

A 2-DAY INTRODUCTORY WORKSHOP IN PK/PD MODELING USING TRIAL SIMULATOR®

A HANDS-ON COURSE USING Trial Simulator®

Thursday, May 24 – Friday, May 25, 2007, Buffalo, NY

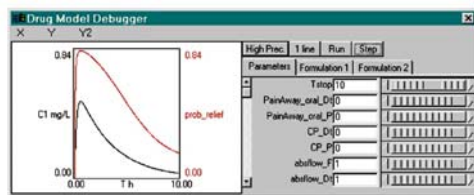
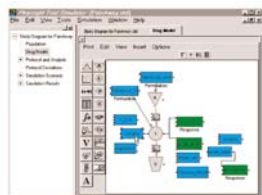
TRIAL SIMULATOR® INTRODUCTION

PHARSIGHT® TRIAL SIMULATOR® 2.2.1

Pharsight Trial Simulator provides a powerful and efficient approach to Computer-Assisted Trial Design. It balances ease-of-use with robust tools for defining study design attributes, statistical analyses, sensitivity analysis and graphical summaries that enable an entire drug development team to improve access to existing scientific knowledge, communicate and test ideas, and plan relevant, effective trials for every phase of clinical drug testing. Companies can anticipate risks and preview the range of expected results before R & D dollars are spent, and human subjects are exposed to experimental therapies.

COMPREHENSIVE MODELING OF DRUG ACTION

With Trial Simulator, you can build population-based drug and disease models that describe drug actions over time in individual subjects. The drug model is created graphically by adding and connecting model blocks to define functions of subject characteristics, treatments, and formulations, drug and disease actions, placebo effects and random factors.



observation times and compliance variations. Estimates of compliance, measurement errors, and biological variability can be included. To save time, common PK, PK/PD and physiologically-based PK models are provided pre-built. You can also include written expressions or differential equations using a simple expression language or custom FORTRAN code, providing enhanced flexibility. Powerful debugging tools such as real-time plots of models outcomes, current equations for the drug model, and error messages for custom expressions and statements help you test and improve the drug model.

This patented component-driven graphical user interface allows you to easily specify attributes such as distributions of patient population variables, dosing and

COURSE OBJECTIVES

- Provide a survey of clinical trial simulator (CTS).
- Provide a connection from the PK/PD Modeling course to applications in the design and optimization of clinical trials.
- Students will be introduced to the motivation behind CTS.
Why do we do it? What are the benefits?
- We will initiate the use of CTS software (Pharsight Trial Simulator) and at the end of the class students will have a set of basic tools to advance their own use of CTS methodologies (e.g., sample models from the Hands-on examples, course documentation, and familiarity with the software and its documentation).
- Provide an interactive dialogue on methodologies, applications, and experiences of the whole class in CTS.



Jeffrey A. Wald, PhD

COURSE INSTRUCTION

The workshop is organized by Jeff Wald, PhD, Director, Pharmacokinetics/Modeling and Simulation, GlaxoSmithKline, Research Triangle Park, North Carolina (jeffrey.a.wald@GSK.com). Software and some training materials are provided by Pharsight Corporation (www.pharsight.com).

This session follows 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 wj Jusko@buffalo.edu .

COURSE PROGRAM

May 24	Thursday	10:00-10:15	Break.
08:30-09:30	Why do Clinical Trial Simulation? A review of practical examples.	10:15-10:45	Exercise 3. A Dose-Response Example (Cont'd).
09:30-10:00	Introduction to Trial Simulator.	10:45-12:00	Exercise 4. Translating NONMEM Output to Trial Simulator - and or -
10:00-10:15	Break.		Exercise 5. Evaluation of Different Formulations for Pain Relief.
10:15-10:45	Introduction to Drug Model Editor.		5.1 Background.
10:45-12:00	Exercise 1. A Simple PK Study. 1.1 Including an Analysis Plan in the Simulation. 1.2 Adding simulation scenarios. 1.3 Expanding the analysis plan. 1.4 Adding a PD Response Which is a function of AUC.		5.2 The Modified PainAway model. 5.3 Modifying the Protocol. 5.4 Specifying an Analysis Plan.
12:00-01:00	Lunch.	12:00-01:00	Lunch.
01:00-01:45	Exercise 1. A Simple PK Study (Cont'd).	01:00-02:30	Exercise 6. Exploring Some Advanced Features of Trial Simulator.
01:45-03:00	Exercise 2. A Simple PK/PD Study. 2.1 Introduction. 2.2 Model building. 2.3 Including a Customized S-PLUS Analysis in the Simulation.		6.1 Custom Differential Equations. 6.2 Multivariate Normal Distributions. 6.3 Covariate Dose Adjustments. 6.4 Dose Adjustments Based on Response. 6.5 Randomized Concentration Controlled Trial (RCCT). 6.6 Using real patient characteristics data as part of simulation. 6.7 Incorporating Custom User Codes. 6.8 Hazard Functions.
03:00-03:15	Break.		Break.
03:15-04:45	Exercise 2. A Simple PK/PD Study (Cont'd).		"Open Topics" free time for Q & A, demonstrations, techniques.
04:45-05:00	Review of the Day.		Review of the Day . Wrap-up. Adjourn.
05:00	Adjourn.		
May 25	Friday	02:30-02:45	
08:00-10:00	Exercise 3. A Dose-Response Example. 3.1 The Basic Model. 3.2 Placebo Response. 3.3 Time Dependency & A from Previous Session.	02:45-04:00	
		04:00	

REGISTRATION DETAILS

Course Location: The course will be held at the University at Buffalo, Cooke-Hochstetter Hall, North Campus.

Fee: The fee is \$1500. A US government employee rate of \$1200 and student rate of \$750 is available for up to 2 participants of each type. The registration fee includes course documentation and handouts. Lunches and beverages during the course are included.

Registration: Given the hands-on nature of the course, enrollment will be limited to 12 persons. Please register by filling out the form and returning to the address shown below. 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 the University at Buffalo Foundation Inc. Bank transfers and credit card payments are also accepted.

Cancellation Policy: Cancellations with a full refund may be made until March 30, 2007. No refunds will be given for cancellations received after this date. Substitutions may be made at any time.

Accommodations: Ramada Inn & Conference Center, 716-636-7500 or Marriott Hotel, 716-689-6900. [Both adjacent to UB]

REGISTRATION FORM: INTRODUCTORY TRIAL SIMULATOR 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 – TRIAL SIMULATOR Workshop, Dept. of Pharmaceutics, School of Pharmacy, University at Buffalo, 519 Hochstetter Hall, Buffalo, NY 14260; phone: 716 645 2842, x. 224; fax: 716 645 3693; e-mail: rrurben@buffalo.edu.