FACT SHEET

LifeSphere SUSAR Reporting™

KEY BENEFITS

- Delivers a quick return on investment by reducing labor, mailing and distribution costs
- Automates and accelerates safety report distribution and ensures compliance with international regulations
- Increases process control
- Improves efficiency through automated paperless distribution
- Improves planning and tracking of registrations
- Frees valuable staff resources for other tasks
- Improves investigator productivity

The distribution of safety reports and cover letters to investigators and IRBs/IECs (institutional review boards/independent ethics committees) is a labor and cost-intensive process for many biopharmaceutical companies still reliant on a manual process. With the notification deadline looming, expensive courier services are sometimes needed. Differing country regulations and local language requirements add to the complexity, making it very difficult to free valuable resources for other tasks and ensure regulatory compliance with confidence.

LifeSphere SUSAR Reporting™

LifeSphere SUSAR Reporting is a Web-based solution to automate the complete process of delivering and tracking safety reports to investigators, IRBs/IECs and other stakeholders. LifeSphere SUSAR Reporting is fully integrated with ArisGlobal®'s LifeSphere Safety Database (leading safety database) and LifeSphere CTMS (comprehensive CTMS) or can be linked to third-party CTMS and safety databases.

Automatic Distribution

Using LifeSphere SUSAR Reporting, companies automatically and securely distribute clinical safety reports, including SUSARs (Suspected Unexpected Serious Adverse Reactions) and aggregate reports like line listings in support of differing regulatory obligations. For a single adverse reaction, different report types such as CIOMS or FDA 3550A (blinded or un-blinded) can be uploaded and distributed so that each investigator receives the required report type. Users can easily prepare reports for distribution and have workflow-driven review and approval of recipient lists generated by the system. Report distribution can be limited to a single study or performed across studies at the product/substance level.

Cover letters, which can be produced in the native language, are generated automatically based on user-defined templates, with different templates available for different countries.

LifeSphere Clinical™ - eClinical Platform
LifeSphere EDC™
LifeSphere CTMS™
LifeSphere Investigator™
LifeSphere Trial Disclosure™
LifeSphere Central Coding™
LifeSphere eTMF™
LifeSphere SUSAR Reporting™
LifeSphere eCOA™
LifeSphere RTSM™
agWorld™ - eClinical Portal

Investigator Friendly

When a report is distributed, the investigator is notified via email that a new safety report is available. Investigators can select their preferred method of receipt, and if they do not have reliable access to the Internet, postal/courier, fax and email-based distribution are supported, including automatic tracking of successful or failed fax or email transmissions.

Distribution Tracking

LifeSphere SUSAR Reporting is compliant with 21 CFR Part 11 and helps sponsors and CROs to ensure compliance with international regulations. Sophisticated reporting capabilities allow managers to keep processes under control. Detailed transaction history reports can be easily produced for audit purposes or to generate the documentation for the TMF (trial master file). Automatically generated, configurable reminders guide an investigator to any safety information that may have been missed.

LifeSphere SUSAR Reporting automatically tracks the date the investigator opens and reads the report via the Web-based investigator portal and informs the sponsor about delivery failures such as due to an invalid e-mail address or fax number. Searching, sorting and filtering capabilities allow the user to easily find information and navigate through the safety reports and, within a selected report, through the list of recipients.

The distribution reports give further insight into the submission activity. Users can adapt the distribution reports to their needs by specifying which product, study, country, site, safety report, time frame and/or status of the acknowledgement are to be included.

Integration with Safety Database and CTMS

LifeSphere SUSAR Reporting provides out-of-the-box integration with the LifeSphere Safety Database adverse event reporting system. Once a case qualifies for expedited reporting, pharmacovigilance users can easily send the case from the safety database to LifeSphere SUSAR Reporting for further processing. LifeSphere SUSAR Reporting also provides out-of-the-box integration with the LifeSphere CTMS, utilizing the data typically stored in the CTMS for automatic generation of distribution lists. Integration to other Safety and CTMS and safety solutions are available using Web services.

Hosted Offering

LifeSphere SUSAR Reporting is available as a hosted solution on the agOnDemand platform, helping companies meet compliance and management requirements with ease.

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.

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