



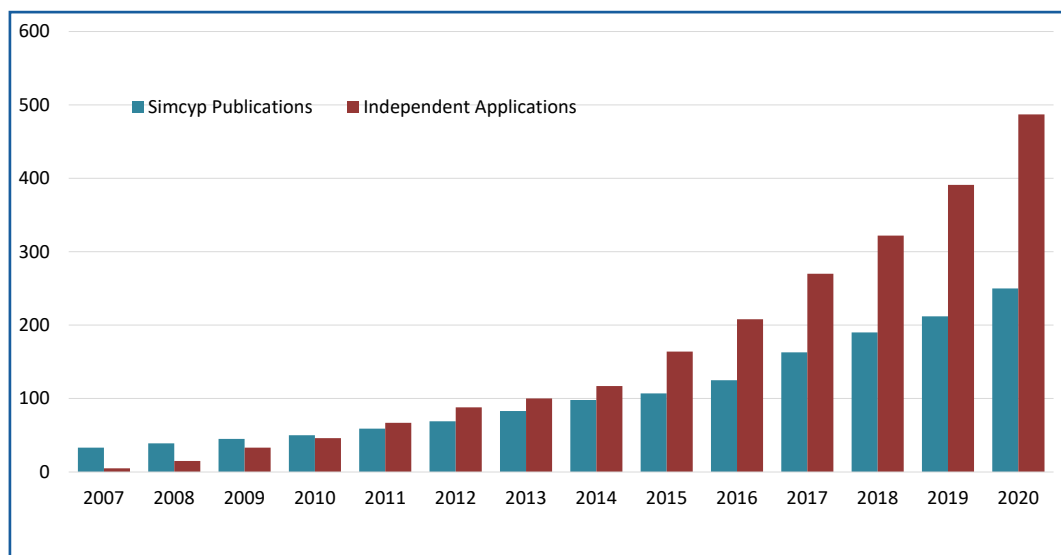
Simcyp Publications and Independent Applications List 2020

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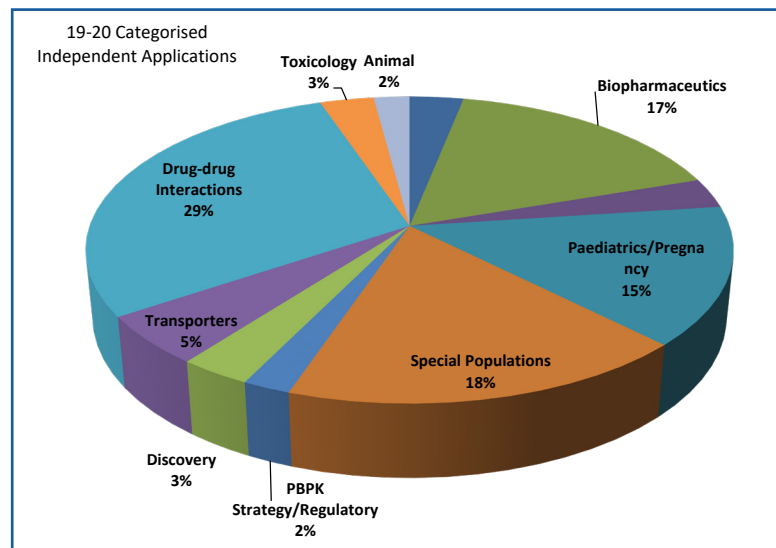
Publications by Simcyp R&D Team (1997 – Present) and Independent Applications of Simcyp by Industry, Academia, and Regulatory Organizations (2007 – Present)

Simcyp Publication Statistics

Simcyp have over 240 published peer reviewed papers, and since 2007 there have been over 480 Independent Publications applying Simcyp.



Overall Simcyp publications (including articles, meeting abstracts, reviews, letters, and book chapters) have been cited 8,889 times (excluding self-citations). The citations are spread over 5,463 citing articles. The chart below shows the areas in which the Independent Applications have focused since 2019.



Simcyp 2020 Publications

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IMI - Oral biopharmaceutics tools project - Evaluation of bottom-up PBPK prediction success part 4: Prediction accuracy and software comparisons with improved data and modelling strategies. *European Journal of Pharmaceutics and Biopharmaceutics* 156, 50-63, November 2020.

Jamei M

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A laboratory specific scaling factor to predict the in vivo human clearance of aldehyde oxidase substrates. *Drug Metabolism and Disposition* Epub Ahead of Print, September 2020.

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PBPK as a Component of Model-Informed Drug Development: Where We Were, Where We Are, and Where We Are Heading. *The Journal of Clinical Pharmacology* In Press, September 2020.

