

PHARSIGHT®

PKS Online

BENEFITS

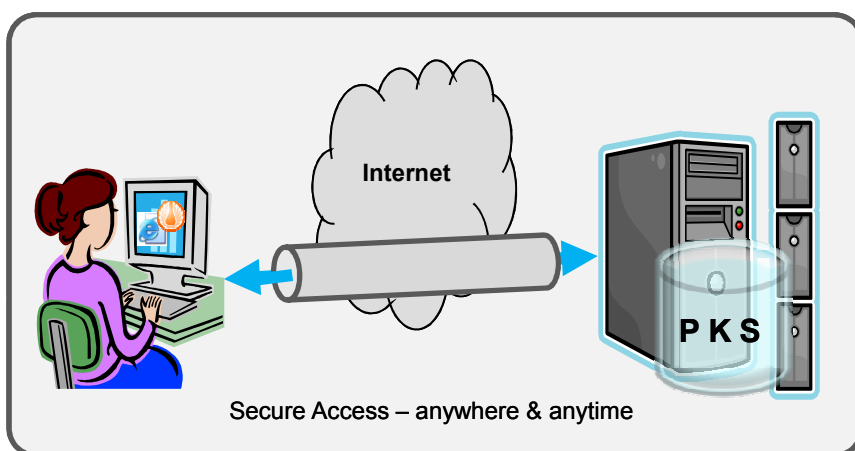
- Full benefit of using PKS without investing time and money for initial custom deployment or continuous IT support
- Immediate productivity support for data management, analysis and modeling, reporting, and collaboration
- Platform for FDA 21 CFR Part 11 compliant data warehousing for critical early drug development data and analysis results from Phase I, ADME, Toxicity, Drug Metabolism, and pharmacokinetic and pharmacodynamic (PK/PD) research
- Secure PK repository available anywhere, at anytime, and to anyone – within a company and across cooperation partners
- Flexible licensing options are available including full access licenses for scientists supporting their analysis work and restricted Web browser access licenses for the specific needs of Reviewers and Managers in your organization

FEATURE HIGHLIGHTS

- **Access With Multiple Clients**: Integrated Access to study data and analysis results from Phoenix™ WinNonlin® 6 or WinNonlin 5 Enterprise, Phoenix Connect™ for SAS®, S-PLUS®, NONMEM® and SigmaPlot®, PKS Client for Microsoft® Word and Excel®, or a standard Web browser. PKS Online allows users to capture and version all kind of files with audit trails and reason for change.
- **PKS Query Tool**: Easily query and merge data sets from multiple studies to support meta data analysis and data mining
- **PKS Data Connectors**: Batch automated loading of data from other data management systems such as Oracle® Clinical, Clintrial™, and Watson™ LIMS™ databases as well as data file formats such as Microsoft Excel and CDISC/SDTM (sold separately)
- **PKS Reporter**: Template driven authoring of compound documents containing tables, text, and graphics with live links into the PKS database supporting electronic signatures for review and approval (sold separately)
- **WinNonlin AutoPilot™**: Pharsight's desktop PK automation application provides the infrastructure and tools to manage and effectively automate common or repetitive PK analyses and the creation of the required tables and figures for reports and presentations (sold separately)

Pharsight has brought Pharsight Knowledgebase Server (or PKS™) to the pharmaceutical industry – a secure and efficient platform for improved data management and access that provides productivity benefits for analysis and reporting tasks, in addition to compliance with existing FDA Electronic Records / Electronic Signatures regulations. For PKS Online, Pharsight is working with a leader in the Software-as-a-Service arena to bring the benefits of PKS to every desktop without the need to invest time and money into deploying PKS in a company's IT environment. Using a standard desktop computer and a standard network connection, users can access PKS Online through a secured channel from virtually anywhere and at anytime.

Pharsight believes that the availability of a comprehensive and accessible PK/PD research data management system will provide a foundation for a more rational and cost-effective drug development process, both by improving scientific productivity and practically eliminating IT overhead.



PKS BENEFITS WITHOUT UPFRONT INVESTMENT

Starting with just Web browser and WinNonlin access for a couple of users at very low flat fee per user, companies can grow their use of PKS Online through addition of users as well as addition of more client applications. Pharsight offers tools from PKS Data Connectors for efficient data management and transfer into PKS Online to PK Automation technology – most prominently represented by the product WinNonlin AutoPilot – that can automate routine analyses and standard reporting generation and works seamlessly with PKS Online.

PKS Online is available from every network connected desktop through a secure Internet connection that links to a company-specific instance of PKS that is hosted by Pharsight and our hosting provider. Your PKS Online instance is not shared with any other PKS Online customer. Pharsight experts setup named user login and passwords that regulate access to study data – based on your decisions. The system is monitored 24/7 by Pharsight and our hosting provider – a leading provider in the Software-as-a-Service space.

Because PKS Online is accessible anywhere, at anytime, by anyone in your organization, you can easily work across departments and in cooperation with your external partners. Secure data exchange and result sharing is happening instantly. Using the separately sold tools WinNonlin AutoPilot™ and PKS Reporter™ in a PKS Online environment enables standardized, regulatory-compliant, secure, and automated generation of reports, where PKS Reporter is used to pick-up the AutoPilot generated output with automatic report updates and secure review and approval processes.

