Title of the workshop

PKPD modeling of large molecules (biologics and biosimilars)

Workshop target audience

Anyone interested in an introduction to theoretical and practical hands-on PKPD modeling of large molecules (biologics, biosimilars). PhD students, postdocs, industry scientists are welcome.

Maximum participants: 30

Time: 09h00 – 17h00

Registration Fees: $25 / R400

Workshop faculty

**Name: Chiara Zecchhin, GlaxoSmithKline**

Dr Chiara Zecchin works as a Quantitative Clinical Pharmacologist at GlaxoSmithKline, where she supports the clinical development of monoclonal antibodies and small molecules for immune-inflammatory mediated diseases, with a focus on the application of model-informed drug development and statistical principles for decision-making, design, analysis, and interpretation of clinical studies. Prior to GlaxoSmithKline, Chiara worked as Post-doctoral research fellow at Eli Lilly and participated in Drug Disease Model Resources (DDMoRe) consortium activities. Her research focused on models for prediction of survival of oncology patients, based on early treatment driven biomarkers and patient characteristics. Chiara completed her PhD and her Master degree in Bioengineering at the University of Padova.

**Nieves Velez de Mendizabal, Eli Lilly and Company**

Dr. Nieves Velez de Mendizabal received her BS and MS in Computer Engineering and Science at the University of the Basque Country (Spain). In 2009, she received her PhD degree in Computer Science from the same university. During her PhD, she did an internship at the Center for Biomedical Informatics at Harvard Medical School (Boston, MA). Her post-doctoral research was developed in University of Navarra (Spain) and IUPUI (Indianapolis, IN), being later promoted to assistant professor. In 2014, she started working at the Pharmacometrics Group, at Eli Lilly and Company (Indianapolis, IN).
Emmanuel Chigutsa, Eli Lilly and Company

Dr Emmanuel Chigutsa is a Pharmacometrics Team Leader at Eli Lilly and Company. Emmanuel applies modeling and simulation-based methods in all phases of clinical drug development across various therapeutic areas including autoimmune, diabetes, oncology and pain. Emmanuel received his PhD degree in Clinical Pharmacology from the University of Cape Town in 2013, a Masters in Pharmacogenetics from the University of Zimbabwe (UZ) and a Bachelor of Pharmacy degree from UZ 2005.

Workshop Learning Objectives

- To understand differences between small and large molecules from a PKPD modeling perspective
- To understand the role of various receptors (e.g. FcRn) and their impact on mAb PK
- To understand immunogenicity and its impact on drug exposure and response
- To be able to model the PK and PD of mAbs and bi-specifics

Workshop Timetable

09h00-10h00 Introduction to biologics.
  Background, importance, types of monoclonal antibodies (mAbs), ADME of mAbs and role of FcRn. Biosimilars

10h00-11h00 Monoclonal antibody absorption modeling hands-on exercise.
  (Semi-mechanistic) Modeling and simulation to investigate role of FcRn, dose-dependency and injection site

11h00-12h00 Bi-specific antibodies lecture + handson exercise

12h00-13h00 Lunch

13h00-14h30 Immunogenicity lecture + handson exercise
  Terminology, occurrence of antidrug-antibodies (ADAs), impact of ADA, PK modeling considerations. Empiric and mechanistic approaches to modeling ADAs

14h30-17h00 TMDD lectures, minimal PBPK models + handson exercise
  Background, types of TMDD models. Application of full, QE and MM models. Minimal PBPK models

17h00 End

Requirements

Participants are expected to bring their laptops with NONMEM and R installed. Datasets and control streams will be provided.