LifeSphere Signal and Risk Management™

KEY BENEFITS

- Real time safety profile employing multiple sources simultaneously

- Harmonize business process using advanced yet simple to use features offering end to end traceability from sources to actions

- Bridge operational gaps between Pharmacovigilance and Regulatory affairs

- Unparalleled qualitative and quantitative tools for data analysis and signal detection

- Streamline regulatory communications and submissions

- Reconcile safety data across sources for easy duplicate handling, missing cases identification, and cross referencing

- Leverage one safety data mart for all analytical tasks from advanced risk management to routine compliance monitoring

- Tailored dashboard for various functional roles within and across the department

- GVP compliant modules for Risk management, Signal management, Additional monitoring, and Safety communications

"LifeSphere Signal and Risk Management™ is a next generation risk management solution for your pharmacovigilance and regulatory compliance needs. Drawn from the best practices and the underlying drivers that led to changes in the pharmacovigilance regulations, LifeSphere Signal and Risk Management reinvents the way, companies define, manage, and communicate the safety profile of products from development to post-marketing. For research centers, agencies, and academia, it provides one-stop platform for assessing and monitoring the benefit-risk balance of marketed medicinal products. "

All Sources in One Place

- A well-planned drug safety program requires monitoring all potential sources of data for safety concerns. LifeSphere Signal and Risk Management's big data platform not only offers external safety sources but also provides seamless integration with in house data

- Access and perform analysis on multiple sources simultaneously

- Support for FDA FAERS*, VAERS, MAUDE Devices, Medline Literature, Company safety, Clinical, and internal data

- Reconcile company safety data with publicly available information

* FDA FAERS cleaned data is available on quarterly subscription

Cumulative Benefit-risk Assessment

- LifeSphere Signal and Risk Management offers unique portfolio driven lifecycle management that helps you characterize and monitor safety profile of medicinal products from development to post-marketing

- Pull safety profile snapshots from cumulative time periods

- Systematic framework offering full traceability from sources to actions

- Track and communicate changing benefit-risk profile to all stakeholders

Harmonize Business Process

Improve operational efficiencies, address compliance issues, and increase control by streamlining business process downstream or upstream using array of business process, productivity, and collaboration tools.

- Remove time consuming tasks through standardization and automation

- Collaborative workspace offering private and shared modes

- Improve regulatory responses through centralized tracking of all actions

Discover Trends Ahead of Time

- LifeSphere Signal and Risk Management's rich analytics and visualization suite offers you wide variety of choices to scan all potential sources for known and unknown risks. Perform in-depth analysis, annotate results, and share findings with key stakeholders

- Advanced visualization techniques delivering critical insights

- Clustered, nested, parallel, heat map, and tree based static and temporal analysis

- Explore, document, and communicate relationships in real time

Advanced Signal 5 Detection and Management

Whether it's ubiquitous disproportionality measures or complex Bayesian data mining techniques for signal detection, LifeSphere Signal and Risk Management puts you in control when it comes to leveraging the quantitative tools for the detection and management of safety signals.

- Disproportionality measures, Drug-Drug interactions, Logistic regression, EBGM/MGPS, and Mantel-Haenszel risk ratios

- Utilize static or user defined runs on stratified dataset of your choice

- Integrated workflow for effective triaging, review, and evaluation of potential signals

Ease Regulatory Submissions

Successful completion of regulatory report submissions such as DSURs, ASRs, PSR/PSURs, upcoming PBRERs and literature reports requires significant personnel involvement. LifeSphere Signal and Risk Management's "Master Portfolio" gives you leading-edge in defining and publishing "ready to use" report sections.

- Closed, ongoing, and new risks identified for a period along with routine workups

- Summary tabulations, line-listing, pivot tables, and approved action plans

- Define, generate, and share reports as per business and regulatory requirements

Performance and Compliance Metrics

- Utilize flexible business rules to intelligently gather information about deviations, bottlenecks, and nonconformance and achieve regulatory compliance by increasing the overall business efficiency

- Weekly and monthly performance, submission and compliance metrics

- Use one safety mart for both risk management and operational metrics

- Powerful querying and reporting capabilities supporting company specific fields

Streamline Regulatory Updates

- Manage and track critical updates pertaining to regulatory documents using regulatory information management interface that offers change management, versioning, and document tracking for the entire portfolio

- Risk Management plan, Core safety data sheet, SmPC, and labeling artifacts

- Track updates and actions originating from safety topics of interests

- Supports interfacing with external regulatory information management system

Role-based Dashboard

- Whether you are Epidemiologist, Safety team member, Medical reviewer, Therapeutic lead, QPPV, or Regulatory affairs personnel, LifeSphere Signal and Risk Management's rich interface and easy to customize dashboard templates give you readily accessed information at one place

- Intelligent alerting, Workspace summary, Reports, and Product safety profile

- Customizable dashboard views for various functional roles in the department

- Rich intuitive interface and dynamic controls provide information at your fingertips

ABOUT ARISGLOBAL®

ArisGlobal is the visionary technology company that's transforming the way today's most successful Life Sciences companies develop breakthroughs, and bring new products to market. Our cognitive technology platform, LifeSphere, integrates machine learning capabilities to automate all 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.