

What's New in Pharsight® Knowledgebase Server™

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Summary

Pharsight® Knowledgebase Server™ 4 is a major update of the previously released PKS 3.x versions. The main purpose of this major release is to provide a version of PKS that is compatible with releases of Pharsight's new Phoenix-based product line, for example, Phoenix™ WinNonlin® and Phoenix™ Connect™. In addition, certain enhancements based on customer feedback have been implemented to further improve the usability and the value of the product, and a number of bugs that were discovered in previous releases were fixed.

For a smooth migration, PKS 4.x is backwards compatible with WinNonlin 5.2.1 and 5.1.1, PKS Reporter 1.3.1, PKS Clients 3.1 and PKS Office Clients 3.1, and WinNonlin AutoPilot 1.2.1 and 1.1.2.

This document summarizes the major enhancements of PKS 4.0 and the subsequent maintenance releases. Note that some of the new features are only available when PKS is used with Phoenix Connect and Phoenix WinNonlin. See also the Release Notes document for more details on PKS 4.0.

What's New in PKS™ 4.0

Web User Interface Enhancements

The screenshot displays the Pharsight Knowledgebase Server web interface in Microsoft Internet Explorer. The browser address bar shows the URL: `http://cary-xp-nt:8988/pks4_0_29/WebUI`. The page header includes the Pharsight logo and the text "Knowledgebase Server™". Below the header, there is a navigation bar with tabs for "Studies", "Security", "Tools", "Library", and "Configuration". The "Studies" tab is active, showing a "Group Action" dropdown menu and an "Execute" button. A "Filter*" section is visible with "Apply Filter", "Clear Filter", and "Refresh" buttons. The main content area displays a table of studies with columns: Study Name, Portfolio, Project, Indication, Compound, Description, Locked, and Action. A context menu is open over the "Action" column, listing options such as "View Data", "New Study View", "New Study Library Object", "Properties", "Unit Conversions", "Lock", "Delete", "History", "Run Connector Transfer", "Connector Transfer History", "Security Settings", "CDISC Export", and "Global Library Associations". Below the studies table, there are sections for "Library" and "Views", each with their respective tables. The "Library" table has columns: Library Object, Version, Description, Type, Created Date, and Created By. The "Views" table has columns: View Name, Version, Description, Created Date, Created By, Last Updated, Status, Audit Reason, and Action. At the bottom of the page, there is a "Done" button and a "Local intranet" indicator.

The layout of the Web browser interface has been redesigned to allow for better and faster navigation. Studies and study-related objects are displayed in a study tree with drop-down menus that allow execution of tasks right in the tree view.

The screenshot shows the Pharsight Knowledgebase Server web interface. At the top, there is a navigation bar with 'LOGOUT' and 'HELP' buttons, and a welcome message 'Welcome Val Write' with 'User Role: WRITE'. Below this is a main menu with 'Studies', 'Security', 'Tools', 'Library', and 'Configuration' tabs. The 'Studies' tab is active, showing a 'Group Action' dropdown set to 'Execute' and a 'New Study' button. A 'Filter*' section contains two filter panels: 'Study Filter Options' and 'Scenario Filter Options'. The 'Study Filter Options' panel includes fields for 'Study Name', 'Project', 'Blinding Type', 'Study Design', 'Created By', 'Minimum Access Level', 'Portfolio', 'Indication', 'Study Type', 'Compound', and 'Locked'. The 'Scenario Filter Options' panel includes fields for 'Scenario Name', 'Created By', 'Scenario Status', 'Contains Dataset', 'Scenario Type', and 'Locked'. Below the filter panels is a table with columns: Study Name, Portfolio, Project, Indication, Compound, Description, Locked, Access Level, and Action. The table contains three rows of study data. At the bottom, a message reads: 'Please use the PKS navigation links. Do not use the browser's BACK Button.'

