Pharsight

WinNonlin®
AutoPilot™

Getting Started Guide

Version 1.1.1

WinNonlin AutoPilot Version 1.1.1

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Chapter 1

Introduction

WinNonlin AutoPilot paradigm, data requirements, and Pharsight Corporation contact information

WinNonlin® AutoPilot™ is a configurable desktop application that works with Pharsight's industry-leading PK/PD analysis software, WinNonlin, and third-party reporting tools, including SigmaPlot® and Microsoft® Word and Excel®, to automate common or repetitive analyses. AutoPilot can perform data transformations and PK and statistical analysis as well as create presentation-quality tables, graphs, and text. These formatted PK analysis outputs can then be directly inserted into documents such as presentations and reports for regulatory submissions. WinNonlin AutoPilot can optionally interface with Pharsight's research management software Pharsight Knowledgebase Server™ for secure and trackable management of data, analyses, and output.

WinNonlin AutoPilot

WinNonlin AutoPilot comprises two main functional modules, the Administrator Module and the User Module. You can use the Administrator Module to configure the formats, nomenclature, and data-handling rules applied in the generation of PK analysis outputs to meet an organization's policies and standard operating procedures (SOPs) for analysis and reporting. The User Module consists of Automation and Comparison tools to automate PK analyses and compare output from automation runs. You can use the User Module to specify selections for input study data, analysis execution, and output on a run-by-run basis. Administrator and user selections are stored in XML (Extensible Markup Language) and PAP (proprietary Pharsight Automation Project) files, respectively, and are applied to additional study data.

AutoPilot File Explorer is a WinNonlin AutoPilot utility that helps users prepare reports that use AutoPilot graph and table output. AutoPilot File Explorer loads the WMF graphs and XLS tables from WinNonlin AutoPilot project output files and exports them into Microsoft Word documents and PowerPoint

presentations. You can access AutoPilot File Explorer from the Microsoft Windows Start menu or by launching AutoPilot and clicking **Explorer**.

System settings

WinNonlin AutoPilot comes pre-configured and ready to use "out-of-the-box" with default settings. Designated WinNonlin AutoPilot administrators (authenticated by user name and password) can modify these settings and adjust them to meet a company's or working group's SOPs. The Administrator-defined settings, or system settings, define the default options available to users for automation and comparison projects. The settings are stored in an XML file that can easily be transferred from one computer to another, or made part of an internal distribution for consistent implementation across an organization. The file content is altered using the Administrator interface. This file can be selected using the System Settings dialog box, which is accessed by clicking **System Settings** on the main AutoPilot screen.

When a non-Administrator user starts AutoPilot for an Automation or Comparison run, the available settings are governed by the system settings and the default settings. System settings take priority over the default settings. For many WinNonlin AutoPilot features, the user can make selections for a specific run that override the administrator-defined system settings, allowing flexibility and control over specific analyses and output. Conversely, there are also several notable cases for which the configuration settings defined in the Administration Module cannot be modified in the User Module, where formats and business rules are considered to be part of SOPs. See "Administrator and user settings" on page 3 for a description of features that are user- or administrator-configurable.

Documentation

The *WinNonlin AutoPilot User Guide* covers AutoPilot installation, administrator configuration, and user settings and workflow for PK Automation and Comparison projects. Those documents are available in Adobe® Acrobat® PDF format in the AutoPilot installation directory, under User Docs. Both user and administrator functions are included in the *AutoPilot Online Help*, available from within the AutoPilot software via the Help or "?" button.

Administrator and user settings

Some attributes in Autopilot are user configurable, while others are only configurable by the administrator. The following tables list the configurable features of WinNonlin AutoPilot and describes the modifications that administrators and users can make.

Table 1-1. Input settings

Feature	Administrator	User
Study data column nomenclature configuration (column mapping)	Admin can configure the mapping of study input column headers to system names in AutoPilot and has ability to create new demographic variables (e.g. phenotype) and define the data type (e.g. discrete). Also can define the concentration column header potentially for matrix and analyte per the concentration variable template.	User cannot modify these settings.
Selection of study data and output location to use in an Automation or Comparison run	Not applicable other than upon installation, the ability to decide if PKS can be used as an input and output location.	User can select the input (load study) and output (save AutoPilot objects created) to PKS and/or non-PKS (local) destinations through a standard browsing feature.
Saving a project from an Automation or Comparison run	Not applicable	User can name, browse to location, and save a pharsight automation project (pap) or pharsight comparison project (pcp) that encompasses all user interface selections made in that run.

Table 1-2. Analysis settings

Feature	Configurable by administrator	Configurable by user
Selection of study design	Not applicable	User can select study design type and subtype (e.g., Crossover, Randomized).
Normalizations	Not applicable	User can select PK Parameters to be normalized by continuous demographics (e.g., weight) located in the study data. The user can select up to two normalization schemes per run.

Table 1-2. Analysis settings (continued)

Feature	Configurable by administrator	Configurable by user
Stratifications	Not applicable	User can select output to be stratified (summarized) by discrete demographics (e.g., gender) located in the study data. The user can select up to two stratification schemes and for each scheme they can define one or two stratification variables (e.g., Gender, Gender and Smoking) per run.
Statistical analysis	Not applicable	During PK automation of crossover studies, a user can select to run inferential statistics on PK Parameters using WinNonlin's LinMIX BE tool.

Table 1-3. Business rules, all output

Feature	Configurable by administrator	Configurable by user
AUC % Extrapolation	Admin can configure rule regarding the display of a flag or a replacement value and associated footnote for PK parameters selected by the Admin where the AUC % extrapolation exceeds the threshold set by the user on an individual run. The Admin can also specify which parameters are affected and if the values that exceed the threshold are used for summary statistics calculations.	User can select whether to use the settings if the rule is activated by Admin and can also set the threshold value (e.g., 30%).
Display of source data	Admin can set the default to display information in the form of a footnote regarding the source data (study file) in tables or graphs.	User can decide to apply the source data footnotes per tables and graphs independently per run and what parts of the source information are displayed (location, path, time and date).
Exclusion	Admin can allow for exclusions and set how exclusions are displayed in final tables and figures, including corresponding footnotes.	If Admin enables exclusions, User can define the exclusion on a profile-by-profile basis. User can also define if corresponding graphs and tables created reflect the excluded profiles.
Display order	Not applicable	User can decide the order of the treatment identifiers (e.g. treatment, day, etc.) that are displayed in in-text tables (top to bottom) and x-axis for categorical graphs (left to right).

Table 1-3. Business rules, all output (continued)

Feature	Configurable by administrator	Configurable by user
Matrix mapping	Admin can configure through addition or deletion matrix abbreviations and map to the concentration column headers to encompass full matrix names into the final tables and graphs. For example PLS in the concentration column would equate to 'Plasma' in the final output.	User cannot modify these settings.
Concentration variable used for concentration final output	Admin can set the default of which concentration column in the study data to use in the creation of the concentration tables and graphs independently.	User can select which concentration column in the study data to use in creation of the concentration tables and graphs independently.

Table 1-4. Business rules, tables

Feature	Configurable by administrator	Configurable by user
Table splitting	Allows splitting of tables if they won't fit on one page per page type and in margins set in the Administration module. Admin can enable or disable the table splitting feature for Users.	If Admin enables table splitting, User can activate/deactivate it per run.
Context-sensitive footnotes-display-calculation of non-numeric values for descriptive statistics	Allows definition/modification via addition or deletion of the default list of non-numeric values (e.g., NS) and associated footnotes (NS = No Sample). In addition, Admin can configure how these non-numeric values are handled during descriptive statistics calculations (missing or zero).	User cannot modify these settings.
In-text table template	Admin can configure the style, including number of descriptive statistics and define if PK parameters are time-dependent. Also, can default the specific descriptive statistics.	User can modify the selection of summary statistics (Mean, SD, etc.), but cannot modify the style nor PK parameters assigned to time-dependent.
Display of different sample sizes in in-text tables	Admin can configure a rule that will display if there are differences in sample size used to calculate summary statistics for PK parameters via flags and corresponding footnotes.	User cannot modify these settings.

Table 1-4. Business rules, tables (continued)

Feature	Configurable by administrator	Configurable by user
Calculation/display of summary statistics for small sample sizes	Admin can configure rule that allows the values of summary statistics involved with small sample sizes (1-3) to be overwritten by text values and apply corresponding footnotes (e.g., NC- Not calculated, sample size is too small).	User cannot modify these settings.
Significance level is displayed in statistics tables	Admin can configure a threshold for the display of p-values (e.g., 0.05), along with a corresponding footnote to be displayed or replaced by non-numeric text if the value is lower than the threshold.	User cannot modify these settings.
Summary statistics based on % threshold	Admin can configure a rule to set a minimum percentage of values relative to total sample size that must exist in a profile before calculations are performed.	User cannot modify these settings.
Individual values of zero treated as “missing”	Admin can configure a rule that allows values of 0 to be treated as Missing prior to any summary statistic calculation.	User cannot modify these settings.
LOQ replacement and display	Admin can configure a rule that allows replacement of numerical values with text values and corresponding footnotes if value is less than the threshold set by the user per run (value of 0.01 is replaced with BQL). Also can configure which PK parameters are governed by this rule.	User can decide whether to use the rule and set the replacement threshold that is used.
Time deviations calculation, flags, and footnotes	Allows Admin to select how the time deviation is calculated and how time deviation is displayed (threshold, footnote, and footnote flag)	User cannot modify these settings.
Display of missing references	Admin can configure the display, including value and corresponding footnote, for 'missing' values for the following table types, time-concentration, demographics, all others.	User cannot modify these settings.
Relative nominal time replacement	Admin can apply the rule and configure the associated footnote that if relative nominal times are used instead of relative actual times, each concentration value is flagged in the time-concentration tables and has an associated footnote assigned.	User cannot modify these settings.

Table 1-4. Business rules, tables (continued)

Feature	Configurable by administrator	Configurable by user
Display analyte, matrix, and day	Admin can independently select as a default for the Matrix (e.g., Plasma), Analyte (e.g. Parent), and Day (e.g., Day 1) to be displayed in the final table as headers.	User can independently select for the Matrix (e.g., Plasma), Analyte (e.g., Parent), and Day (e.g., Day 1) to be displayed in the final table as headers.

Table 1-5. Formatted output, tables

Feature	Configurable by administrator	Configurable by user
Selection of tables	Admin can determine which tables are available for the user and from this list initially create the default list of available tables.	From the list of available tables as set by Admin, User can determine which of these tables are actually generated per run, i.e., User can modify the default list set by Admin.
Selection of variables for tables	For each table, Admin can determine which variables are available for inclusion, along with their order. From the list of available variables, Admin determines which variables are actually included and their default ordering in the generated table.	From the list of available table variables based on the Admin settings, User can determine which of these variables are actually included in the table and their order per run, i.e., User can change the defaults that were set by Admin.
Summary statistics	Admin can determine which summary statistics are available to be included in the table along with their order. From the list of available statistics, Admin determines which statistics are actually included and their default ordering in the generated tables.	From the list of available summary statistics based on the Admin settings, User can determine which of these summary statistics are actually included in the table and their order per run, i.e., User can change the defaults that were set by Admin.
Precision	Admin can set the defaults for the precision of variables and summary statistic values.	User can modify the Admin defaults for precision per variable. Precision choices include number of significant figures or decimal places.

Table 1-5. Formatted output, tables

Feature	Configurable by administrator	Configurable by user
Formatting	Tables are considered to be constructed from basic elements such as Header, Body, Footnotes, Variable Names, Variable Values, etc. Admin can set the font, font style, font size, alignment, and underline/no underline for these elements. In addition the thickness of separation lines (e.g., between the header and body of a table) can be set and grid lines can be switched on and off. Output settings such as paper size (US Letter vs. A4) and orientation (portrait vs. landscape) can be configured and set as defaults per table type.	User cannot modify most of the formatting options for tables. The exceptions are the settings for output setting, which can be user-modified for a specific run.

