

RECOMMENDED REQUIREMENTS

Requirements for WinNonlin and Web Clients

- > Processor: Pentium® III 700MHz or better
- > OS: Windows® 2000, 2000J, Windows XP, XPJ or Citrix® Metaframe™
- > Memory: 256MB
- > Hard Disk: 70MB

Requirements for servers

- > Processor: Pentium III 1 GB
- > Software supplied by customer: Oracle® 8i, 9i, 10g (Standard and Enterprise Edition)
- > OS: Windows 2000 Pro, Sun® Solaris™, HP Unix Ili or Redhat Linux 9
- > Memory: 512MB
- > Hard Disk: 20GB

INTEGRATED SOLUTIONS

Pharsight provides an integrated suite of products and services including:

- > WinNonlin® Pro/Enterprise
- > WinNonMix® Pro/Enterprise
- > Pharsight® Trial Simulator™
- > Pharsight® Knowledgebase Server™
- > PKS Reporter™
- > Drug Model Explorer™
- > Product and Methodology Training
- > PK Analysis and Reporting Automation



For additional information

contact the Pharsight sales department at 888-708-7444 (650-314-3800 outside U.S.). Or visit our web site at <http://www.pharsight.com>

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This information applies to PKS version 3.1

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PRODUCTIVITY TOOLS

Clients for NONMEM, SAS and more

PKS includes a separate desktop application to store and manage SAS, NONMEM, S-PLUS and SigmaPlot files and analyses as part of PKS studies and scenarios. Share PKS data, and store and run SAS or NONMEM analyses using the PKS Clients.

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

The PKS Query Tool is a data mining tool to support and automate comprehensive cross-study and cross-analysis queries for use in later meta-analysis activities.

Clients for Microsoft Word and Excel

PKS supports compliant and traceable use of standard productivity tools, Microsoft® Excel and Word 2000. 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 Connectors

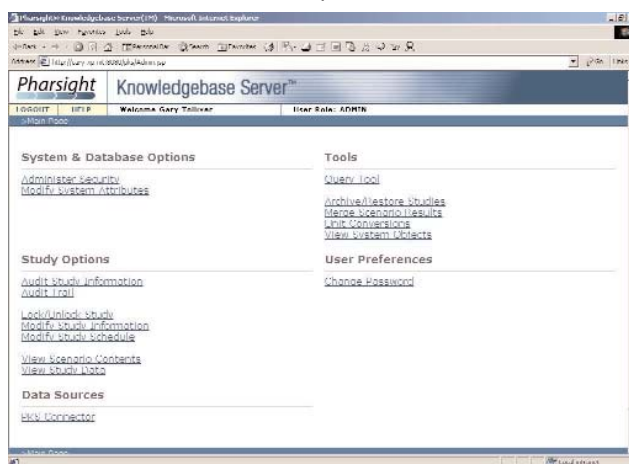
The PKS Connectors provide automated loading of study data from various sources such as data management systems, LIMS (laboratory information management systems), legacy databases, and other data sources. The PKS Data Connector can be configured for common data management systems, such as Watson and Oracle Clinical.

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.



PKS REPORTER

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

AUTOMATION SERVICES

PKS and Pharsight Automation Services can automate routine analyses and standard report generation.

21 CFR PART 11 COMPLIANCE

In combination with your SOPs, the PKS helps to achieve full compliance with FDA regulation 21 CFR Part 11 (Electronic Records; Electronic Signatures; Final Rule).

The PKS uses electronic signatures, reason for change capture, and comprehensive audit trails to store and manage PK/PD data and analysis results from WinNonlin Enterprise 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.