CERTARA

Cross-study Search and Analysis of Pre-clinical Safety Data

Certara's D360 enables scientists to focus on uncovering trends in their data, without the pain of figuring out how to access it

Background

A global top 10 pharmaceutical company, devoted to discovering new medicines and new technologies for managing personal health, engaged in an initiative to better address cross-study analysis of pre-clinical safety data.

Challenge

Toxicologists, pathologists, and pre-clinical study directors regularly examined safety data to investigate data trends across multiple studies, draw correlations between results and exposure, and design future studies but were frustrated by the inability to effectively access and analyze the data according to their individual needs.

Safety data was stored in multiple sources which were not integrated, making data mining across these sources difficult, if not impossible. Scientists were required to perform their analyses in multiple applications, increasing the possibility of introducing human error. Existing tools restricted data analysis to one study at a time, making cross-study analysis of the data extremely tedious and time-consuming. Searching the historical control data to answer questions from regulatory agencies required manually reviewing previous study reports, resulting in days to weeks of effort.

Drawing correlations between findings and drug exposure required manually extracting data from several reports into a common table due to the disparate sources in which the data resided. Investigating time-dependent trends in the data required extracting data study-by-study into other applications and then manipulating the data to create the necessary graphs. It was not uncommon for a scientist to present data to answer these questions and have fellow colleagues unaware of how the presenter gathered this information.

Solution

After an extensive competitive review process of multiple vendors, the customer chose Certara's D360 as its enterprise solution for conducting single-study and cross-study search and analysis

Challenge

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Solution

Researchers used D360 to easily query and analyze data from multiple studies simultaneously.

Benefit

Pre-clinical drug development, including cross-study analysis, can proceed with fewer delays.

of pre-clinical safety data citing D360's easy-to-use interface, Certara's workflow analysis, and Certara's understanding of the end users' needs as deciding factors.

Benefit

Certara worked closely with the company's project team to configure D360 so end users could easily query and analyze data from multiple studies simultaneously without requiring IT intervention, and have the results presented in a manner they preferred.

Previous workflows that required days to weeks of effort could now be performed in minutes. Scientists could now access data via a single application rather than extracting it from multiple reports. The search, visualization, and analysis of data could be performed in a single application rather than exporting and merging data from multiple applications.

Impact

Pre-clinical drug development, including cross-study analysis, could proceed with fewer delays and with a greater understanding of the safety data related to that drug. Study teams could spend less time researching their questions and more time examining the meaning of their answers.

Questions from regulatory agencies could be answered much more quickly and effectively. IT is provided with an application that has a low cost of maintenance and is easily adaptable as the amount of accessible data or the number of users increases over time.

Researchers can perform more in-depth analysis of both current and historical safety data, asking questions of the data that were previously not feasible.