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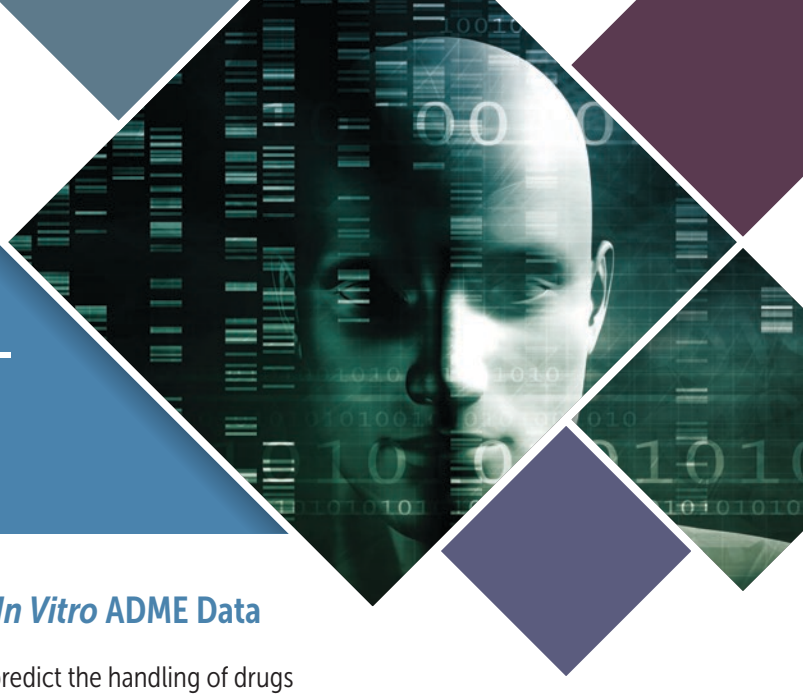
Simcyp



Simcyp Consulting Services PBPK – Modeling and Simulation

Building Prospective Clinical Knowledge From Your *In Vitro* ADME Data

Physiologically-based pharmacokinetic (PBPK) models describe and predict the handling of drugs by the body in a realistic way based on demography, physiology, biochemistry and genetics. We integrate this information with *in vitro* drug absorption, metabolism and transport data to simulate and predict *in vivo* pharmacokinetics (PK) in virtual patient populations.

Such "population-based" PBPK modeling is increasingly being used in regulatory review to facilitate decisions on the necessity for specific clinical studies, to inform study design and guide appropriate labeling language.

Simcyp is the leader in mechanistic PK with an international reputation *in vitro-in vivo* extrapolation of drug absorption, distribution, metabolism and elimination (ADME) data.

In addition to licensing the Simcyp Simulator we offer consultancy services on all aspects of drug ADME and pharmacokinetics/pharmacodynamics (PK/PD) data analysis and interpretation.

Using your data, Simcyp's scientists can provide advice on the design of your ADME experiments and deliver independent analysis, interpretation and reports. This service is ideally suited to those clients who do not have the resource, time or need to use our simulation technology directly.

Recently the Simcyp Consultancy team has:

- Evaluated the likely magnitude of interaction between caffeine and a new neurological drug
- Designed a dosing regimen for a new anticancer drug taking into account drug-drug interaction (DDI) potential
- Supported development of new and pediatric formulations
- Evaluated potential PK changes in specific disease populations
- Developed a "virtual clinical PK package" for a NCE
- Evaluated the likelihood and magnitude of DDIs prior to clinical investigation
- Developed company-specific PBPK models for use within the Simcyp Simulator
- Investigated likely mechanisms behind clinically observed PK nonlinearities
- Developed specific populations and compound files for exclusive use within the Simcyp Simulator

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.

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