

# PHARSIGHT®

## WinNonlin® AutoPilot™ 1.2.4

### BENEFITS

- Reduce the time to complete interim and final PK reports by up to 75%
- Improve quality of reports leading to reduced effort in QA and Regulatory Affairs groups
- Capture and implement best practices and business rules within a department and across organizations
- Enable PK scientists to acquire new skills and focus their efforts on rewarding drug development research
- Reduce report cycles (i.e. the average time to report completion)

### HIGHLIGHTS

- Supports NCA analysis of crossover (randomized, non-randomized, replicated) and parallel design study and all combinations of study designs with different matrix, route, and dose regimen
- Uses WinNonlin NCA analysis engine and operates on standard WinNonlin model setup by the PK Scientist
- Generates output using SigmaPlot®, Microsoft® Word and Excel®
- Administration module for customer configuration of formats, content, and business rules
- Multiple customer-defined configurations allow the organization to support specific requirements of departments or tasks
- Clear communication and application of standards across organizations through customer-defined configurations
- Automation module using a wizard-based interface to input clinical PK study data, define analyses and specify output to match an organization's SOPs and best practices.
- Wizard-based comparisons of analysis runs (e.g., analyte, accumulation, bioavailability) with side-by-side display and creation of additional specific comparison output.
- Ability to execute on wide and stacked-by-analyte data sets and models with some PK output created automatically depending on the data organization
- Integrated Automation File Explorer allows user to browse generated content and to conveniently transfer content into documents and presentations
- Optional full integration with Pharsight Knowledgebase Server™ for secure storage and change tracking of input data, analysis settings, results and reports. (AutoPilot PKS Edition)

### Automation – [aw-tuh-mey-shuhn] - The automatic operation or control of equipment, processes, or systems.

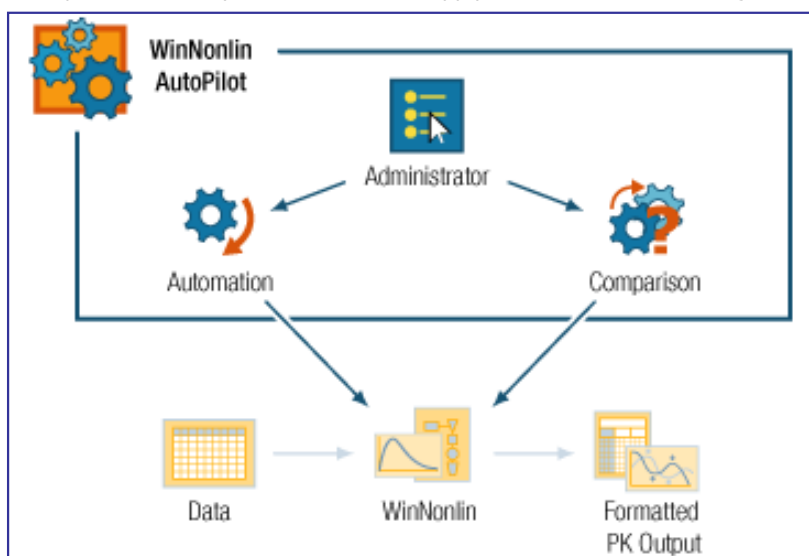
Pharmacokinetics (PK) Automation is a technology that gives companies the means to vastly increase productivity of their scientific staff while improving the quality and consistency of their PK analyses and reports. When the concept of PK Automation is applied to routine and repetitive analyses for the creation of presentation-quality PK tables, figures, and text output, it will dramatically shorten the turn-around time for intermediate and final reports and presentations – making time available that can be used for deeper and more analyses.

### WinNonlin AutoPilot

WinNonlin AutoPilot is a configurable PK Automation software package. AutoPilot uses WinNonlin, the industry standard for Non-Compartmental Analysis (NCA) and PK / PD modeling, to perform analyses and produces report-quality tables, figures and text output (generated in SigmaPlot®, Microsoft® Word and Excel®) for regulatory submissions and interim reports. AutoPilot can operate on study data and models from the user's file system (AutoPilot Standard Edition) as well as in a controlled PK data management system based on Pharsight Knowledgebase Server™ (PKS™) (AutoPilot PKS Edition).

