

# Optimisation of first clinical studies in special populations : towards semi-physiological pharmacokinetic models

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### Curriculum vitae

Ashley Strougo was born on March 24th, 1979 in Rio de Janeiro, Brazil. In 2001, Ashley graduated as a pharmacist at the Federal University of Rio de Janeiro and immigrated to the Netherlands. After two years of adaptation in the country, she started her masters in Bio-Pharmaceutical Sciences at the University of Leiden. The first internship during her master's degree was on the use of modelling and simulation in the pre-clinical field at the Division of Pharmacology under the supervision of Dr. Dymphy Huntjens, Dr. Oscar Della-Pasqua and Prof. dr. Meindert Danhof. During the second internship she learned about clinical pharmacology and the use of modelling in the clinical field at the Centre of Human Drug Research under the supervision of Dr. Linneke Zuurman, Dr. Rik Schoemaker and Prof. dr. Joop van Gerven. Her final master script was on the use of modelling and simulation in the field of paediatrics. In 2005, just after acquiring her master's degree, Ashley joined LAP&P Consultant BV (Leiden experts in Advances Pharmacokinetics & Pharmacodynamics) as a pharmacometrician and specialised in the use of modelling and simulation to identify and address key drug development issues. Between 2007 and 2015, Ashley worked for Astellas Pharma where she held the position of a Senior Pharmacokinetics, Modelling and Simulation Manager. During the period she worked for Astellas, Ashley was offered the chance to work on this PhD thesis in collaboration with Leiden University as part of the PKPD modelling platform within the Top Institute Pharma. In October 2015, Ashley immigrated again, this time to Germany, in order to join Sanofi as an Expert in Clinical Pharmacometrics.

### **List of publications**

- 1: Strougo A, Yassen A, Danhof M, Freijer J. Response to letter to the editor from Dr. Mahmood: Original publication: "Predicting the 'first dose in children' of CYP3A-metabolized drugs: evaluation of scaling approaches and insights into the CYP3A7-CYP3A4 switch at young ages". J Clin Pharmacol. 2015 Jun;55(6):721.
- 2: Strougo A, Yassen A, Monnereau C, Danhof M, Freijer J. Predicting the "First dose in children" of CYP3A-metabolized drugs: Evaluation of scaling approaches and insights into the CYP3A7-CYP3A4 switch at young ages. J Clin Pharmacol. 2014 Sep;54(9):1006-15.
- 3: Bonate PL, Strougo A, Desai A, Roy M, Yassen A, van der Walt JS, Kaibara A, Tannenbaum S. Guidelines for the quality control of population pharmacokinetic-pharmacodynamic analyses: an industry perspective. AAPS J. 2012 Dec;14(4):749-58.
- 4: Strougo A, Eissing T, Yassen A, Willmann S, Danhof M, Freijer J. First dose in children: physiological insights into pharmacokinetic scaling approaches and their implications in paediatric drug development. J Pharmacokinet Pharmacodyn. 2012 Apr;39(2):195-203.
- 5: Strougo A, Yassen A, Krauwinkel W, Danhof M, Freijer J. A semiphysiological population model for prediction of the pharmacokinetics of drugs under liver and renal disease conditions. Drug Metab Dispos. 2011 Jul;39(7):1278-87.
- 6: Ploeger BA, Smeets J, Strougo A, Drenth HJ, Ruigt G, Houwing N, Danhof M. Pharmacokinetic-pharmacodynamic model for the reversal of neuromuscular blockade by sugammadex. Anesthesiology. 2009 Jan;110(1):95-105.
- 7: Strougo A, Zuurman L, Roy C, Pinquier JL, van Gerven JM, Cohen AF, Schoemaker RC. Modelling of the concentration--effect relationship of THC on central nervous system parameters and heart rate -- insight into its mechanisms of action and a tool for clinical research and development of cannabinoids. J Psychopharmacol. 2008 Sep;22(7):717-26.
- 8: Huntjens DR, Strougo A, Chain A, Metcalf A, Summerfield S, Spalding DJ, Danhof M, Della Pasqua O. Population pharmacokinetic modelling of the enterohepatic recirculation of diclofenac and rofecoxib in rats. Br J Pharmacol. 2008 Mar;153(5):1072-84. doi: 10.1038/sj.bjp.0707643. Epub 2008 Jan 14. Erratum in: Br J Pharmacol. 2008 Apr;153(8):1762.