



## Certara Simcyp™ Group Awarded Two New Grants from US FDA

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### **Programs focus on use of physiologically-based pharmacokinetic (PBPK) modeling for demonstrating virtual bioequivalence and predicting drug absorption of topical formulations**

PRINCETON, N.J., Aug. 29, 2023 (GLOBE NEWSWIRE) -- Certara (Nasdaq: CERT), a global leader in biosimulation, today announced that the [Simcyp](#) group has been awarded two new grants from the U.S. Food and Drug Administration (FDA) to expand its predictive models for assessing drug virtual bioequivalence (VBE) and to create a formulation toolbox for topically applied drugs. These capabilities will help enable safer, faster and more cost-effective product development of both complex generics and novel drugs.

"We are proud to collaborate with the FDA in developing innovative model-informed approaches for accelerating drug development of complex generic and innovator drugs," said Rob Aspbury, President of Certara, Scientific Software. "The Simcyp Simulator has already proved its ability to replace clinical studies in both VBE and dermal absorption. These new grants will further demonstrate the predictive performance and reliability of biosimulation for improving patient health."

#### **Virtual Bioequivalence**

Bioequivalence (BE) studies, which are used to show that the rate and extent of absorption of the investigational product are not significantly different from those of the comparable reference drug product, can be costly and time-consuming. VBE trial simulations, using mechanistic PBPK modeling, address this challenge by simulating realistic virtual cohorts of patients to reduce and or replace clinical trials. This grant will support increased automation of this process by developing verified workflows and multiple case studies to increase wider adoption of VBE by industry and regulators.

#### **Dermal Formulation Modeling**

Dermal PBPK modeling has been applied to the development of topical formulations by predicting drug absorption into the skin in virtual populations. Topical products undergo changes immediately upon application due to formulation metamorphosis, which may alter the critical characteristics of the formulations. This grant will support the development and verification of a reliable and robust dermal PBPK model enhanced with the specialized dermal formulation toolbox to aid decision-making and result in lower risk, more efficient and cost-effective development of generic drug products providing benefits to patients.

Learn more about how [Certara supports virtual bioequivalence here](#).

#### **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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