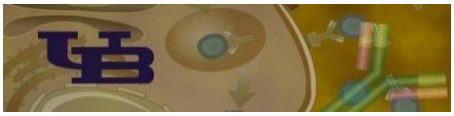
An ADAPT Workshop on Biologics

UB Center for Protein Therapeutics



Saturday, June 7 – Sunday, June 8, 2014
Niagara Falls, NY

BMSR bmsr.usc.edu | Biomedical Simulations Resource

WORKSHOP OVERVIEW

The ADAPT Workshop on Biologics is designed as a companion to the Workshop on Monoclonal Antibody Pharmacokinetics and Pharmacodynamics, and will illustrate and expand on the modeling methods and approaches used to describe the PK/PD of mAb, as well as other biologics. This Workshop is intended for basic and clinical researchers and 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, and to have participated in the Workshop on mAb PK/PD.

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 individual and population analysis 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), as well as PK/PD models, and will also demonstrate the application of ADAPT's simulation, parameter estimation (individual and population) 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, as 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 and the American Association of Pharmaceutical Sciences, a past member of the FDA Advisory Committee for Pharmaceutical Science and Clinical Pharmacology, and a founding member of the International Society of Pharmacometrics (ISoP). 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 serves as a consultant to the NIH and the pharmaceutical industry.

Donald E. Mager, PharmD, PhD is an Associate 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 is President-Elect 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://pharmsci.buffalo.edu/symposia/ or contact mis@buffalo.edu.

WORKSHOP SCHEDULE

Saturday, June 7, 2014

08:30 **Introductions and Overview**

08:45 Background: ***Modeling with ADAPT***

09:30 Case Study: ***Target Mediated Drug Disposition*** **(SIM)**

10:15 **Break**

10:30 Case Study: ***Rapid Binding, Quasi-SS, MM Models*** **(SIM)**

11:15 Background: ***Individual Estimation: Principles***

12:00 **Lunch**

01:00 Case Study: ***TMDD Modeling*** **(ID/NPD)**

01:45 Case Study: ***Rapid Binding, Q-SS, MM Models*** **(ID/NPD)**

02:30 Break

02:45 Background: ***Population Modeling and Estimation***

03:45 Case Study: ***Extravascular Absorption PK*** **(MLEM)**

04:15 Case Study: ***Nondepleting Anti-CD4 mAb*** **(MLEM)**

05:00 Recap, Looking Forward, Adjourn

Sunday, June 8, 2014

08:30 Case Study: ***Antibody-Antigen Interactions*** **(MLEM)**

09:15 Case Study: ***Reduced PBPK Model for mAbs*** **(ID)**

10:30 **Break**

10:15 Case Study: ***PBPK Modeling of mAbs*** **(SIM)**

11:00 Case Study: ***Sampling Schedules for TMDD Modeling*** **(SAMPLE)**

12:00 **Lunch**

01:00 Case Study: ***PD Model for Anti-Platelet Antibodies*** **(NPD)**

01:45 Case Study: ***Denosumab PD in Multiple Myeloma*** **(MLEM)**

02:30 **Break**

02:45 Case Study: ***Anti-IgE/FEV1 Response of Omalizumab*** **(MLEM)**

03:30 Case Study: ***PBPK modeling for mAb-ligand interaction*** **(SIM)**

04:15 Final Q&A and Discussion

04:30 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 Conference Center is 28 min. from the Buffalo Niagara International Airport. Website: http://www.conferencecenterniagarafalls.com

Accommodations: *Sheraton at the Falls***,** 300 Third Street, Niagara Falls, NY 14303. USA. Phone: (716) 285-3361. The price is $114/night. *Hotel Deadline: May 4, 2014* Website: http://sheratonatthefalls.com

Workshop Fee: The fee is $500. A US government employee rate of $300 and student rate of $100 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 as all ADAPT examples will be made available as stand-alone executable programs.

Registration: Course enrollment will be limited to 30 people. Confirmation of registration will be returned upon receipt, together with an invoice for the course fee. Registration will not be final until payment is received. Checks should be made out to University at Buffalo Foundation, Inc. Bank transfers and credit card payments also accepted.

Cancellations: Cancellations with a full refund may be made until April 24, 2014. No refunds will be given for cancellations received after this date. Substitutions may be made at any time.

REGISTRATION FORM: ADAPT Biologics Workshop

Name: _____

Organization: _____

Address: _____

City: _____ **State/Country:** _____

Postal Code: _____

Telephone: _____ **Fax:** _____

E-mail: _____

For credit card payment:

Credit card number: _____

Signature: _____ **Expiration Date:** _____

Kindly return to: PK/PD MODELING – ADAPT Workshop, Dept. of Pharmaceutical Sciences, University at Buffalo, SUNY, 445 Kapoor Hall, Buffalo, NY 14214; phone: 716 645 4831; fax: 716 829 6569; e-mail: Suzette Mis at mis@buffalo.edu.