PHARMACOKINETIC/PHARMACODYNAMIC SYSTEMS ANALYSIS WITH ADAPT

A Software Short Course of the

Biomedical Simulations Resource
University of Southern California

August 6, 7 & 8, 2003
Amgen, Inc

Sponsored by

Biomedical Simulations Resource, University of Southern California
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Course Instructor

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Preface

This Short Course is intended for drug development researchers who are actively involved with the application of pharmacokinetic/pharmacodynamic principles in drug development. The Short Course will focus on the use of the ADAPT software for simulation, parameter estimation, and design of experiments in pharmacokinetics and pharmacodynamics. The course will include background lectures on mathematical, statistical, and computational aspects of pharmacokinetic/pharmacodynamic modeling and simulation, parameter estimation, error analysis, design of experiments and Monte Carlo simulation for clinical trial design.

Case studies will illustrate the application of the ADAPT software for solving a variety of modeling, estimation and experiment design problems. The case studies involve hands-on computer work and will cover the following topics: modeling with covariates; pharmacodynamic modeling (including direct and indirect response models); least squares and maximum likelihood estimation; Bayesian estimation; estimation with multiple response models; sample schedule design; Monte Carlo 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.

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David Z. D'Argenio Los Angeles August 6, 2003

ADAPT Short Course Schedule
Wednesday, August 6, 2003

8:30 Background: **Modeling with ADAPT**

9:30 Case Study: **Doses and Covariates**

10:15 ***Break***

10:45 Background: **Parameter Estimation**

11:30 Case Study: **WLS/ML Estimation**

12:15 ***Lunch Break***

ADAPT Short Course Schedule
Wednesday, August 6, 2003

1:15 Case Study: **Multiresponse Estimation**

2:00 Case Study: **Bayesian Estimation**

2:45 ***Break***

3:00 Case Study: **Direct Response PD Models**

3:45 Case Study: **Indirect Response PD Models**

4:30 Case Study: **More PD Models**

5:00 **Summary and a Look Ahead**

ADAPT Short Course Schedule
Thursday, August 7, 2003

8:30	Case Study:	**PD Model for Tolerance/Rebound**
9:15	Case Study:	**Measured Inputs**
9:45	Case Study:	**Mechanism-Based PD for IVIV Correlations**
10:15	***Break***	
10:45	Case Study:	**Absorption Delays**
11:30	Case Study:	**Relative Bioavailability**
12:15	***Lunch Break***	

ADAPT Short Course Schedule
Thursday, August 7, 2003

1:15 *Case Study:* **Sample Schedule Design**

2:00 *Background:* **Monte Carlo Simulation**

2:45 ***Break***

3:00 *Case Study:* **Fixed vs Weight-Based Dosing Monte Carlo Simulation**

3:45 **Open Q&A Session**

4:30 **Summary Comments and ADAPT version 5**

ADAPT Short Course Schedule
Friday, August 8, 2003

9:00 **Individual Problem Session 1**

10:00 **Individual Problem Session 2**

11:00 **Individual Problem Session 3**