### Integrated Workflow

WinNonlin AutoPilot provides the infrastructure and tools to manage and effectively automate common or repetitive PK analyses and the creation of the required tables and figures for reports and presentations. Because these outputs must reflect the requirements and SOPs of each specific research organization, AutoPilot provides a user interface that allows customers the extensive configuration of formatting and business rules applied to analyses and to generated output, and the setting of standards for content of graphs and tables. These customer defined configurations allow companies to clearly communicate and apply standards across the organization.



With AutoPilot the very same WinNonlin model that is used for the initial analysis of study data, is automatically executed by AutoPilot to generate the tables and figures for reports and presentations in a fraction of the time that a scientist would take. And though this process is automated, there are still choices that allows the user to optimize the output: An easy-to-use wizard-like user interface allows for selection of PK analysis results and specific tables, graphs, or text output to be generated or not. Finally, an integrated file explorer supports a quick review of the generated output and the transfer of files from the local file system to documents or presentations.

Used in a PKS™ environment with PKS Reporter™, WinNonlin AutoPilot provides standardized, regulatory-compliant, secure, and automated generation of reports, enabling PKS Reporter to pick-up the generated output with automatic report updates and secure review and approval processes.

Used for study data on the local file system of a scientist's computer, WinNonlin AutoPilot can provide significant return on investment through productivity and quality improvements in PK analyses and reporting.

## SYSTEM REQUIREMENTS

- OS: Windows® XP, Citrix on Windows 2003 Server, Windows Vista (32-bit), Windows 7 (32- and 64-bit)
- Pharsight Software: WinNonlin 5.1.1, 5.2, 5.2.1, 5.2.1a, or 5.3 (required); PKS 3.1, 4.0, 4.0.1, 4.0.2 (optional), PKS Reporter 1.3, 1.3.1 (optional)
- 3rd Party Software (all required): Microsoft .NET 1.1; Microsoft Office XP, 2003, or 2007; SigmaPlot 9.01, 10, 11.1, or 11.2
- Processor: 1.0 GHz (minimum); > 1.4 GHz (recommended)
- Memory: 512 MB RAM (minimum); 2 GB RAM (recommended)
- Hard Disk: 100 MB (installed software only, excludes data and generated output)

## INTEGRATED SOLUTIONS

Pharsight Corporation provides an integrated suite of products and services including

- Phoenix® WinNonlin®
- Phoenix® NLME™
- Phoenix® Connect™
- IVIVC Toolkit™ for WinNonlin®
- Pharsight® Trial Simulator™
- Pharsight® Knowledgebase Server™
- PKS Reporter™
- 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 of the U.S.).

Or visit our web site at <http://www.pharsight.com>

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This information applies to WinNonlin AutoPilot version 1.2.4

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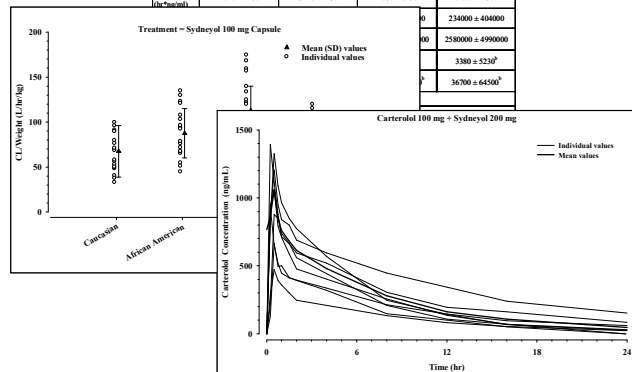
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## Automation Module

WinNonlin AutoPilot's automation wizard allows for selection of analysis inputs (study data), types of analysis generated (e.g., stratifications by demographics, normalizations, statistics), specific types of PK output (tables, graphs, and text), and initiates the run within the application. In many cases, the user can make selections for a specific run that modify the administrator-defined

