batch operations, including validations, case updates and report generation. New interactive views allow users to view or represent data in the form of charts or listings for immediate analysis.

**Aggregate reporting –Chinese Requirements** LifeSphere Safety MultiVigilance generates line listings to meet PSUR requirements in China. The ability to have MedDRA coded adverse event data in the form of line listings and summary tabulations where adverse events are categorized according to their seriousness and expectedness facilitates easier interpretation of benefit-risk profile of the medicinal product or vaccine for which the PSUR is being prepared. Having dropdown menus and data displayed in the PSUR report in Chinese makes the process easier for users.

## Expedited and Aggregate Case Reporting- Global Requirements

LifeSphere Safety MultiVigilance provides a wide variety of expedited and aggregate reports to aid in global adverse event reporting, including the FDA MedWatch, CIOMS, PBRER, PSUR, DSUR, ASR and other major international reporting formats. For electronic exchange, the system supports the export and import of E2B files with recipient-based mapping for compliance with local deviations. To facilitate case distribution, the integral distribution server automatically determines reporting responsibilities and timelines depending upon the case detail.

## Open Integration

LifeSphere Safety MultiVigilance is an open system based on industry standard architecture. It can be easily integrated with third-party systems such as regulatory, clinical, document management and medical information systems to improve collaboration, information consistency between departments, and eliminate transcription errors

## A Proven Solution from the Market Leader

LifeSphere Safety MultiVigilance is the most complete, mature and proven drug safety software solution on the market today. ArisGlobal has continuously refined and updated LifeSphere Safety MultiVigilance in close collaboration with its customers, including many of the world's largest life sciences organizations. The system has been designed to support all Chinese pharmacovigilance regulatory reporting requirements, enabling organizations to establish a worldwide platform for pharmacovigilance and clinical safety. Ensuring companies are ready for all regulatory developments, ArisGlobal strives to support all current and future CFDA legislations, including any electronic submission regulations as China transitions to eCTD. The result: a robust, highly-configurable application designed to meet real-world market challenges, adapt to rapid industry changes and consistently deliver business value.

### 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](http://arisglobal.com) or follow ArisGlobal on LinkedIn and Twitter.