Table 1-6. Business rules, graphs

Feature	Administrator	User
Time-Scale factors set on a per time scale range basis	Admin can configure time scale factors independently for each time scale range, to define the number of major ticks based on minutes, hours, days, and weeks for time-concentration graphs. Admin can also configure if all concentration graphs have the same scaling and ticks independently for the x-and y-axis.	User can make changes for individual runs.
Display analyte, matrix, and day	Admin can default to have independently the Matrix (e.g., Plasma), Analyte (e.g., Parent), and Day (e.g., Day 1) be displayed in the final graph as labels.	User can independently have the Matrix (e.g., Plasma), Analyte (e.g., Parent), and Day (e.g., Day 1) be displayed in the final graph as labels.
X-Axis format for categorical graphs	Admin can default if categorical graphs have split or offset display for the x-axis.	User can select if categorical graphs in a run have split or offset display for the x-axis.
Axis starting points	Admin can default independently to either force the X-axis and/or y-axis to start from zero or not.	User cannot modify these settings.

Table 1-7. Formatted output, all output

Feature	Configurable by administrator	Configurable by user
Variable and PK parameter nomenclature (mapping)	Admin can configure the display name to be used in the final output created by AutoPilot for variables (e.g., gender) and PK parameters (e.g., AUCinf). Also, Admin can configure the name of the PK parameter graph filenames.	User cannot modify these settings.
PK parameter selection	Admin can configure which PK parameters are available to the user independent of specific table, but rather on model type, including regimen.	User cannot modify which PK parameters are available, but can assign per table which PK parameters are displayed in the output.
Descriptive statistics selection	Admin can configure which descriptive statistics are available to the user for the overall system.	User cannot modify which descriptive statistics are available, but can assign per table which PK parameters are displayed in the output.
Precision selection	Admin can configure the precisions per variable for the overall system.	User can modify these precisions per output and run.

Table 1-8. Formatted output, graphs

Feature	Configurable by administrator	Configurable by user
Selection of graphs	Admin can determine which graphs are available and from this list initially create the default list of available graphs.	From the list of available graphs as determined by Admin, User can determine which of these graphs are actually generated per run, i.e., User can modify Admin default for generated graphs.
Output details	Admin can determine default values for output details on the graphs that are generated. Depending on graph type, these details can include: • Creation of lin and/or log y-axis • Display of a summary value such as mean or median • Display of an error value such as Standard Deviation or Standard Error • Display of up and/or down error bars • Display of regression line (for PK Parameters) • Display of LOQ lines (for PK Parameters)	User can modify all of the output details on a per-run basis.

Table 1-8. Formatted output, graphs

Feature	Configurable by administrator	Configurable by user
Formatting	Admin can determine the following formatting options for graphs: • Print options such as orientation, paper size and margins. • Text elements of a graph such as title, legend, and labels can be activated or deactivated and the format (font, font style, font size, line thickness) can be set. • Line elements of a graph such as grid lines, error bars, axis line, tick lines, etc. can be activated.	User cannot modify most of the options for the formatting of graphs. An exception is the print orientation (portrait vs. landscape).

Table 1-9. Formatted output, text, and appendix text

Feature	Configurable by administrator	Configurable by user
Selection	Admin can determine which text items are available for the user and from this list initially create the default of available text items.	From the list of available text items as determined by admin, User can determine which items are actually generated per run, i.e., User can modify the Admin default for generated text output.
Formatting	Admin can set the defaults for orientation, paper size, and margins and select the order and layout options for the graphs that are included in the text document that incorporates all the individual time-concentration, excretion rate, and percent dose remaining graphs.	User can modify all of the Admin formatting settings on a per-run basis.

About Pharsight Corporation

Pharsight Corporation provides software and services designed to improve the efficiency of drug development. The company's proprietary technology and world-class consulting expertise enable pharmaceutical and biotechnology companies to make more confident decisions in dealing with complex issues of drug development and product portfolio management. Pharsight Corporation helps companies make more informed and objective decisions that lead to more successful and predictable trial outcomes.

Pharsight Corporation is a public company headquartered in Mountain View, California. More information is available on the Web at www.pharsight.com.

Products

Pharsight offers a comprehensive suite of software products, including WinNonlin®, WinNonMix®, Pharsight Trial Simulator™, Drug Model Explorer,® and the Pharsight Knowledgebase Server™ suite of products. For further information, please visit Pharsight on the Web at www.pharsight.com.

Scientific and consulting services

Our scientific consultants can design and optimize clinical trials and clinical development programs to meet an individual company's objectives. Pharsight Scientific Services are project-centered, planned and delivered in accordance with specific needs and agreed-upon objectives. Consultants can facilitate:

- Gathering and interpreting data
- Building drug and population models
- Guiding variability testing and trial optimization
- Addressing specific development program objectives
- Process automation

Training

Pharsight Corporation offers workshops and training courses at regular intervals. On-site training is available by request. Contact Pharsight for schedules, pricing, and availability. The training schedule is also available on Pharsight's corporate Web site at www.pharsight.com/training/.

Technical support

Consult the product documentation to address questions. If further assistance is needed, contact Pharsight technical support by e-mail or Web (preferred), phone, fax, or mail.

E-mail:	support@pharsight.com (fastest response time)
Web:	http://www.pharsight.com/support/support_sflogin.php
Phone:	1-919-852-4620
Fax:	1-919-859-6871
Mail:	Pharsight Corporation 5625 Dillard Dr., Suite 205

Cary, North Carolina 27518

For the most efficient service, e-mail a complete description of the problem, including copies of input data, model file, pap file and/or pcp file, and instructions detailing how the error with AutoPilot originated, as well as the ASCII output, if applicable.

Licensing and product upgrades

For license renewals and product upgrades, contact Pharsight sales:

E-mail: sales@pharsight.com
Telephone: 1-888-708-7444 (from US only)
Fax: 1-650-314-3811

Request assistance with Pharsight software licensing by e-mail or telephone:

E-mail: license@pharsight.com
Telephone: 1-919-852-4620

Customer feedback

Submit requests for product enhancements and defect corrections by e-mail, fax, or through Pharsight's customer support Web site:

E-mail: support@pharsight.com
Web: support.pharsight.com
Fax: 1-919-859-6871

Chapter 2

Installation

System requirements and installation instructions

Review the following material before installing WinNonlin AutoPilot.

- "System requirements" below
- "Installing AutoPilot" on page 14

Note: For installation instructions for WinNonlin, see the WinNonlin *Getting Started Guide*.

System requirements

For acceptable performance, the following requirements are highly recommended for a system running WinNonlin AutoPilot.

Table 2-1. System requirements for WinNonlin AutoPilot

Item	Minimum	Recommended
System software	Windows 2000 Service Pack 4, Windows 2000 Japanese SP4, Windows XP Service Pack 2, Windows XP Japanese SP2, or Citrix Presentation Server 4 on Windows 2003	Windows XP
Browser (to view online help)	Microsoft Internet Explorer 5.0 or higher	Internet Explorer 6.0 or higher
Processor	Pentium® III 1GHz	Pentium IV 1.4GHz
RAM	512 MB	1 GB

Table 2-1. System requirements for WinNonlin AutoPilot

Item	Minimum	Recommended
Hard disk space: installation drive[a]	60MB (install footprint only, excludes study data and generated output)	NA
Graphics	SVGA or better	NA

a. Hard drive onto which AutoPilot is installed.

The following software must be installed on the system running AutoPilot.

Table 2-2. Required software

Software	Version(s) supported	Version(s) recommended
WinNonlin Professional or Enterprise	version 5.0.1, 5.1.1, or 5.2	version 5.2
SigmaPlot	version 8 or later For Citrix, version 9 or later Note: A network license for SigmaPlot is required when running on Citrix.	version 9
Microsoft Word	2000, 2003, 2003J, XP, or XPJ	XP or 2003
Microsoft Excel	2000, 2003, 2003J, XP, or XPJ	XP or 2003
Microsoft .NET	Microsoft .NET framework 1.1	NA

For (optional) study data repository and reporting functions, WinNonlin Enterprise edition with Pharsight Knowledgebase Server version 3.0 or later and PKS Reporter version 1.2.2 can be used in conjunction with AutoPilot.

Installing AutoPilot

AutoPilot installation requires read/write access to the Windows system directory and the installation directory. The files in the Windows system directory are used internally by the application.

Also, AutoPilot also requires write access to the folder C:\Program Files\Pharsight\AutoPilot\APSystem as error logs are written to subfolders under that folder.

Note: Installation on Windows 2000 or XP requires administrator rights.

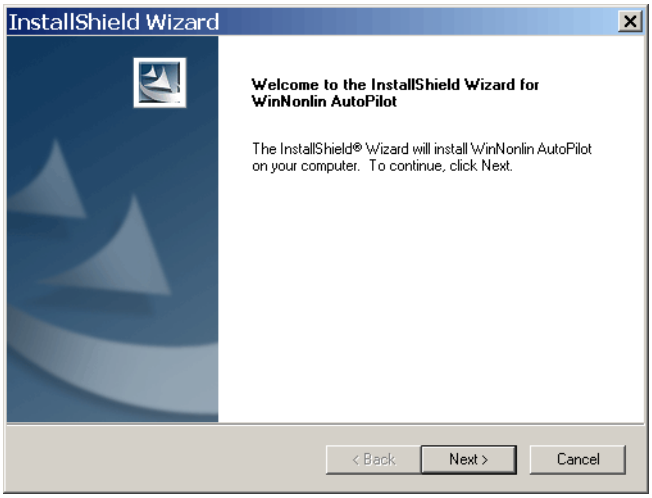
AutoPilot installation

To install AutoPilot:

1. Confirm that the system meets the requirements outlined under "System requirements" on page 13, including required software.
2. Close all Windows applications.
3. If an anti-virus program is running, turn it off before installing AutoPilot. Anti-virus programs can severely degrade installation performance. If the AutoPilot CD must be checked for viruses, run the virus scanning software on the CD (being sure to scan all compressed files) before installing the application.
4. Insert the AutoPilot CD into the CD-ROM drive.

   If the Installation Wizard does not start automatically:

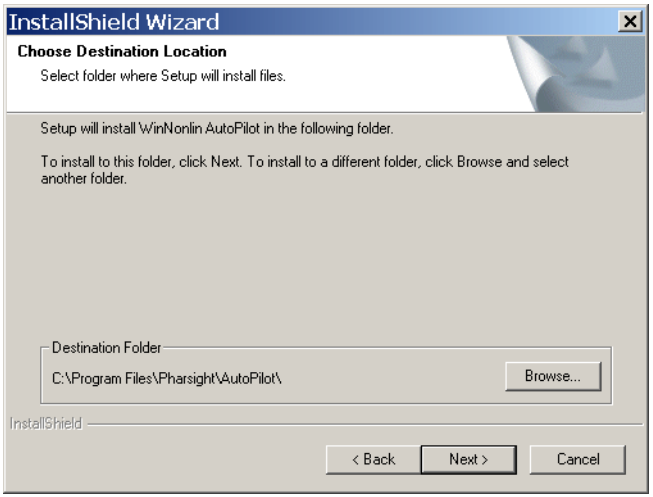
   a. From the Windows **Start** menu choose **Run**.
   b. In the Run dialog box, type `d:\setup`, where d is the letter assigned to the CD-ROM drive, and click **OK**.
5. The software scans the system for a previous installation of AutoPilot. If one is located, remove it, then re-launch the installer (step 4 above) to proceed.
6. The following Welcome screen is displayed.



