Aris Global®
Product Overview

agXchange™
IRT and OST
Inbound Receipt and Triage
Outbound Submissions Tracking
agXchange IRT™

The traditional method of responding to adverse event reports, as and when they arise, has been replaced with proactive safety surveillance measures. As a result, most life sciences companies now deal with a large influx of potential adverse event reports (items) from a variety of sources, both centrally and at local affiliates. All these reports need to be reviewed, categorized and assessed for case processing and reporting.

One of the biggest problems facing all life sciences companies is dealing with the vast number of reports received. Further complicating the process, potential reports can be received in a variety of formats through different routes with varying degrees of quality, often in different languages.

Reports can generally be categorized as structured (e.g., E2B) or unstructured (e.g., fax or paper). Regardless of the source, format, or content of the report, it is essential to assess each report and track all follow-up activities.
Inbound Item Receipt

The agXchange IRT module enables life sciences organizations to more efficiently collect and process safety information from any source, including affiliate locations, license partners, CROs, physicians, and the patient/consumer.

agXchange IRT enables you to capture both structured and unstructured potential adverse event reports from a variety of sources over different communication media, including fax, email, postal mail, an electronic data interchange gateway, or online Web form entry. Available information/documents, e.g., faxes, attachments, emails, Web form, etc., are automatically converted and stored as source documents.

**Structured data receipt**

Typically, structured data refers to the receipt of electronic reports in a defined format such as E2B XML, or data pulled from other databases (e.g., CRM or CDM databases). agXchange IRT includes a built-in ETL (extract/transform/load) tool that allows you to bring data from other databases directly into the IRT database. With Aris Global’s agXchange ESM™, E2B reports received via an ESTRI gateway can be directly routed for processing in agXchange IRT, in the same way as other non-E2B safety reports.

agXchange IRT also supports the creation and deployment of data entry forms for the online submission of adverse event reports from affiliate or clinical study locations. These online forms can be designed suitable to the source of the report, e.g., investigators, affiliates/partners, CROs or internal medical representatives, to simplify the reporting process.
Unstructured data receipt

Handling of unstructured data such as emails, faxes and paper reports is obviously more difficult and time consuming.

Many reports are received via these traditional routes, and each report needs to be processed in the system. agXchange IRT facilitates this process by supporting integration with fax and email servers to allow reports to be received and indexed automatically. Further, an embedded OCR capability allows pre-defined index fields to be picked up from faxed (form) documents. Index fields can also be picked up from an email subject header. The indexed fields can then be used for categorizing and routing documents appropriately in the workflow. The field values may also be carried forward to the assessment (triage) form. Additional features include document splitting (to create multiple items), version control, check-out/check-in to allow redacting private information.

When a potential adverse event report is received, users can check against the existing cases in both the IRT database and the safety database to prevent duplicate case entry. If information is for follow-up action, it can be assessed and forwarded as appropriate.
**Assessment/Triage**

Once an item is received, the user can enter an initial report assessment to determine if the required data is available for a valid adverse event report. This can be supported using a simple assessment/triage form with a limited set of data entry, or the complete assessment, including entry of the available case data. Assessment forms can be designed to support customer triage processes. Different forms may be utilized for clinical, post-marketing and other reports.

Assessment

If there is insufficient data or the data quality is suspect, the user can track any follow-up activities and/or queries related to the received report.
Communication/Notification Tracking

agXchange IRT supports communication with external and internal parties as part of follow up with queries on the received items. Fully integrated with email and fax systems, the communications module allows users to send and receive communications and track follow-up activities.

Centralized tracking of communications between the safety department and the affiliate locations ensure that requests for clarification or additional information are adequately monitored.

Upon assessment, appropriate individuals can be notified about the received report.

![Notification tracking form](image)
Workflow

An internal workflow can be defined to process the inbound item. The workflow can be configured to support both local and headquarter processes.

After completion of all workflow activities, based on the item assessment, the item may be disposed appropriately. The assessment determines whether to create a new case in the safety database (ARISg), add the report as a follow-up to a previous case, forward it to another system (e.g., a product complaint or medical inquiry system), or archive the report for future reference. When the case is promoted to ARISg, all data, documents and communication logs are also transferred to the ARISg database.

As an additional benefit, agXchange IRT allows organizations to more closely integrate their affiliate offices into the process of collecting and processing safety information without requiring access to the centralized drug safety system.
With most pharma companies operating in a global environment, local or regional regulatory reporting responsibilities are typically managed by local safety offices. These offices are accountable for local compliance and need to be inspection-ready for demonstrating appropriate tracking systems and processes are in place for supporting local regulatory compliance.

Working with limited resources, local safety offices need to ensure timely safety submissions to their local regulators and partners once safety cases are ready for reporting. Report recipients may need to be informed using different report formats and via different media, such as fax, email, ESTRI gateway, etc.

In conjunction with the agXchange IRT module, agXchange OST – Outbound Submissions Tracking – enables automated handling of all safety items from initial receipt to final submission to appropriate regulators and partners.

**Ready-for-Reporting Case List**

Upon completion of processing in the safety system (ARISg) workflow, cases can be automatically routed to agXchange OST for final review, reporting decision and submission by the local offices.

The ARISg distribution server rules determine which cases and reports are routed to the agXchange OST inbox of an affiliate office. The listing distinguishes between submissions to health authorities and to partners. For each submission, the report in the appropriate format is available together with the cover letter.
Reporting Decision
The cases can be routed through defined workflow steps for review and reporting decision. Key case data and attached report are available to facilitate these activities. The user may make the reporting decision at the case level or at the recipient level. This way, the local office can get an additional level of control over submission to only qualifying recipients based on local assessment.

Sender’s comments or reason for not reporting can be captured as part of the submission decision.

Submission
Upon completing the reporting decision activity, the reports are submitted using the appropriate media associated with each recipient. The system supports automated submission by fax, email, or (in conjunction with agXchange ESM) via E2B gateway.

Queries/Communications Tracking
The agXchange OST module shares the communications module with agXchange IRT (and with ARISg - planned). This allows the local office to track and post-submission queries/questions from regulatory authorities and partners.
**Contact Us**

agXchange IRT and OST are part of Aris Global’s Total Safety™ suite of integrated software solutions that enable life science organizations, regardless of status or size, to implement effective domestic and global pharmacovigilance, clinical safety and risk management programs. Used by more than 300 companies worldwide, including 24 of the top 50, ARISg is recognized as the world’s leading clinical safety and pharmacovigilance system. For more information about agXchange IRT or to schedule a demo, please visit www.arisglobal.com/contact_us.php or call +1 203 588 3000 to speak to an Aris Global representative. More details on how to reach our offices are provided on the back cover.
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