Study Name	Portfolio	Project	Indication	Compound	Description	Locked	Access Level	Action
R1_WIDE 20090327 095718	portfolio X	project X	Indication X	Compound X	test	No	Write	View Data [dropdown] Execute
SBB - CDISC - Export Study #2	portfolio X	project X	Indication X	Compound X	test	No	Write	View Data [dropdown] Execute
SBB - QE-Phoenix_R1_Wide-Units	portfolio X	project X	Indication X	Compound X	test	No	Write	View Data [dropdown] Execute

Additional search and filter options allow faster drill down to the wanted information and improve efficiency.

Study Views

Note that Study Views can only be used for analyses with Phoenix Connect and Phoenix WinNonlin.

Owner Study: Carterolol
Study View Name: New
Study View Version:

	Study Name	Status	Subject Identifiers				
			Subject Identifier 1	Subject Identifier 2	Subject Demographic 1	Subject Demographic 2	
<input type="button" value="Edit..."/> <input type="button" value="Remove"/>	Carterolol		Column: Subject Units (N/A)		Column: AGE Units (m*m)	Column: BSA Units (m*m)	Column: Subject Units (kg)
<input type="button" value="Edit..."/> <input type="button" value="Remove"/>	PS_Carterolol		Column: Subject Units (N/A)	Column: Study_ID Units (N/A)	Column: AGE Units (y)	Column: BSA Units (m2)	Column: Subject Units (kg)
			Result Name: Subject	Result Name: Study_ID	Result Name: AGE	Result Name: BSA	Result Name: Subject

Show Format Options

[Back to Studies](#)

Please use the PKS navigation links. Do not use the browser's BACK Button.

Study Views are used to prepare the data for use with Phoenix WinNonlin. They allow the user to combine data from several studies and to selectively include data to create a ‘view’ into PKS. This view can be downloaded into Phoenix Connect or Phoenix WinNonlin for analysis and reporting. The view remembers the sources of the data (i.e., there is an “active link”), so that if any of the data sources is updated, the view will use the new data.

CDISC Export – Import and Improved Data Transfer

PKS 4.0 has a built-in SDTM export feature. The data of a selected study or scenario can be exported into a set of files in SAS Transport format (.xpt files) that represent the SDTM domains DM (for general demographics), SC (for additional subject characteristics), EX (for dosing data), PC (for PK concentrations), and PP (for PK Parameters, available when exporting data from a scenario). The user can use predefined maps or interactively determine the mapping of PKS variables to the required SDTM variables. The content and format of these files follow the SDTM standard as defined by the CDISC organization. All created files are compressed and saved as a “.zip” file. Note that because of SDTM requirements limitations may apply or data preparation may be required before a successful and complete export can be executed. This first implementation of a CDISC Export assumes that the data structure in PKS resembles to a certain degree the required SDTM data structure.

Pharsight offers a PKS Connector to import SDTM formatted data into PKS. This connector will be built to order based on a time-and-materials contract by our Deployment Services Group.

PKS 4.0 provides a simple feature to export a complete study from one PKS instance and save the content in a compressed file. The resulting “.zip” file can be transferred and imported into another instance of PKS 4.0. Note that this feature is only available when PKS 4.0 is deployed using Oracle 10g or higher.

Introduction of Study Objects

The screenshot displays the PKS interface with several sections:

- PS1_Carterolol**: A study entry with fields for Name, Description, Type, and Status.
- Library**: A table listing objects for the study. Two rows are circled in red:

Library Object	Version	Description	Type	Created Date	Created By	Audit Reason	Action
Create Study Map	2009-05-14 10:45:39 1		Study Map	2009.05.14 10:45:44 EDT	PSCHAEFER		Export Execute
Create Study Data	2009-05-14 10:45:39 1		Study Data	2009.05.14 10:45:44 EDT	PSCHAEFER		Export Execute
- PS_Carterolol**: A study entry with fields for Name, Description, Type, and Status.
- Scenarios**: A table listing scenarios. One row is visible:

