



# Phoenix® WinNonlin®

## The Gold-Standard in Pharmacokinetic, Pharmacodynamic and Non-compartmental Analysis

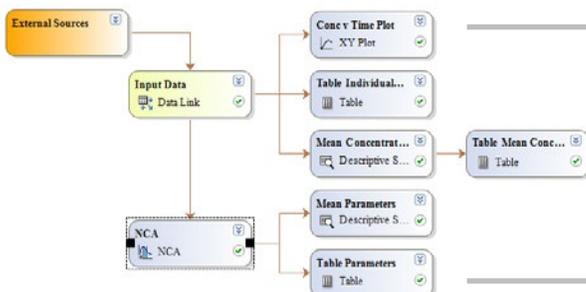
Phoenix WinNonlin is the industry standard for the analysis of pharmacokinetic and pharmacodynamics data. The integrated tools for data processing, non-compartmental analysis (NCA), PK/PD modeling, post-analysis statistics, table creation, and graphics create an all-in-one collaboration workbench for analysts, reviewers, medical writers, and quality assurance team members. The intuitive graphical user interface allows you to spend less time learning the software and managing data and more time to model, interpret, and understand the data. The result? Efficient drug development decisions can be made faster with more confidence.

### Proven Software with a Vast Global Footprint

Phoenix WinNonlin has a proven 30-year history of providing trustworthy PK/PD analysis results. It is used by 6,000 scientists in 60 countries, by 1,500 organizations and 200 academic institutions including the top 50 global pharmaceutical companies. Regulatory agencies, including seven divisions of the US Food and Drug Administration (FDA), Japan Pharmaceutical and Medical Device Agency (PMDA), China Food and Drug Administration (CFDA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA), use Phoenix WinNonlin for analysis and to evaluate drug submissions.

### An Intuitive Graphical User Interface Delivers the Most Efficient PK/PD Analysis Available Today

Phoenix WinNonlin was designed to help you efficiently move from data to reporting results using a graphical workflow design to visualize data flow and analysis pathways. Each workflow contains separate objects for each action—eg, data processing, NCA, PK/PD models, table creation, figures and plot creation, and reporting—which are linked together within an intuitive graphical user interface. Traceable workflows increase analyst productivity by nearly 2-fold.



Workflows enable analysts to spend less time preparing and manipulating data and results—scientific and QA reviewers can use tools for rapid error identification to reduce review time.

### Workflows are the key to consistency across an organization:

- Increased productivity—workflows are reusable across multiple projects and analyses
- Output with the click of a button—data processing/formatting, analysis, figure, plots, and tables
- New or updated data? Not a problem—drag and drop new data into the existing workflow to generate updated results effortlessly
- Eliminates time-consuming analyst work or the need for a separate data programmer

## Do you need to have the same tables for each report?

- Individual results can be easily formatted in publication-quality tables that include standard summary statistics.
- Tables can be added to default workflow templates to create standardized versions for each organization.
- Tables can be exported to Microsoft® Word for PK/PD reports.

## The WinNonlin NCA Engine Can Do It All

### The Most Comprehensive Set of Analysis Tools for any Non-clinical or Clinical PK/PD Study

From early non-clinical research with a few animals to large clinical trials, the NCA engine, individual PK/PD modeling engine, and statistical analysis tools can be used for a wide-range of studies and analyses:

- Single, multiple or steady-state dosing
- Sparse sampling studies
- Drug concentration data in plasma or urine, or pharmacodynamics data
- Formulation comparison
- Toxicokinetics
- First-in-human
- Single and multiple ascending dose
- Drug-drug interaction
- Bioequivalence
- Mass balance
- ...and many more

### Statistical Tools Help Answer Critical Questions

Did the new formulation meet bioequivalence criteria? Is the exposure dose proportional? Did the drug cause an increase in a biomarker? Use statistical tools in WinNonlin to integrate and report inferential analysis of study results.



