

Publications October 2020 – October 2021

1. Al-Majdoub ZM, Couto N, Achour B, Harwood MD, Carlson G, Warhurst G, Barber J and Rostami-Hodjegan A (2020) Quantification of Proteins Involved in Intestinal Epithelial Handling of Xenobiotics. *Clin Pharmacol Ther*, doi: 10.1002/cpt.2097. 3 citations
2. Al-Majdoub ZM, Achour B, Couto N, Howard M, Elmorsi Y, Scotcher D, Alrubia S, El-Khateeb E, Vasiliogianni AM, Alohali N, Neuhoff S, Schmitt L, Rostami-Hodjegan A, Barber J (2020) Mass Spectrometry-Based Abundance Atlas of ABC Transporters in Human Liver, Gut, Kidney, Brain and Skin. *FEBS Lett*, doi: 10.1002/1873-3468.13982. 4 citations
3. Lang, J., Vincent, L., Chenel, M., Ogungbenro, K. and Galetin, A. (2020), Impact of hepatic CYP3A4 ontogeny functions on DDI risk in paediatric PBPK/PD modelling: critical literature review and ivabradine case study. *Clin Pharmacol Ther*. <https://doi.org/10.1002/cpt.2134> 3 citations
4. El-Khateeb E, Achour B, Scotcher D, Al-Majdoub ZM, Athwal V, Barber J, Rostami-Hodjegan A (2020) Scaling Factors for Clearance in Adult Liver Cirrhosis. *Drug Metab Dispos* 48(12), 1271-1282. doi.org/10.1124/dmd.120.000152. 2 citations
5. Reddy VP, El-Khateeb E, Jo H, Giovino N, Lythgoe E, Sharma S, Tang W, Jamei M, Rostami-Hodjegan A (2020) Pharmacokinetics under the COVID-19 Storm. *Br J Clin Pharmacol* bcp.14668.doi:10.1111/bcp.14668. 0 citations
6. El-Khateeb E, Burkill S, Murby S, Amirat H, Rostami-Hodjegan A, Ahmad A (2020) Physiological-based pharmacokinetic modeling trends in pharmaceutical drug development over the last 20-years; In-depth analysis of applications, organizations, and platforms. *Biopharm. Drug Dispos*.doi: 10.1002/bdd.2257. 5 citations
7. Achour B, Al-Majdoub ZM, Grybos-Gajniak A, Lea K, Kilford P, Zhang M, Knight D, Barber J, Schageman J, Rostami-Hodjegan A (2020) Liquid Biopsy Enables Quantification of the Abundance and Interindividual Variability of Hepatic Enzymes and Transporters., *Clin Pharmacol. Ther*, Eraly Online DOI: 10.1002/cpt.2102 5 citations
8. Couto N, Newton JAR, Russo C, Karunakaran E, Achour B, Al-Majdoub ZM, Sidaway J, Rostami-Hodjegan, Clench MR, Barber J (2020) Label-Free Quantitative Proteomics and Substrate-Based Mass Spectrometry Imaging of Xenobiotic Metabolizing Enzymes in Ex Vivo Human Skin and a Human Living Skin Equivalent Model. *Drug Metab. Dispos.* 49: 1-14. <https://doi.org/10.1124/dmd.120.000168>. 1 citation
9. Darwich AS, Polasek TM, Aronson JK, Ogungbenro K, Wright DFB, Achour B, Reny J-L, Daali Y, Eiermann B, Cook J, Lesko L, McLachlan A, Rostami-Hodjegan A (2020) Model-Informed Precision Dosing: Background, Requirements, Validation, Implementation and Forward Trajectory of Individualizing Drug Therapy. *Annl Rev Pharmacol Toxicol*, 61, DOI: 10.1146/annurev-pharmtox-033020-113257. 8 citations
10. Takita H, Barnett S, Zhang Y, Ménochet K, Shen H, Ogungbenro K, Galetin A (2020) Application of PBPK model for coproporphyrin I to evaluate the impact of SLCO1B1 genotype, ethnicity, and sex on its inter-individual variability. *CPT Pharmacometrics Syst Pharmacol*. doi: 10.1002/psp4.12582. 3 citations
11. Takita H, Scotcher D, Chinnadurai R, Kalra PA, Galetin A (2020) Physiologically-Based Pharmacokinetic Modelling of Creatinine-Drug Interactions in the Chronic Kidney Disease Population. *CPT Pharmacometrics Syst Pharmacol*. doi: 10.1002/psp4.12566. 4 citations
12. Takita H, Darwich AS, Ahmad A, Rostami-Hodjegan A (2020). Application of the nested enzyme-within-enterocyte (NEWE) turnover model for predicting the time course of pharmacodynamic effects. *CPT Pharmacometrics Syst Pharmacol*. 9, 617–627.
13. Lombard A, Mistry H, Chapman SC, Gueogueieva I, Aarons L & Ogungbenro K (2020) Impact of tumour size measurement inter-operator variability on model-based drug effect evaluation. *Cancer Chemother Pharmacol* DOI.org/10.1007/s00280-020-04049-5 1 citation

