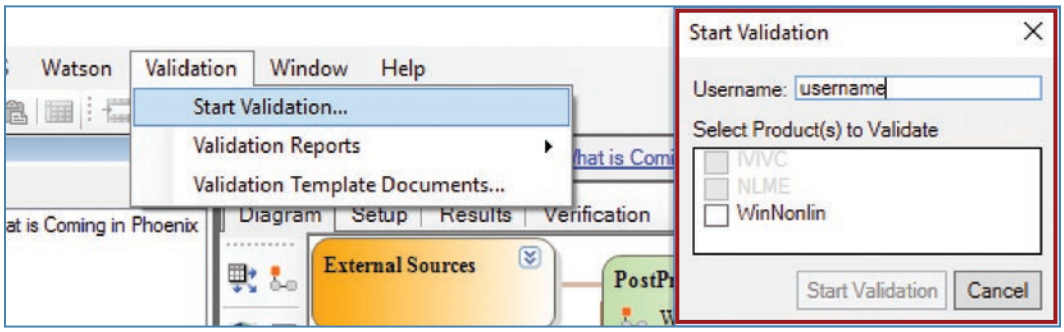
CERTARA

Phoenix WinNonlin Validation Suite

Validation Made Fast and Easy

As required by US FDA's 21 CFR Part 11, International Conference on Harmonization of Technical Requirements (ICH), EudraLex Annex 11, and other regulatory agency guidance documents, computer systems used in the pharmaceutical industry, and output from software used in regulatory submissions, must be validated to assure proper performance. This necessitates companies to invest significant time and resources to manually write and perform the validation steps used in software execution.

The enhanced Phoenix® WinNonlin® Validation Suite is integrated into Phoenix and provides software validation in less than 30 minutes with non-editable PDF reports containing links to saved reference files, user output files, and difference files. Updated validation template documents are aligned with the latest regulatory guidance computer system validation such as ICH E6 Good Clinical Practice (GCP) R2 and can be readily modified to fit individual user/organizational policies and procedures..



Obtain automated WinNonlin validation test results in minutes rather than days

- Automates validation with test results available in less than 30 minutes
- Integration into Phoenix WinNonlin eliminates the need to install a separate application
- Allows other applications to run during execution of the Validation Suite, resulting in minimal down-time
- Automatically executes detailed test scripts, ensuring rapid, consistent, and error-free testing of WinNonlin functionality
- Provides documentation of activities by automatically generating a Validation Report
- Compares output to standard, verified, known results and generates a report of comparisons that is saved in Phoenix and immediately accessible for easy reference

Validation Life Cycle Templates included in Phoenix WinNonlin Validation Suite

- Validation Plan
- Phoenix WinNonlin Requirements Specification
- Test Plan
- Phoenix WinNonlin Traceability Matrix
- Validation Summary Report

Functions Tested by Phoenix WinNonlin Validation Suite

General Functionality	WinNonlin NCA Engine	WinNonlin Classic Engine	Phoenix Modeling Engine	Toolbox Functions
• Installation Qualification (IQ) • Descriptive statistics • Data Wizard calculations	• IV Bolus • Extravascular • Infusion • Single-dose • Steady-state • Sparse sampling	• 28 PK models • 9 PD models	• 8 PK models • 2 PD models	• 4 Bioequivalence models • Crossover models • Deconvolution • Linear mixed effects • Nonparametric superposition • Semicompartmental modeling

Automatic execution of WinNonlin Validation Suite scripts

Validation Suite includes test scripts that efficiently test and document calculations performed by the WinNonlin NCA engine, WinNonlin Classic modeling engine, Phoenix model (Naïve-pooled method), bioequivalence calculations, descriptive statistics, data wizard calculations, linear mixed effects, deconvolution, non-parametric superposition, semi-compartmental analysis, bioequivalence, and more. Each test script automatically operates Phoenix WinNonlin to generate output, compares the output to verified results, and generates a Validation Report that is saved and available immediately in Phoenix.