Bioequivalence



Superposition



Analysis of variance/General linear models



Semi-compartment modeling



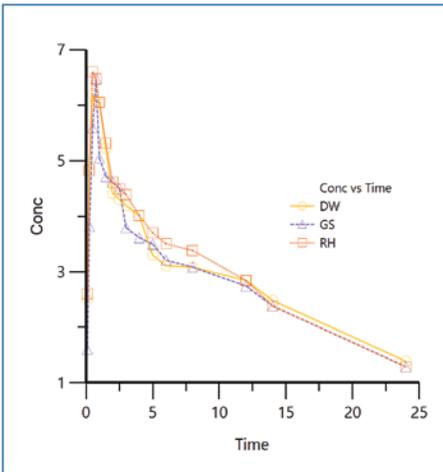
Deconvolution



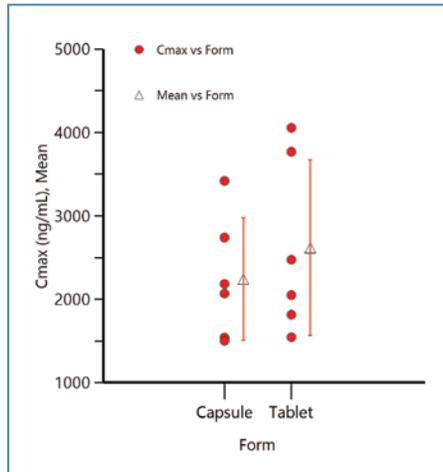
Descriptive statistics

### Powerful Integrated Graphics Engine and Table Generator

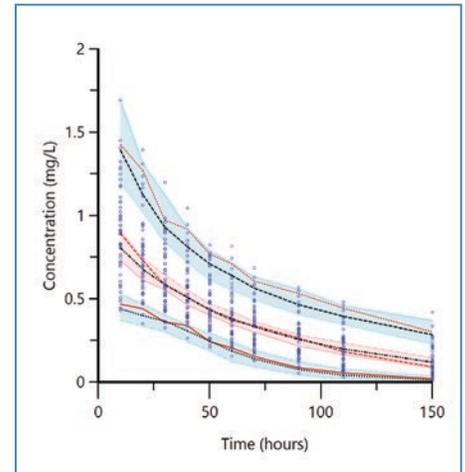
The integrated graphics engine in Phoenix WinNonlin automatically creates publication-quality plots and figures and well-organized tables to help create standardized PK/PD reports more efficiently. High native resolution plots and figures can be easily customized to meet user-specifications without the need for 3rd party software packages. Do you have standard plots and figures in your organization? Custom plot templates can be shared by everyone and loaded with one command. Using the Phoenix Connect Reporter tool users can compile plots, figures and tables into a single Microsoft® Word file with customized numbering and headers. The output can be quickly and easily attached to a PK/PD report for communicating results internally and to regulatory agencies.



Customizable Legend Placement



X-Categorical Plot with Error Bars and Offsets



VPC Plot with Shading of 2° Quantiles

## Tools for Data Processing and Preparation

Analysis dataset preparation is a breeze with Phoenix WinNonlin's data processing tools. The Phoenix workflow traces data from the moment it is imported through the final analysis, preventing data loss and costly re-analysis.

Integrated data processing functions—sorting, splitting, filtering, transforming, merging, appending, stacking, pivoting, joining and more—provide full visibility into the incoming data and the results of each data set.



Sorting/Splitting/Filtering/Transforming



Stacking



Merging



Pivoting



Appending



Joining

## Phoenix WinNonlin Does the Compliance Work for You

The analysis of PK, PD, and TK data requires users to follow regulations to ensure compliance with regulatory agencies around the world. Each object includes a validation tab to confirm proper operation, a history tab that keeps an audit trail of any changes, and a settings output that records the settings used for analysis.

Phoenix WinNonlin gives you confidence that your analyses meet all required regulations

The Validation Suite for WinNonlin uses automated technology to complete validation in days not months. And full integration of Phoenix WinNonlin with the Phoenix Knowledgebase Server (PKS) enables the management of clinical and non-clinical PK and PD data and analyses in compliance with the US FDA electronic records and signatures regulation (21 CFR Part 11).

The Phoenix family provides an integrated solution to efficiently share pre-clinical and clinical knowledge throughout an organization and track a drug through the development lifecycle via a secure and consistent workflow:

- Phoenix NLME™, Phoenix IVIVC™, Phoenix Connect™
- Phoenix Knowledgebase Server (PKS)

## Access to Continuing Education and Support

Coming up to speed on WinNonlin is simple and easy with the graphical user interface. We provide a wide range of education and support tools to get you started and to keep you up-to-date with the most important advancements in modeling:

- Step-by-step user guide and examples
- Classroom and on-demand e-learning training courses available through Certara University (<http://www.certarauniversity.com>)
- Webinars from world-renowned investigators and modelers
- White papers, educational blog posts and access to an active user forum community (<https://support.certara.com/forums/>)

## System Specifications

For more information on the minimum and optimal recommended hardware and system requirements, please refer to the Phoenix 7.0 System Specification Sheet.

## Are you ready to find out why WinNonlin is the industry gold standard for NCA, TK, and PK/PD modeling and simulation?

Contact us at [sales@certara.com](mailto:sales@certara.com) to learn how you can join thousands of other modelers and start using WinNonlin today.

The Phoenix Connect tool provides interoperability with a wide range of software packages to ensure compliance and data traceability, including:

- SAS®, R, TIBCO™ Spotfire® S+, SigmaPlot®
- NONMEM®, PsN
- Watson LIMST™

## 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](http://www.certara.com) or email [sales@certara.com](mailto:sales@certara.com).