

Implementation of a Compliant Clinical Data Repository in 21 Days

Certara's PKS Online enabled PKPD Bioscience Inc to become regulatory compliant and enhanced partnering with pharma companies

Background

PKPD Bioscience Inc is a specialized pre-clinical/clinical pharmacology and pharmacometrics contract research organization based in Exton, Pennsylvania. They provide computer-based data analysis and modeling and simulation consultancy services to pharmaceutical and biotech companies.

Challenge

Scientists from PKPD Bioscience Inc perform their non-compartmental and compartmental analyses of pharmacokinetic/pharmacodynamic (PK/PD) study data using Certara's Phoenix WinNonlin. While they appreciated WinNonlin's comprehensive analysis environment, workflow templates, and its ability to create high quality outputs, they were spending too much valuable time on tedious and labor-intensive management of paper trails associated with regulatory documentation for study data.

They sought a secure, electronic, regulatory compliant, clinical data repository. But being a small organization, they didn't have the internal IT resources to build one in-house. Their ideal solution would also manage their project data efficiently.

Solution

After researching the FDA guidelines for 21 CFR part 11 and documenting their Master Validation Plan and User Requirement Specifications, PKPD Bioscience Inc purchased Certara's Phoenix Knowledgebase Server (PKS) Online. The PKS Online data repository provides support for 21 CFR Part 11 compliance, and offers audit trails and version control. It enhances productivity and supports compliance requirements by managing complex time-based data, the foundation for all PK/PD modeling. Since PKS monitors each cell in the database, the user is notified if any underlying data has been modified prior to running a new analysis.

Challenge

PKPD Bioscience Inc was spending too much valuable time on tedious and labor intensive management of paper trails associated with maintaining 21 CFR Part 11 compliance.

Solution

Certara deployment staff assisted with the implementation, validation, and training for PKS Online, Phoenix WinNonlin, and Phoenix Connect.

Benefit

Adopting PKS Online has allowed them to efficiently manage their data, achieve regulatory compliance, and meet their project deadlines.

With the assistance of Certara's deployment staff, PKPD Bioscience Inc was able to complete the implementation, validation, and training in only 21 days. First, Certara deployment staff set up the user account for PKS Online. Then, the client's staff used the Phoenix WinNonlin Validation Suite to perform onsite validation, including generation of the validation run report, validation summary report, and testing summary report with deviations from automated scripts, in only one week. Next, they validated Phoenix Connect in a day and connected PKS Online the next day. Finally, PKPD Bioscience Inc staff completed two 3-hour PKS Online end-user training sessions.

While PKS Online addresses the technical control requirements for a Part 11-compliant computer system, the customer still must implement the Part 11-required procedural controls. Certara deployment staff helped the client implement the procedural controls by providing the required standard operating procedures and other relevant documentation.

Benefit

Adopting PKS Online has allowed PKPD Bioscience Inc scientists to meet several goals regarding their data infrastructure. The overall solution has improved data traceability, decreased the overhead for file management, and streamlined QC/QA processes. Because PKS Online is a fully validated hosted solution, they were able to avoid the time and expenses of custom deployment and continuous IT support.

Impact

Successful implementation of PKS Online supports PKPD Bioscience Inc scientists by providing a regulatory compliant, streamlined clinical data repository. This enables them to spend less time managing their data infrastructure and helps them to meet project deadlines more quickly and 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.

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