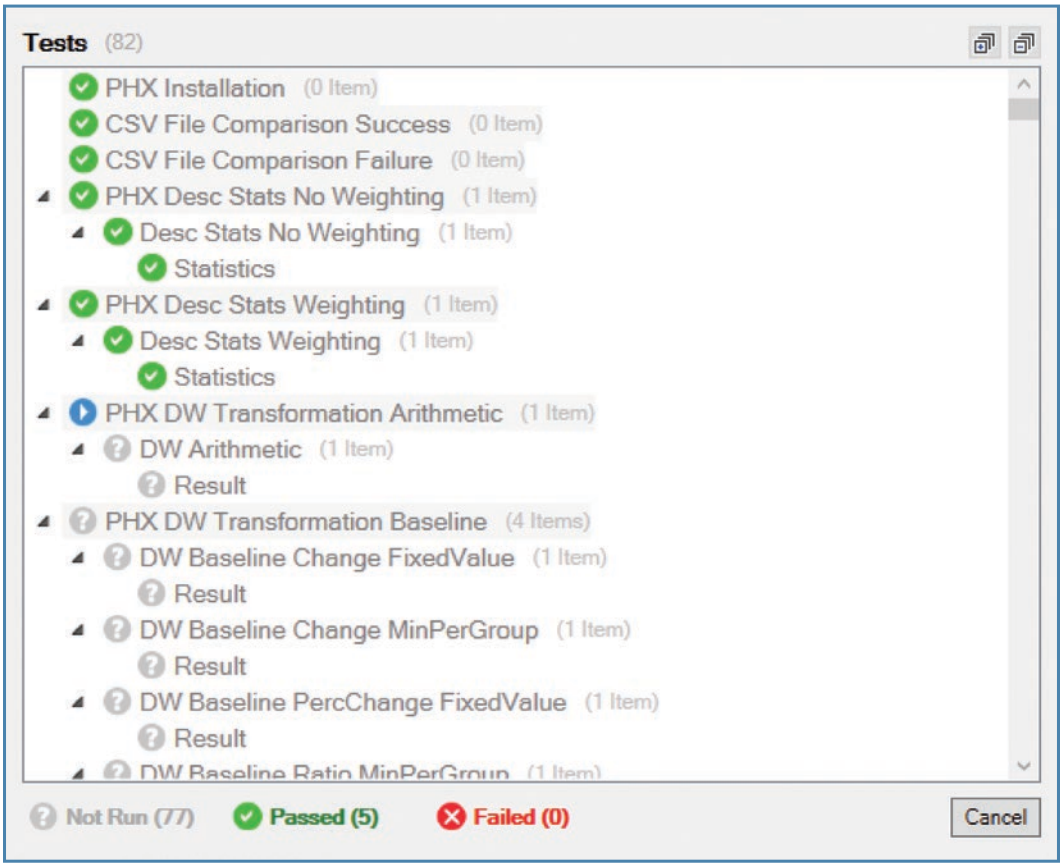
Test Case	Status	Results Worksheet	Reference	Run	Difference
WNL Bioeq Average Crossover 2x2	Passed	Average Bioequivalence	Reference	Run	Difference
		Ratios Test <test formulation name>	Reference	Run	Difference
		Diagnostics	Reference	Run	Difference
		Final Fixed Parameters	Reference	Run	Difference
		Final Variance Parameters	Reference	Run	Difference
		Least Squares Means	Reference	Run	Difference
		LSM Differences	Reference	Run	Difference
		Partial SS	Reference	Run	Difference
		Partial Tests	Reference	Run	Difference
		Residuals	Reference	Run	Difference
		Sequential SS	Reference	Run	Difference
		Sequential Tests	Reference	Run	Difference

Use Phoenix WinNonlin Validation Suite to ensure compliance under the following conditions:

- Upon a new installation of Phoenix WinNonlin
- After upgrade to Phoenix WinNonlin from a previous version of Phoenix WinNonlin
- Upon re-installation of Phoenix WinNonlin
- If a change to the implemented Phoenix WinNonlin system is determined as part of the internal change control process to impact the validation status of the system

Successful Execution of WinNonlin Validation Suite Scripts

The graphical user interface allows you to easily drill down into the Validation Run Report to assess outcome of all test scripts.



Are you ready to streamline your Phoenix WinNonlin validation testing?

Contact us at sales@certara.com to learn how to automate your validation testing to gain efficiency and productivity.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.