

**Simulations Plus presents:
A 3-DAY INTRODUCTORY WORKSHOP
IN POPULATION PK DATA ANALYSIS WITH NONMEM®**



**October 10-12, 2016 at the Hyatt Regency Bethesda
in Bethesda, Maryland**

Simulations Plus, the industry's leading provider of simulation and modeling software and consulting services for drug discovery and development, will be hosting a 3-day introductory workshop in Population PK Data Analysis with NONMEM® in Bethesda, Maryland, October 10-12, 2016.

This workshop has been designed to provide the necessary information to successfully implement population pharmacokinetic methodology in a drug development program and to provide the foundation for understanding the basics of NONMEM coding and interpretation of NONMEM output. The material is structured to impart both the theoretical and practical aspects of the population approach and is versatile so that participants with diverse backgrounds and areas of expertise may benefit. Examples of the use of population PK studies in drug development programs will be presented to provide specific details of various implementations and better illustrate essential aspects of population PK methods. Emphasis will be placed on compliance with the FDA's Guidance for Industry on Population PK and the EMA's Guideline on Reporting the Results of Population PK Analyses; participants will gain an appreciation for the importance of accurate and sufficient data collection and learn how to proactively plan in order to maximize study effectiveness.

Course Instruction

The course is organized and taught by Jill Fiedler-Kelly, co-author of *"Introduction to Population Pharmacokinetic/Pharmacodynamic Analysis with Nonlinear Mixed Effects Models"* (John Wiley & Sons Inc., 2014). Jill is an Adjunct Associate Professor at the University at Buffalo Department of Pharmaceutical Sciences and leads the Pharmacometric Services group at Cognigen Corporation, a wholly owned subsidiary of Simulations Plus, Inc. Cognigen has been providing clinical pharmacology and pharmacometric consulting services, including population PK/PD modeling and simulation to the global pharmaceutical industry for over 20 years to generate and communicate the knowledge required for time-sensitive decision making and regulatory review.



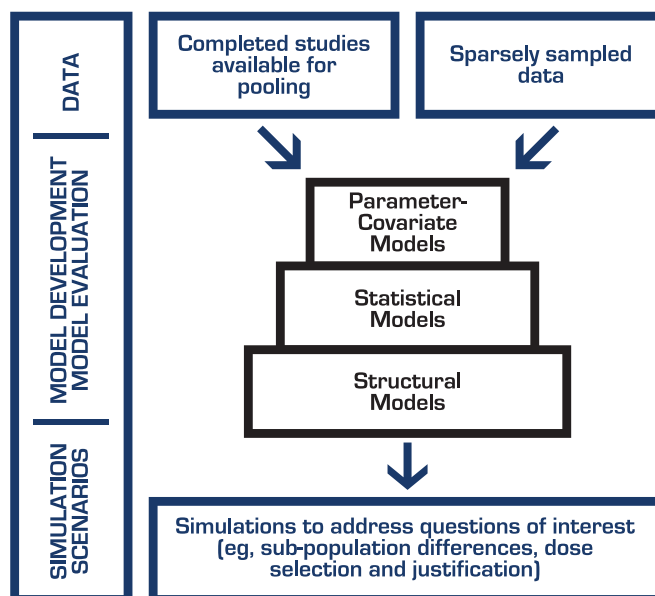
Jill Fiedler-Kelly

What will you learn?

This workshop will provide the participants with a comprehensive understanding of the population PK approach to data analysis, its usefulness and added value in drug development, as well as when and where to employ population PK methods and sparse sampling within a given development program. The format is designed to be both comprehensive and interactive.

Following the workshop, the participant should be able to:

- Understand the conceptual basis and rationale for the population approach to data analysis, its benefits and advantages, including where and when population methods may be optimally applied during the drug development process
- Write, execute, and de-debug basic NONMEM® control streams for structural PK models
- Outline the requirements and format for basic NONMEM® datasets
- Understand the importance of exploratory data analysis (EDA) and the interpretation of standard goodness-of-fit diagnostic plots
- Perform covariate analyses to evaluate determinants of variability by understanding, identifying, and coding basic functional forms for covariate-parameter relationships
- Understand the basis for model selection strategies and discriminate between candidate models on the basis of both quantitative and qualitative factors
- Understand and interpret NONMEM output, including error messages, and have insight into potential model refinement issues



When and where will this be held?

The workshop will be held October 10-12, 2016 at:

Hyatt Regency Bethesda
One Bethesda Metro Center
(7400 Wisconsin Avenue)
Bethesda, MD 20814
+1-301-657-1234



How will the workshop operate?