21 CFR PART 11 COMPLIANCE

In combination with your SOPs, PKS Online 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. Pharsight provides several levels of validation services (offered separately) for PKS Online within your environment to meet your specific validation needs and SOPs and to become compliant with Electronic Records; Electronic Signatures; Final Rule (21 CFR Part 11) and Guidance for Industry – Computerized Systems Used in Clinical Trials.

SYSTEM REQUIREMENTS

Typical requirements for desktops

(Desktop requirements depend on the respective software used on the desktop)

- OS: Windows® 2000, 2000(J), XP, XP(J), or Citrix on Windows® 2003 Server
- Processor: Pentium III, 700 MHz or better
- Memory: 512 MB RAM or higher
- Hard Disk: 70 MB

INTEGRATED SOLUTIONS

Pharsight provides an integrated suite of products and services including

- Phoenix™ WinNonlin®
- Phoenix™ Connect™
- IVIVC Toolkit™ for WinNonlin®
- WinNonMix® Pro/Enterprise
- Pharsight® Trial Simulator™
- Pharsight® Knowledgebase Server™
- WinNonlin® AutoPilot™
- PKS Reporter™
- Drug Model Explorer™
- Product and Methodology Training
- PK Reporting and Analysis Services
- Validation and Integration Services

Pharsight
A Certara™ Company

For Additional Information

Visit us on the web at www.pharsight.com or call:
+1 919-852-4685 (US)
+41 22-990-2410 (EU/India)
+81 471-74-9918 (Japan)

Pharsight - a Certara™ Company

5625 Dillard Dr., Suite 205
Cary, North Carolina 27518
Tel: 919-852-4685 · Fax: 650-314-3810
Email: info@pharsight.com

This information applies to PKS Online based on PKS 4.0.

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FEATURE RICH SUPPORT FOR LEADING TOOLS

Modeling and Analysis Tools

PKS Online is directly integrated with Pharsight's industry-leading PK/PD modeling and analysis tool WinNonlin and other desktop tools such as SAS®, S-Plus®, 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 companies that continue using WinNonlin 5 versions, PKS Online is backward compatible to WinNonlin 5.x Enterprise releases.

Clients for NONMEM, SAS and more

PKS Online is closely integrated with Phoenix Connect, a Phoenix-based desktop application to store and manage SAS, NONMEM, S-PLUS, 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.

Clients for Microsoft Word and Excel

PKS Online supports compliant and traceable use of standard productivity tools, Microsoft® Excel and Word. Optional PKS add-ins install additional PKS options into the File menus of Word and Excel, allowing files to be stored and tracked with audit trail, reason for change capture, and electronic signatures.

PKS Query Tool and Data Explorer

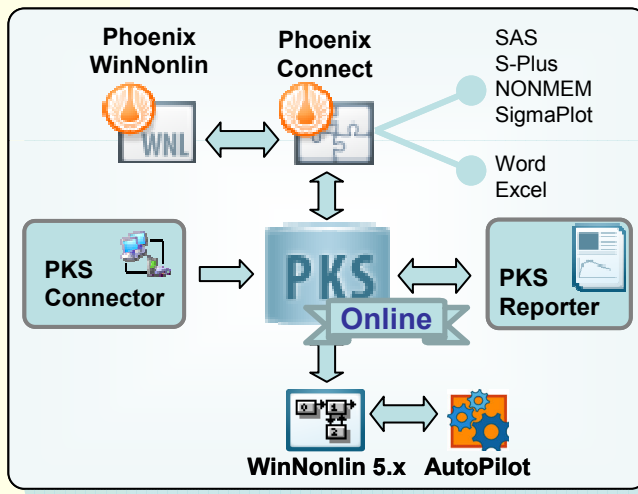
The Query Tool and the Data Explorer are data mining tools to support and automate comprehensive cross-study and cross-analysis queries for use in later meta-analysis activities.

Support for multitude of File Formats

File formats of any type (ASCII, JPG, DOC, etc.) can be saved and loaded into PKS Online to support capture of output from a wide variety of visualization and analysis tools.

Change Tracking

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.



Secure Data Management

PKS Online provides Oracle-based security to control and track access to your data. Database management is provided by Pharsight experts with no drain on your IT resources.

PKS Library Objects

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

Audit Trail

PKS tracks all changes to study data and scenarios. For each change, PKS Online 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 database or restored as needed.

PKS Data Connectors

The 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 SDTM standard as defined by the CDISC organization.

PKS Reporter

PKS Reporter, sold under separate license, provides an automated system for the authoring, updating and review/ and approval of standardized or customized reports and documents. It operates as a Microsoft Word add-in and is directly integrated with PKS Online, accessing data, models and analysis results saved in PKS Online studies and scenarios.

WinNonlin AutoPilot

Pharsight'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 and presentations loading data from PKS Online and saving the created PK output and analysis results to PKS Online - ready to be picked up by reporting tools such as PKS Reporter.