



## PK/PD Modeling using Phoenix WinNonlin/NLME

May 17-19, 2018

Niagara Falls, NY

A three day PK/PD modeling course that transitions from simple modeling problems using the industry leading Phoenix WinNonlin software into more complex modeling examples using the nonlinear mixed effect modeling program Phoenix NLME. This hybrid course will focus on basic tutorials along with hands-on problem solving using Phoenix WinNonlin and NLME.



**Daniel L. Weiner, Ph.D.** Dr. Weiner has extensive drug development experience and has served as an expert consultant to the U.S. Food and Drug Administration (FDA) on pharmacokinetic modeling and bioequivalence assessment. Dr. Weiner is the co-author of *Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications*' 5th ed. (2016). He is a co-developer of PCNonlin, NONLIN84, and WinNonlin and has presented numerous workshops on the statistical evaluation of pharmacokinetic and bioavailability data.

Dr. Weiner is currently an industry consultant and a member of the Simulations Plus Board of Directors. He has held previous management positions including Chief Scientific Officer and Senior Vice President at Certara/Pharsight Corporation; Head of Biostatistics, Merrell Dow Pharmaceuticals; Vice President, Statistical Consultants, Inc.; Vice President, Syntex Development Research; Senior Vice President and Principal Scientist, Quintiles; and Senior Vice President and Global Head of Clinical Development at IVAX Research.

### Course Agenda:

#### Thursday, May 17

08:00-08:30 Continental Breakfast/Registration

08:30-09:15 Introduction

09:15-10:15 Introduction to WinNonlin – Demo

10:15-10:30 Coffee

10:30-12:00 Introduction to Hands-on Examples – Part 1 (Graphs and NCA)

12:00-13:00 Lunch

13:00-14:00 Properties of Parameter Estimates



14:00-15:00 Error Models  
15:00-15:15 Refreshments  
15:15-16:00 Assessment of Goodness of Fit  
16:00-17:00 Introduction to Hands-on Examples – Part 2 (Built in PK Models)  
18:00-19:30 Group Dinner

#### **Friday, May 18**

08:00-08:30 Continental Breakfast  
08:30-09:15 Comparing Models  
09:15-10:00 Introduction to Hands-on Examples – Part 3  
10:00-10:15 Coffee  
10:15-12:00 Hands-on (PD Equilibrium Emax Models)  
12:00-13:00 Lunch  
13:00-15:00 Hands-on (PK/PD Distributional delays)  
15:00-15:15 Refreshments  
15:15-17:00 Hands-on (PK/PD Turnover)

#### **Saturday, May 19**

08:00-08:30 Continental Breakfast  
08:30-10:00 Hands-on (transduction)  
10:00-10:15 Coffee  
10:15-11:15 Combining Several Sources of Data: Nonlinear Mixed Effects  
11:15-12:00 Hands-on (Population PK/PD data and TMDD)  
12:00-13:00 Lunch  
13:00-15:00 Hands-on (Population PK/PD data and TMDD)  
15:00-15:15 Wrap up and Closing Remarks

**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 Center is 28 min from Buffalo International Airport. Website: <http://www.ccnfny.com>

**Registration:** Online registration will begin September 1<sup>st</sup>, 2017. Given the special nature of the course, enrollment will be limited to 30 persons. Confirmation email of registration will be returned upon successful registration at the following website: <http://pharmacy.buffalo.edu/> -- under Quick Links.

**Hotel location:** *Sheraton at the Falls*, 300 Third St., Niagara Falls, NY 14303. USA. Phone: (716) 285-3361. The price is \$124/night single/double occupancy (triple/quadruple add \$10 per person). *Hotel Deadline: April 16<sup>th</sup>, 2018.* Website: <https://www.starwoodmeeting.com/Book/Pharmacokinetic2018>

**Fee:** Individual fee is \$2000. Up to 5 graduate students may enroll at a fee of \$1,200 (registered MS and PhD). US Government rate: \$1,600. The registration fee includes course documentation and temporary software license. Continental breakfasts, lunches, break-time refreshments, and opening dinner are also included.

**Cancellations:** Cancellations with a full refund may be made until March 13, 2018. No refund is possible on cancellations received after this date. Substitutions may be made at any time. Please inform course secretary of any substitutions.

**Payment:** MasterCard, Visa, American Express, and Discover card payments will be accepted only at the following website: <http://pharmacy.buffalo.edu/> -- under Quick Links.