



# Simcyp™ Biopharmaceutics

Elevating 'Gold Standard' PBPK Technologies for Biopharmaceutics, Drug Formulation, and CMC Experts

## Trusted Technology Tailored for Biopharmaceutical, Formulation, and CMC Professionals

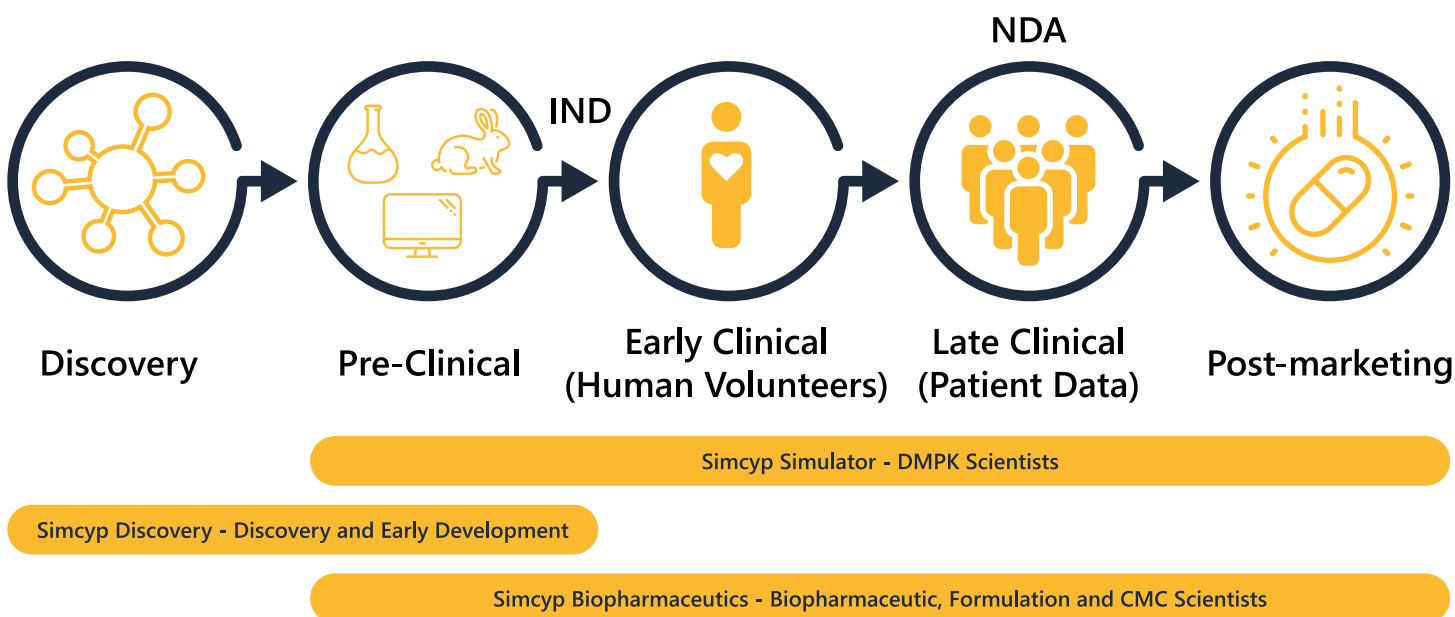
The impact and acceptance of physiologically-based pharmacokinetic (PBPK) modeling continues to exhibit strong growth within the pharmaceutical industry, and PBPK approaches are increasingly being advocated by regulatory agencies to streamline drug development. The potential applications of PBPK within drug development are plentiful. However, in recent years, there has been increasing interest in using PBPK to address the challenges faced by biopharmaceutics scientists, otherwise known as model-informed formulation development (MIFD). In recognition of this burgeoning field, Certara is proud to announce the release of Simcyp Biopharmaceutics, the newest member of the Simcyp Suite of products, and the first of which to be specifically tailored for MIFD applications.

### What is Simcyp Biopharmaceutics?

Simcyp Biopharmaceutics is a small-molecule human PBPK platform with built-in capabilities for simulating healthy volunteer populations, the most commonly used subjects in clinical pharmacology studies. As a part of the esteemed Simcyp family of mechanistic and predictive modeling technologies, Simcyp Biopharmaceutics joins Simcyp Animal, Simcyp Discovery, and the renowned Simcyp Simulator for physiologically based pharmacokinetic (PBPK) modeling.

This platform supports biologically realistic simulation of gastrointestinal drug absorption using both the Advanced Dissolution and Metabolism Absorption (ADAM) Model (ADAM) and multi-layered ADAM (M-ADAM) models. The base product also supports intravenous administration, and other routes such as subcutaneous, intra-muscular, rectal, and vaginal may also be accommodated through supplemental modules. Given the pivotal role of in vitro data in the MIFD approach, Simcyp Biopharmaceutics includes both mechanistic in vitro-in vivo correlation (IVIVC) and the SIVA toolbox. Likewise, Simcyp's VBE module, an add-on for the main simulator, is included with Simcyp Biopharmaceutics.

### Predictive modeling technology across the drug development cycle



## Simcyp quality. Expansive use cases. Affordably priced.

Simcyp Biopharmaceutics delivers value across several critical areas for achieving formulation success. It goes beyond being just software, as this groundbreaking platform is designed to streamline formulation development, navigate the intricacies of novel and generic drugs, and enhance the success rate of obtaining biowaivers.

### Key differentiators include:

- Virtual Bioequivalence (VBE)- robust estimation in sample size
- BCS Class II, III, IV Drugs – robust mechanistic formulation strategies
- Food Effect Staggering and Impact of Acid reducing Agents (ARA) – robust case studies incorporated into optimizing dosing strategies.
- Automated “safe space” identification

## Features and Capabilities

Advanced GI  
Chemistry and  
Physiology

VBE Module

Modified  
Formulation  
Simulations

Mechanistic IVIVC.  
IVIVE

Simcyp™ In Vitro  
Analysis (SIVA)  
Toolbox

## Primary Use Cases

Early Formulation  
Development

Manufacturing and  
Quality Control

Food Effect

Virtual Bioequivalence  
(VBE)

Formulation Bridging

Alternative Routes of  
Administration

Biowaver Submission  
Strategy

Product Lifecycle  
Management

*Discover new insights,  
drive smarter decisions,  
and unleash new  
opportunities with  
the power of Simcyp  
Biopharmaceutics.*



SCAN ME

*Request a demo.*



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## About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions and regulatory agencies across 62 countries.

For more information, visit [www.certara.com](http://www.certara.com).