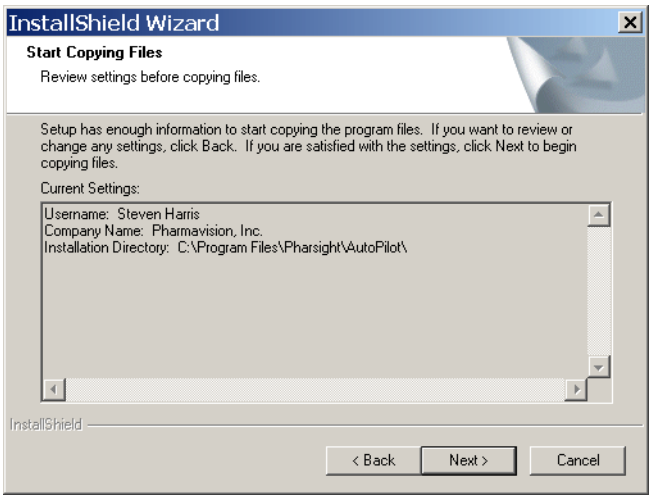
Click **Next**.

7. The user license agreement is displayed. Click **I Agree**.
8. The customer infomation screen is displayed. Type the primary user's name and company (optional).

9. Select whether you want the software to be available to all users who log onto the computer or only the currently logged-in user. Then, click **Next**.
10. Click **Browse** to locate the folder into which to install Autopilot. The default installation location is C:\PROGRAM FILES\PHARSIGHT\AUTOPILOT.



Then, click **Next**. The following screen is displayed:



Click **Next** to begin the installation.

11. You are asked whether to enable PKS access:

    Choosing Yes allows the user to load input study data and save output using PKS in addition to a local (non-PKS) folder.

    Choosing No allows the user to only load input study data and save output to a local folder.

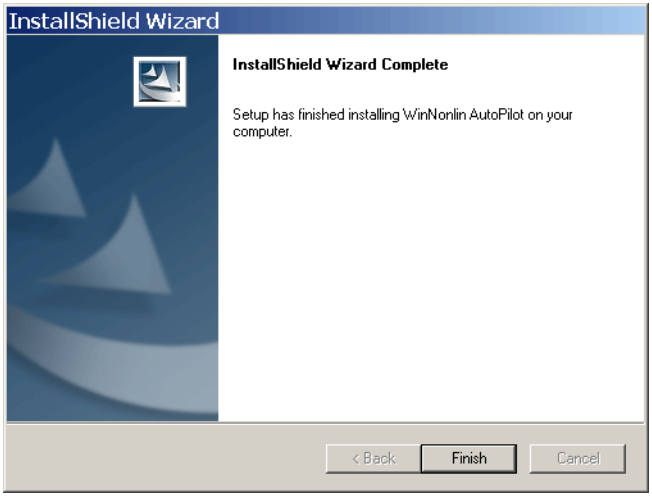
12. The following content is loaded:

Table 2-3. AutoPilot installation content

Description	Default location
AutoPilot software and online help	C:\Program Files\Pharsight\AutoPilot and sub-directories
Example input (study data)	C:\Program Files\Pharsight\AutoPilot\Examples
PDF user manual	C:\Program Files\Pharsight\AutoPilot\User Docs

Note: Contact Pharsight Customer Support (support@pharsight.com) for a complete list of files that are installed with AutoPilot and their default locations.

The InstallShield Wizard is displayed when the installation is complete.



Click **Finish** to exit the wizard.

Note: AutoPilot requires a current license for WinNonlin. See "Licensing" on page 21 for details and instructions.

Usage requirements

The following settings are required before using AutoPilot.

1. In WinNonlin, click **Tools>Options**, and then set the following:

a. *Models*: Select **Workbook**, **Charts**, and **Exclude profiles with insufficient data** as Default Output Options.

b. *Units*: Select **Show units with column headers**, **Show units on chart labels**, and **Show units on tables** as Default Unit Options.

2. Pharsight Knowledgebase Server (if applicable):

   a. WinNonlin AutoPilot requires system-level WRITE access to save results back to PKS, or system-level READ access to access data and save results to a local hard drive.

   b. If you are installing Autopilot and WinNonlin on a system for the first time, to use Autopilot with PKS, you must first load a study from PKS into WinNonlin. To do this, open WinNonlin, select Load, and select any study from PKS. After performing this step, you are able to load studies from PKS in Autopilot.

3. SigmaPlot:

   a. In the spw.ini file, set the MaxNumberAutoLegends to at least 600.

   b. In SigmaPlot, go to **Tools>Options** and click the **Page** tab. Deselect the **Graph objects resize with graph** check box.

Chapter 3

Licensing

Installation of AutoPilot software licenses

AutoPilot requires installation of current license key codes for both AutoPilot and WinNonlin. There are two types of license key codes:

1. A *node license key code* activates the software on the system on which it is installed. The license agreement restricts installation of the software and license to a single personal computer (PC) per node license.
2. *A floating license key code* enables multiple PCs in a networked environment to run the product using a shared pool of software licenses. The number of simultaneous users is limited to the total number of licenses on the license server.

Installation Notes

Install the license that applies to your application. For the installation of the required WinNonlin licenses, see additional directions in the *WinNonlin Getting Started Guide.*

Node License

An AutoPilot node license is sent via e-mail. The license information sent contains the correct license code to be used.

Floating License

The AutoPilot floating license is sent via e-mail. The license information sent contains the correct license code to be used.

For WinNonlin version 5.0.1

For WinNonlin version 5.0.1, the WinNonlin and AutoPilot licenses must be of the same type. They both must be node or they both must be floating licenses. The two licenses must be installed in the WinNonlin directory.

Installing a node or a floating license key code

Use the Pharsight License Wizard to install both the WinNonlin and AutoPilot licenses.

For WinNonlin versions 5.1.1 and higher

WinNonlin 5.1.1 and higher and AutoPilot 1.1 have separate license wizards.

1. The WinNonlin 5.1.1 and higher license wizard is located at **All Programs>Pharsight>WinNonlin>Pharsight License Wizard** in the Windows **Start** menu.
2. The AutoPilot 1.1.1 license wizard is located at **All Programs>Pharsight>WinNonlin AutoPilot 1.1.1>AutoPilot License Install Wizard** in the Windows **Start** menu.

CAUTION: The license installation process will not work if a user tries to install licenses for both programs using the same wizard.

For WinNonlin versions 5.1.1 and higher, WinNonlin and AutoPilot can have different license types. For example, WinNonlin can have a Node license and AutoPilot can have a Floating license.

The order in which you install the licenses is important. First, install the WinNonlin license in the WinNonlin installation directory using the Pharsight License Wizard. Then, after you received by e-mail the AutoPilot license information, install the AutoPilot license in the AutoPilot installation directory using the AutoPilot License Install Wizard.

The license key code and product tracking ID

One license key code and one product tracking ID are included with each license or set of licenses purchased. For mail shipments and computer downloads, the key code and product tracking ID are sent by e-mail. For electronic

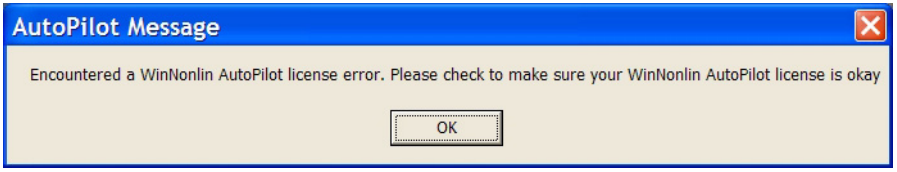
license renewals, the key code, product tracking ID, and license type are sent by e-mail.

Include the product tracking ID in all correspondence with Pharsight Corporation about the product and its license, including license renewals, software updates, and product upgrades.

Note: Contact Pharsight Customer Support (support@pharsight.com) for suggestions on automated deployment of network (floating) versions of Pharsight software.

Install an AutoPilot 1.1.1 license

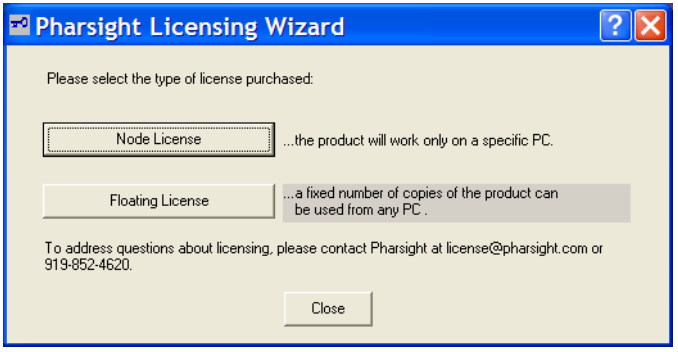
If you attempt to run AutoPilot 1.1.1 without first installing an appropriate license, the following error message is displayed:



To install a node license for AutoPilot 1.1.1:

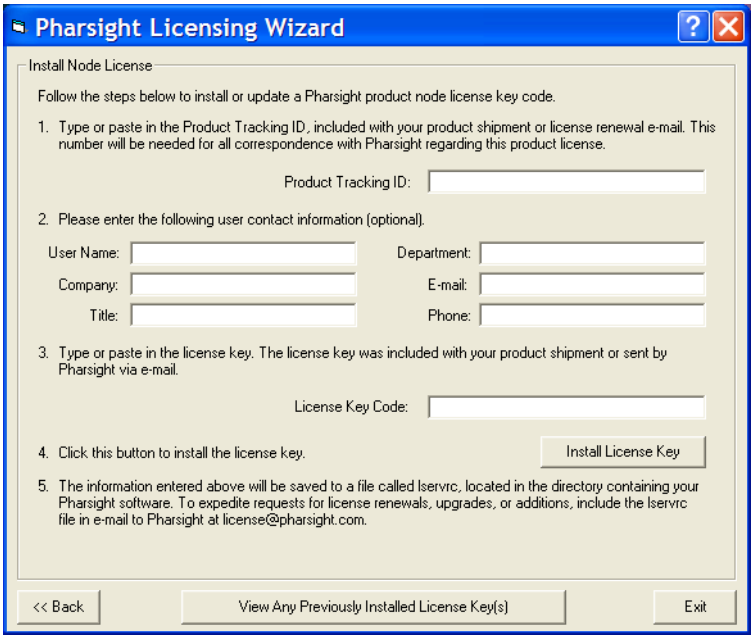
1. From the Windows **Start** menu, go to **All Programs>Pharsight>WinNonlin AutoPilot 1.1.1>AutoPilot License Install Wizard**.

   The Pharsight Licensing Wizard is displayed:



2. Click **Node License** to install a node license for AutoPilot 1.1.1.

Figure 3-1. Install node license wizard.



3. Enter your product tracking ID in the **Product Tracking ID** field.
4. Enter your contact information in the appropriate fields.
5. Type or paste your license key into the **License Key Code** field.
6. Click **Install License Key**.

   A message box is displayed that confirms that your license information has been correctly installed:

7. Click **View Any Previously Installed License Key(s)** to display the Previously Installed License Code(s) message box.

Note: The Previously Installed License Code(s) message box contains the license code and other licensing information about your Pharsight software product.

Click **Support** to copy this information to the clipboard so it can be pasted into an e-mail if you need to contact customer support.

8. Click **Exit** to exit the message box.
9. Click the Pharsight Licensing Wizard's **Exit** button when you are finished or click the **<< Back** button if you need to install another license.

   The node license information is written to the LSERVRC file, which is located by default at C:\Program Files\Pharsight\AutoPilot.
10. Load AutoPilot 1.1.1 to ensure that the product tracking ID and license key information entries were successful.

To install the floating license server:

1. Load the AutoPilot CD into the computer that will act at as the Floating Network License server.
2. Run the LicenseServerInstall.exe file, which is located in the AutoPilot CD's \Floating License Server\ directory.

   The default directory path to the executable is D:\Floating License Server\LicenseServerInstall.exe
3. Follow the instructions in the installation wizard.

CAUTION: The Pharsight Floating License Server must be installed in the process space of the intended server. It must be installed and run on the server itself and not on a mapped drive on a client machine.

