Simcyp Leadership is Unmatched

- Created a renowned technology for virtualizing R&D and accelerating the development of hundreds of novel drugs
- Built a unique consortium of 36 major biopharmaceutical companies, contributing to innovation in PBPK and mechanistic modeling
- Educated hundreds of scientists across commercial, academic, and regulatory organizations
- Provided numerous grants to academic scientific teams including
 Simcyp licenses at no cost to hundreds of academic institutions
- Groundbreaking use of PBPK in regulatory filings including >200 label claims using modeling & simulation in lieu of clinical trials



Thank You

Thank you to the consortium members for partnering with Simcyp and Certara during these past 20 years. Together, we have advanced the science of drug development through modeling & simulation.

- Steve Toon

A BOD

Abbvie, Amgen, Astellas, Astra Zeneca, Biogen, Bristol-Myers Squibb, Celgene, Daiichi- Sankyo, Eisai, Eli Lilly, Gilead, GSK, Grünenthal, Idorsia, Incyte, Johnson & Johnson, Kyowa Kirin, Lundbeck, Merck, Merck Serono, Mitsubishi Tanabe, Nektar, Novartis, Ono, Otsuka, Pfizer, Roche/Genentech/Chugai, Sanofi Aventis, Servier, Shionogi, Shire, Sumitomo Dainippon/Sunovion, Taisho, Takeda, UCB, Vertex

Simcyp: 20 Years of Innovation





Categories

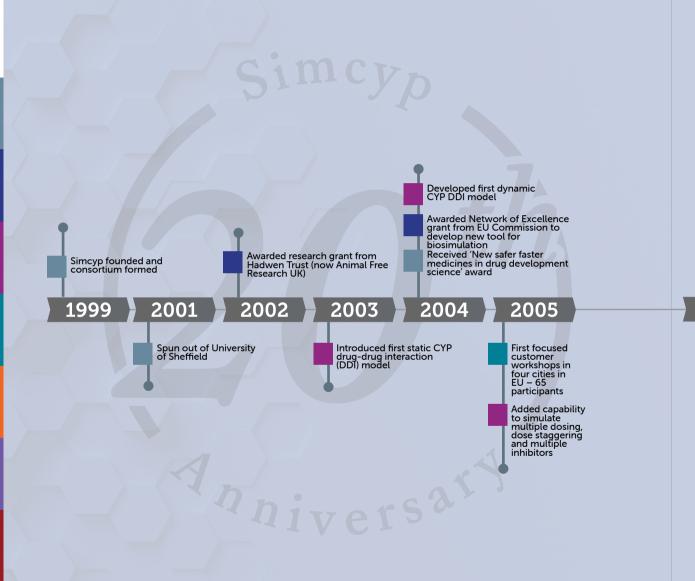
Grants awarded to Simcyp

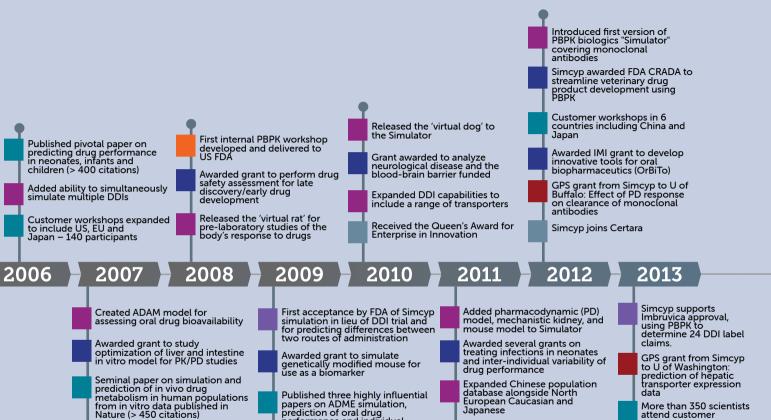
Product innovation

Customer education

Drug development

Grant & Partnership Scheme: Awards given by Simcyp





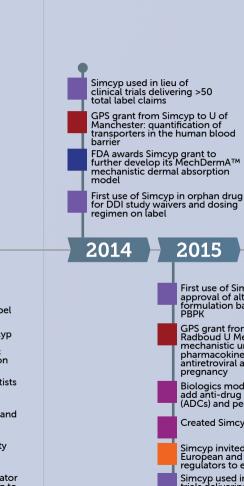
performance and individual

variability

from in vitro data published in Nature (> 450 citations)

First version of pediatric

"Simulator" launched



Introduction of Simcyp Grant & Partnership Scheme (GPS),

awarding grant to Flinders University: olanzapine dosing

using the Simulator

More than 350 scientists attend customer workshops

Geriatric population and IVIVC tool added to

Simcyp Cardiac Safety Simulator product

Modeling with Simulator used to enable a drug to come off FDA clinical safety hold

Simcyp received grants from EUToxRisk to study toxicity risk assessment and OcuTher to study ocular drug delivery The US EPA leveraged the Simulator to determine risk assessment on commercial chemicals Simcyp used to model various First use of Simcyp for FDA approval of alternative study designs and develop FDA-approved dosing strategy förmulation based solelv or for patients with hepatic GPS grant from Simcyp to Radboud U Medical Center: GPS awarded by Simcyp to Long Island U: Predicting drug disposition and guide dosing mechanistic understanding of pharmacokinetics of antiretroviral agents in decisions in preterm neonates pregnancy Certara Simcyp launched first QSP consortium on Biologics module expanded to add anti-drug conjugates immunogenicity (ADCs) and pediatrics Oncology and premature pediatrics populations added to Created Simcyp virtual monkey Delivered focused workshop on mechanistic modeling to Simcyp invited by the US, European and Japanese FDA and Health Canada regulators to educate on PBPK Awarded two more grants to use mechanistic modeling to Simcyp used in lieu of clinical predict toxicity trials delivering >100 total labe

Certara Simcyp and the University of Manchester

personalized drug dosing with 15 case studies

develop a mechanistic

(mechanistic multi-

modeling and simulation framework to predict the

compartment granuloma model) to Simulator

behavior of supersaturating drug products in the body

Added enhanced lung mode

GPS awarded by Simcyp to U of

Washington: renal secretion and toxicity of drugs in children

sponsor first-ever conference

FDA awarded Simcyp a grant to

Simcyp used to support first FDA virtual bioequivalence approval for complex generic drug 7 novel drugs approved by FDA in 2019 YTD used

Simcyp used in lieu of clinical trials delivering ~200 total label claims

Certara Simcyp launched

US FDA Awarded Certara

Simcvp two new dermal

Gastrointestinal data to

virtual bioequivalence grants

GPS awarded by Simcyp to U

better understand dissolution

Advanced tumor model and

ability to simulate food and

Simcyp scientists invited to

speak at FDA workshops on

topics of biopharmaceutics

and absorption in pediatric

600 scientists attend

customer workshops

fluids in trial design

and skin.

immuno-oncology

of Birmingham:

second QSP consortium on



Prof. Amin Rostami delivering a lecture on 'Demystifying the Path for **PBPK Applications'**



Hands-on Simcyp workshop The intersection of science software and drug development