CERTARA

Phoenix Knowledge-base Server

Recent analytical advances support more rapid and detailed collection of pharmacokinetic/pharmacodynamic (PK/PD) data at the component/mechanistic levels of absorption, distribution, metabolism, and excretion (ADME). This flood of new knowledge—relating to both existing compounds and new chemical entities—must be securely captured, stored, managed, analyzed, summarized, reported upon, and submitted to regulatory authorities. However, often little technical infrastructure exists to effectively and securely manage this information (and the associated analysis results) on an enterprise level (ie, on the level of a complete development program or indication).

Certara's research data management system, the Phoenix Knowledgebase Server (PKS), provides a platform for improved data management and access, productivity benefits for analysis and reporting tasks, in addition to compliance with Food and Drug Administration (FDA) Electronic Records/Electronic Signatures regulations. When deploying PKS as an integrated environment that includes AutoPilot Toolkit for Phoenix, companies can automate routine analyses and standard report generation and realize substantial efficiency gains.

Deployment of a comprehensive and accessible PK/PD research knowledge management system provides a foundation for a more rational and cost-effective drug development process, both improving scientific productivity and reducing information management overhead.

Support for leading modeling and analysis tools

PKS is directly integrated with Certara's industry-leading PK/PD modeling and analysis tools Phoenix WinNonlin and Phoenix NLME as well as other desktop tools such as SAS, S-Plus®, R, and NONMEM® through a plug-in that is part of the Phoenix Connect product. Phoenix, SAS and NONMEM users can easily access data loaded into PKS studies, and then create one or more analysis scenarios that capture the models, parameters, and modeling results from each session.

File formats of any type (ASCII, JPG, DOC, etc) can be saved and loaded into PKS to support capture of output from a wide variety of visualization and analysis tools. Analysis and modeling results are linked back to the underlying study data, to enable out-of-date results to be flagged and updated when study data change.

Clients for NONMEM, SAS, and more

PKS is closely integrated with Phoenix Connect, a Phoenix-based desktop application to manage and execute SAS, NONMEM, S-PLUS, R, and SigmaPlot files and analyses as part of PKS studies and scenarios. Using Phoenix Connect, users can create workflows that include WinNonlin and SAS or NONMEM analyses, get data from PKS, run the analysis and store the results—all in a compliant and validated workflow.

Benefits

- Productivity support for data management, analysis/modeling, reporting, and collaboration
- Secure data warehousing for critical early drug development data and analysis results from Phase I, ADME, toxicity, drug metabolism, and pharmacokinetic and pharmacodynamic (PK/PD) research
- Modern, scalable, and proven three-tier architecture based on Java™ and XML with a secure Oracle® database back-end

Highlights

- **Client Access:** Use Phoenix Connect for integrated access to study data and analysis results with Phoenix WinNonlin, Phoenix NLME, and the plug-ins for NONMEM, S-Plus, R, and SAS
- **Web Browser Client:** Standard Web browser allows access to data and analysis results as well as administration features
- **Flexible Data Handling:** Integrated tools allow to easily query and merge datasets from multiple studies to support meta-analysis and data mining
- **PKS Connectors:** Batch automated loading of data from other data management systems such as Oracle® Clinical, Clintrial™, and Watson™ LIMS™ databases as well as from data file formats such as Microsoft® Excel® and CDISC/SDTM
- **PKS Clients for Word/Excel:** Integrated support for Microsoft Excel and Word®, allowing files to be captured and versioned, with audit trails and reason for change
- **21 CFR Part 11 Compliance:** PKS provides the technical controls for 21 CFR Part 11 compliant use of Phoenix-based and other analysis and modeling tools

Secure Data Management

PKS provides Oracle-based security to control and track access to your data.

PKS Libraries and Shares

Share standard analysis scripts and settings across your organization through the PKS library and share features.

PKS Query Tool and Data Explorer

The PKS Query Tool and the Data Explorer are data mining tools to support and automate comprehensive cross-study and cross-analysis queries for use in later meta-analysis activities.

PKS Data Connectors

PKS Data Connectors provide automated loading of study data from various sources such as data management systems, LIMS (laboratory information management systems), legacy databases, and other data sources. The PKS Data Connector can be configured for common data management systems, such as Watson and Oracle Clinical, as well as for data files from Microsoft Excel or that are formatted in the Study Data Tabulation Model (SDTM) standard as defined by the Clinical Data Interchange Standards Consortium (CDISC) organization.

Audit Trail

PKS tracks all changes to study data and scenarios. For each change, PKS records the specific change made, with the time, date, user and change reason.

Archive and Restore

Create secure archives of study data that can be removed from your production database or restored as needed.

AutoPilot Toolkit for Phoenix

Certara's PK automation product, sold under separate license, can automate routine analyses and the creation of PK output (tables and graphs) that are required for standard reports. AutoPilot Toolkit is integrated into the Phoenix framework and will work with projects that are loaded from PKS scenarios as well as on local Phoenix projects. When a project is saved, the created PK output automatically is saved as part of the project—putting the source data, the non-compartmental analysis setup and results and the tables and graphs all in one place.

21 CFR Part 11 Compliance

In combination with your standard operating procedures, PKS helps to achieve full compliance with FDA regulation 21 CFR Part 11 (Electronic Records; Electronic Signatures; Final Rule). PKS uses electronic signatures, reason for change capture, and comprehensive audit trails to store and manage PK/PD data and analysis results from WinNonlin and other analysis tools. PKS is intended to be validated as a "closed system" compliant with Electronic Records; Electronic Signatures; Final Rule (21 CFR Part 11) and Guidance for Industry—Computerized Systems Used in Clinical Trials, deployed on a pharmaceutical R&D organization's intranet.

System requirements

Server requirements

- Processor: Intel® Pentium® III
- Memory: 1,020 MB
- Hard Disk: 20 GB

Database

Oracle 10g R2, 11g R2 (US Enterprise and Standard Edition)

Middle tier

Apache Tomcat® Server 5.5 and 6.0 or Oracle WebLogic 9.2, Java JDK 1.5, a middle tier and database server operating system that supports the required third-party software is considered a supported operating system. Desktop system requirements apply as defined for the respective desktop software products.

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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