

FACT SHEET

LifeSphere EV Triage™

KEY FEATURES
Importing Zip File

- Automated pooling - Zip files from a folder
- Provision to Upload Zip file downloaded from EVWEB

Smart Analysis – Auto Matching

- Direct match
- Fuzzy match
- Synonym Search
- Narrative Analysis
- Matching against local corpus
- Corpus Sync with Safety Product library
- Seamless Safety database match with product library
- Auto import of direct Match's
- Auto updating of local corpus

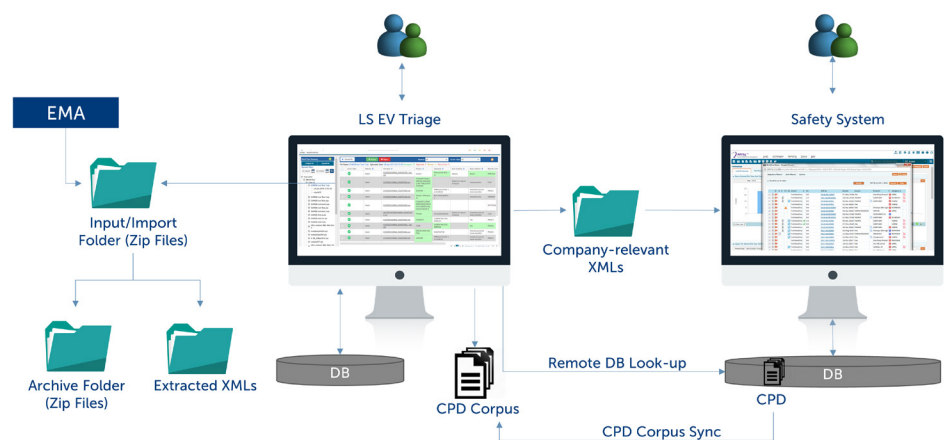
Reconciliation

- Reconciliation Report generation based on date range.

Automated triage and reconciliation of MAH-applicable E2B (R3) cases from EVWEB

Today's global Marketing Authorization Holder (MAH) now downloads cases from EVWEB based only on the active substance as per the hierarchy of XEVMPD. The vast majority of downloaded cases are not relevant, requiring significant time and effort to review and determine which ones are specific to a MAH's products before triage can begin.

LifeSphere EV Triage is the plug-in tool (multi-tenant cloud-based or on-premise, based on customer preference) that automates the triage and reconciliation of applicable ICSRs from other non-specific cases. It can be used with any pharmacovigilance (PV) system or E2B converter, and is fully integrated with ArisGlobal's LifeSphere Safety MultiVigilance™ and LifeSphere Intake and Triage™ solutions.

Automated Process Speeds Triage and Reconciliation


MORE FEATURES

Intuitive User Interface

- Date-wise segregation of processed zip files
- Summary of each download - zip file
- All the matching attributes in single listing
- Easy visualization on Matched Attribute, Relevance, Action Taken, and more
- Ease of data exchange - Export to Excel
- Easy Filters – on action taken and relevance

Configuration

- Filtering rule - Configuration
- Configuration of Import/Export Folders
- Integration with Safety system

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.

Giving PV Teams and CROs More Time to Focus on More Critical Tasks

LifeSphere EV Triage eliminates the significant time spent examining Excel spreadsheets to find which ICSRs are relevant to a company's product(s), giving both internal PV teams and CROs faced with high volumes of adverse events time to focus on more critical tasks than segregating cases manually by eye. An intuitive user interface provides date-wise segregation of Zip files, a summary of each download, matching attributes in a single listing, easy visualization and data exchange, and easy filters for action taken and relevance.

Automated ICSR Segregation of Applicable Cases

After downloading the XML ZIP file from EVWEB, LifeSphere EV Triage unzips them and runs an auto-match algorithm that quickly identifies the applicable product-specific tags. Based on those tags, incoming reports are either tagged as Applicable ICSRs or as Potential ICSRs. All Applicable ICSRs are sent for further processing to either the company's PV system of choice or E2B converter tool. Potential ICSRs are automatically archived for future reference.

CPD with Local Corpus

For better application performance, LifeSphere EV Triage maintains local corpus of company products and their attributes (trade name, substance, form of admin, route of admin and authorization country). During the E2B(R3) triage process, the tool considers the local corpus to segregate company cases from other company cases, eliminating the need to interact with the safety system database. The sync between LifeSphere Safety MultiVigilance CPD and EV Triage corpus is out of the box.

Remote Safety Database Lookup for Products

For any product combination not found in the local corpus, EV Triage comes with a configuration to look into safety system database of CPD. It will bring any match found into the local corpus before processing the XMLs. For Lifesphere Safety customers, the remote database look-up feature is out of the box.

Streamlining the Reconciliation of ICSRs

EV Triage streamlines reconciliation by extracting data, if needed, and then checks how many ICSRs were received, imported and rejected. A reconciliation report is generated based on data range.