



## Certara introduces Simcyp™ Biopharmaceutics software to increase efficiency of novel and generic drug formulation & development

November 21, 2023

### Simcyp Biopharmaceutics helps drug developers replace costly clinical bioequivalence studies and optimize formulations for complex therapies

PRINCETON, N.J., Nov. 21, 2023 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced the introduction of Simcyp™ Biopharmaceutics software. It is designed for use by biopharmaceutic, formulation, and CMC scientists to aid in formulating complex novel and generic small molecule medicines quickly and cost effectively. Simcyp Biopharmaceutics software is part of the Simcyp Simulator biosimulation platform, which has supported label claims for more than [100 approved novel therapies](#).

"The Simcyp Simulator is well recognized for its applications in clinical development, including prediction of drug-drug interactions, drug-food interactions, and drug performance in populations such as pediatrics and organ impairment," said Rob Aspbury, President of Certara Scientific Software. "To further meet client requests and regulatory needs in earlier stages of drug development, we have been investing in advanced scientific formulation modeling technology and participating in US FDA R&D grant programs in this area for the past five years."

Simcyp Biopharmaceutics software also helps sponsors develop the evidence needed to attain biowaivers which are used in lieu of conducting clinical studies. It is available as a standalone product and is designed for life sciences companies of all sizes looking to optimize their therapies' formulations to maximize safety, efficacy, and patient convenience.

Simcyp Biopharmaceutics software delivers value and unique capabilities across several areas that are critical to achieving formulation success, including:

- **Replace Costly Clinical Bioequivalence Studies** - With growing encouragement from regulators, virtual bioequivalence studies (VBE) leverages physiologically based pharmacokinetic (PBPK) modeling to demonstrate bioequivalence (BE) between test and reference drugs. Simcyp Biopharmaceutics software includes a VBE module that automates elements of trial design significantly enhancing opportunities for attaining biowaivers.
- **Optimize Formulation for Complex Drugs:** Biopharmaceutical Classification System (BCS) Class II-IV drugs are challenging to create oral formulations for because of their poor solubility and/or absorption. Simcyp Biopharmaceutics software facilitates developing these drugs, which constitute 90% of new drug candidates.
- **Inform Drug Labels** - Recent FDA guidance recognizes physiologically-based pharmacokinetic (PBPK) models as a valuable technology for identifying and optimizing the impact of gastrointestinal effects such as meal type and pH. [Simcyp Biopharmaceutics](#) software advances these capabilities for optimizing dosing strategies and providing label guidance to clinicians.

For more information about Simcyp Biopharmaceutics software, please visit our [website](#).

#### About Certara

Certara accelerates medicines using biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,300 biopharmaceutical companies, academic institutions, and regulatory agencies across 70 countries. Learn more at [Certara.com](#).

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