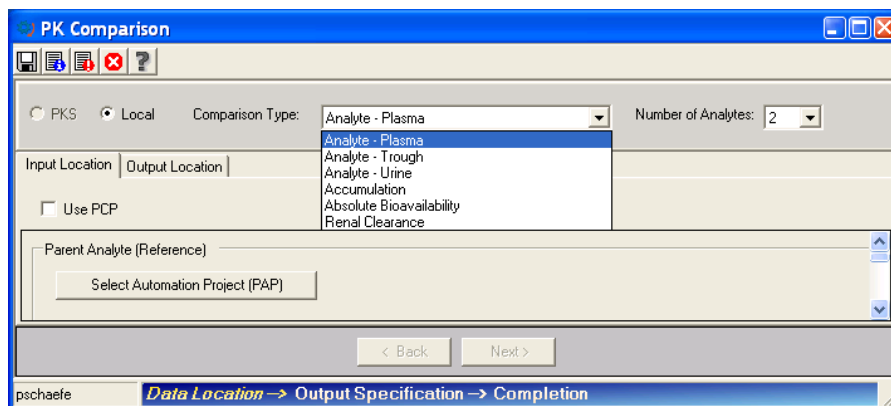
default system settings, allowing for greater analysis flexibility. A broad variety of tables and graphs in report-ready quality are generated using Microsoft Excel and SigmaPlot.

| Mean ± SD                     | Analyte = Plasma Carvedilol    |                                |                              |                              |
|-------------------------------|--------------------------------|--------------------------------|------------------------------|------------------------------|
|                               | Female<br>Controlled PK Form A | Female<br>Controlled PK Form B | Male<br>Controlled PK Form A | Male<br>Controlled PK Form B |
| N                             | 4                              | 4                              | 8                            | 8                            |
| C <sub>max</sub> (ng/mL)      | 165 ± 205                      | 619 ± 432                      | 668 ± 1180                   | 1030 ± 2130                  |
| T <sub>max</sub> (hr)         | 0.44 (0.25 - 0.50)             | 0.63 (0.50 - 0.75)             | 0.52 (0.25 - 0.75)           | 0.66 (0.50 - 1.00)           |
| t <sub>1/2</sub> (hr)         | 7.02 ± 2.32                    | 4.33 ± 1.11                    | 6.59 ± 1.59                  | 7.39 ± 2.62                  |
| AUC <sub>0-∞</sub> (ng·hr/mL) | 953 ± 1200                     | 3020 ± 2370                    | 3760 ± 6940                  | 6480 ± 13200                 |
| AUC <sub>0-t</sub> (ng·hr/mL) | 1040 ± 1280                    | 3120 ± 2430                    | 4080 ± 7450                  | 7270 ± 14500                 |



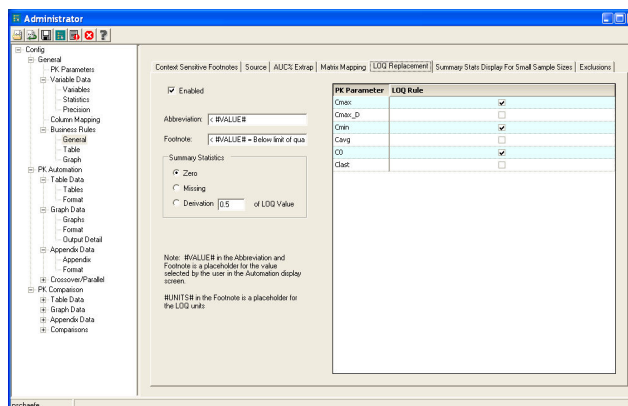
## Comparison Module

The comparison wizard provides the ability to compare and report on the results of previous PK automation runs. Using the wizard, the user can conduct comparative analyses over different dosing routes (bioavailability of IV vs. PO), different dosing regimens (accumulation of steady-state vs. single-dose), different matrices (calculation of renal clearance), and multiple analytes (parent vs. metabolite).



## Administration Module

Because PK analysis outputs must reflect the requirements and SOPs of each research organization, WinNonlin AutoPilot provides a flexible user-interface that allows extensive configuration of formatting, nomenclature, and business rules that apply in the generation of these analyses. Accept pre-configured, factory default settings or easily modify them to efficiently implement your organization's analysis and reporting requirements via the secure Administrator module. Modifying the system configuration does not require



changes to the underlying computer user. The settings are stored in XML-based settings files, enabling clear communication of standards and immediate use across the organization. New SOPs or regulatory changes can be implemented without the need to revalidate the entire application.