Case Study: SAE Reconciliation

thoughtsphere

THE SMART WAY TO RESULTS

SAE Reconciliation

To run safe, efficient, and compliant clinical studies, companies need tools for risk assessment that are easy-to-use, even if you aren't a statistician or scientist. They need a way to recognize and interpret clinical data easily so they can make smart and fast decisions about clinical trial processes. ThoughtSphere's holistic approach to risk assessment drives measurable results for its users.

The Challenge

This large global pharma company needed a strategy for reconciling AE data from EDC with SAE data in the safety system that would make integration faster and analysis easier. Specifically, its goals were to:

- Provide a reporting/visualization solution that would be used to provide non-statisticians with access to clinical safety data for benefit risk assessment
- Run reports and perform exploratory analysis on a regular basis to perform clinical safety review and signal detection.
- Provide early access to clinical trial data to support early signal detection in diverse source systems for both ongoing trials in Oracle Clinical and RAVE and completed trials in legacy data repositories.

The ThoughtSphere Solution

ClinDAP and ClinACT are one-of-a-kind clinical data lake, interactive visualization and analytics platform that allows users to manage and integrate data from any data sources to gain a holistic view of study progress and to identify potential risks sooner. The solution included:

- Design and development of a cloud-based clinical data lake for ingesting data from diverse systems across three organizations.
- Development of interfaces between various source systems (Oracle Clinical, RAVE, legacy systems) and the central data hub.
- A visualization platform and a library of validated, ready-to-use report templates for both signal detection and interactive safety review, including export capabilities for graphs.
- The ability to derive insights from aggregated data and recognize early indications/safety signals for studies being profiled.

The Results

The pharma company achieved its goals and benefited from:

80% speed of safety data access

80% faster compound safety profile characterization

75% in required change control processes

The Results

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- Reusable Data Transformation Engine across multiple clinical trials/therapeutic areas
- The ability to derive actionable insights through seamless integration with analytics tools.
- The ability to glean insights into benefit risk assessment for strong business impact via product go/no-go decisions.
- Metadata Driven, Dynamic and Automated Solution
- Framework for data mining & innovative future capabilities