The workshop content is provided as a combination of formal lectures, review of data, code, and data analysis results, and hands-on exercises. Participants will use their own laptop computers, with which they will be able to practice coding control streams, running various models, and evaluating the results. A thorough examination of an example dataset, from development of the structural and statistical models through covariate analysis will be covered.

The registration fee includes hard-copy course documentation, USB drive with code examples, and a copy of the textbook, *"Introduction to Population Pharmacokinetic/Pharmacodynamic Analysis with Nonlinear Mixed Effects Models"* by Owen and Fiedler-Kelly (John Wiley & Sons Inc., 2014).

Continental breakfast, refreshment breaks, and lunch will be provided each day.

Requirements: Laptop computers required to fully participate in hands-on exercises. Minimum configuration required: Google Chrome with Flash 9+ plugins.

Agenda

Day 1: Monday, October 10, 2016

- Welcome and Introduction to the Workshop
- The Population Approach in Drug Development
- Population Modeling Basics
- NONMEM® Terminology
- Estimation Methods in NONMEM®
- Brief Overview of the NONMEM® Program and Writing an NMTRAN Control Stream
- NONMEM® Dataset Structure
- Exercise: Writing Control Streams and Diagnosing Dataset Problems

Day 2: Tuesday, October 11, 2016

- Discuss Control Stream and Dataset Exercise
- Exploratory Data Analysis
- Exercise: Introduction to KIWI
- Running NONMEM® and Interpreting the Output
- Data Review: Introduction to the Example Dataset and Exploratory Data Analysis
- Exercise: Developing a Base Structural Model
- Data Review: Base Model

Day 2: Tuesday, October 11, 2016 (cont'd)

- Model Diagnostic Plots
- Model Selection and Covariate Evaluation:
Part 1: The Covariate Assessment Process
- Covariate Evaluation:
Part 2: Functional Forms
- Data Review: Introduction to Covariate Analysis and Coding Issues
- Exercise: Forward Selection of Covariate Effects

Day 3: Wednesday, October 12, 2016

- Forward Selection Exercise (cont'd)
- Data Review: Forward Selection Results and Multivariable Model Checking
- Exercise: Backward Elimination of Covariate Effects
- Applications of Bayesian Parameter Estimation
- Diagnosing Errors, Model Checking, Model Refinement, and Model Evaluation Techniques
- Data Review: Backward Elim & Model Refinement
- Pharmacometric Analysis Planning and Population PK/PD Modeling and Simulation
- Wrap-up and Final Q&A

REGISTRATION FORM

Attendance is limited • Please register by October 1, 2016

Please fill in this form and return to Renee Bouche (renee@simulations-plus.com) Fax: +1-661-723-5524
To register by phone, please call Renee at +1-661-723-7723 ext. 227

The 3-Day Workshop in Population PK Data Analysis with NONMEM® • October 10-12, 2016

Title: Professor / Dr. / Mr. / Mrs. / Miss / Ms.

FIRST NAME: _____

LAST NAME: _____

COMPANY: _____

POSITION: _____

DEPARTMENT: _____

ADDRESS: _____

TELEPHONE: _____

EMAIL: _____

PURCHASE ORDER NO. (if applicable): _____

Cost for the workshop is USD \$2,500 per person (industry). A US government employee rate of \$1,900 and student rate of \$1,200 is available for up to 3 participants of each type. The registration fee includes all workshop materials, continental breakfast, refreshment breaks and lunch each day.

Hotel accommodations are not included with registration, but special room rates are available through the Hyatt Regency.

Method of payment *(Please check one)*

Credit card *(a confirmation message will be sent to the email address provided)*

Name on card: _____ Email: _____ Tel: _____

Card billing address: _____

_____ Zip/Post Code: _____

Type of card: Visa MasterCard AMEX Card Number: _____

Expires: _____ Security code: _____

Payment by check (you will be invoiced upon receipt of your completed registration form)

Payment by wire transfer (you will receive wire transfer information upon receipt of your completed registration form)

Terms and Conditions

Cancellation Policy: Cancellations made prior to October 1, 2016 will be eligible for an 80% refund. Refunds for cancellations will be honored up to 45 days after the date of payment for credit card transactions. Substitutions are allowed up to 10 days before the event.

Payment Terms: Following completion and return of the registration form, the total fee must be paid within 30 days of receipt of invoice or prior to the start of the workshop (whichever is earlier).