CERTARA

Optimized Pre-clinical Informatics for Faster, Surer Development Decisions

A top 40 pharmaceutical company enhanced data access and decision support for pre-clinical safety with Certara's D360 data access and analysis application and a specialized CDISC SEND-based database

Background

Pre-clinical scientists at a top 40 pharmaceutical company faced delays of a day or more for data collation and transformation with each incremental data update received from their Contract Research Organizations (CROs). Data arriving in spreadsheets or PDF study reports needed to be merged, copied, pasted and formatted for analysis and presentation—a time-consuming and error-prone process. The increasing use of CDISC® (Clinical Data Interchange Standards Consortium) SEND (Standard for Exchange of Nonclinical Data), while a richer data format, posed additional data manipulation issues. Further, inconsistent terminology in use across CROs and studies complicated data preparation. The requirement for manual data preparation delayed decisions on adjustment or continuation of on-going studies, while the nomenclature differences made it nearly impossible to compare and analyze data across different studies.

Challenge

The delayed availability of new information impacted study monitoring, slowed learning about candidate drugs, and delayed critical early development decisions. In addition to problems in monitoring on-going studies, responding to FDA and project team questions proved especially challenging, requiring tedious adjustments to resolve inconsistent field names and units before trends across studies could be evaluated for potential biomarkers and deeper scientific understanding.

The team sought faster and richer access to new study information in order to speed understanding of data trends, adjust or cancel ongoing studies based on incoming data, and better monitor CRO protocol adherence.

Certara created a custom database application to capture data from the varied incoming formats (including SEND and CRO-specific custom data formats) and standardize it using a SEND-like schema with rich metadata. The solution enabled mapping of data fields with conflicting terminology to a common name space for analysis. It included validation of incoming data, alerting the researcher to problems on upload.

Challenge

Pre-clinical scientists wanted immediate, direct access to the latest study data to support faster, more informed development decisions.

Solution

PCSS and D360 enabled the scientists to quickly upload data and then immediately start data exploration and analysis with standardized terminology applied.

Benefit

The informatics platform reduced the time needed for data manipulation, querying and reporting from days to minutes without the need for IT support.

Together, the new database and D360 enabled the scientists to quickly upload data from SEND files, and other custom formats such as spreadsheets using a simple web interface. Immediately after upload, the data became available for exploration and analysis with standardized terminology applied. The system now allows scientists one-click access to their standard data views and self-service access to ad hoc data querying furthering their ability to identify scientific trends across multiple studies.

Benefit

The pre-clinical team's new, self-service informatics platform reduced the time needed for data manipulation, querying and reporting from days to minutes without the need for specialist IT support. The team could now explore, understand and act on new trends in study data within hours of receiving updates. The D360 interface provided the scientists with direct, real-time access to the most recent information for analysis and exploration. Standardization of terminology enabled data queries to be built quickly and simplified analysis across studies from different sources, while also reducing the risk of errors in data processing and interpretation.

Impact

Faster and more-efficient information access using D360 and the new safety database not only reduced tedious tasks and error risk, but also encouraged further exploration of trends for faster, better-informed decisions. Pre-clinical scientists can access data within minutes of receipt from a CRO. On-going studies can be assessed and adjusted with same-day turnaround, and FDA and project team questions can be answered in minutes rather than days or weeks. It was most notable that the D360-PCSS system was employed for real research work well in advance of its official production deployment.

The CDISC SEND pre-clinical safety database is now available from Certara as the Pre-clinical Safety Store™ (PCSS). In tandem with Certara's D360, this solution enables internal groups and CROs to access and analyze pre-clinical data quickly and easily, improving the effectiveness of pre-clinical studies and the success of future clinical trials.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.

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