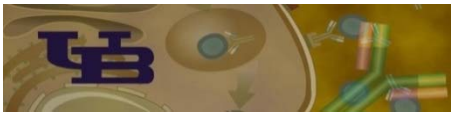
Modeling Biologics using ADAPT

UB Center for Protein Therapeutics



Saturday, May 13 – Sunday, May 14, 2017
Niagara Falls, NY

BMSR bmsr.usc.edu | Biomedical Simulations Resource

WORKSHOP OVERVIEW

The workshop will introduce and apply modeling approaches and software solutions for understanding the PK/PD of biologics. Topics covered included: TMDD modeling; TMDD PK/PD; modeling antibody-antigen interactions; PBPK modeling of mAbs; modeling PK/PD of ADCs; modeling bispecific mAbs. Participants are expected to have experience with PK/PD modeling methods and applications, but not necessarily applied to biologics.

The workshop will include background lectures on mathematical, statistical, and computational aspects of pharmacokinetic/pharmacodynamic modeling, with an emphasis on the principles and applications of simulation and estimation methods. Case studies will focus on the application of the ADAPT software to modeling problems involving biologics, and will include hands-on computer work. The case studies will give participants an in-depth exposure to modeling approaches and issues relevant to studying biologics (e.g., target mediated drug disposition, rapid binding, quasi-steady state, Michaelis Menten, PBPK, PK/PD) used for biologics, together with a comprehensive hands-on exposure to the use of the ADAPT software. Laptop computers are required to participate in case studies. No special software is needed, and all ADAPT examples will be made available as stand-alone executable programs.

ADAPT is made freely available through the Biomedical Simulations Resource at the University of Southern California, which is supported by the Bioengineering Program of the National Institute for Biomedical Imaging and Bioengineering at the NIH (P41-EB001978).

COURSE INSTRUCTORS

David Z. D'Argenio, PhD is Professor of Biomedical Engineering at the University of Southern California and holder of the Chonette Chair of Biomedical Technology. He is a Fellow of the American Institute for Engineering in Medicine and Biology, American Association of Pharmaceutical Sciences, International Society of Pharmacometrics, and a past member of the FDA Advisory Committee for Pharmaceutical Science and Clinical Pharmacology. Since 1985 he has served as co-director of the Biomedical and Simulations Resource (BMSR) at USC, which develops, applies and disseminates advanced modeling methods for studying biological systems, where he has also led the development of the ADAPT software for PK/PD modeling and analysis.

Joseph P. Balthasar, PhD is Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York, where he serves as the Director of the Center for Protein Therapeutics. His PK/PD modeling interests and expertise include the development and preclinical evaluation of anti-toxin immunotherapies, the development and preclinical evaluation of anti-cancer immunotherapies (including immunoconjugate immunotherapies), and the development and preclinical evaluation of novel immunotherapies for humoral autoimmune conditions (immune thrombocytopenia, myasthenia gravis). He is a consultant to the NIH and the pharmaceutical industry.

Donald E. Mager, PharmD, PhD is Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York. He was also a Visiting Professor at the University Paris Descartes (Jan. 2007-2013). He currently serves on the Clinical Pharmacology Advisory Committee to the FDA, and as an Associate or Consulting Editor at CPT:Pharmacometrics & Systems Pharmacology, J. of Pharmacology & Experimental Therapeutics, and Pharmacology, Research & Perspectives. His research involves identifying molecular and physiological factors that control the pharmacological properties of drugs, with a focus on anti-cancer and immunomodulatory agents.

Dhaval K. Shah, PhD is Assistant Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York. His research focuses on understanding the determinants for the ADME of protein therapeutics. He is involved in the development of a platform PBPK model for biologics that can characterize and predict the pharmacokinetics of diverse protein therapeutics in several preclinical species and human. Dr. Shah also directs the discovery, development and clinical translation of novel protein therapeutics like antibody-drug conjugates and bi-specific molecules in his laboratory. His research is supported by NIH & pharmaceutical industry.

This Workshop is preceded by separate courses on the concepts and applications of Pharmacokinetic/Pharmacodynamic Modeling and on Antibody PK/PD. For information see: http://pharmacy.buffalo.edu/ under Quick Links.

WORKSHOP SCHEDULE

Saturday, May 13, 2017

8:00 **Continental Breakfast**

8:30 **Introductions and Overview**

9:00 Background: ***Modeling with ADAPT***

10:15 **Break**

10:30 Case Study: ***Target Mediated Drug Disposition***

11:15 Case Study: ***Rapid Binding and MM Models***

12:00 **Lunch**

1:00 Background: ***Individual Estimation***

2:00 Case Study: ***Nondepleting Anti-CD4 mAb***

3:00 **Break**

3:15 Case Study: ***Rituximab Extravascular Absorporption***

4:15 Case Study**:** ***Antibody-Antigen Interactions***

5:00 Recap, Looking Forward, Adjourn

Sunday, May 14, 2017

8:00 **Continental Breakfast**

8:30 Case Study: ***PD Model for Anti-Platelet Antibodies***

9:15 Case Study: ***PK/PD of Antibody-Drug Conjugates***

10:00 **Break**

10:15 Case Study: ***PBPK Modeling of IgG***

11:15 Case Study: ***PBPK of mAb-ligand interaction***

12:00 **Lunch**

1:00 Case Study*:* ***Modeling of Bispecific mAbs***

2:00 Case Study: ***Interferon ß PK/PD***

3:00 **Break**

3:15 Case Study: ***Denosumab PD in Multiple Myeloma***

4:30 Final Q&A and Discussion

5:00 Adjourn

REGISTRATION DETAILS

Course location: The course will be held at The Conference Center Niagara Falls, 101 Old Falls Street, Niagara Falls, NY 14303. USA. Phone: (716) 278-2100. Fax: (716) 278-0008. The Center is 28 min from Buffalo International Airport. Website: http://www.ccnfny.com

Hotel location: *Sheraton at the Falls***,** 300 Third St., Niagara Falls, NY 14303. USA. Phone: (716) 285-3361. The price is $124/night single & double occupancy (add $10 per person for triple, quadruple occupancy). *Hotel Deadline: April 3rd, 2017.* *Website:* https://www.starwoodmeeting.com/Book/UBPharmacokinetic2016

Workshop Fee: The fee is $600. A US government employee rate of $400 and student rate of $200 is available. The registration fee includes printed and electronic copies of all course materials. Continental breakfasts, lunches and break-time refreshments during the course are included.

Computer Requirements: Laptop computers are required to participate in case studies. No special software is needed, and all ADAPT examples will be made available as stand-alone executable programs.

Registration: Online registration will begin October 15th, 2016. The course is limited to 30 participants. Confirmation email of registration will be returned upon successful registration at the following website: http://pharmacy.buffalo.edu under Quick Links.

Cancellations: Cancellations with a full refund may be made until March 13, 2017. No refund is possible on cancellations received after this date. Substitutions may be made at any time. Please inform course secretary of any substitutions.

Payment: Mastercard, Visa, American Express, and Discover card payments will be accepted only at the following website: http://pharmacy.buffalo.edu under Quick Links. Contact course secretary: Suzette Mis, (716) 645-4831; mis@buffalo.edu, if you need further assistance.