

# PHARSIGHT® PKSREPORTER™ 1.3.1

## BENEFITS

- > Secure document authoring compliant with 21 CFR Part 11 regulations
- > Improve researcher productivity, reduce rework, and free-up vital scientific resources
- > Improves quality and reduces QA effort through use of template-driven standardization and automation of routine reports
- > Simplifies management and documenting of clinical data analysis and reporting processes
- > Ensure compliance with SOPs and regulations by creating standardized templates for common reports

## HIGHLIGHTS

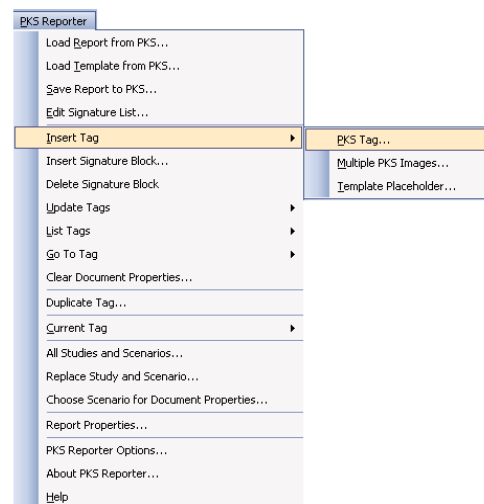
- > Insert tables, plots, text, and data created in WinNonlin® and other analysis tools or by WinNonlin® AutoPilot™, Pharsight's PK Automation tool
- > Use templates to create standardized formats for routine reports or to manage boiler-plate text
- > Complete access to all Word functionality for formatting and document layout
- > Capture interpretations and other text with option to prompt for updates when data changes
- > Option to verify all content each time a document is opened, ensuring that the document contents match the most recent version
- > Electronic signature support for review/approval process, including generating a list of signers and a signature page
- > Provided as a Microsoft® Word add-in to simplify deployment

In producing reports for internal use or regulatory submission, pharmaceutical R&D organizations expend considerable staff resources transforming data, creating tables and graphs, laying out and editing documents, validating data references and analysis, and updating documents when new data are received. Often this work must be performed by skilled researchers, taking them away from more productive and beneficial work. While this activity is necessary, much of the overhead, repetition, and potential for error can be minimized by moving to an automated, standardized system to produce regulatory reports. An automated solution can also help to be more efficient in achieving compliance with Electronic Signature/Records regulations (21 CFR Part 11).

Pharsight has developed PKS Reporter to address this need. With the Pharsight Knowledgebase Server (PKS) as an underlying secure source of regulatory-compliant data and analysis results, PKS Reporter allows researchers to use familiar tools, such as WinNonlin, AutoPilot, and Microsoft Word, to construct, update, review, approve, and maintain any type of report. PKS Reporter improves scientific productivity, reduces QA overhead, and provides a way to standardize and automate routine document authoring tasks.

## COMPLIANT PRODUCTIVITY TOOL SUPPORT – MICROSOFT WORD AND EXCEL

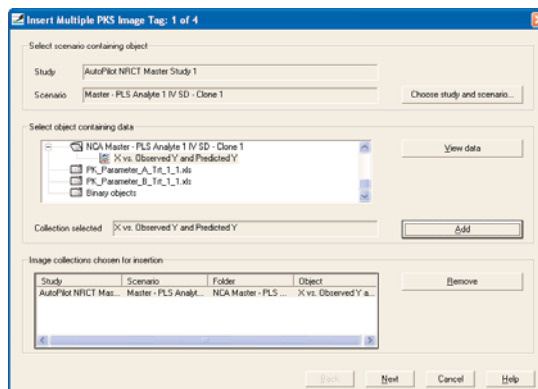
PKS Reporter is integrated into Microsoft Word, reducing the learning curve for researchers and simplifying deployment for IT professionals. PKS Reporter adds a series of new capabilities to Word, accessed directly from easy-to-use menus and dialogs. Users can quickly become proficient at building, maintaining, and finalizing documents by inserting tags that refer to specific items in the PKS database such as a plot, table, graphic visualization of the data, or even a specific range of cells in a WinNonlin data or analysis workbook. And PKS Reporter integrates seamlessly into the advanced 3-tier, web and XML-based architecture of Pharsight Knowledgebase Server (PKS).



## AUTOMATION OF DOCUMENT AUTHORING AND UPDATING

The PKS Reporter provides an automated system for the authoring, updating, review, and approval of standard or customized reports and documents. It is directly integrated with PKS and accesses data and modeling results saved by WinNonlin Enterprise, Pharsight's industry-leading PK/PD modeling and analysis tool, as well as results from other analysis tools and

data sources. In addition, PKS Reporter will directly import the tables and graphs created by WinNonlin AutoPilot, Pharsight's PK Automation tool. Users can browse the PKS database, loading objects and values drawn from various analysis scenarios into tags inserted into the document. Standardized templates can be defined and PKS Reporter will step through the templates, tag by tag, allowing you to select and insert specific objects to match the format specified in the template.



