CERTARA

Top 10 Reasons Why Phoenix NLME is the Population PK/PD Modeling and Simulation Software of Choice

Population PK/PD analyses are required by the FDA

The Food and Drug Administration (FDA) uses Phoenix NLME when analyzing and reviewing submissions, especially for clinical pharmacology and safety reviews. The FDA has over 290 Phoenix NLME licenses and users at the agency are training on Phoenix NLME by Certara population pharmacokinetics/pharmacodynamics (PK/PD) experts.

1 The all-in-one software platform for population PK/PD modeling

Phoenix NLME, unlike any other population PK/PD modeling software, contains all the needed tools for pre-processing, analysis and post-processing in one software platform. Phoenix NLME enables you to perform exploratory analyses, develop, evaluate and compare multiple models, create a library of models using templates, create figures for reporting and organize the entire project. There is no need to spend time acquiring and learning multiple third party software; Phoenix NLME is the all-in-one PK/PD modeling software platform.

2 Is easy to learn and intuitive to use

With Phoenix NLME, there is no need to master complex coding or multiple software products. Phoenix NLME provides an intuitive graphical user interface (GUI) that simplifies modeling and allows for customization.

Current Phoenix WinNonlin users will find the same intuitive GUI in Phoenix NLME and can focus on performing population PK/PD modeling rather than learning new software.

Additionally, a step by step guide helps you navigate Phoenix NLME and an active user forum helps you get answers quickly. Training courses and webinars by PK/PD experts are available regarding Phoenix NLME and optimal model building.

3 Enables users to make informed decisions at each stage of development

- Conduct population PK/PD analyses required for a new drug application
- Estimate PK responses based on formulations and routes of administration
- Enable sparse sampling strategies to save time and money and support ethical imperatives during pre-clinical R&D

> - Phoenix NLME is a powerful population modeling and simulation software for experienced as well as beginner PK/PD scientists. With an intuitive user interface, Phoenix NLME is an integrated solution that allows researchers to pre-process, analyze and post-process modeling projects all within one system.

- Simulate PK/PD responses to minimize the number of dose-ranging trials needed in Phase II

- Simulate clinical trial outcomes prior to initiation of Phase III trials

- De-risk Phase III trials

- Predict the major sources of variability in drug exposure and response

4 Flexible development tools allow users to choose method best suited to the project

Phoenix NLME has an extensive built-in library of standard models for most PK/PD relationships complete with guidance on each step of the modeling and simulation process. For situations that require modifications to the standard library model, the Drug Model Editor (DME), a visual graphics modeling interface, enables the user to customize models using graphical representations of PK/PD profiles. For advanced modeling, the Pharsight Modeling Language (PML) gives users full access to text models to further customize the analysis. PML models can be executed from either from the GUI or the command line.

5 Increases efficiency

The initial estimates tool in Phoenix NLME allows users to visualize model fits with potential initial PK/PD estimates, make adjustments before modeling and start with better initial estimates for faster model convergence. In addition, prior to starting a model fit, Phoenix NLME has several optional pre-programmed techniques to further improve starting points for an efficient convergence. Phoenix NLME provides large gains in efficiency by enabling users to build models in an intuitive workflow schematic that can be copied, reused, and shared with colleagues, collaborators and regulatory agencies. Users can make changes to the workflow and refresh it without rebuilding the whole analysis project. All work is mapped in a visual workflow enabling more efficient project management, modification, evaluation, and error identification.

6 Generates powerful, customizable graphics automatically with each model

- Convergence plots

- Goodness-of-fit plots to evaluate model structure and residual error models

- Plots of observed and predicted PK/PD profiles

- Quantile-quantile plots for random effects

7 Solves complex modeling and simulation problems

Phoenix NLME is capable of handling any PK/PD analysis that may be encountered including continuous variables, binary data, ordered data, count, and time-to-event data. Phoenix NLME uses the most current and advanced optimization strategies and algorithms to give robust and stable model predictions. Only Phoenix NLME has the highly accurate Quasi-Random Parametric Expectation Maximization method (QRPEM) algorithm that is faster than other expectation methods and better at convergence.

8   Fast and adaptable to unique IT infrastructures

Phoenix NLME is able to take advantage of high performance computing environments by enabling parallel execution of a single job across multiple cores resulting in significant speed gains. There are no incremental costs or core restrictions when purchasing a Phoenix NLME license. Take advantage of as many cores as you have access to for Phoenix NLME jobs.

9   Facilitates collaboration both internally and externally

All Phoenix NLME input files, models, workflows, graphics, emails and Word® documents can be conveniently stored in a single Phoenix project file that can be shared with staff members, collaborators or regulatory agencies. In the event of personnel changes, audits or the need to rerun an analysis, the Phoenix project file becomes a valuable company asset that contains all the data, work and other communication relevant to a project.

10   Part of the Phoenix Platform — the premier software solution to manage, analyze and report PK/PD data

Phoenix NLME and the entire Phoenix platform enables the sharing of pre-clinical and clinical knowledge throughout the organization.

Phoenix WinNonlin is the industry standard for non-compartmental analysis (NCA) and PK/PD modeling and simulation.

Phoenix Connect streamlines report generation and provides connections between the Phoenix platform and the clinical data repository, Phoenix Knowledge-base Server (PKS), and third party pharmacometrics tools.

IVIVC Toolkit for Phoenix WinNonlin brings enhanced deconvolution methods, numerical convolution, new plotting capabilities, and the "IVIVC Wizard" to pharmacokineticists and formulators.

AutoPilot Toolkit for Phoenix integrated with WinNonlin and PKS Workflows, generates report-ready tables, figures and listings for regulatory submissions, interim reports and presentations.

Phoenix Knowledgebase Server is a secure Oracle®-based data repository that supports 21 CFR Part 11 compliance requirements by providing a full audit trail and version control analyses performed within any Phoenix application.

About Certara

Certara is a global biosimulation and regulatory writing company, committed to optimizing drug development decisions. Its clients include hundreds of international biopharmaceutical companies, leading academic institutions, and key regulatory agencies. Certara's solutions, which span drug discovery through patient care, increase the probability of regulatory and commercial success by using the most scientifically-advanced modeling and simulation technologies and regulatory strategies.

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