Scenario	Version	Created Date	Created By	Status	Type	Locked	Action
Base_Scenario	1	2009.05.14 13:08:53 EDT	PSCHAEFER	UPTODATE	Phoenix	No	Properties Execute
- Library**: A table listing objects for the scenario. Two rows are circled in red:

Library Object	Version	Description	Type	Created Date	Created By	Audit Reason	Action
Create Study Map	2009-05-14 09:50:27 1		Study Map	2009.05.14 09:50:33 EDT	PSCHAEFER		Export Execute
Create Study Data	2009-05-14 09:50:27 1		Study Data	2009.05.14 09:50:33 EDT	PSCHAEFER		Export Execute
- Views**: A table listing views. Two rows are visible:

View Name	Version	Description	Created Date	Created By	Last Updated	Status	Audit Reason	Action
Base_View_All	1		2009.05.14 10:00:17 EDT	PSCHAEFER	2009.05.14 11:25:52 EDT	UPTODATE	Study View Creation	View Data Execute
Base_View_All	2		2009.05.14 10:19:50 EDT	PSCHAEFER	2009.05.14 11:25:51 EDT	UPTODATE	update study view	View Data Execute

PKS 4.0 allows users to add objects to studies rather than just to the global library. This allows for better organization of objects by linking objects directly to the appropriate study.

Introduction of Custom Scenario Attributes

The screenshot shows the 'Manage Custom Attributes' interface within the 'Configuration' tab. The interface is divided into two main columns: 'Attribute Group' and 'Attributes'. The 'Attribute Group' column contains a dropdown menu with 'Peters_Addition(Scenario)' selected, a 'New Group' section with 'Name' and 'Type' (set to 'Study') fields, and a 'Delete Group' button. The 'Attributes' column contains a list of attributes: 'Use for PHX', 'Use for WNLS', and 'Use for test', a 'New Attribute' section with a 'Name' field and an 'Add' button, and a 'Delete Attribute' button. At the bottom, there are 'Undo Changes' and 'Submit' buttons, and a 'Back to Controlled Lists' link. A footer note reads: 'Please use the PKS navigation links. Do not use the browser's BACK Button.'

PSK 4.0 allows users to define Custom Attributes not only for studies, but for scenarios as well. Custom Attributes are managed in the Configuration tab of the Web browser interface.

Scenario Properties
General information for a scenario

Scenario Name: Base_1
Version: 1
Checkpoint ID: 1903362
Sponsor: [Field]
Description: Model with corrected data

Custom Attributes

Attribute	Attribute Group
<input checked="" type="checkbox"/> Use for PHX	Peters_Addition
<input type="checkbox"/> Use for WNL5	Peters_Addition
<input type="checkbox"/> Use for test	Peters_Addition
<input type="checkbox"/> Optional	SubmissionType
<input checked="" type="checkbox"/> Required	SubmissionType

*Reason for change: Setting Attributes for Search

Added Criteria
Peters_Addition: "Use for PHX"

Study Name	Portfolio	Project	Indication	Compound	Description	Locked	Action
Carterolol	Respiratory	Project Perf	Asthma	Carterolol	Crossover Drug Interaction, 12 Subjects	No	View Data [Dropdown] Execute

Scenarios

Scenario	Version	Created Date	Created By	Status	Type	Locked	Action
Base_1	1	2009.05.12 15:50:06 EDT	PSCHAEFER	UPTODATE	WinNonlin	No	Properties [Dropdown] Execute

Please use the PKS navigation links. Do not use the browser's BACK Button.

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Once Custom Attributes are set for scenarios or studies, these attributes can be used in the filter for a targeted search, e.g., in this example the scenario Base_1 of the study Carterolol is filtered out based on the Custom Attribute “Use for PHX”.

PKS Data Explorer – Configurable Data Mining Capabilities

The PKS Data Explorer is a configurable data mining tool that allows users to examine data across all studies and study subsets based on criteria in the data. In contrast to the Query Tool, the Data Explorer does not require that studies be pre-selected to be examined. In fact, in the Data Explorer, the user defines selection criteria for the data and the tool searches across all studies to extract data that match. In addition, the Data Explorer provides a few simple summary statistics across the extracted data.