14. Lombard A, Mistry H, Aarons L & Ogungbenro K (2020) Dose individualisation in oncology using chemotherapy-induced neutropenia: example of docetaxel in non-small cell lung cancer patients. *Br J Clin Pharmacol* DOI 10.1111/bcp.14614 1 citation
15. Rostami-Hodjegan, A. & Toon, S (2020) Physiologically Based Pharmacokinetics as a Component of Model-Informed Drug Development: Where We Were, Where We Are, and Where We Are Heading. *J Clin Pharmacol*, 60, S12-S16 1 citation
16. Salem, F., Johnson, T.N., Hodgkinson, A., Ogungbenro, K. & Rostami-Hodjegan, A. Does "Birth" as an Event Impact Maturation Trajectory of Renal Clearance via Glomerular Filtration? Re-examining Data in Preterm and Full-Term Neonates by Avoiding the Creatinine Bias. *J Clin Pharmacol*, 61, 159-171 (2021). 7 citations
17. Lee J, Gong Y, Bhoopathy S, DiLiberti CE, Hooker AC, Rostami-Hodjegan A, Schmidt S, Suarez-Sharp S, Lukacova V, Fang L, Zhao L. Public Workshop Summary Report on Fiscal Year 2021 Generic Drug Regulatory Science Initiatives: Data Analysis and Model-Based Bioequivalence. *Clin Pharmacol Ther*. 2020 Nov 24. doi: 10.1002/cpt.2120. Epub ahead of print.
18. Alsalhat, I., Al-Majdoub, Z.M., Taha, M.O., Barber, J., Aojula, H., Hodson, N., et al. (2021). Inhibition of aggregation of amyloid- β through covalent modification with benzylpenicillin; potential relevance to Alzheimer's disease. *Biochem. Biophys. Reports* 26: 100943.
19. Francis LJ, Houston JB, and Hallifax D (2021) Impact of Plasma Protein Binding in Drug Clearance Prediction: A Data Base Analysis of Published Studies and Implications for In Vitro-In Vivo Extrapolation. *Drug Metab Dispos* doi: 10.1124/dmd.120.000294 5 citations
20. Razavi S, Jakeman A, Saltelli A, Prieur C, Iooss B, Borgonovo E, Plischke E, Lo Piano S, Iwanaga T, Becker W, Tarantola S, Guillaume JHA, Jakeman J, Gupta H, Melillo N, Rabitti G, Chabridon V, Duan Q, Sun X, Smith S, Sheikholeslami R, Hosseini N, Asadzadeh M, Puy A, Kucherenko S, Maier H (2021) The future of Sensitivity Analysis: An essential discipline for systems modeling and policy support. *Environ Model Softw*, doi: 10.1016/j.envsoft.2020.104954 25 citations
21. Ahmad A, Ogungbenro K, Kunze A, Jacobs F, Snoeys J, Rostami-Hodjegan A, Galetin A (2021) Population pharmacokinetic modelling and simulation to support qualification of pyridoxic acid as endogenous biomarker of OAT1/3 renal transporters. *CPT Pharmacometrics Syst Pharmacol*. doi: 10.1002/psp4.12610. 3 citations
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23. Lombard A, Mistry H, Chapman SC, Gueorguieva I, Aarons L, Ogungbenro K (2021) Investigating the impact of target lesion selection on drug effect evaluation and tumour growth rate determination using tumour growth inhibition models: example of malignant pleural mesothelioma patients treated with cisplatin alone or in combination with pemetrexed. *Eur J Clin Pharmacol* doi: 10.1016/j.ejps.2021.105781
24. Rostami-Hodjegan, A & Bois, F (2021) Open Debate on Open-Source Modelling Tools: Pouring Fuel on Fire vs. Extinguishing the Flare of a Healthy Debate. *CPT: Pharmacometrics Syst Pharmacol*, Epub ahead of print, doi: [10.1002/psp4.12615](https://doi.org/10.1002/psp4.12615) 4 citations
25. Wu F, Cristofolletti R, Zhao L & Rostami-Hodjegan A (2021) Scientific Considerations to Move Towards Biowaiver for BCS Class III Drugs: How Modeling and Simulation Can Help? *Biopharm Drug Dispos*, Epub ahead of print, doi: [10.1002/bdd.2274](https://doi.org/10.1002/bdd.2274) 1 citation
26. Lee J, Gong Y, Bhoopathy S, Di Liberti C, Hooker A, Rostami-Hodjegan A, Schmidt S, Suarez-Sharp S, Lukacova V, Fang L & Zhao L (2021) FY2020 Generic Drug Regulatory Science Initiatives Public Workshop Summary Report: Data analysis and model-based bioequivalence (BE). *Clin Pharm Ther*, Epub ahead of print, doi: 10.1002/cpt.2120