To install a floating license on the license server:

1. Open the Windows **Start** menu on the network server and choose **Programs>Pharsight>Pharsight Floating License Server>Pharsight License Wizard for Server**.

   The Pharsight License Wizard for Server window is displayed.

2. Enter the Product Tracking ID, which was included with your AutoPilot shipment or license renewal e-mail. Refer to this number in all correspondence with Pharsight about this product license.

Note: To locate the Product Tracking number after installation, open the Pharsight Licensing Wizard.

3. Enter the contact information, if desired. This information is saved in the license key file, which you can use to provide Pharsight with information for license renewals and customer support correspondence.
4. Enter the license key code included with your product shipment or license renewal e-mail.
5. Click **Install License Key** to save the information to the license key file and install the license, and then click **OK**.
6. Click **Exit** to close the wizard.

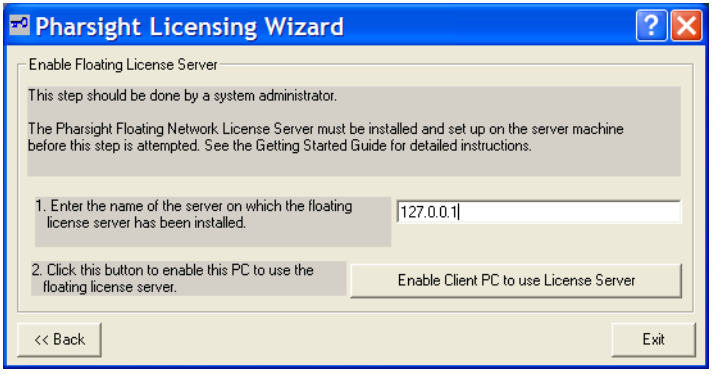
To install a floating license for AutoPilot 1.1.1:

1. From the Windows **Start** menu, go to **All Programs>Pharsight>WinNonlin AutoPilot 1.1.1>AutoPilot License Install Wizard**.

   The Pharsight Licensing Wizard is displayed.

2. Click **Floating License** to install a floating license for your local copy of AutoPilot 1.1.1.

Figure 3-2. Install floating license wizard.

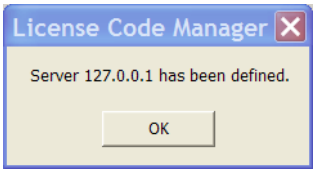


3. Enter the IP address of the server on which the Pharsight Floating Network License Server is installed. For example: 127.0.0.1.

Note: 127.0.0.1 is a generic server IP address that is used as an example for this set of instructions. Your actual server IP address will be different.

4. Click **Enable Client PC to use License Server**.

   A message box is displayed:



5. Click **OK** to continue.
6. Click the Pharsight Licensing Wizard's **Exit** button when you are finished or click the **<< Back** button if you need to install another license.

   The floating licensing information is written to the LSHOST file, which is located by default at C:\Program Files\Pharsight\AutoPilot.

7. Load AutoPilot 1.1.1 to ensure that the product tracking ID and license key information entries retrieved were successful.

Renewing a floating license key code

To renew a floating license, enter the new license key code and product tracking ID on the network license server using the Pharsight Floating License Wizard for Server. No changes are necessary on the client systems.

AutoPilot floating license issue

When AutoPilot is launched, it searches for a valid license for both AutoPilot and WinNonlin. If both licenses are found, then AutoPilot opens and it releases the AutoPilot and WinNonlin licenses back into the pool of available floating licenses.

AutoPilot retrieves floating licenses for AutoPilot and WinNonlin in the same manner when a user performs an automation run. After the automation run is

complete, AutoPilot releases the licenses back into the pool of available floating licenses.

The problem:

If a company has two AutoPilot floating licenses and two WinNonlin floating licenses, and there are three users who all need to use AutoPilot, all three users could successfully load AutoPilot without receiving a licensing error message.

However, once the third person starts her automation run, then she will receive an error message from AutoPilot, "Failed to obtain license information."

The solution:

Purchase enough licenses to satisfy user needs, or ensure that users are aware that the number of simultaneous automation runs is limited by the number of available, valid licenses.

Chapter 4

Testing the Installation

Confirming proper installation of WinNonlin AutoPilot

To test that the AutoPilot installation has been successful, you can generate limited output (tables, graphs, and appendices) using sample data files provided with the software. If you select all default tables, graphs, and appendices, the automation run is time-consuming because of the volume of the output. However, by following these instructions, a time-consuming run is avoided.

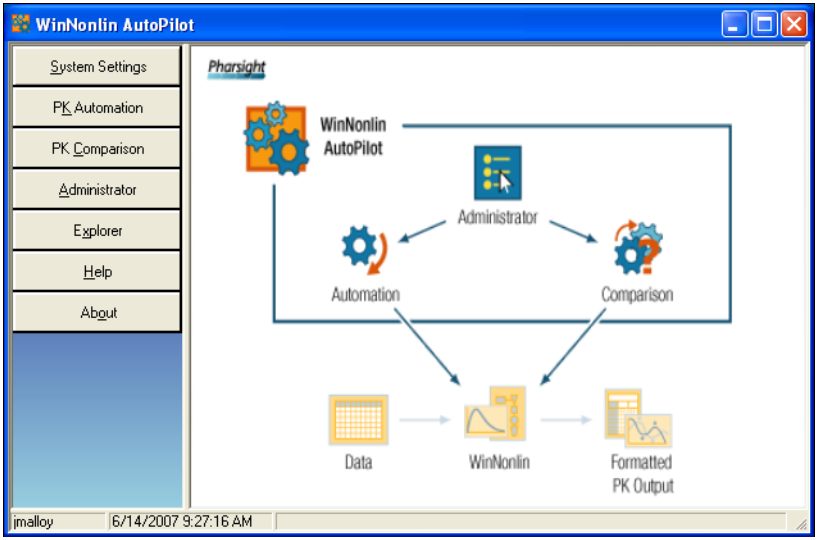
CAUTION: This chapter is not a full validation of the AutoPilot software.

Installation test

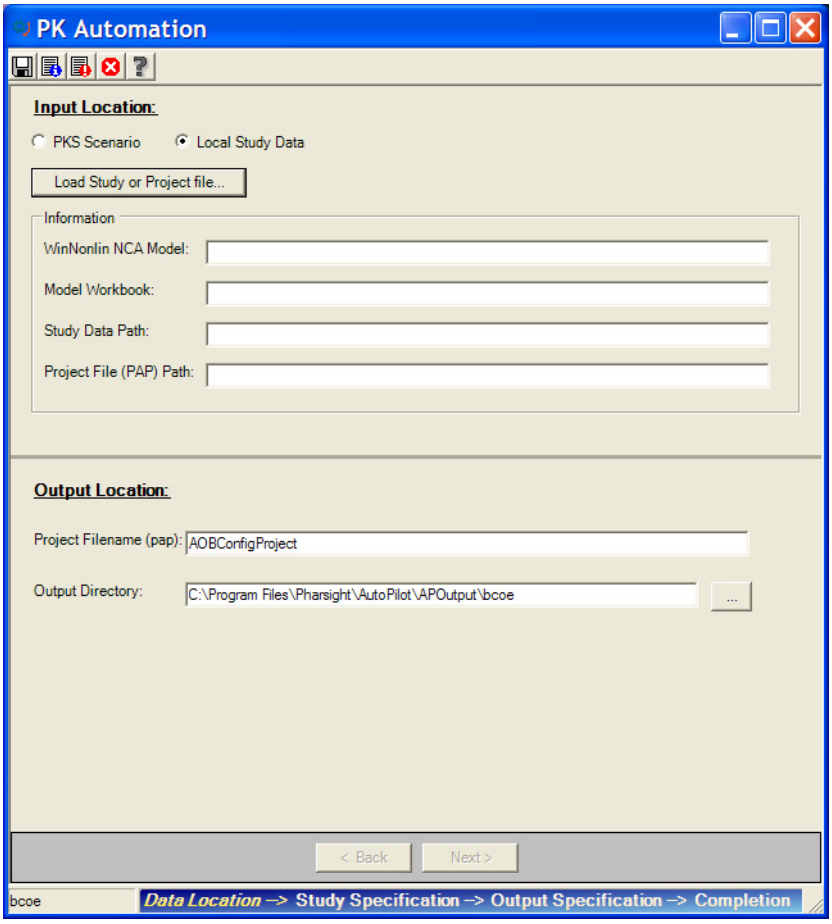
To confirm that AutoPilot is successfully installed and working with WinNonlin:

1. Double-click the AutoPilot icon on your Windows desktop.

   The AutoPilot main window is displayed.



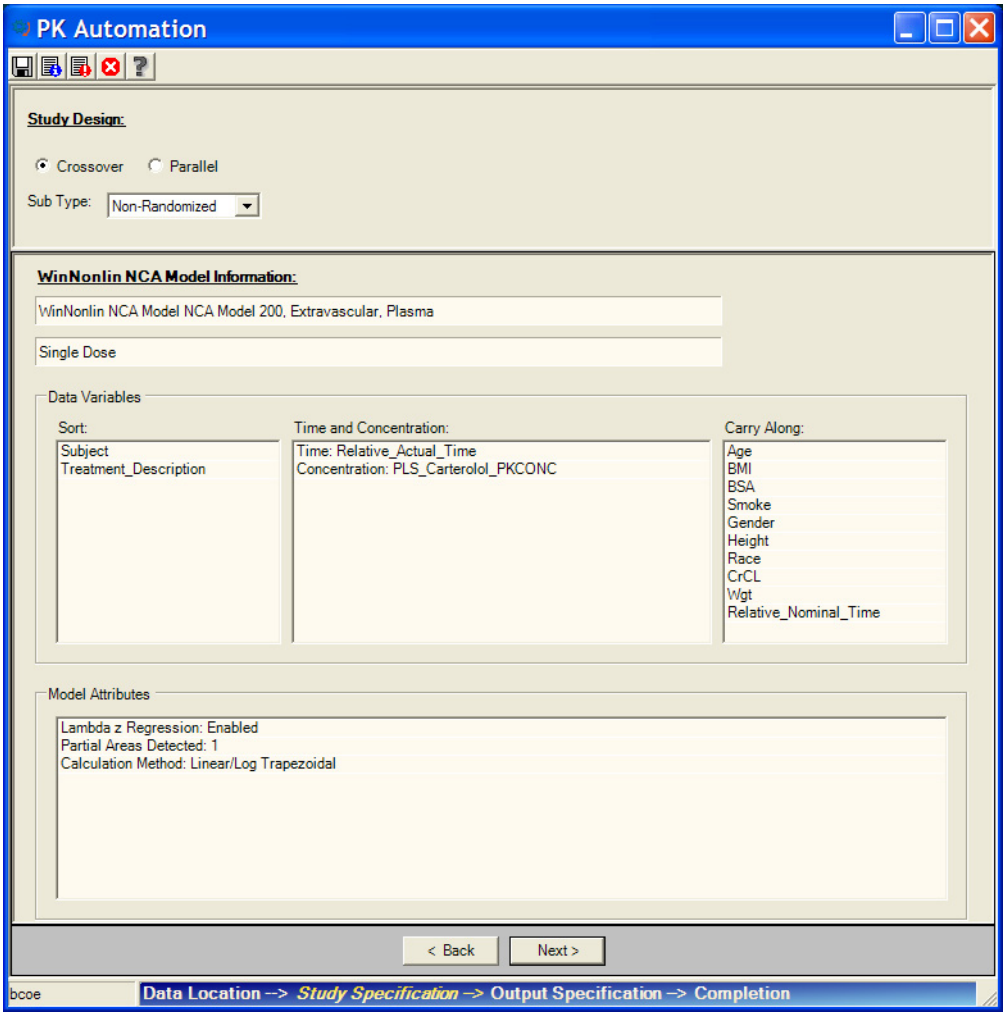
2. Click **PK Automation**. The PK Automation window is displayed.
3. Click **Local Study Data**, then click **Load Study or Project File**.