Salem F et al.

Does "Birth" as an Event Impact Maturation Trajectory of Renal Clearance via Glomerular Filtration? Reexamining Data in Preterm and Full-Term Neonates by Avoiding the Creatinine Bias. *Journal of Clinical Pharmacology* September Epub Ahead of Print, 2020.

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Use of a physiologically based pharmacokinetic-pharmacodynamic model for initial dose prediction and escalation during a paediatric clinical trial. *British Journal of Clinical Pharmacology* Epub Ahead of Print, August 2020.

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Six years of progress in the oral biopharmaceutics area - A summary from the IMI OrBiTo project. *European Journal of Pharmaceutics and Biopharmaceutics* 152, 236-247, July 2020.

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Well-tempered MCMC simulations for population pharmacokinetic models. *Journal of Pharmacokinetics and Pharmacodynamics* Epub Ahead of Print, July 2020.

Liu D et al.

Considerations and Caveats when Applying Global Sensitivity Analysis Methods to Physiologically Based Pharmacokinetic Models. *AAPS J* 22 (5), 93, July 2020.

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Mass Spectrometry of Human Transporters. *Annual Review of Analytical Chemistry (Palo Alto, Calif.)* 13 (1), 223-247, June 2020

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Impact of Disease on Plasma and Lung Exposure of Chloroquine, Hydroxychloroquine and Azithromycin: Application of PBPK Modeling. *Clinical Pharmacology and Therapeutics* Epub Ahead of Print, June 2020.

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Fetal Physiologically Based Pharmacokinetic Models: Systems Information on Fetal Blood Components and Binding Proteins. *Clinical Pharmacokinetics* 59 (5), 629-642, May 2020.

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Translational Modeling Strategies for Orally Administered Drug Products: Academic, Industrial and Regulatory Perspectives. *Pharmaceutical Research* 37 (6), 95, May 2020.

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Physiologically-Based Pharmacokinetic Models for Evaluating Membrane Transporter Mediated Drug-Drug Interactions: Current Capabilities, Case Studies, Future Opportunities, and Recommendations. *Clinical Pharmacology and Therapeutics* 107 (5), 1082-1115, May 2020.

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Quantitative Systems Toxicology Modeling To Address Key Safety Questions in Drug Development: A Focus of the TransQST Consortium. *Chemical Research in Toxicology* 33 (1), 7-9, January 2020.

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The nested enzyme-within-enterocyte (NEWE) turnover model for predicting dynamic drug and disease effects on the gut wall. *European Journal of Pharmaceutical Sciences* 131, 195-207, April 2019.

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Standing JF et al.

Comment on "Effect of Age-Related Factors on the Pharmacokinetics of Lamotrigine and Potential Implications for Maintenance Dose Optimisation in Future Clinical Trials". *Clinical Pharmacokinetics* 57(11), 1471-1472, November 2018.

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Personalized medicine in digital innovation. *International Journal of Pharmacokinetics* 3(4), 103-106, November 2018.

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Past, Present, and Future of Bioequivalence: Improving Assessment and Extrapolation of Therapeutic Equivalence for Oral Drug Products. *Journal of Pharmaceutical Sciences* 107(10), 2519-2530, October 2018.

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Development of a physiologically based pharmacokinetic model for mefloquine and its application alongside a clinical effectiveness model to select an optimal dose for prevention of malaria in young Caucasian children. *British Journal of Clinical Pharmacology* 85(1), 100-113, January 2019.

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Physiologically Based Pharmacokinetic-Quantitative Systems Toxicology and Safety (PBPK-QSTS) Modeling Approach Applied to Predict The Variability of Amitriptyline Pharmacokinetics and Cardiac Safety in Populations and Individuals. *Journal of Pharmacokinetics and Pharmacodynamics* 45(5), 663-677, October 2018.

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Physiologically Based Pharmacokinetic Model Qualification and Reporting Procedures for Regulatory Submissions: A Consortium Perspective. *Clinical Pharmacology and Therapeutics* 104(1), 88-110, July 2018.

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The absorption kinetics of ketoconazole plays a major role in explaining the reported variability in the level of interaction with midazolam: Interplay between formulation and inhibition of gut wall and liver metabolism. *Biopharmaceutics & Drug Disposition* 38(3), 260-270, April 2017.

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Revisiting the role of gut wall in the fate of orally administered drugs: Why now and to what effect? *Biopharmaceutics and Drug Disposition* 38(2), 87-93, March 2017.

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