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ASIA EDITION

Certara Celebrates 20th Anniversary of the Simcyp Simulator Consortium

October 17, 2019 | News

The most influential scientific research consortium of its kind: 37 biopharmaceutical companies work in a pre-competitive environment to advance PBPK modelling and simulation, progress new drug and biologics research, create new regulatory frontiers, foster ongoing modelling and simulation education, and present industry awards

Certara®, the global model-informed drug development and decision support leader, today announced that it is celebrating the 20th anniversary of its Simcyp® Consortium.

The Simcyp Consortium was created as a collaborative research centre to develop best practices and progress physiologically-based pharmacokinetic (PBPK) modelling and simulation, the science of studying drug handling by the body in computer-generated, virtual patients. Today, it counts 37 leading biopharmaceutical companies among its members and is a global authority on mechanistic PBPK modelling and simulation. Consortium members work together in a pre-competitive environment to progress model-informed drug development and create annual updates to Certara's Simcyp Population-based Simulator.

"Simcyp Simulator advances have enabled member companies to evaluate new therapies in patient groups and clinical scenarios that might historically have been considered 'untestable,'" said Steve Toon, PhD, Simcyp President and Managing Director. "For example, biopharmaceutical companies now use the Simcyp Simulator to predict drug-drug interactions (DDIs) and PK outcomes, and select the most appropriate drug doses for vulnerable populations, such as pregnant women, neonatal and pediatric patients, patients with complex conditions or co-morbidities that require polypharmacy, and patients with impaired hepatic or renal systems."

"Having inaugurated this business and technology in 1999, I am delighted to see the Simcyp Consortium reach this milestone anniversary. It has been a wonderful experience to collaborate with colleagues all around the world to advance PBPK modelling and simulation first as a science and later as a requirement for new drug regulatory submissions. Our organization continues to grow and evolve to tackle new frontiers. In addition to its use in clinical and regulatory approval, the Simcyp Simulator is actively being leveraged for formulations and pharmaceutics development purposes," said Amin Rostami, PharmD, PhD, Certara's Chief Scientific Officer.

Mechanistic PBPK modelling and simulation has become a key technology in modern drug development. Simcyp Simulator modelling and simulation has resulted in the approval of more than 200 labels claims for more than 55 drugs without the need for clinical trials. The Simcyp Simulator has been adopted by all the leading regulatory agencies, including the US FDA, Europe's EMA and Japan's PMDA. The Simcyp Simulator is also employed to design optimal clinical trials, evaluate new drug formulations, and conduct virtual bioequivalence studies. In fact, earlier this year, the Simcyp Simulator was successfully used to demonstrate bioequivalence (BE) for the first US FDA approval of a complex generic drug on the

agency's abbreviated new drug application (ANDA) pathway.

Simcyp Consortium Awards

The Simcyp Consortium presents two annual awards to recognize research excellence and give back to the scientific community. It presented this year's Most Informative Scientific Report Award to Flinders University in Adelaide, Australia for its paper entitled "Guidance for Rifampin and Midazolam Dosing Protocols to Study Intestinal and Hepatic Cytochrome P450 (CYP) 3A4 Induction and De-induction." Its 2019 Most Effective Teaching Application Award was presented to Aristotle University of Thessaloniki, Greece for Clinical Pharmacokinetics, a core course in its five-year Diploma of Pharmacy degree program. In addition, Certara's Simcyp Division Grant and Partnership Scheme fund either a PhD or a post-doctoral research program every year. The 2018/2019 grant winners were project leader Dr Hannah Batchelor and PhD student Jan Goelen at the University of Birmingham, UK. Their project is entitled ''Using Pediatric GI Data to Better Understand Dissolution and Absorption in Pediatric Populations."

In addition to its annual awards, Simcyp provides academic teaching and research licenses at no cost to more than 140 universities and research institutions around the world. Further, Simcyp publications (including articles, meeting abstracts, reviews, letters, and book chapters) have been cited more than 8,000 times.

Celebratory Timeline

Certara has created an interactive timeline to illustrate the Simcyp Consortium's extensive industry impact during the past two decades. That timeline can be accessed as a pdf at https://www.certara.com/wp-content/uploads/2019/10/timeline-final-web.pdf or in video format at https://www.youtube.com/watch?v.