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Certara partners with PUMC to support drug development

01 June 2017 | News

Certara is partnering with Phase I Unit, Peking Union Medical College (PUMC) Hospitalâ??s Clinical Pharmacology Research Center (PUMCH-CPRC) in Beijing to help Chinese pharmaceutical companies enhance their drug development processes.



Certara, the leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes, announced that it is partnering with Phase I Unit, Peking Union Medical College (PUMC) Hospital's Clinical Pharmacology Research Center (PUMCH-CPRC) in Beijing to help Chinese pharmaceutical companies enhance their drug development processes.

Phase I Unit at PUMCH-CPRC will employ Certara's Simcyp Population-based Simulator to develop physiologically-based pharmacokinetic (PBPK) models in support of Chinese new and generic drug applications to the Chinese Food and Drug Administration (CFDA).

"We are proud to support China's efforts to foster healthcare innovation. By increasing its adoption of PBPK modeling and simulation, it will expedite its pharmaceutical companies' drug development processes and regulatory submissions, whilst also helping to bring safer therapies to market," said Simcyp President and Managing Director Dr. Stephen Toon.

"An increasing number of Chinese pharmaceutical companies want to use PBPK modeling and simulation as part of their drug development plans. We felt that the best way to maintain Certara's high scientific standards for these Chinese customers and help circumvent some of the language-related commercial impediments was to partner with Phase I Unit at PUMCH-CPRC, which is one of the most prestigious academic pharmaceutical research institutions in China," added Dr. Toon.

"We are delighted to expand our partnership with Certara and be able to provide Chinese pharmaceutical companies with modeling and simulation consulting support to strengthen their regulatory submissions," said Professor Pei Hu, MD, professor and director of Phase I Unit at PUMCH-CPRC.

Certara and Phase I Unit at PUMCH-CPRC already have a great partnership track record. The two organizations have been working together for several years to increase PBPK modeling and simulation education and training in China and have co-hosted several national workshops.

Phase I Unit at PUMCH-CPRC uses Certara's modeling and simulation technology for first-in-human, point-of-care, and late-phase clinical trials. It has many years' experience using both Certara's Simcyp Simulator and Phoenix® software and has published numerous peer-reviewed papers based on research conducted using those platforms. Phase I Unit at PUMCH-CPRC is a Phoenix Center of Excellence.

CFDA also employs Certara's Phoenix software and is a regulatory affiliate member of the Simcyp Consortium.

PUMC Hospital, which was founded by the Rockefeller Foundation in 1921, conducts clinical research into severe, rare and complicated diseases. It has 4,000 employees and is affiliated with both PUMC and the Chinese Academy of Medical Sciences.

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 clinical populations. These include vulnerable populations such as pediatric patients, pregnant women, and patients with impaired organ function.

Phoenix is the most advanced, intuitive, and widely-used software for PK, pharmacodynamic, and toxicokinetic modeling and simulation.

Through this new partnership with PUMC Hospital, Certara is providing Chinese customers with access to its modeling and simulation technology and helping accelerate safer and more effective drug development in China.