FDA Renews and Expands Its Use of Certara Software to Facilitate New Drug and Biologics Regulatory Review

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FDA employs Certara Phoenix®, Simcyp® and Synchrogenix GlobalSubmit software platforms to efficiently assess and evaluate sponsor submissions data

PRINCETON, NJ – Oct. 9, 2018 – Certara®, the global leader in model-informed drug development, regulatory science, market access and real-world evidence solutions, today announced that the US Food and Drug Administration (FDA) has renewed, and in many cases increased, its number of Certara software licenses for reviewing new drug and biologics applications.

FDA has renewed its use of Synchrogenix's electronic Common Technical Document (eCTD) review software, GlobalSubmit REVIEW™, providing enterprise-wide use at both FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) divisions. Synchrogenix is Certara's regulatory science division.

The FDA has stated that "it is aggressively moving towards an electronic regulatory submission to streamline the regulatory review process." GlobalSubmit REVIEW is being used by FDA to review New Drug Application (NDA), Biological License Application (BLA), Abbreviated New Drug Application (ANDA), Investigational New Drug (IND), Drug Master File (DMF), Annual Period Safety Report, and Advertising and Promotional Labeling submissions following the eCTD standard. FDA also uses GlobalSubmit VALIDATE™ to process and validate eCTD submissions. The agency selected GlobalSubmit in 2005 when it began its eCTD initiative.

FDA has increased its use of Certara's Phoenix software platform to nearly 400 users, which includes Phoenix WinNonlin®, non-linear mixed effects (NLME™), *in vivo-in vitro* (IVIVC), Connect, Trial Simulator™ and training. Certara's relationship with FDA dates back to 2001, when its previously named Pharsight division formed a Cooperative Research and Development Agreement (CRADA) with the agency's CDER division. Today, nine offices within FDA use Certara's Phoenix pharmacometrics software for internal research and to independently analyze, verify and complete the review of sponsor IND, BLA, NDA, ANDA and other submissions.

FDA has also renewed its licenses for Certara's physiologically-based pharmacokinetic (PBPK) Simcyp Population-based, Pediatric, Animal, and Cardiac Safety Simulators. The agency, which has been an associate member of the Simcyp Consortium since its inception in 2001, also uses Simcyp software to independently analyze and verify the review of sponsor IND, BLA, NDA, ANDA and other submissions. Additionally, FDA has awarded several grants to Simcyp and has renewed its CRADA with the company to create canine models to help streamline veterinary drug development and evaluation.

"We are proud of our long history of partnering with FDA to optimize the drug development and regulatory review processes," said Certara CEO Dr. Edmundo Muniz. "The FDA Commissioner has been an outspoken advocate for the use of innovation, and electronic technologies to advance the delivery of safer, more effective medicines for patients. For example, Dr. Gottlieb recently stated: 'I want to highlight one example of these steps, which we're investing in, and will be expanding on, as part of our broader innovation initiative. It's the use of *in silico* tools for improving drug development and making regulation more efficient.' Certara continues to support this approach by providing ongoing education, training and collaboration initiatives for the industry."

About Certara's Software Technology

- Phoenix is the most advanced and widely-used validated software for pharmacokinetics (PK), pharmacodynamics (PD) and toxicokinetic (TK) modeling and simulation worldwide. Sponsors use Phoenix extensively to perform data analyses for their new drug and biologics applications – 90-95% of novel drugs approved by US FDA are from companies that leverage Phoenix in their R&D programs. Trial Simulator, for example, is a powerful technology for evaluating clinical study design attributes and conducting statistical and sensitivity analyses likely to impact the trial's success.

- GlobalSubmit REVIEW facilitates the regulatory review process by providing both the sponsor company and FDA with an identical vantage point, ensuring that each regulatory activity can be filed and viewed according to regulations. GlobalSubmit VALIDATE is used exclusively by FDA to assess the technical validation criteria of all eCTD submissions passing through its Electronic Submissions Gateway (ESG), confirming compliance standards are met.

- Certara's Simcyp Simulator is the pharmaceutical industry's most sophisticated platform for determining first-in-human dose selection, designing more efficient and effective clinical studies, evaluating new drug formulations, and predicting drug-drug interactions and PK outcomes in various healthy and patient populations. These include vulnerable populations such as pediatric patients, pregnant women, and patients with impaired organ function.

The aforementioned contract awards are HHSF223201850063A, HHSF223201820140A, and HHSF223201810279P.

About Certara
Certara enables superior drug development and patient care decision-making through model-informed drug development, regulatory science, real-world evidence solutions and knowledge integration. As a result, it optimizes R&D productivity, commercial value and patient outcomes. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 60 countries. For more information, visit www.certara.com.

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