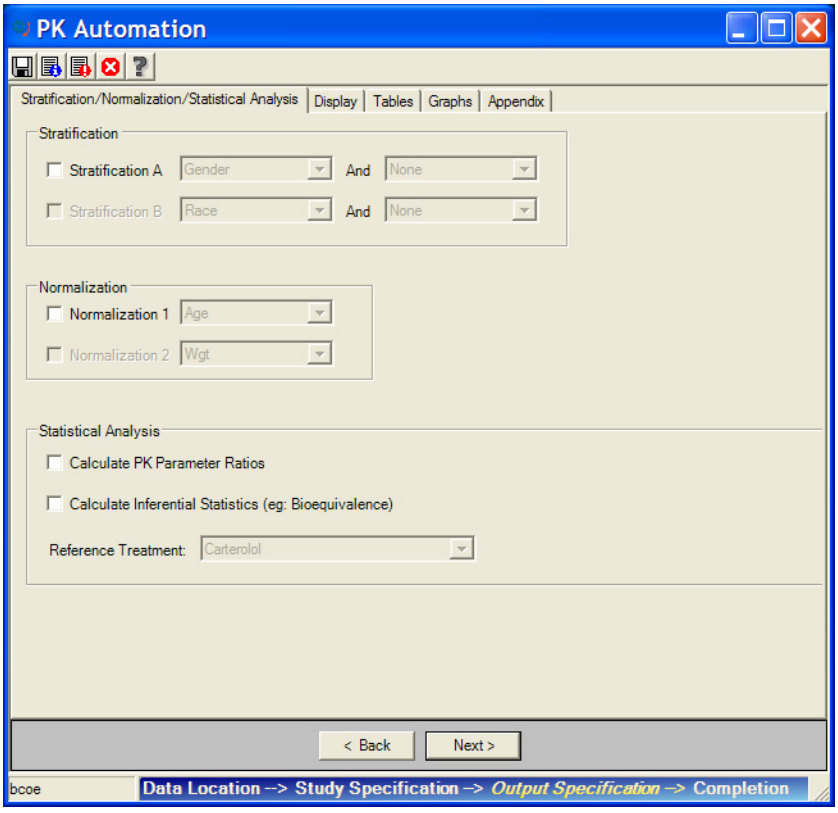
4. In the AutoPilot installation directory, locate the EXAMPLES folder and open the example file AUTOPILOT CROSSOVER DEMO - CARTEROLOL.PMO.

   AutoPilot launches WinNonlin to locate the model and associated data files and load the appropriate settings into the PK Automation wizard. This step confirms successful communication between AutoPilot and WinNonlin.

5. If desired, edit the local directory under Output Location to specify a directory to contain test output. Then, click **Next** to proceed to the Study Specification page.

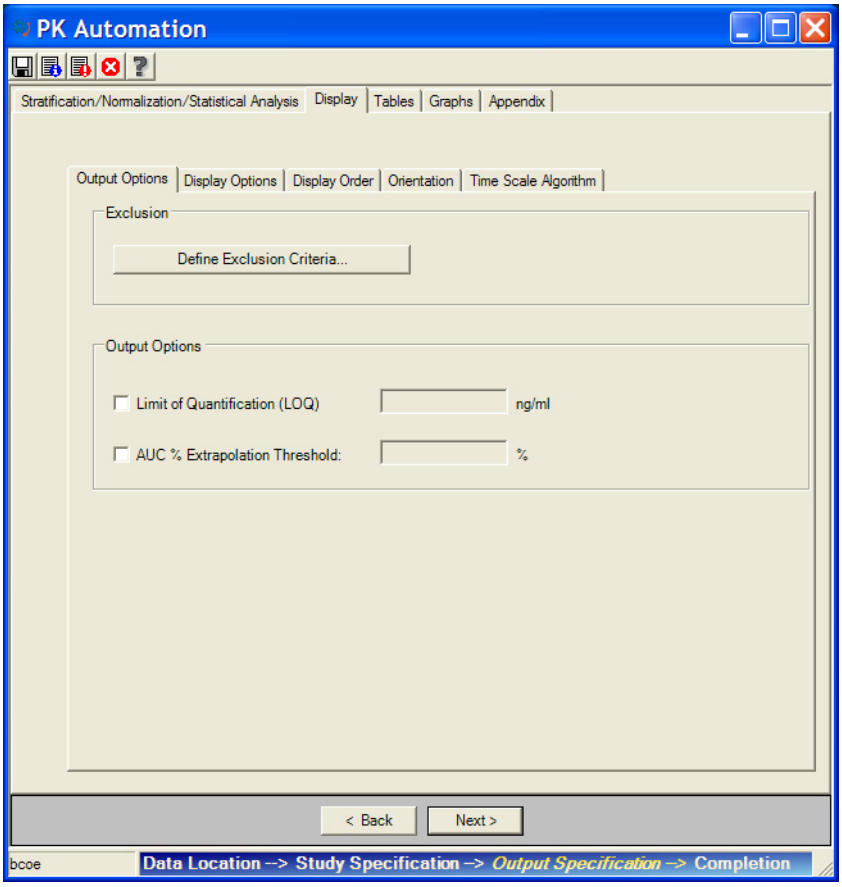


6. For this example, the default options are correct. This step confirms that AutoPilot is reading the NCA model (.pmo file) with the correct attributes. Click **Next**. The Output Specification page is displayed.

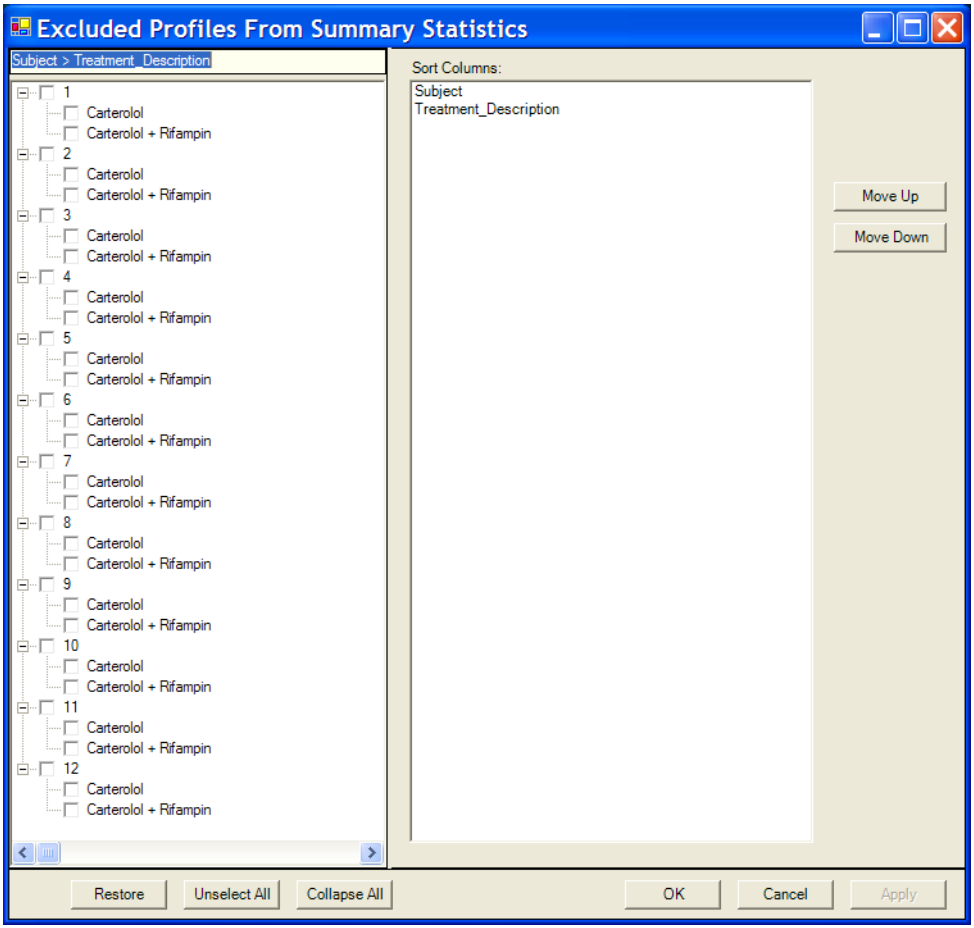


Note the other 4 tabs. These tabs are explained and displayed as you progress through this wizard.

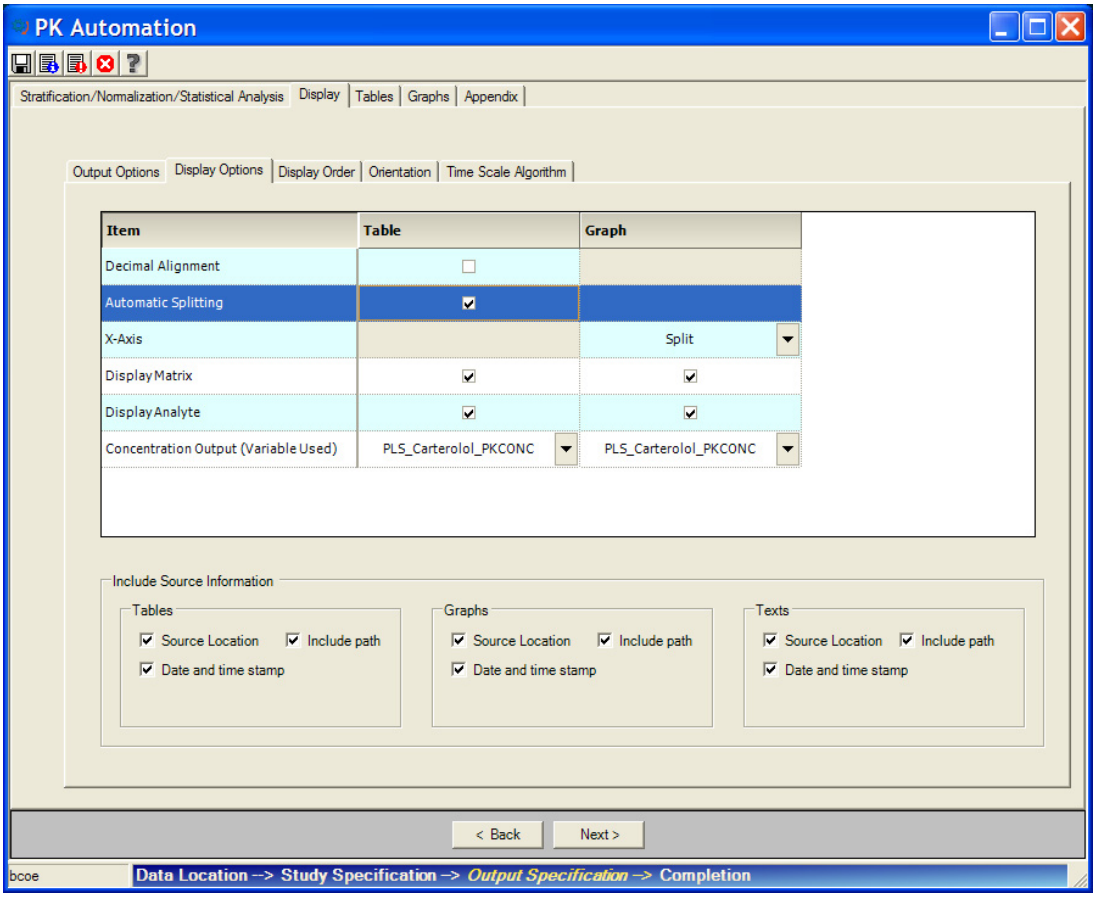
7. Click the **Display** tab to set the parameters. Note the **Output Options** tab on this page is selected by default.



