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Certara launches V8.2 of Phoenix PK/PD modeling & simulation software for drugs

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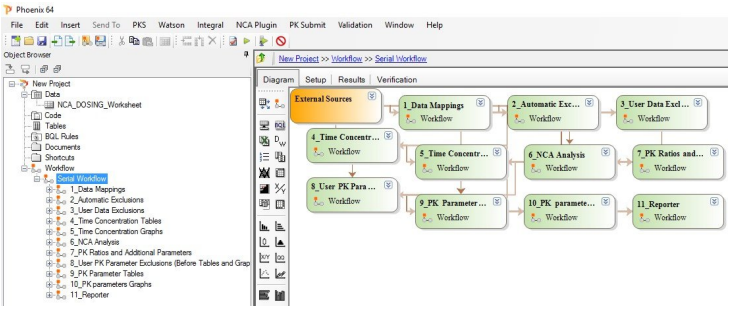
Aligned with newly issued FDA Draft Guidance, Phoenix supports electronic data, methods and results audit, traceability and communication requirements



Certara®, the global model-informed drug development and decision support leader, on 12 Sep 2019, announced the launch of Phoenix® 8.2, the industry gold standard in pharmacokinetic/pharmacodynamic (PK/PD) modeling and simulation software for drug development.

Phoenix is the most advanced and widely-used validated software for PK, PD, and toxicokinetic modeling and simulation worldwide. More than 90% of all novel drugs approved by the US Food and Drug Administration (FDA) in the past four years are from companies that use Phoenix in their R&D programs.

“As the industry leader in leveraging modeling and simulation to improve decision making throughout the drug development process, Certara works to continually enhance our products to meet clients’ current needs and anticipate their future requirements. Phoenix 8.2 includes key new capabilities that were developed in direct response to client feedback, delivering both faster performance and greater ease of use. Of equal importance, our commitment to providing the regulated community with auditable data and methodology packages is evidenced in not just Phoenix, but across our product suite for pharmacometrics use in drug development,” said Thomas Kerbusch, PhD, President CSC at Certara.

“For instance, integrating Certara’s Nonlinear Mixed Effects Modeling (NLME™) Validation Suite into Phoenix will improve the speed and ease with which clients can complete the validation process tremendously, saving them both time and money. We have been able to run all 78 standard test cases in under 30 minutes, whereas manual validation can take weeks,” said Dr. Kerbusch.

Certara’s Phoenix NLME Validation Suite is used by clients to run a series of standard test cases and validate the software in their own environment. Once the tests are complete, the NLME Validation Suite compares those results with reference output results and generates a non-editable PDF validation report with embedded links to csv files of outputs and differences in outputs. That detailed report allows scientists to quickly identify and rectify the source of any output variations.

With Phoenix 8.2, users can now also access PK Submit™ and Certara Integral™ directly using Phoenix plug-ins. PK Submit is Certara’s new Clinical Data Interchange Standards Consortium (CDISC) compliance tool, which ensures that all client data are stored in the CDISC formatted files required for FDA PK regulatory submissions. It also provides the necessary supporting documentation. Certara Integral is the company’s 21 CFR Part 11 compliant central data repository,

which enables clients to store their models, study data and results in a validated environment ready for data mining and ultimately, submission. The combination of Phoenix 8.2, PK Submit and Certara Integral provides two key benefits for Certara clients: 1) Externally - regulatory compliance with the FDA and other regulatory authorities across the world and 2) Internally - consistency in project structure and workflow allowing for efficient project conduct and traceability for business continuity where project members may change over time.

Phoenix's Reporter Tool has also had several updates; it now allows report documents to be displayed immediately in Word, a PDF or both. It can also support clients' own templates with macros imbedded.

The Phoenix Online Help section has been modernized. User guides have been replaced by a searchable help page with direct links to product release notes, PML examples, tutorial videos, and user forums. It also has a log viewer, which allows clients to identify any errors or issues quickly.