

MODELING AND ANALYSIS IN PK/PD WITH ADAPT: Jagiellonian University 7TH COMPUTATIONAL PHARMACY WORKSHOP



UNIWERSYTET JAGIELLOŃSKI
COLLEGIUM MEDICUM

17-18 September 2015
Kraków, Poland

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Biomedical
Simulations
Resource

WORKSHOP OVERVIEW

The workshop is intended for basic and clinical researchers involved with the application of modeling, simulation and data analysis to problems involving drug kinetics and drug response. 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, as well as *in vitro-in vivo* extrapolation in PK/PD. Case Studies will focus on the application of the ADAPT software to modeling problems and will involve hands-on computer work covering the following topics: pharmacokinetic/pharmacodynamic modeling; least squares and maximum likelihood estimation; Bayesian estimation; estimation with multiple response models; PBPK & recirculatory models; population modeling. The workshop will give the participants an exposure to the broad class of PK/PD modeling problems that can be solved using ADAPT.

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 and LECTURERS

David Z. D'Argenio, PhD is Professor of Biomedical Engineering and holder of the Chonette Chair of Biomedical Technology at the University of Southern California, Los Angeles, CA. USA.

Wojciech Krzyzanski, PhD is Associate Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York, Buffalo, NY. USA.

Michael Weiss, PhD is Professor Emeritus of Pharmacokinetics and Pharmacodynamics, Martin Luther University, Halle, GERMANY.

Barbara Wiśniowska, Ph.D. Unit of Pharmacoepidemiology and Pharmacoeconomics, Faculty of Pharmacy, Jagiellonian University Medical College, Kraków, POLAND.

Maciej Swat, Ph.D. The European Bioinformatics Institute, Hinxton, Cambridge, UK.



WORKSHOP SCHEDULE

Thursday, 17 September 2015

- 8:30 **Introductions and Overview**
- 8:15 Background: **Modeling with ADAPT**
- 9:30 Case Study: **Model Building (SIM)**
- 10:15 **Break**
- 10:30 Background: **Individual Estimation Fundamentals**
- 11:15 Case Study: **WLS/ML Estimation (ID)**
- 12:15 **Lunch**
- 1:15 Case Study: **Direct Response PK/PD Models (ID)**
- 2:00 Case Study: **Indirect Response PK/PD Models (ID)**
- 2:45 **Break**
- 3:00 Case Study: **Extravascular Absorption PK (ID)**
- 3:45 Case Study: **Metabolite Modeling (ID)**
- 4:30 Recap, Looking Forward, Adjourn

Friday, 18 September 2015

- 8:30 Background: **In Vitro-In Vivo Extrapolation in Drug Safety**
- 8:50 Background: **PharmML & SO – Encoding Standards for Exchange of Models and Results in Pharmacometrics**
- 9:30 Case Study: **Recirculatory Models of Drug Disposition (ID)**
- 10:15 **Break**
- 10:30 Case Study: **PBPK Modeling (SIM)**
- 11:15 Background: **Population Modeling Fundamentals**
- 12:00 **Lunch**
- 1:00 Case Study: **Population PK Example (MLEM)**
- 1:45 Case Study: **Population PK/PD Example (MLEM)**
- 2:30 Case Study: **Population Modeling with Covariates (MLEM)**
- 3:15 Final Q&A and Discussion
- 3:30 Adjourn

REGISTRATION INFORMATION

Course Location: The course will be held in the Libraria Hall of Collegium Maius Museum, the oldest university edifice in Poland, located in the historic city center of Kraków. Address: Jagiellonian University Museum – Collegium Maius, Jagiellońska 15 Street, 31-010 Kraków, <http://www.uj.edu.pl/en/universytet/muzea/collegium-maius>

Hotel: **Holiday Inn** is located in the historic city center, 800 m to main train station and 800 m to the meeting venue. The cost of hotel accommodations (including breakfast) is \$150 USD per night. Instructions for registering may be found at the hotel web site www.cpw.edu.pl

Workshop Fee: The fee is \$250 USD (acad), \$500 USD (industry). A student rate of \$150 USD is available. The registration fee includes electronic copies of all course materials. Lunches and break-time refreshments during the course are included.

Registration: Course enrollment will be limited to 30 people. You may request registration via the web site below, following which a confirmation of your intent to register will be emailed to you along with instructions for payment via bank transfer. Registration will not be final until payment via bank transfer is received.

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. Participants will receive all course slides and other materials, including the source code and files for all the examples and Case Studies presented, via electronic media at the meeting.

Cancellations: Cancellations with a full refund may be made until July 15, 2015. No refunds will be given for cancellations received after this date.

WORKSHOP WEBSITE

For complete information, including Workshop registration and hotel booking details, visit the Workshop website:

<http://www.cpw.edu.pl>