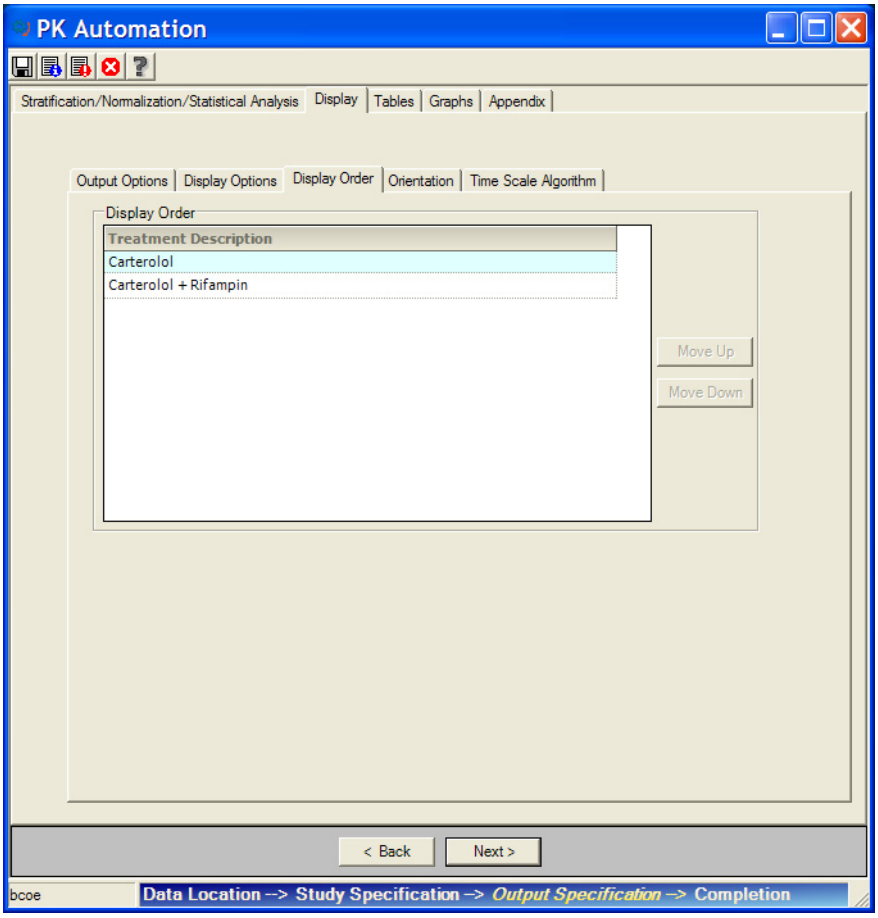
8. Click **Define Exclusion Criteria**, where you can add or remove profiles.



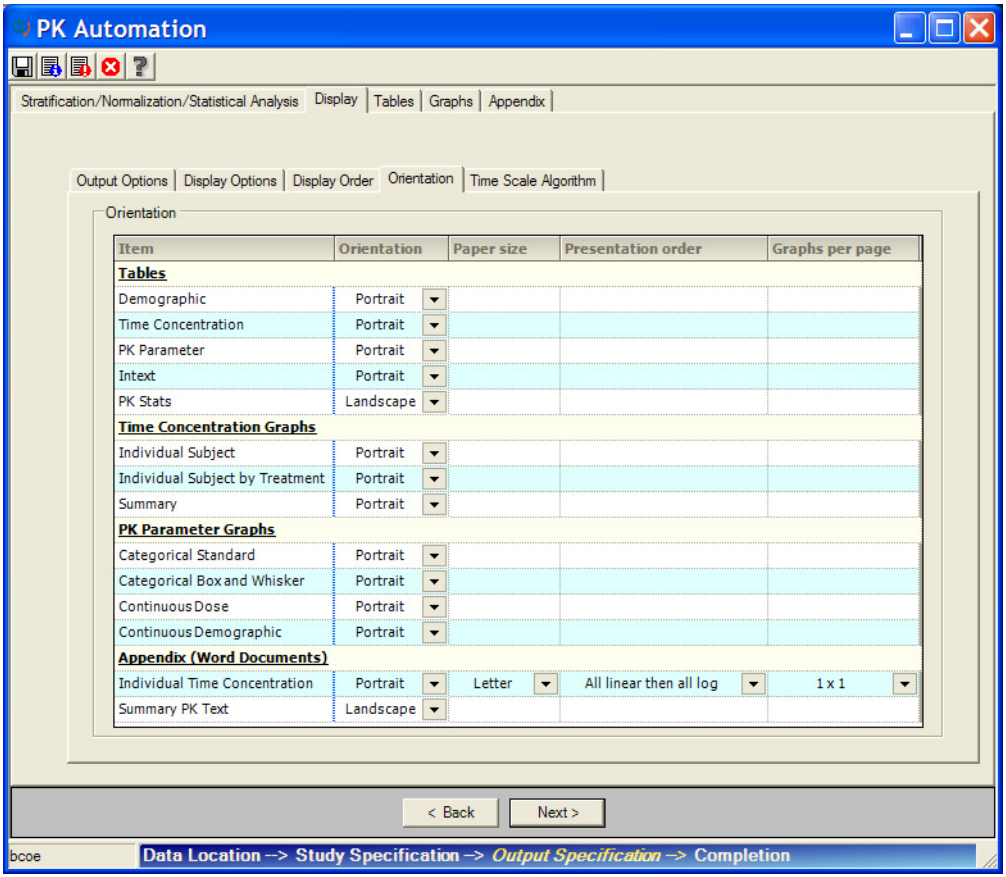
9. In the left window, select the appropriate checkboxes for the criteria you want to exclude from the summary statistics. In the Sort Columns window on right, you can move the selections up or down in the order preferred.
10. Click **OK** after all of your selections have been made in this dialog.
11. Click the **Display Options** tab.



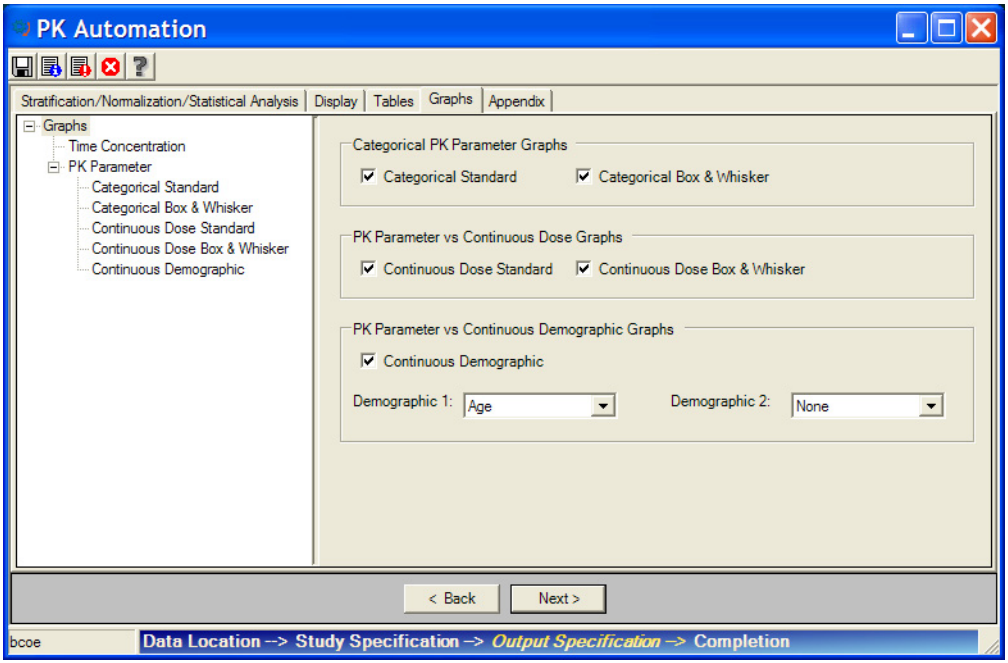
12. Click the **Display Order** tab. Use this page to rearrange the Treatment Description options.



13. Click the **Orientation** tab. Use this page to select the portrait or landscape options in the Tables, Time Concentration Graphs, PK Parameter Graphs, and Appendix items.

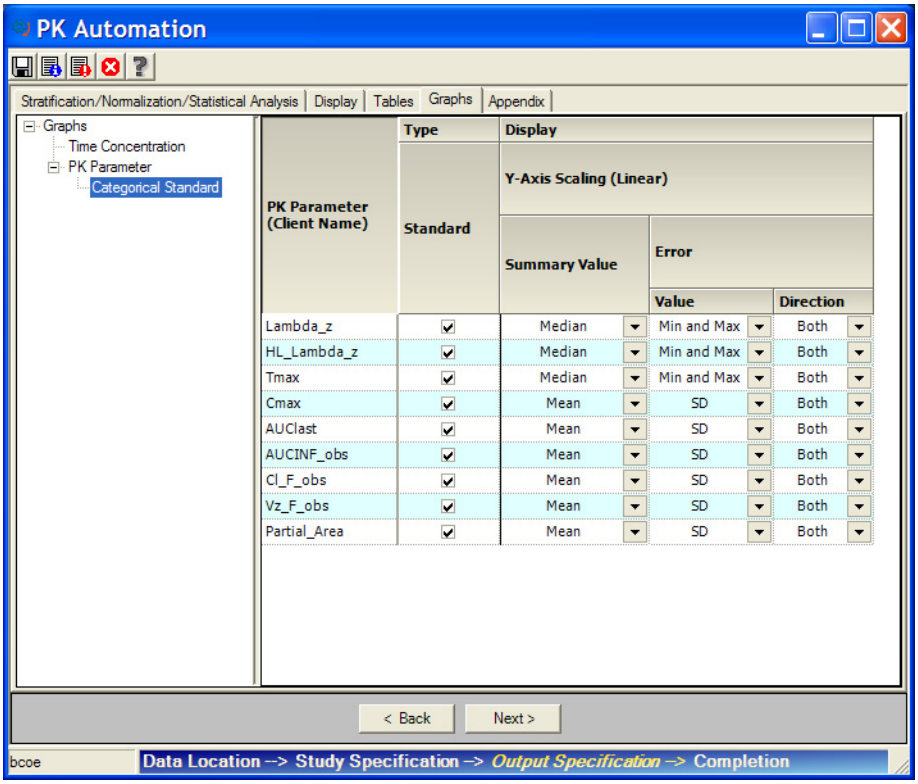

PK Automation
Stratification/Normalization/Statistical Analysis
Display
Tables
Graphs
Appendix
Output Options
Display Options
Display Order
Orientation
Time Scale Algorithm
Orientation
Item
Orientation
Paper size
Presentation order
Graphs per page
Tables
Demographic
Portrait
Time Concentration
Portrait
PK Parameter
Portrait
Intext
Portrait
PK Stats
Landscape
Time Concentration Graphs
Individual Subject
Portrait
Individual Subject by Treatment
Portrait
Summary
Portrait
PK Parameter Graphs
Categorical Standard
Portrait
Categorical Box and Whisker
Portrait
Continuous Dose
Portrait
Continuous Demographic
Portrait
Appendix (Word Documents)
Individual Time Concentration
Portrait
Letter
All linear then all log
1 x 1
Summary PK Text
Landscape
< Back
Next >
bcoe
Data Location --> Study Specification --> Output Specification --> Completion