## MINIMAL REQUIREMENTS

- > **Processor:** Pentium® III 800MHz (1.8 Mhz recommended)
- > **OS:** Windows® 2000 or XP (with Service Pack 1 or later applied), Citrix on Windows 2003 Server
- > **Memory:** 512MB, (1 GB recommended)
- > **Hard Disk:** 70MB
- > **Other Required Software:** Microsoft Office 2000/XP/2003, Internet Explorer 6.0, Pharsight Knowledgebase Server 3.x

## INTEGRATED SOLUTIONS

Pharsight provides an integrated suite of products and services including:

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

**Pharsight**  
A Certara™ Company

### 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>

### Pharsight Corporation

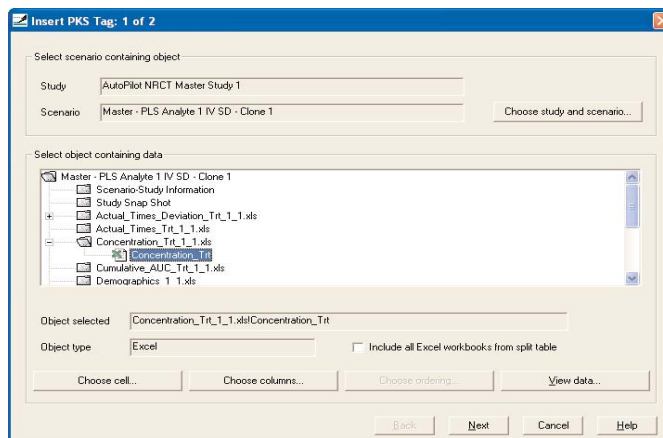
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This information applies to PKS Reporter version 1.3.1

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## INTEGRATION WITH LEADING ANALYSIS TOOLS - WINNONLIN

PKS Reporter works directly with data, tables, and plots produced by WinNonlin, Pharsight's industry-leading tool for PK/PD modeling and Noncompartmental Analysis. WinNonlin Enterprise, provides import and export interfaces to other modeling and analysis tools including SAS® and NONMEM®. File formats of any type (ASCII, JPG, DOC, etc.) can be saved and loaded into PKS, supporting compliant capture of output from a wide variety of visualization and analysis tools.

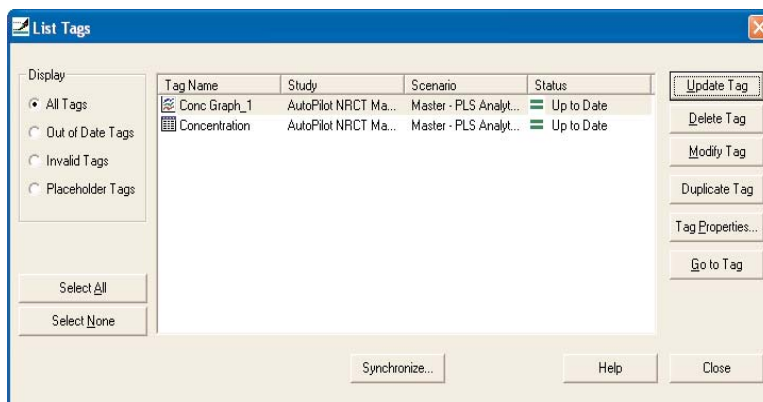


PKS Reporter can be used as a separate tool, but it is also designed to work with WinNonlin AutoPilot, the PK Automation tool provided by Pharsight. When used together, AutoPilot and PKS Reporter can support a seamless workflow that includes generating PK tables and graphs automatically and inserting these into final or interim reports.

## 21 CFR PART 11 COMPLIANCE FOR REPORT AUTHORING AND REVIEW

In combination with your SOPs and because it is integrated with PKS, PKS Reporter helps to achieve full compliance with FDA regulation 21 CFR Part 11 (Electronic Records; Electronic Signatures; Final Rule), supporting activities during both document authoring and during review and approval phases. PKS Reporter uses electronic signatures, reason for change capture, and comprehensive audit trails to store and manage Word documents containing PK/PD data and analysis results from WinNonlin Enterprise and other analysis tools.

Analysis and modeling results are linked back to the underlying study data and changes to the data, such as rerunning analysis or loading additional data, cause the linked report elements to be marked for review and possible updates. PKS Reporter can provide full versioning and audit trail control over finished reports, by using the capabilities of PKS to manage the report file along with all supporting data and analysis needed for a regulatory submission.



PKS Reporter and PKS are 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.