New Course: Structural PK/PD Model Building for Basic Clinical and Pre-Clinical Pharmacology Studies
May 16-18, 2019
Niagara Falls, NY

This course is designed to fill a gap between basic population PKPD methodology training and the application of population methods to the types of studies and data often encountered by attendees in practice during the course of drug development.

Each exercise will involve both model building and interpretation of output – this will improve attendees’ general population PKPD model building and interpretation of output skills. Although some examples will use covariates, the course will primarily focus on structural model building and model fitting (in a population setting) and not covariate analysis per se.

The course will be fully population PKPD based, and assumes attendees have had an introduction to population PKPD modeling. While we will use Phoenix NLME for the hands-on exercises, the model building techniques and approaches are applicable to any model fitting software. Prior experience with the Phoenix platform is not required.

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 a co-designer of Phoenix NLME and has presented numerous workshops on the statistical evaluation of PKPD 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. Dr. Weiner is an Adjunct Associate Professor with the Division of Pharmacotherapy and Experimental Therapeutics in the School of Pharmacy, University of North Carolina and is an Affiliate Professor of Pharmacometrics, Center for Translational Medicine in the School of Pharmacy at the University of Maryland. During his career he has provided PKPD training to over 3,000 students.
Course Schedule:

Thursday, May 16  8:00 to 17:00, followed by a group dinner at 18:00
Friday,    May 17  8:00 to 17:00, evening on own
Saturday, May 18  8:00 to 15:00, course adjourns

Examples will include structural population model building for
  o Simultaneous modeling of plasma and urine data
  o Simultaneous modeling of data from different routes (e.g. iv and oral)
  o Metabolite modeling – single vs multiple metabolites, formation in plasma and/or tissue, reversible and irreversible metabolite formation, metabolites measured in plasma and/or urine
  o Modeling dual absorption such as from a controlled release formulation (containing IR and ER formulations)
  o Modeling endogenous drugs
  o TMDD modeling approaches
  o Modeling data from crossover designs

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 October 1st, 2018. 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 $93/night single/double occupancy (triple/quadruple add $10 per person). Hotel Deadline: April 8th, 2019. Website: https://www.starwoodmeeting.com/Book/Pharmacokinetic2019

Fee: Individual fee is $2800. Up to 5 graduate students may enroll at a fee of $1,400 (registered MS and PhD). 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 12, 2019. 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.