Data Explorer is based on so-called ‘data mines’, a PL/SQL procedure which is executed to extract the data from the database. This procedure has to follow certain restrictions so it can be embedded into the existing infrastructure for data mines. In addition to writing this procedure, the data mines need to be deployed. These steps are typically performed by a database administrator or they can be part of the deployment of PKS by Pharsight or the customer’s IT group. Once the data mines are in place, they can be easily used by any user by just specifying the desired output and criteria.

Data Explorer

Select Data Mine: TestStaticDemo

static data set for testing


Statistics Data


Parameter Name	Unit	None	Group	Summary	Criteria	Summary Stats
STUDYID		<input checked="" type="radio"/>	<input type="radio"/>		Specify Studies	<input checked="" type="checkbox"/> Count
STUDYNAME		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	<input checked="" type="checkbox"/> Average
INTERNAL_SUBJECT_ID		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	<input checked="" type="checkbox"/> Min
SID1		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	<input checked="" type="checkbox"/> Max
SID2		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	<input type="checkbox"/> Standard Deviation
SID3		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	
SID4		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	
SID5		<input checked="" type="radio"/>	<input type="radio"/>		Specify Criteria	
AGE		<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Specify Criteria	
HEIGHT		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Specify Criteria	
WEIGHT		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Specify Criteria	
RACE		<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Specify Criteria	
SEX		<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Specify Criteria	
BMI		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Specify Criteria	
CLCR		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Specify Criteria	

Get Results

File Download

Do you want to open or save this file?

 Name: Results.csv
Type: Microsoft Office Excel Comma Separated Values Fil...
From: cary-xp-nt

 While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. [What's the risk?](#)

The above data mine will extract the Race and Gender information across all studies in the database and create the listed statistics for the Age parameter of the subjects (see below).

Row #	RACE	SEX	Parameter	Count	Average	Min	Max
1			AGE	13	55.462	22	69
2	ASIAN	F	AGE	13	30.385	21	39
3	ASIAN	M	AGE	15	34.533	20	56
4	CAUCASION	F	AGE	5	30.2	23	37
5	CAUCASION	M	AGE	9	34.444	20	58

By default, PKS is deployed with two working data mines (and the static test example that is used for demonstration and test purposes). Additional examples that can be deployed ‘as is’ and that can also be used as starting points for custom data mines are included with the PKS 4.0 product.

LDAP Authentication

PKS 4.0 supports external authentication against an LDAP (Lightweight Directory Access Protocol) server. This feature provides users with the ability to use the same username and password as used for other systems within their corporate network.

Control of Number of Licensed Users

In PKS 4.0 the number of licensed users is controlled by a licensing feature. A system administrator needs to set the number of active users, i.e. users that have any access to studies or scenarios, and the type of access in the configuration module of PKS.

Customizable Fields to Identify Global Library Objects

Library objects that are not associated with a particular study or scenario are added to the “global” library. PKS stores specific metadata about each library object, including name, type, and version. In PKS 4.0, additional key and non-key fields can be used to include more user-defined metadata that can be configured and used to organize, filter, and group library objects. The column labels for these fields are defined through the “Preferred Field Labels” feature (see next section).

Preferred Field Labels

The screenshot shows the Pharsight Knowledgebase Server 4.0 web application interface. The browser window title is "Pharsight® Knowledgebase Server™ - Microsoft Internet Explorer". The page header includes the Pharsight logo and "Knowledgebase Server™". Below the header, there are navigation tabs: "Studies", "Security", "Tools", "Library", and "Configuration". The main content area is titled "Preferred Field Labels" and contains a table with the following data:

Field	Default Name	Preferred Name
SAMPLENUM	Sample_Number	<input type="text"/>
RELATIVE_NOMINAL_TIME	Relative_Nominal_Time	<input type="text"/>
RELATIVE_NOMINAL_END_TIME	Relative_Nominal_End_Time	<input type="text"/>
RELATIVE_ACTUAL_TIME	Relative_Actual_Time	<input type="text"/>
RELATIVE_ACTUAL_END_TIME	Relative_Actual_End_Time	<input type="text"/>
ACTUAL_CLOCK_TIME	Actual_Clock_Time	<input type="text"/>
OBSSTATUSNAME	Status	<input type="text"/>
UNITDISPLAY	Unit	<input type="text"/>
AUDIT_REASON	Audit_Reason	<input type="text"/>
SOURCE	Source System	<input type="text"/>
DCP_DESCRIPTION	DCP_Description	<input type="text"/>
DCP_PERIOD	Period	<input type="text"/>
DCP_PHASE	Phase	<input type="text"/>
DCP_MATRIX	Matrix	<input type="text"/>
DCP_DAY	Day	<input type="text"/>
DCP_VISIT	Visit	<input type="text"/>
DCP_ANALYTE	Analyte	<input type="text"/>
TREATMENT_CODE	Treatment	<input type="text"/>
TREATMENT_DESC	Treatment_Description	<input type="text"/>
TREATMENT_ROUTE	Route	<input type="text"/>
TREATMENT_REGIMEN	Regimen	<input type="text"/>
TREATMENT_FASTEDFED	Fasted_Fed	<input type="text"/>

PKS 4.0 allows customers to use so-called Preferred Field Labels to change the name of the fields in the data results. The default name is what currently displays in PKS.

What's New in PKS™ 4.0.1

PKS 4.0.1 is a maintenance release to address a performance problem with a large number of studies and with large studies. In addition, PKS 4.0.1 supports locking and unlocking of library objects from desktop client software such as the PKS browser in Phoenix Connect.

What's New in PKS™ 4.0.2

Additional platform support

PKS was tested on additional Operating Systems Windows Server 2008 and 64-bit Red Hat Linux Enterprise for the server (for the database and middle tier server) and Windows 7 (32-/64-bit) and Citrix on Windows Server 2008 for the desktop operating system. In addition, an existing defect related to Oracle 11g R2 was fixed.

New features and fixed defects

The following new features and bug fixes were implemented:

- Added the ability to upload multiple study objects at once
- PKS Administrator can execute SQL scripts against the database from the Web Browser user interface
- PKS Administrator can add a message to the login screen to pass information to users
- Added error check to prevent users from using reserved column names when adding and naming custom columns
- Fixed a few display issues in the Web Browser
- Fixed issue with CDISC export in a multiple instance environment
- Fixed several issues with access rights and electronic signatures

What's New in PKS™ 4.0.3

Supported Systems and Environments

Support for Oracle RAC (Real Application Cluster): The PKS database can now be deployed in an Oracle RAC environment and use the benefits of Oracle RAC.

Support of Microsoft Excel “.xlsx” files for data connectors: PKS has been modified to allow for the implementation of support for .xlsx files in PKS Data Connectors for Excel.

Study View Page Improvements

Multiple page view for the content on the Studies and Library tabs: A new Navigation Bar has been added to the Studies and Library tabs. This Navigator Bar has a default page size of 100 items, and is configurable via the Page Size field. A user configuration setting located in the User Options for the logged in user is preserved across sessions. The user settings also allow the logged in user to define which tab is selected for display automatically at login. All display changes will be enabled at the next login.

Improved performance of study view for large number of studies: Studies tab Load and Refresh times have been improved for PKS 4.0.3.

Improved order of study child nodes: The content on the Studies tab is now ordered in the following fashion for Study Objects, Study Views and Scenario Nodes:

- Primary: by initial letter accounting for capitalization
- Secondarily: by the parent object name

Security feature

PKS Web browser interface improvement: The PKS Web browser login component has been modified to disallow “auto complete” for username and password even if AutoComplete is enabled in the Web browser.