14. Click the **Graphs** tab.



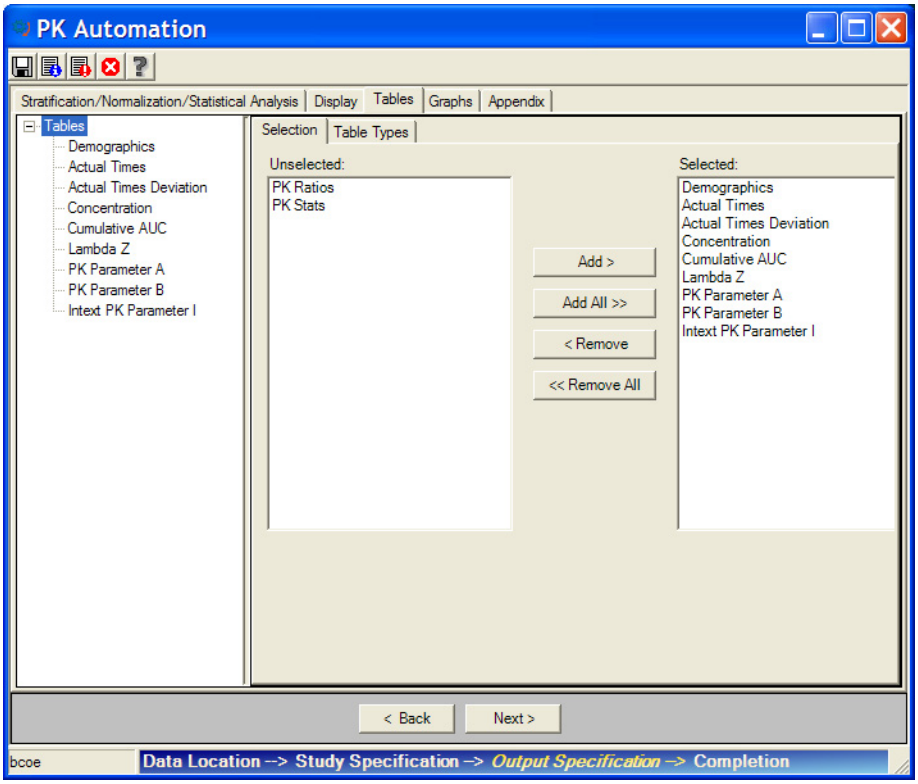
15. For this test run, deselect all check boxes except **Categorical Standard**.

16. In the left window, select **Categorical Standard** in the PK Parameter category. Select the appropriate checkboxes in the tables that will display. An example of the Categorical Standard table is displayed below.



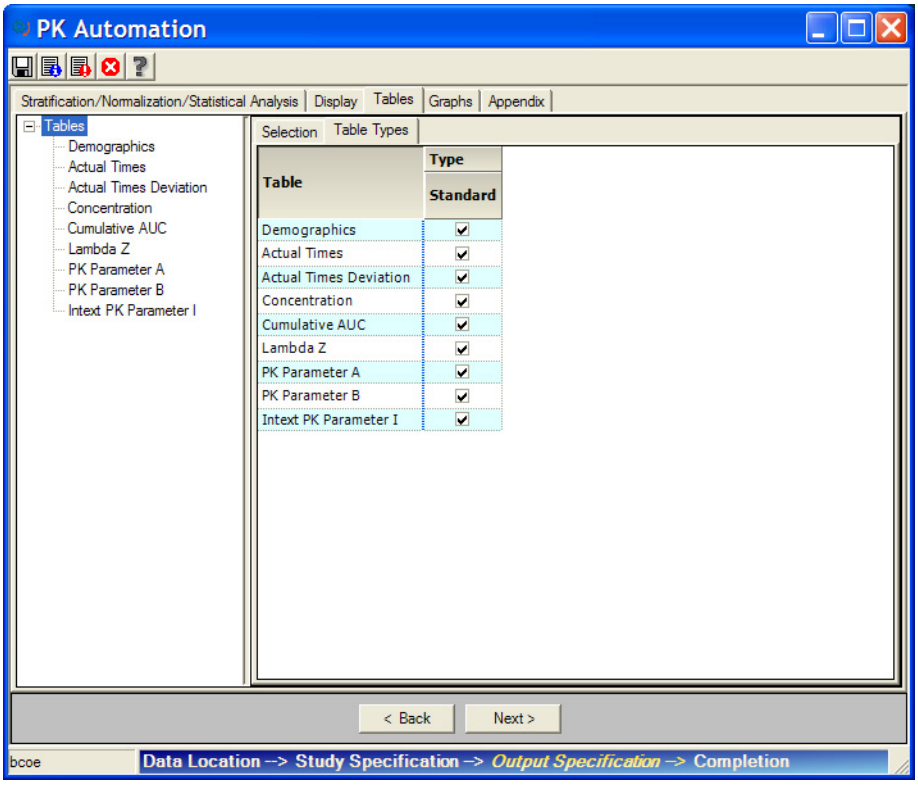
17. Click the **Tables** tab. The Tables window (Selection tab) is displayed. In the left pane, navigate to a table type, such as Actual Times. In the Selection tab pane, click **Remove All**.

Note: Some table types, such as Lambda Z, will have a Variables tab and a Statistics tab. For table types with variables and statistics, click **Remove All** for both.

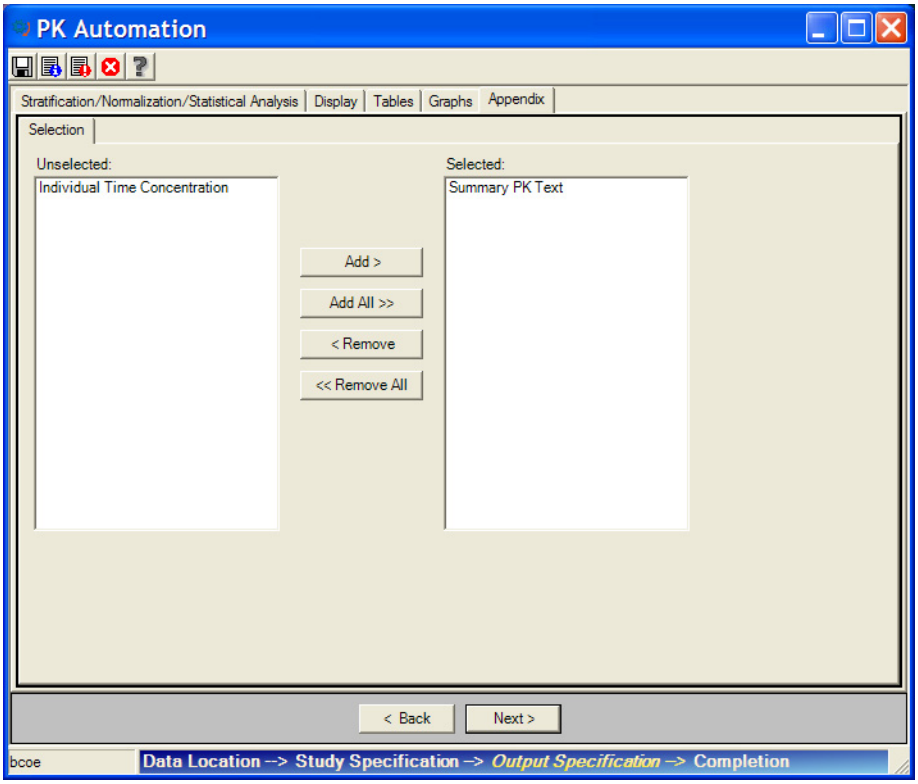


18. Repeat step 17 for each remaining table category, except Demographics, to limit the number of tables produced for this sample run.

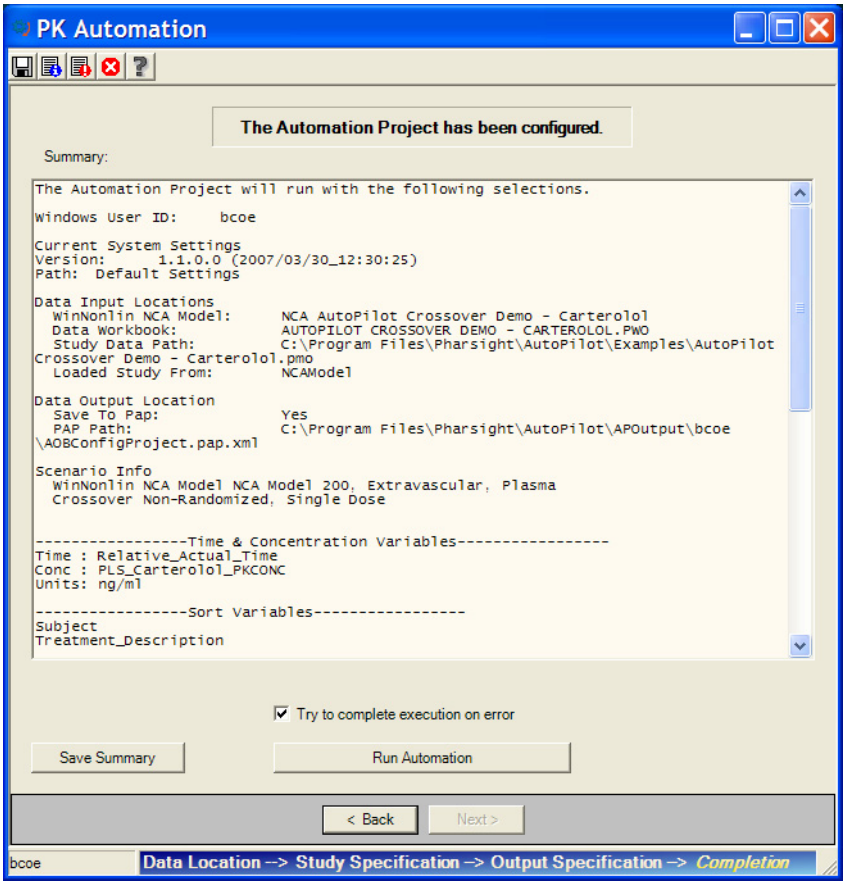
19. Select Tables in the left pane and click the **Table Types** tab. The Tables, Type, and Exclusion Criteria columns are displayed. Select the appropriate Table options listed in Table Types window.



20. Click the **Appendix** tab. In the right pane, in the Selected column, select all but one appendix and click **Remove** to limit the number of appendices generated for this run.



21. Click **Next** after all of your selections have been made in this dialog. The "Automation Project has been configured" dialog is displayed.



22. Click **Run Automation** to run a test automation.

    AutoPilot runs the analysis in WinNonlin and generates tabular, graphical, and text output in the assigned output directory.

23. After the run has completed successfully, a confirmation message is displayed.

    Navigate to the output directory, which contains several Excel spreadsheets, Word documents, and plots.

24. Exit AutoPilot.

Chapter 5

Study Preparation

Data columns and NCA model setup

WinNonlin AutoPilot analyses require that study data include specific variables for automation input. The variables fall into the following categories:

- Subject
- Demographic
- Dosing
- Sample Collection Point (SCP)
- Data Collection Point (DCP)

Required and recommended variables are listed under “Study data” on page 45.

Once the study data variables are defined, the user must create a WinNonlin model that defines model settings and parameters for an AutoPilot automation project. Specific model requirements are given under “NCA model requirements” on page 51.

Study data

Variable names

Variable names are not fixed. AutoPilot administrators can map study data variable names used in your organization to AutoPilot system variables and also assign custom output column names (“display names”) for the final tables, graphs, and so on as needed. In addition, the WinNonlin configuration file DEFAULTNCAPARAMETERNAMES.MAP can be used to map WinNonlin

custom PK parameter names to AutoPilot. (See the WinNonlin user documentation for instructions.)

Data variables

The tables below list the default variables for an AutoPilot-ready study, including required variables and additional variables that are often useful. AutoPilot administrators can add variables by providing the name, category, and data restrictions such as discrete or continuous. Associated units from these added variables are taken directly from the column headers in the study data.

In the tables below, "WinNonlin name" refers to the required column name as the data is displayed in WinNonlin; "Display name" is the default column name used in final AutoPilot output. An administrator can specify custom WinNonlin and display names. See "Required data variables by study type" on page 49 for a listing of required and optional variables for each study type. See "NCA model requirements" on page 51 for a listing of required variables by NCA model.

Table 5-1. Subject variables

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Subject	Subject	NA	No	Alphanumeric string	Patient (subject) identifier

Table 5-2. Dosing variables

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Dose	Dose	Yes	dec / 0	Numeric	Dose administered.

