

Simulations Plus presents:
The 3-Day Introductory Workshop in Population PK Data Analysis with NONMEM®



October 17- 19, 2019 at the University of Florida

Simulations Plus, the industry's leading provider of simulation and modeling software and consulting services for drug discovery and development, will be hosting its "3-Day Introductory Workshop in Population PK Data Analysis with NONMEM®" at the University of Florida in Orlando, Florida on October 17 - 19, 2019.

This three-day 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. 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. Throughout the workshop, the presenters will provide examples from their experience to inform best practices for implementation and avoiding problems. 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.

To ease the learning curve and ensure that participants are up and running with NONMEM very quickly, the [KIWI™ Pharmacometric Communication Platform](#) will be used in conjunction with NONMEM. KIWI is useful in facilitating code writing, finding errors, comparing output from different models, and generating point-and-click model diagnostics.



Department of Pharmaceutics Lake Nona
University of Florida
6550 Sanger Road, Office 467
Orlando, FL 32827

Attendance for this event is limited, so register today!



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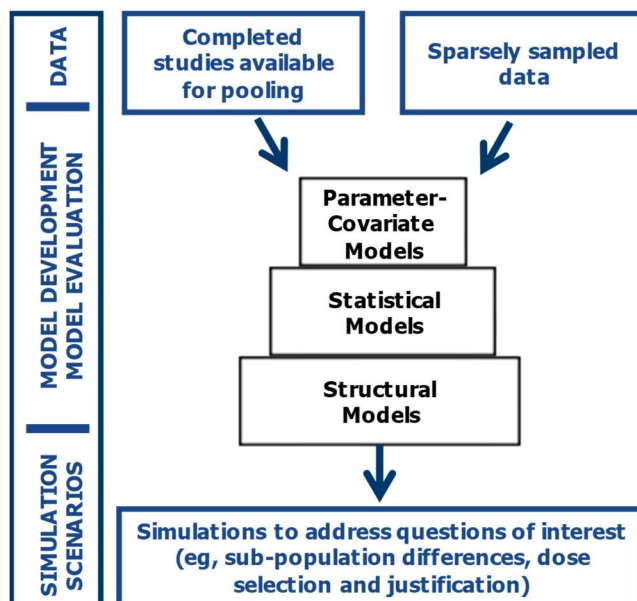
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What will you learn?

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:

- Write, execute, and de-bug 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



Course Instruction

The course will be taught by Jill Fiedler-Kelly, Sebastien Bihorel, and Stefan Roepcke. Jill is an Adjunct Professor at the University at Buffalo Department of Pharmaceutical Sciences, leads the Pharmacometric Services group at Cognigen Corporation, and is co-author of “Introduction to Population Pharmacokinetic/Pharmacodynamic Analysis with Nonlinear Mixed Effects Models” (John Wiley & Sons Inc., 2014). Sebastien and Stefan are expert pharmacometricians and modelers with years of experience applying population methods to address drug development and regulatory milestones. Cognigen has been providing clinical pharmacology and pharmacometric consulting services, including population PK/PD modeling and simulation to the global pharmaceutical industry for over 25 years to generate and communicate the knowledge required for time-sensitive decision making and regulatory review.



Jill Fiedler-Kelly



Stefan Roepcke



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

Agenda

Day 1: Thursday, October 17, 2019

- 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: Friday, October 18, 2019

- 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: Friday, October 18, 2019 (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: Saturday, October 19, 2019

- 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 Elimination & Model Refinement
- Pharmacometric Analysis Planning and Population PK/PD Modeling and Simulation
- Wrap-up and Final Q&A



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REGISTRATION FORM

Attendance is limited • Please register by September 19, 2019

Please fill in this form and return to Jill Morrison (morrison@cognigencorp.com). To register by phone, please call Jill at +1-716-633-3463 ext. 224

The 3-Day Introductory Workshop in Population PK Data Analysis with NONMEM® October 17 - 19, 2019 in Orlando, Florida

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

FIRST NAME: _____

LAST NAME: _____

COMPANY: _____

POSITION: _____

DEPARTMENT: _____

ADDRESS: _____

TELEPHONE: _____

EMAIL: _____

PURCHASE ORDER NO. (if applicable): _____

RATE (circle one):

Industry

Student

Cost for the workshop is \$2,500 per person (industry) for anyone not affiliated with the University of Florida. A student rate of \$1,250 is available for up to 2 (non-UFL) participants.

The registration fee includes all workshop materials, continental breakfast, refreshment breaks, and lunch each day.

Hotel accommodation is not included with registration.

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 September 19, 2019 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. All fees must be paid in full prior to the start of the workshop.



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