27. Al-Majdoub ZM, Scotcher D, Achour B, Barber J, Galetin A, Rostami-Hodjegan A (2021) Quantitative Proteomic Map of Enzymes and Transporters in the Human Kidney: Stepping Closer to Mechanistic Kidney Models to Define Local Kinetics. *Clin Pharmacol Ther*. Epub ahead of print, doi: 10.1002/cpt.2396
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30. El-Khateeb E, Al-Majdoub ZM, Rostami-Hodjegan A, Barber J, Achour B (2021) Proteomic quantification of changes in abundance of drug-metabolizing enzymes and drug transporters in human liver cirrhosis: Different methods, similar outcomes. *Drug Metab Dispos*, doi: 10.1124/dmd.121.000359.
31. El-Khateeb E, Darwich AS, Achour B, Athwal V, Rostami-Hodjegan A (2021) Time to revisit Child-Pugh score as the basis for predicting drug clearance in hepatic impairment. *Aliment Pharmacol Ther*, 54(4): 388-401. 2 citations
32. El-Khateeb E, Achour B, Al-Majdoub ZM, Barber J, Rostami-Hodjegan A (2021) Non-uniformity of changes in drug-metabolizing enzymes and transporters in liver cirrhosis: Implications for drug dosage adjustment. *Mol Pharm* doi: 10.1021/acs.molpharmaceut.1c00462
33. Lang J, Vincent L, Chenel M, Ogungbenro K, Galetin A (2021) Reduced physiologically-based pharmacokinetic model of dabigatran etexilate-dabigatran and its application for prediction of intestinal P-gp-mediated drug-drug interactions. *Eur J Pharm Sci*. doi: 10.1016/j.ejps.2021.105932
34. Lucas AJ, Ogungbenro K, Yang SY, Aarons LJ, Chen C (2021) Evaluation of area under the concentration curve adjusted by the terminal-phase as a metric to reduce the impact of variability in bioequivalence testing. *Br J Clin Pharmacol*. doi: 10.1111/bcp.14986.
35. Neuhoff S, Harwood MD, Rostami-Hodjegan A, Achour B (2021) Application of proteomic data in the translation of in vitro observations to associated clinical outcomes. *Drug Discov Today: Technologies*, doi: 10.1016/j.ddtec.2021.06.002.
36. Scotcher D, Melillo N, Tadimalla S, Darwich AS, Ziemian S, Ogungbenro K, Schütz G, Sourbron S, Galetin A (2021) Physiologically Based Pharmacokinetic Modeling of Transporter-Mediated Hepatic Disposition of Imaging Biomarker Gadoxetate in Rats. *Mol Pharm*. doi: 10.1021/acs.molpharmaceut.1c00206
37. Takahashi RH, Achour B, Prasad B (2021) Quantitative determination of cytochrome P450 using LC-MS/MS, In: Yan Z & Caldwell GW (eds.), *Cytochrome P450: In Vitro Methods and*

Protocols, part of the Methods in Pharmacol and Toxicology book series, Springer, New York, pp. 55-69, doi: 10.1007/978-1-0716-1542-3_3.

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39. Vasilogianni A-M, Achour B, Scotcher D, Peters SA, Al-Majdoub Z, Barber J, Rostami-Hodjegan A (2021) Hepatic scaling factors for in vitro-in vivo extrapolation (IVIVE) of metabolic drug clearance in patients with colorectal cancer with liver metastasis. *Drug Metab Dispos*, 49(7): 563-571.