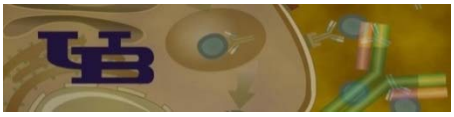
An ADAPT Workshop on Biologics

UB Center for Protein Therapeutics



Saturday, May 21 – Sunday, May 22, 2016
Niagara Falls, NY

BMSR bmsr.usc.edu | Biomedical Simulations Resource

WORKSHOP OVERVIEW

The ADAPT Workshop on Biologics will illustrate modeling methods and approaches used to describe the pharmacokinetics and pharmacodynamics of monoclonal antibody, as well as other biologics. This Workshop is intended for both basic and clinical researchers, as well as drug development scientists who are actively involved with the application of modeling, simulation and data analysis methods to problems involving drug kinetics and drug response. 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 illustrate different PK modeling approaches (e.g., target mediated drug disposition, rapid binding, quasi-steady state, Michaelis Menten, PBPK) used for biologics, and will demonstrate the application of ADAPT's simulation, estimation and sample schedule design tools for understanding the PK/PD of biologics. 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.

This Workshop will give participants an in-depth exposure to modeling approaches and issues relevant to studying biologics, with a comprehensive hands-on exposure to the use of the ADAPT software. 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 INSTRCUTORS

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, a past member of the FDA Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, and a founding member of the International Society of Pharmacometrics. 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. He is a Fellow of the ACCP and Past President of the International Society of Pharmacometrics. His research involves identifying molecular and physiological factors that control the pharmacological properties of drugs, with a focus on anti-cancer and immunomodulatory agents.

This Workshop is preceded by a 3-day separate course in the concepts and applications of Pharmacokinetic/Pharmacodynamic Modeling coordinated by Dr. William J. Jusko. For information see: http://pharmacy.buffalo.edu/ under Quick Links.

WORKSHOP SCHEDULE

Saturday, May 21, 2016

8:30 **Introductions and Overview**

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

10:15 **Break**

10:30 Case Study 1: ***Target Mediated Drug Disposition*** **(SIM)**

11:15 Case Study 2: ***Rapid Binding and MM Models*** **(SIM)**

12:00 **Lunch**

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

2:00 Case Study 3: ***Estimating Parameters in TMDD*** **(ID)**

3:00 **Break**

3:15 Case Study 4: **Extravascular Absorp. Rituximab (NPD)**

4:15 Case Study 5**: Antibody-Antigen Interactions (SIM)**

5:00 Recap, Looking Forward, Adjourn

Sunday, May 22, 2016

8:30 Case Study 6: ***PD Model for Anti-Platelet Antibodies*** **(NPD)**

9:15 Case Study 7: ***Introduction to PBPK Modeling*** **(SIM)**

10:00 **Break**

10:30 Case Study 8: ***PBPK Modeling of IgG*** **(SIM)**

11:15 Case Study 9: **Interferon β PK/PD (SIM)**

12:00 **Lunch**

1:00 Case Study 10: ***Denosumab PD in Multiple Myeloma*** **(SIM)**

2:00 Case Study 11: ***PBPK of mAb-ligand interaction*** **(SIM)**

3:00 **Break**

3:15 Background: **Population Modeling with ADAPT**

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 Street, Niagara Falls, NY 14303. USA. Phone: (716) 285-3361. The price is $117/night. *Hotel Deadline: April 1st, 2016, w*ebsite: http://sheratonatthefalls.com

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. 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 1st, 2015. The course is limited to the capacity of 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 25, 2016. 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. Those registering for the PK/PD course will receive 20% discount on any other courses.