



Phoenix Technology Services

Facilitating the Art and Science of Biosimulation

Increase Your Analytical Productivity and Leave the Routine Tasks to Us

What if you can enhance your efficiency by leaving the tedious and time-consuming aspects of biosimulation (modeling and simulation) in the hands of experts?

At Certara we understand the ever-increasing demands, challenges, and rising costs of introducing new drugs to the market. Our goal? We want to help streamline your biosimulation efforts so that you can optimize R&D productivity to achieve your goals faster.

Introducing Phoenix Technology Services

Biosimulation Platform Services:

Biosimulation is increasingly used in drug submissions for IND, NDA, BLA, MAA, now accounting for 60-70% of all submissions.

As biosimulation has become more mainstream in drug development and expected by regulators, Certara's professional services team has been asked by sponsor companies to assist them in designing enterprise solutions specifically for biosimulation, ranging from developing the conceptual design and architecture of the system to migration to a hosted, cloud or grid-based infrastructure.



Workflow Template Services: Creating templates that are reusable across different studies with varying numbers of treatments, analytes, matrices, doses, etc, requires expertise and significant development time. Certara has developed pre-packaged Phoenix Workflow Templates, including CDISC SEND, Toxicology (serial and sparse sampling), Discovery PK, and Clinical PK, as a set of "best practices" to optimize R&D productivity, increase analysis time, standardize calculations and output, minimize need for QC checks, and achieve regulatory compliance.

Plugin Services: Certara's professional services team leverages the Phoenix extendable framework to integrate Phoenix with both upstream and downstream systems such as LIMS, Study Protocol, Compound Management, Dosing/Treatment, Randomization, and CDISC Submission. Phoenix plugins, such as our PopPK data preparer, First-in-Human allometric scaler, CDISC data preparer, and

dosing/treatment randomization builder, streamline data flow by providing access to data required for analysis and submission.

PKS Repository Services: Phoenix Knowledge-base Server (PKS) and PKS Online products provide a 21 CFR Part 11 compliant repository with full audit trail and version control for the storage of biosimulation data using the Phoenix platform. The Certara services team supports client installations to optimize regulatory readiness, providing implementation, migration, integration, and validation support services.

Validation Services: Eliminate the burden for your internal project team or avoid extended timelines using generic validation consulting firms. Our validation professionals are experts in the Phoenix platform and are experienced in Phoenix WinNonlin, NLME and PKS validation methodology. By leveraging Certara's team, you will minimize your in-house validation effort for IQ and OQ, saving valuable time, while meeting FDA and EMA regulatory compliance requirements.

Transition Services: Certara's team of professionals offer cloud transition services including change management, infrastructure provisioning, migration and integration. Additionally, Certara's Phoenix in the Cloud offering provides a robust scalable platform for PK/PD modeling and simulation in a hosted environment, reducing maintenance and support overhead.

The Phoenix PK/PD Software Suite

Phoenix WinNonlin is the industry-standard for Non-Compartmental Analysis (NCA) and PK/PD modeling and simulation.

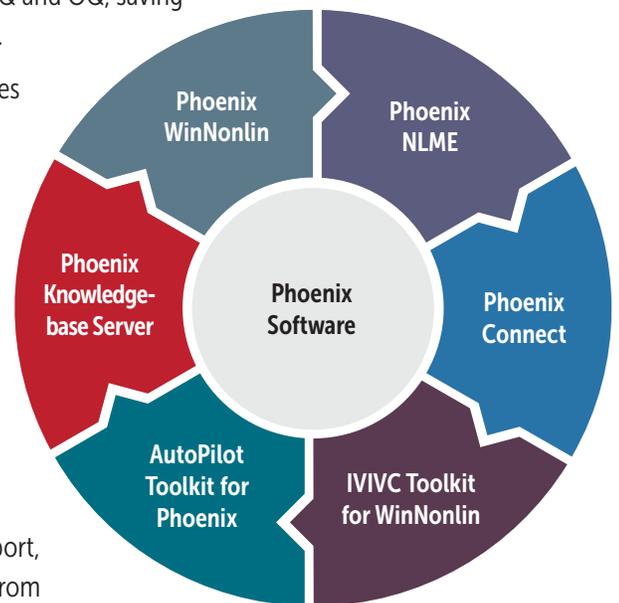
Phoenix NLME is a powerful data processing and modeling tool for population PK/PD analysis.

Phoenix Connect is a productivity tool for pharmacometric data import and export, collaboration, and report generation that allows you to seamlessly import data from Watson LIMS™ and CDISC® data sources.

IVIVC Toolkit for Phoenix WinNonlin correlates the *in vitro* dissolution profile of a dosage form with the *in vivo* pharmacokinetic (PK) profile for attaining a biowaiver.

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 full audit trail and version control analyses performed within any Phoenix application.



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.