Phoenix WinNonlin™

The Gold-Standard in PK/PD, Non-compartmental and Toxicokinetic Analyses

Phoenix WinNonlin is the industry standard for the analysis of pharmacokinetic and pharmacodynamic data. The integrated tools for data processing, non-compartmental analysis (NCA), PK/PD modeling, toxicokinetic analysis, 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 users 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 with more confidence.

Proven software with a vast global footprint

Phoenix WinNonlin has a proven 30-year history of providing trusted PK/PD analysis results. It is used by over 10,000 scientists in 60 countries at nearly 2,000 institutions, including the top 50 global pharmaceutical companies. Regulatory agencies, including 11 divisions of the US Food and Drug Administration (FDA), Japan Pharmaceutical and Medical Device Agency (PMDA), and China National Medical Products Administration (MNPA) use Phoenix WinNonlin for analysis and to evaluate drug submissions.

The most comprehensive set of analysis tools for any non-clinical or clinical PK/PD study

From early non-clinical research 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
- Bioequivalence

- Toxicokinetics
- First-in-human
- Single and multiple ascending dose
- Drug-drug interaction
- Mass balance

Workflows for consistency across your organization

- Increase productivity by reusing workflows across multiple projects and analyses
- Output with the click of a button—data processing/formatting, analysis, figure, plots, and tables
- Drag and drop new data into an existing workflow to generate updated results effortlessly
- Eliminate time consuming analyst work or the need for a separate data programmer

- Append Worksheets
- BQL
- Crossproduct Worksheets
- Enumerate Worksheets
- Join Worksheets
- Merge Worksheets
- Pivot Worksheet
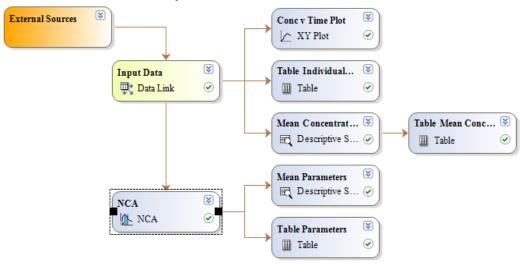- Rank Worksheet
- Ratios and Differences
- Split Worksheet

An intuitive graphical user interface

Phoenix WinNonlin was designed to help users efficiently move from data to reporting results using a graphical workflow designed to visualize data flow and analysis pathways. Each workflow contains separate objects for each action, which are linked together within an intuitive graphical user interface. Locking the workflow provides consistent results and eliminates QC checks for approved workflows. Traceable workflows increase productivity by nearly 2-fold.

Phoenix Workflow Example

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 third party software packages.

Fast and easy validation in under 30 minutes

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 changes, and a settings output that records the settings used for analysis. The Validation Suite in Phoenix WinNonlin executes detailed test scripts, completing validation in less than 30 minutes with locked PDF reports containing links to saved reference files, user output files, and difference files.

Discover why WinNonlin is the gold-standard for PK/PD, NCA and TK analyses.

Contact us at sales@certara.com to start using WinNonlin today.

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions, and regulatory agencies across 62 countries.

For more information, visit **www.certara.com**.