

# PHARSIGHT® Knowledgebase Server™ 4.0.2 (PKS™)

## 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 backend

## 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®. PKS is also backward compatible to WinNonlin 5.x versions.
- > **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 data sets from multiple studies to support meta-analysis and data mining
- > **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
- > **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 Reporter:** Template driven authoring of compound documents containing tables, text, and graphics with live links into the PKS database supporting electronics signatures for review and approval (sold separately)
- > PKS provides the technical controls for 21 CFR Part II compliant use of Phoenix-based and other analysis and modeling tools

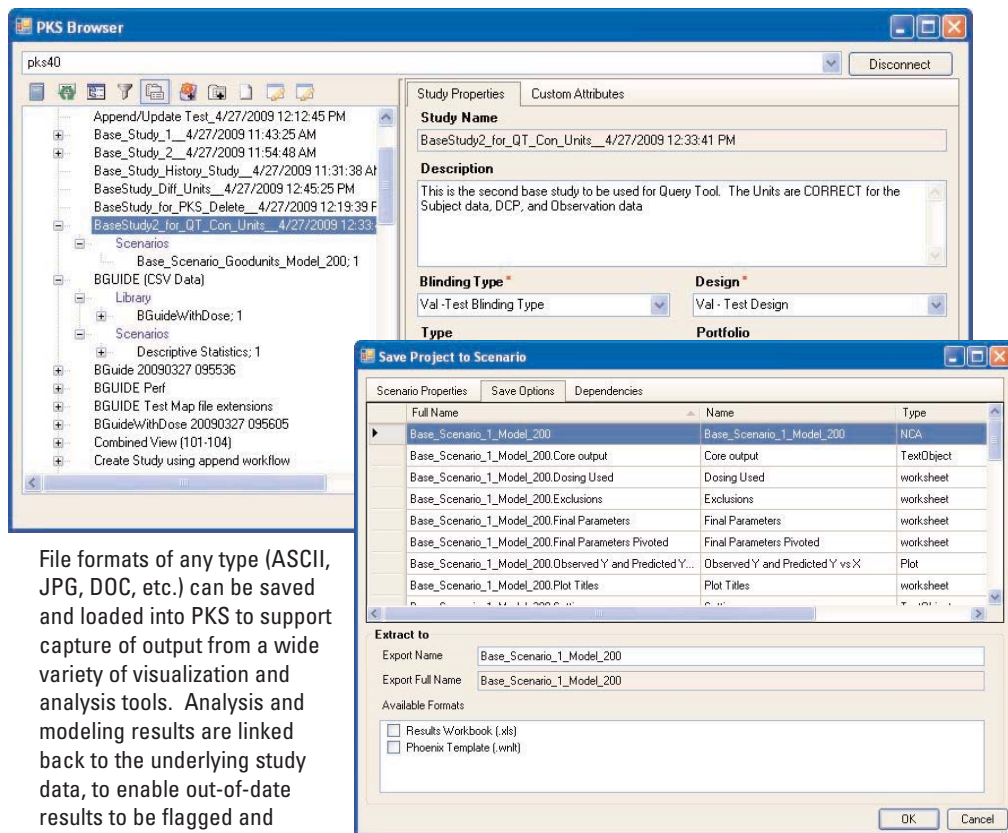
Recent analytical advances support more rapid and detailed collection of pharmacokinetic/pharmacodynamic data at the component/mechanistic levels of absorption, distribution, metabolism, and excretion (ADME). This flood of new knowledge – relating to both existing compounds and new chemical entities – 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 (i.e. on the level of a complete development program or indication).

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

Pharsight believes that deployment of a comprehensive and accessible PK/PD research knowledge management system will provide 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

Pharsight Knowledgebase Server is directly integrated with Pharsight's industry-leading PK/PD modeling and analysis tools 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. WinNonlin, 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. For a smooth migration process from previous versions, PKS 4.0.2 is backward compatible to WinNonlin 5.x Enterprise and the PKS Clients 3.1 releases.



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.

