



Certara Launches Version 8.1 of its Industry-leading Phoenix PK/PD Modeling and Simulation Software; Introduces Professional Certification Program

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Certara provides scientists with automated, comprehensive tools for PK/PD analysis and modeling, and announces industry's first PK/PD certification program for Phoenix software in partnership with Credly

PRINCETON, NJ – June 5, 2018 – Certara®, the global leader in model-informed drug development, regulatory science, market access and real-world evidence services, today announced the launch of Phoenix® 8.1.

Phoenix is the most advanced and widely-used validated software for pharmacokinetic (PK), pharmacodynamic (PD), and toxicokinetic (TK) modeling and simulation worldwide. 90% of novel drugs approved by the US FDA are from companies that leverage Phoenix in their R&D programs.

“Certara’s mission is to improve decision-making throughout the drug development continuum; we are involved at every step from selecting the best drug candidate to demonstrating its value to payers and health authorities. To that end, we are committed to providing a full range of modeling and simulation technology, advisory services, compliance support, and training programs to ensure that scientists optimize their work. We are proud to launch Phoenix 8.1, which offers significant statistical, graphical and validation enhancements to automate processes, saving both time and resources,” said Thomas Kerbusch, PhD, President of Certara Strategic Consulting.

Phoenix is used by 6,000 researchers at 1,500 biopharmaceutical companies and academic institutions in 60 countries. Key to its wide adoption is the native graphical user interface (GUI) and easy-to navigate workflow templates that enable all modelers—both new and experienced—to quickly and accurately leverage the software. Furthermore, the Phoenix team provides users with robust documentation, technical and educational support, and a continuing community to leverage best practices. Phoenix is also employed by many global regulatory agencies for submittal review, including the European Medicines Agency, Japanese Pharmaceuticals and Medical Devices Agency, China Food and Drug Administration, and 11 divisions of the US Food and Drug Administration.

Included in the Phoenix 8.1 rollout are a new Ratios Tool for noncompartmental analysis (NCA), an enhanced Validation Suite for Phoenix WinNonlin®, and an improved Visual Predictive Check (VPC) in Phoenix NLME™.

- **New NCA Ratios and Differences Tool**

Ratio calculations on PK parameters are essential for study reports and for interpreting results, but calculating them can be time-consuming, taking too many steps and external tools. Phoenix WinNonlin delivers one-step, automated calculation of NCA ratios for renal clearance, accumulation ratio, gender differences, linearity index, and parent to metabolite exposure ratios. This new tool eliminates the need to create a workflow or use external tools, resulting in greater efficiency and time savings. For example, scientists can access a report-ready table of exposure parameters and easily identify any gender differences within seconds and use those data to create plots to highlight the differences. Phoenix WinNonlin 8.1 also provides additional automated statistical calculations, such as geometric SD, user-specified percentiles, and an option to select statistics for outputs. Certara has upgraded the Phoenix graphics engine which now allows chart controls by sort or group variable, order profiles in legend, error bars for bar/column plots, and offset for any overlaid plot.

- **Easy and Expedited Validation for Phoenix WinNonlin**

WinNonlin Validation Suite 8.1 provides validation template documents and full software validation in under 30 minutes with evidence of validation including locked PDF reports containing links to saved reference files, user output files, and difference files. It automatically executes 83 detailed test scripts and creates a validation history within Phoenix. Updated validation template documents are also aligned with the latest regulatory guidance for computer system validation, ICH E6 Good Clinical Practice R2 with added sections for risk assessment, SOP requirements, security, and data backup and recovery.

- **Improved Visual Predictive Check (VPC)**

Simulation-based tools are increasingly used to evaluate non-linear mixed effects (NLME) models. VPC is one method that provides a graphical comparison of the distribution of observations and predictions versus an independent variable such as time, dose, or another covariate. Phoenix NLME 8.1 can create high-quality VPC plots for continuous and count data, categorical data, and time-to-event data.

PK/PD Certification Program

Along with the Phoenix 8.1 release, Certara is introducing its Professional Certification Program through Certara University. Earning professional certification through this new online accreditation program will validate scientists' PK/PD data analysis skills using Certara software such as Phoenix WinNonlin and expand their professional reach. A recent poll of scientists indicated strong

interest in participating in this certification program since it would not only validate their knowledge and skills but also identify gaps in their knowledge and help them learn.

“As Phoenix is employed extensively by biopharmaceutical companies and regulatory agencies worldwide, we recognize that being able to demonstrate proficiency in PK/PD analysis using this industry-leading software is an asset. Therefore, we will be offering Phoenix Certified NCA Analyst accreditation through our new Certara Professional Certification Program,” said Ana Henry, Certara’s Executive Director of Training—Certara University.

The Phoenix Certified NCA Analyst examination, using Phoenix WinNonlin Version 8.0 or 8.1, will be available on June 18, 2018.

Certara is partnering with Credly’s Acclaim platform to issue digital badges for professional certification, which will be valid for three years. Credly is a leader in badge technology, and their Acclaim platform provides secure badges that can be easily embedded in résumés, emails, corporate websites, and social and professional networking websites, including Facebook and LinkedIn.

Phoenix 8.1 will be available for download from Certara’s website on June 18.

Phoenix Webinar

In preparation for the release of Phoenix 8.1 and the new certification program, interested parties can attend a one-hour webinar entitled “Accomplish More with Phoenix,” which will be held at 11 am EDT on June 6.

About Certara

Certara is a leading decision support technology and consulting organization committed to optimizing drug development and improving health outcomes. Certara’s solutions, which span drug discovery through patient care, use the most scientifically-advanced modeling and simulation technologies and regulatory strategies to increase the probability of regulatory and commercial success. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions, and key regulatory agencies. For more information, visit www.certara.com.

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