CERTARA

Enhanced, Shared Workflows for Clinical Pharmacology and Pharmacometrics

Customer-driven enhancements to the Certara Phoenix modeling platform saved time, enhanced collaboration, and improved access to high-performance computing for a diverse group of scientists

Background

A global pharmaceutical company was investigating data solutions to enhance capabilities of their clinical pharmacology and pharmacometrics (Pmx) groups. Their challenge: to provide enterprise-wide access to shared data, models, analyses, and reports for a diverse user base in a regulatory compliant manner, with direct integration of the scientists' existing software tools.

Challenge

The company sought a single platform that could support the varied and specialized workflows of their clinical pharmacology and Pmx scientists across the globe, while reducing time spent on data manipulation. The company's clinical pharmacologists relied on Phoenix WinNonlin daily. Pharmacometricians performed population pharmacokinetic/pharmacodynamic (PK/PD) modeling and simulation through NONMEM® supplemented with Perl Speaks NONMEM modules, and statistical computing and graphics in the R language. Additional tools such as MATLAB® were also required.

In addition to integration with those software tools, the scientists needed a solution that could facilitate submission of analysis jobs to the company's high-performance computing (HPC) cluster, by connecting with a custom in-house interface. No off-the-shelf informatics platform could meet the full set of requirements.

Solution

The company partnered with Certara to push the boundaries of information infrastructure capabilities, starting from the flexible and powerful Certara Phoenix platform. The project began with rollout of Certara's Phoenix Knowledgebase Server (PKS), supporting 21 CFR Part 11 compliant, traceable storage and sharing of data, models, results and report documents across the organization. With Certara's Phoenix Connect, the team provided smooth integration of PKS content with Phoenix WinNonlin, NONMEM and other analysis tools.

Challenge

The client sought a regulatory compliant solution that enabled HPC, was integrated with existing pharmacometrics tools, and supported a multinational team of scientists.

Solution

The company adopted PKS to support 21 CFR Part 11 compliance and used a custom Phoenix plugin to gain HPC access; Phoenix Connect provided seamless integration between PKS, Phoenix WinNonlin, and 3rd party tools.

Benefit

The company's scientists can now quickly access datasets, run HPC jobs seamlessly within Phoenix, and save data output in a unified, secure, searchable, traceable, sharable and compliant manner with PKS.

Next, Certara and company scientists worked together to develop two custom Phoenix plug-ins to enhance their data management and HPC access. The first plug-in would enable modelers to submit, monitor and retrieve analyses using the HPC cluster via the company's in-house interface. The second Phoenix plugin provided a new means to create NONMEM-ready datasets quickly and efficiently. Certara specialists provided training to company users across the world.

Benefit

The custom plug-ins streamlined the scientists' analysis workflows, enabling them to quickly access analysis-ready datasets and run HPC jobs seamlessly, without ever leaving the Phoenix environment. With PKS as their new data platform, clinical pharmacologists and Pmx staff worldwide could easily pull data from the analysis and reporting toolset into NONMEM and Phoenix WinNonlin ready formats, saving their analyses and output back to PKS, with full traceability.

Modeling workflows could now be saved and shared through Phoenix run-record functionality. All data and output were stored in a unified, secure, searchable, shareable and compliant manner with PKS.

Impact

The new platform sped repeated tasks while remaining flexible enough to support creative modeling and simulation. Providing smooth integration with users' existing software tools, including direct submission of analysis jobs to the HPC cluster, the new Phoenix solution saved time previously spent in data preparation and programming. Datasets containing the latest updates could be pulled in minutes rather than days. With Phoenix workflow objects, scientists could now record, repeat and share steps in data handling, modeling, analysis and reporting—saving further time.

The new plug-ins will provide extended functionality in ongoing releases of the Certara Phoenix platform.

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.