Table 5-3. Sample Collection Points (SCPs)

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Relative_Nominal_Time	Nominal Time	Yes	dec / 2	Numeric	Protocol/nominal time of sampling since last dose. Used for Time, Time-Conc, and Cumul AUC output and possibly X-var in model.

Table 5-3. Sample Collection Points (SCPs) (continued)

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Relative_Actual_Time	Actual Time	Yes	dec / 2	Numeric	Actual time of sampling since last dose. Used for Time, Time-Conc output. Often used for the X-var in model.
Relative_Nominal_End_Time	Nominal End Time	Yes	dec / 2	Numeric	Two purposes: Observation sheet = actual interval end time from last dose of sampling for urine (Upper Time in model) and Dosing sheet = nominal end time for infusion.
Relative_Actual_End_Time	Actual End Time	Yes	dec / 2	Numeric	Two purposes: Observation sheet = actual interval end time from last does of sampling for urine (Upper Time in model) and Dosing sheet = actual end time for infusion.
[Matrix]_[AnalyteID]_[Route]_*[a]	[Matrix] (AnalyteID) Concentration[a]	Yes	sig / 3	Numeric or identified as Missing	Concentration of sample collected. Every column name that uses this template is identified as a concentration column, for example, [Matrix]_(AnalyteID)_RawCONC.
Volume	Volume	Yes	dec / 0	Numeric	Sample Collection Volume (Required for Urine Models 210-212 only)
Midpoint	Midpoint_Time	Yes	dec / 2	Numeric	Midpoint_Time is the calculated time point that is equidistant between the Lower and Upper collection times of a given urine collection interval.
Rate	Rate	Yes	sig / 3	Numeric	Rate is the excretion rate for each interval (amount eliminated per unit of time) = (Concentration * Volume) / (Ending time - Starting time).

a. [Matrix] is replaced with the matrix value from the study data. (AnalyteID) is replaced with the Analyte ID from the study data. Using the Administrator module, an administrator can configure the concentration columns regarding name, use, and order of Matrix and AnalyteID.

Table 5-4. Data Collection Points

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Treatment_ Description[a]	Treatment =	No	NA	None	A description of the Treatment a subject receives, used both as sort variable in model and as output display.
Period	Period	No	NA	None	The period of time that a Treatment was received. Used primarily for statistical analyses, but also as both a sort variable and in output for Repeated Crossover designs.
Day	Day	No	dec / 0	Numeric	Profile Day, needed as a Sort model variable when more than one profile day in an automation run (e.g., Day 7 and 14). Not needed for single-dose (Day 1) studies.

a. In PKS mode, an additional column called 'Treatment' is also needed. This column is a requirement in mapping of data into PKS, but is not used by AutoPilot.

Table 5-5. Demographic variables (current defaults; not mandatory)

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Sequence*	Sequence	NA	NA	Discrete, alphanumeric	Sequence of treatments received (randomized crossover studies only)
Gender	Gender	NA	NA	Discrete, values: male, female	Subject sex
Age	Age	year	dec / 0	Continuous, numeric	Subject age
Race	Race	NA	NA	Discrete, alpha. e.g., "Caucasian"	Subject ethnicity
Wgt	Weight	kg	dec / 1	Continuous, numeric	Subject body weight at screening
Height	Height	cm	dec / 0	Continuous, numeric	Subject height
BMI	BMI	kg/m2	dec / 1	Continuous, numeric	Subject Body Mass Index
LBW	LBW	kg	dec / 1	Continuous, numeric	Subject Lean Body Weight
BSA	BSA	m2	dec / 2	Continuous, numeric	Subject Body Surface Area
Smoke	Smoke	NA	NA	Discrete, values: yes / no	Subject smoking status

Table 5-5. Demographic variables (current defaults; not mandatory)

WinNonlin name	Display name	Default units	Default precision	Default restrictions	Comments
Alcohol	Alcohol	NA	NA	Discrete, values: yes / no	Subject status: consumes alcohol or not
Child_Pugh	Child Pugh	NA	NA	Discrete variable	Subject Child Pugh classification
CrCL	CrCL	mL/min	sig / 3	Continuous, numeric	Subject Baseline Creatinine Clearance
Genotype	Genotype	NA	NA	Discrete, alphanumeric, e.g., "CYP2D6 Extensive"	Subject Baseline genotype status

***** Required for randomized crossover study designs to conduct inferential statistics.

Required data variables by study type

The following tables list which data variables are required or optional, by study type and matrix (plasma or urine).

Table 5-6. Variable requirements for plasma data (NCA models 200-202)

Variable	Study Design				
	*RCT	**nRCT	Replicated	Parallel	Trough (All)
Subject	Required	Required	Required	Required	Required
Treatment_Description	Required	Required	Required	Required	Required
Period	Required	Optional	Required	Optional	Required for replicated, else optional
Day	Required	Required	Required	Required	Required
RAT	Optional	Optional	Optional	Optional	Optional
RNT	Required	Required	Required	Required	Required
XX_Dose	Required	Required	Required	Required	Required

Table 5-6. Variable requirements for plasma data (NCA models 200-202)

Variable	Study Design				
	*RCT	**nRCT	Replicated	Parallel	Trough (All)
Concentration variable[1]	Required	Required	Required	Required	Required
Sequence	Required	Optional	Optional	Optional	Optional
Demogs (Categorical)	Optional	Optional	Optional	Optional	Optional
Demogs (Continuous)	Optional	Optional	Optional	Optional	Optional

[1] Either XX_RawCONC or XX_PKCONC is required.

* RCT – Randomized Crossover Trial

** nRCT – Non-randomized Crossover Trial

Table 5-7. Variable requirements for urine data (NCA models 210-212)

Variable	Study Design			
	*RCT	**nRCT	Replicated	Parallel
Subject	Required	Required	Required	Required
Treatment_Description	Required	Required	Required	Required
Period	Required	Optional	Required	Optional
Day	Required	Required	Required	Required
RAT	Optional	Optional	Optional	Optional
RNT	Required	Required	Required	Required
RAET	Optional	Optional	Optional	Optional
RNET	Required	Required	Required	Required
XX_Dose	Required	Required	Required	Required
Concentration variable[1]	Required	Required	Required	Required
Volume	Required	Required	Required	Required
Sequence	Required	Optional	Optional	Optional
Demographics (Categorical)	Optional	Optional	Optional	Optional
Demographics (Continuous)	Optional	Optional	Optional	Optional
Midpoint_Time	Optional	Optional	Optional	Optional

Table 5-7. Variable requirements for urine data (NCA models 210-212)

Variable	Study Design			
	*RCT	**nRCT	Replicated	Parallel
Rate	Optional	Optional	Optional	Optional

[1] Either XX_RawCONC or XX_PKCONC is required.

* RCT – Randomized Crossover Trial

** nRCT – Non-randomized Crossover Trial

NCA model requirements

AutoPilot PK Automation projects require an NCA model, which is created in WinNonlin before running AutoPilot. The model requirements vary depending on the study design selected in the AutoPilot User Module and the WinNonlin NCA model used. Model requirements fall into the following categories:

- Variables (Sort, X-, Y-, and Carry Along)
- Dosing Regimen
- Regression (Lambda z)
- Partial Areas
- Model Options

Variable assignments

The tables below detail the WinNonlin NCA model requirements for plasma and urine matrices, respectively, for different PK Automation study designs. The Sort Variables in the model must be ordered as they are presented in the table below (e.g., Subject then Treatment_Description).

Note: Trough analyses do not require an NCA model.

Table 5-8. NCA requirements for plasma data (models 200-202)

Variable	Automation study design			
	Crossover			Parallel
	RCT	non-RCT	Replicated	
Sort variables				
Subject	X	X	X	X
Treatment_Description	X	X		
Period[a]			X	
Day[b]	X	X	X	X
X-variable				
Relative_Actual_Time or Relative_Nominal_Time	X	X	X	X
Y-variable				
Concentration variable	X	X	X	X
Carry-alongs				
Sequence[c]	X			
Period[a]	X			
Treatment_Description			X	X
Relative_Nominal_Time[d]	X	X	X	X

a. The variable Period is required as a Sort variable for a Crossover - Replicated study design or as a Carry-along variable for a Crossover - Randomized study that includes inferential statistics.

b. The variable Day is needed as a sort variable only when the study has multiple full-profile days.

c. The variable Sequence is needed as a Carry-along variable only for a Randomized Crossover that includes inferential statistics.

d. If the variable Relative_Nominal_Time is not used as the X-variable in the NCA model, it must be assigned as a Carry-along in order to create the Cumulative AUC output table.

Table 5-9. NCA requirements for urine data (models 210-212)

Variable	Automation study design			
	Crossover			Parallel
	RCT	non-RCT	Replicated	
Sort variables				
Subject	X	X	X	X
Treatment_Description	X	X		
Period[a]			X	
Day[b]	X	X	X	X
Lower times				
Relative_Actual_Time or Relative_Nominal_Time	X	X	X	X
Upper times				
Relative_Actual_End_Time or Relative_Nominal_End_Time	X	X	X	X
Volume				
Volume	X	X	X	X
Concentration				
Concentration variable	X	X	X	X
Carry-alongs				
Sequence[c]	X			
Period[a]	X			
Treatment_Description			X	X

a. The variable Period is required as a Sort variable for a Crossover - Replicated study design or as a Carry-along variable for a Crossover - Randomized study that includes inferential statistics.

b. The variable Day is needed as a sort variable only when the study has multiple full-profile days.

c. The variable Sequence is needed as a Carry-along variable only for a Randomized Crossover that includes inferential statistics.

Dosing regimen

AutoPilot requires that dose data be specified in the WinNonlin model, as is usual when running NCA models.

When using PKS study data, WinNonlin draws all dose information (e.g., values and units) for single-dose data from the PKS study data into the Dosing Regimen field of the NCA model. That information carries over to AutoPilot. For steady-state conditions, WinNonlin draws all dose information from the PKS study data with the exception of Tau (dosing interval). This value must be entered manually into the Dosing field for each profile in WinNonlin.

Under non-PKS conditions, all dosing information must be entered manually into WinNonlin before the model is saved for use in AutoPilot.

Lambda Z

AutoPilot supports the following options, all of which are set in the WinNonlin Lambda Z Ranges dialog (**Model>Lambda Z Ranges...** in the WinNonlin menus).

1. **Disable curve stripping** is selected: no lambda z selections are assigned. In this case, WinNonlin does not calculate any PK Parameters that use the Lambda Z regression in their computation (e.g., AUCinfinity, Clearance, Volume), and subsequently no output is created with these parameters.
2. Lambda Z ranges assigned by manual selection.
3. No Lambda Z selections are made: by default, WinNonlin automatically assigns Lambda Z ranges per its algorithm (see the *WinNonlin User's Guide* for details).

Partial AUCs

Optionally, you can assign partial AUC intervals manually in the NCA Model (**Model>Partial Areas...** in the WinNonlin menus). AutoPilot allows up to three partial AUC calculations per profile to be included in the output.

Model options

The following selections are required for AutoPilot to function correctly. Set these options in the WinNonlin Model Options dialog (**Model>Model Options**).

Output Options: Select the following options only:

- Workbook
- Chart
- Exclude profiles with insufficient data

Units: Select units for the PK parameters. These units are displayed in AutoPilot directly from the WinNonlin model (.pmo) output unless specified differently in this document.

Parameter names: AutoPilot accepts either one of the following conditions:

- WNL Default PK Parameter names
- A DEFAULTNCAPARAMETERNAMES.MAP file as described in the *WinNonlin User's Guide*
- Do not exclude any parameters from the model output.

All other options should be left at their default values. AutoPilot settings control those elements of the analysis and output.

CAUTION: Any changes to parameters names in the Model Options dialog could cause erroneous results.

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