CERTARA

Driving Efficiency and Impact with Comprehensive PK/PD Solutions

Overcome outdated system incompetence and revolutionize your analyses

Background

A global biopharmaceutical organization committed to developing and delivering innovative medicines that help patients prevail over serious diseases. Through excellence and rigor in scientific research, this Certara customer provides innovative, high-quality medicines that improve patients' lives.

Challenge

For the past decade, research scientists at this company developed on a manual system for pharmacokinetics and toxicokinetics (PK/TK) analysis. The tool was static, unstable, and required extraneous data manipulation, which increased the opportunity for human error. The system was unable to handle large datasets, which were critical to research studies, or streamline data to automate PK/PD or TK analysis and reporting.

The rigidity of the system did not allow for consistency or standardization within or among studies, which made for significant inefficiencies in basic analysis, reporting, and regulatory submission. Not only was the tool impractical, but it was also being discontinued in both development and support by the vendor.

With increased regulatory requirements placing higher demand and time constraints on scientists, as well as a continual need for transparency and ease of information sharing, the organization required a scalable system that ultimately enabled efficient data analysis to inform faster decision-making and kept the company's time to market competitive. The project had the added complexity of requiring the repository of data and system to be replaced within a three-year timeframe.

Solution

The client selected the Phoenix Knowledgebase Server and Phoenix WinNonlin from Certara to create a comprehensive solution that enabled both streamlining and automation of pharmacokintec/pharmacodynamic (PK/PD) and TK analysis and reporting, while also consolidating

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Solution

The Phoenix Knowledgebase Server and Phoenix WinNonlin from Certara created a comprehensive solution that enabled both streamlining and automation of PK/PD and TK analysis and reporting, while consolidating the analysis itself. By leveraging the right set of technology as part of a complete platform, the customer was able to engage in more impactful quantitative decision-making.

the analysis itself. By leveraging the right set of technology as part of a complete platform, the customer was able to engage in more impactful quantitative decision-making by providing researchers with:

- An intuitive interface for data management, plotting, non-compartmental analysis, individual compartmental PK/PD modeling, bioequivalence tests, table creation and other PK/PD work.
- Scalability that allowed for more than 40 users for large, complex datasets.
- The ability to visualize work performed in a diagram where dependencies between steps are highlighted, allowing for continuity within a single study.
- Secure and traceable distributed access to study data, analyses, and reports.
- Validated storage of data and analyses for regulatory submissions.

Benefit

Researchers are now able to save several hours per study by leveraging faster analysis and reporting, making for generally more efficient studies. The new system not only eliminates manual data manipulation, which results in fewer errors identified in quality reviews, but also is able to handle large datasets and more complex data input. The comprehensive tool allows for a much more seamless collaboration process with all data in one location, with full visibility into the study and analysis data. Researchers can more easily share data with regulatory agencies for improved compliance and more successful auditing.

Impact

With an initial deployment, this organization has already seen baseline savings in both time and money. Researchers were able to take on 14 additional studies despite having additional requirements to satisfy per study with the ability to import, analyze and report data in a more comprehensive environment that does not require heavy manual computation, thereby decreasing the opportunity for error. Time saved can now be reinvested in the studies to drive the quality of output.

Benefit

The new system not only eliminates manual data manipulation, which results in fewer errors identified in quality reviews, but also is able to handle large datasets and more complex data input more quickly and more efficiently.

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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