

MODELING AND DATA ANALYSIS IN PHARMACOKINETICS AND PHARMACODYNAMICS USING ADAPT

Lutherstadt Wittenberg, GERMANY
April 16-17, 2004



Lecturers

David Z. D'Argenio, Ph.D. *University of Southern California, Los Angeles*
Michael Weiss, Ph.D. *Martin Luther University Halle-Wittenberg, Halle/Saale*

Aims & Scope

The Short Course is intended for basic and clinical research scientists who are actively involved in the application of modeling, computational and data analysis methods to problems involving drug kinetics and drug response. Since the focus is both on theoretical concepts and application to problems in practice, prior ADAPT experience is not necessary. Background lectures and case studies will cover the following topics: modeling with covariates; PK/PD models (including direct and indirect response models); modeling using inverse Laplace transformation (absorption, metabolite PK); physiologically based modeling; least squares, maximum likelihood and Bayesian estimation; estimation with multiple response models; sample schedule design; and clinical trial simulation.

Location

Leucorea Foundation (building above right, former University founded in 1502). There are trains to the Airports Leipzig/Halle and Berlin (90 km south and north of Wittenberg, respectively).

Registration

Short course is limited to 25 participants, *on a first-come first-served basis*. Additional information and registration should be emailed to dagmar.guenther@medizin.uni-halle.de. Registration fee is 80 Euro (acad/gov) or 200 Euro (industry). The cost of accommodation is 25 Euro per night (a block of rooms has been reserved from April 15-18).

Note- Current version of ADAPT (and manual) may be downloaded at *no charge* from the software section of the BMSR website <http://bmsr.usc.edu>. Copies of ADAPT including the case studies will be provided at the short course.

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Modeling and Data Analysis in Pharmacokinetics and Pharmacodynamics Using ADAPT

Lutherstadt Wittenberg
Germany
16-17 April 2004

Course Instructors

David Z. D'Argenio, Ph.D.
University of Southern California
Los Angeles

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Martin Luther University Halle-Wittenberg
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With Support From

The Biomedical Simulations Resource, University of Southern California
Section of Pharmacokinetics, Martin Luther University
Bayer Bitterfeld GmbH



Preface

The Short Course is intended for basic and clinical research scientists who are actively involved in the application of modeling, computational and data analysis methods to problems involving drug kinetics and drug response. Since the focus is both on theoretical concepts and application to problems in practice, prior ADAPT experience is not necessary. Background lectures and case studies will cover the following topics: modeling with covariates; PK/PD models (direct and indirect response models, as well as mechanistic PD models); modeling using inverse Laplace transformation (absorption, metabolite PK); physiologically based modeling; least squares, maximum likelihood and Bayesian estimation; estimation with multiple response models; sample schedule design; and clinical trial simulation.

It is hoped that this Short Course will give the participants a thorough exposure to the broad class of pharmacokinetic/ pharmacodynamic modeling and data analysis problems that can be solved using ADAPT.

David Z. D'Argenio
Los Angeles

Michael Weiss
Halle/Salle



ADAPT Short Course Schedule
Friday, 16 April 2004

- 8:30 Background: **Modeling with ADAPT**
9:45 Case Study: **Doses and Covariates**
10:30 **Break**
10:45 Background: **Parameter Estimation**
11:45 Case Study: **WLS/ML/MAP Estimation**
12:30 **Lunch Break and Tour of Wittenberg**



ADAPT Short Course Schedule
Friday, 16 April 2004

- 15:00 Background: **Modeling in the Laplace Domain**
16:00 Case Study: **Absorption/Disposition**
16:45 **Break**
17:00 Case Study: **Recirculatory Modeling of Disposition**
17:45 Case Study: **Physiologically-Based PK/PD Models**
18:30 **Summary Remarks and a Look Ahead**
20:00 **Dinner**



ADAPT Short Course Schedule
Saturday, 17 April 2004

- 9:00 Case Study: **PK/PD Modeling**
- 10:00 Case Study: **Direct Response PK/PD Models**
- 10:45 **Break**
- 11:00 Case Study: **Indirect Response PK/PD Models**
- 11:30 Case Study: **PD Models of Tolerance & Rebound**
- 12:00 Case Study: **Models for Drug-Receptor Interaction**
- 12:30 **Lunch Break**



ADAPT Short Course Schedule
Saturday, 17 April 2004

- 13:30 Background: **Clinical Trial Simulation**
- 14:15 Case Study: **Fixed vs Weight-Based Dosing**
- 14:45 **Break**
- 15:00 Problem Session: **Participant Suggested Problems**
- 16:45 **ADAPT Version 5: Overview & New Features**
- 17:00 **Adjourn**

