Food and Drug Administration Renews and Expands Use of Certara's Biosimulation Software for Reviewing Regulatory Submissions

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FDA's Office of Pharmaceutical Quality adds new licenses of Simcyp ™ Simulator

PRINCETON, N.J.—October 1, 2020. Certara, a global leader in biosimulation, today announced that the U.S. Food and Drug Administration (FDA) has again renewed and expanded its licenses of Certara's biosimulation software, with more than 400 user licenses of Simcyp™ and Phoenix™ platforms. Eleven divisions and offices of the FDA use Certara's software for internal research and to independently analyze, verify, and review regulatory submissions.

Certara's Simcyp Simulator, an industry-leading platform for physiologically-based pharmacokinetic (PBPK) modeling and simulation, is used to determine first-in-human dose, design more efficient and effective clinical studies, and predict drug-drug interactions using virtual populations. The FDA's Office of Clinical Pharmacology has renewed its licenses for the Simcyp Simulator, including Simcyp Pediatric and the Simcyp Cardiac Safety Simulator. Furthermore, the FDA's Office of Pharmaceutical Quality recently ordered Simcyp user licenses, expanding the FDA's use of the platform. The agency uses Simcyp software to independently analyze, verify, and review sponsor IND, BLA, NDA, ANDA, and other submissions.

"Regulators around the world rely on our sophisticated software to inform their reviews of regulatory submissions," said Rob Aspbury, Ph.D., president of the Simcyp division at Certara. "It is a privilege to continue partnering with the FDA to demonstrate the ever-increasing uses of PBPK modeling to optimize drug development and support the regulatory review process in an effort to bring safe and efficacious therapies to market."

Additionally, the FDA has renewed its user licenses of Certara's Phoenix Platform, a comprehensive and widely-used software for pharmacokinetic, pharmacodynamic, and toxicokinetic modeling and simulation. Eleven divisions and offices at the FDA, along with ten other global regulatory agencies such as Japan's Pharmaceuticals and Medical Devices Agency and China's National Medical Products Administration, use the Phoenix Platform to evaluate regulatory submissions.

Certara's customers use Phoenix extensively to perform data analyses for their new drug and biologics applications. Since 2014, 90% of novel drugs approved by the FDA are from companies that have leveraged the Phoenix platform in their R&D programs. In addition to using Phoenix WinNonlin and Phoenix NLME, the FDA also uses Certara's Trial Simulator, IVIVC Toolkit, and PK Submit, which was recently recognized as a finalist in R&D's 100 Awards.

"We work with many biopharmaceutical companies and regulatory agencies to accelerate drug development, because our software can be used to test a wide range of 'what if' scenarios and research questions," said William F. Feehery, Ph.D., Certara's chief executive officer. "Our biosimulation software is routinely relied upon to support the development of complex therapies, such as cell and gene therapies, and medicines for much needed areas, including pediatrics, rare diseases, and COVID-19."

For more information on Certara's software platforms, please visit https://www.certara.com/virtual-patients/.

About Certara

Certara optimizes R&D productivity, commercial value and patient outcomes through its unique end-to-end platform of model-informed drug development, regulatory science, and market access solutions. Its clients include 1,600 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 60 countries. For more information, visit www.certara.com.

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