CERTARA

Simcyp

SIMCYP WORKSHOPS

Welcome to

An Introduction to IVIVE-Linked PBPK modelling

Workshop Agenda

May 2nd -3rd, 2018

Seminar Room
Certara UK – Simcyp Office
Sheffield, UK

Wednesday May 2, 2018

08:30	*Arrival*
09:00	Introduction to PK
10:00	Prediction of metabolic clearance: *In vitro-in vivo* extrapolation using different systems
10:45	*Refreshment Break*
11:00	**Hands-on Workshop** on quantitative prediction of metabolic clearance
12:00	Incorporating biological variability into IVIVE and co-variation of system parameters
12:45	*Lunch Break*
13:30	**Demo of the Simulator**
14:00	**Hands-on Workshop** on automated prediction of clearance
15:00	*Refreshment Break*
15:15	Prediction of fa, ka and Fg and their inter-individual variability
16:00	**Hands-on Workshop** on quantitative prediction of gut wall permeability and metabolism
17:00	*End*

Thursday, May 3, 2018

09:00	Prediction of concentration-time profiles
10:00	**Hands-on Workshop** on predicting concentration-time profiles and assessing dose non-linearity
11:00	*Refreshment Break*
11:15	Prediction of metabolic drug-drug interactions
12:00	*Lunch Break*
12:45	**Hands-on Workshop** on investigation of metabolic DDIs
14:00	Fitting PBPK models to observed data—Combining bottom-up and top-down approaches
15:00	*Refreshment Break*
15:15	IVIVE of transporters (absorption, biliary excretion and metabolism)
16:15	**Hands-on Workshop** on IVIVE of transporters
17:00	*End*

Tutors:

Masoud Jamei is the Vice President of Research and Development at Certara UK Limited (Simcyp Division) where he works with a team of around 35 scientists and 15 developers focusing on the design, development and implementation of various aspects of systems pharmacology models including *in vitro-in vivo* extrapolation techniques, physiologically-based PK/PD models of small and large molecules and applying top-down PopPK data analysis to PBPK models in healthy volunteer and patient populations. He has been the author or co-author of over 70 manuscripts and book chapters and 150 abstracts in the field of modelling and biosimulation.
He has also been an invited speaker and a session organiser/moderator at national and international meetings and also leads well-known Simcyp hands-on workshops on model-informed drugs development. He currently serves as a Vice-Chair of the Special Interest Group (SIG) on PK/PD and Systems Pharmacology of the Board of Pharmaceutical Sciences (BPS) of International Pharmaceutical Federation's (FIP) and is a community leader of AAPS Systems Pharmacology community. In 2002 he earned a PhD in Control Systems Engineering at the University of Sheffield, UK, and carried out one year of post-doctoral research there. In 2003 he joined Simcyp.

Dr Iain Gardner (Senior Scientific Advisor & Head of Translational Science (DMPK)) After qualifying as a Pharmacist Iain received his PhD from the University of Sheffield in 1993 for a thesis examining structure activity relationships for hepatic uptake and biliary clearance of drugs.
Since July 2011 Iain has been Head of the Translational Science in DMPK team at Simcyp (a Certara Company). The science team at Simcyp is responsible for further developments of the population based physiologically based PK-PD simulators to meet the needs of Simcyps consortium members.
Prior to joining Simcyp Iain spent 12 years working in the Pharmacokinetics, Dynamics and Metabolism Department at Pfizer Global Research & Development in the UK and the US. In this role he was responsible for optimising pharmacokinetics (PK) properties of compounds for Drug Discovery projects and resolving any ADME issues for projects later in Development. Particular areas of interest were prediction of human PK and application of in silico physiologically based PK approaches to projects.
Before joining Pfizer Iain worked as a post-doctoral scientist at the University of Toronto, Canada and Imperial College, UK investigating the links between the metabolism and toxicity of drugs and chemicals.

Anam Fayyaz is a PhD student at Certara UK Limited's Simcyp Division with Dr Masoud Jamei (Vice President of R&D, Simcyp Division) and Dr Iain Gardner (Senior Scientific Advisor and Head of Translational Science (DMPK), Simcyp Division) as her industrial supervisors. Anam obtained her Doctor of Pharmacy degree from the University of Lahore, Pakistan and her Master's degree in General Toxicology and Environmental Risk Assessment from the University of Eastern Finland, Finland. Anam's master's thesis was in drug metabolism where she studied enzyme kinetics and drug-drug

interactions for coumarin compounds. Her PhD work is to develop physiological based system pharmacological models for the rabbit and human eye. Anam is gaining expertise in In vitro In vivo extrapolation (IVIVE), QSPR data analysis, In vitro cell culture techniques, pharmacokinetic/ pharmacodynamics modelling and data analysis.