Title of the workshop

A 2-Day Introductory Workshop In Population PK Data Analysis With NONMEM®

Sponsored by

Cognigen Corporation, a Simulations Plus Company co-hosted by Pharmacometrics Africa NPC

Workshop target audience

The course 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. No prior experience with NONMEM is expected.

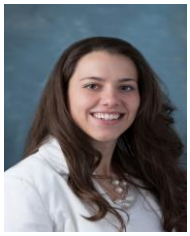
Date:	Saturday, 4 April – Sunday, 5 April 2020
Maximum participants	30 (13 seats will be reserved unit 28 February for tuition waivers for participants from low and middle income countries.
Time:	08h00 - 17h00 (each day)
Registration fees	$1200 / R18000 (Commercial and industry) $ 600 / R9000 (Government and Academia) $ 50 / R 800 (Students)

Workshop faculty

Joel S. Owen, PhD, Cognigen Corporation, a Simulations Plus Company
and Union University, College of Pharmacy, Jackson, TN

Joel Owen is VP, Pharmacometric Services at Cognigen and Adjunct Professor at Union University. Joel has 25 years experience in the application and research of quantitative methods for the development and use of therapeutic compounds. The majority of that time has been in the pharmaceutical industry, with 10 years in the College of Pharmacy. Throughout his career, Joel has sought to teach and mentor others. He has taught a NONMEM short-course at Makerere University, Kampala, Uganda and in other settings on multiple occasions and founded a postdoctoral fellowship program in pharmacometrics at Union University.

Aksana Jones, MS, Cognigen Corporation, a Simulations Plus Company



Aksana Jones is an Associate Director of Pharmacometrics at Cognigen Corporation, a Simulations Plus Company. She received her BSc in Biomathematics from the University of Applied Science, Koblenz, Germany in 2009 and her MS in Pharmacometrics from the University of Maryland in 2016. Aksana has 10 years of experience within pharmacometrics and her current focus is to assist Pharma and biotech companies with the strategic design, implementation, and subsequent analysis of data from a pharmacometric perspective in new drug development programs. Aksana has also been teaching pharmacometrics related topics, mainly focused on applying population methods during drug development.
Headshot submitted: yes

Workshop Learning Objectives

Following the workshop, the participant should be able to:

1. 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 drug development
2. Write, execute, and de-bug basic NONMEM® control streams for structural PK models
3. Outline the requirements and understand the format for basic NONMEM® datasets
4. Understand the importance of exploratory data analysis (EDA) and the interpretation of standard goodness-of-fit diagnostic plots
5. Perform covariate analyses to evaluate determinants of variability by understanding, identifying, and coding basic functional forms for covariate-parameter relationships
6. Understand and interpret NONMEM® output, including error messages, and have insight into potential model refinement issues
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Workshop Timetable

Synopsis: Day 1 of the workshop will include an introduction to the population approach and some modelling basics, along with a thorough presentation of NM-TRAN control stream coding and NONMEM dataset structure requirements. In addition, the pharmacometric analysis process will be reviewed, beginning with exploratory data analysis (EDA) and structural model development. Day 2 will include discussion of model selection issues, model refinement and evaluation techniques, as well as tips on diagnosing errors. Participants will use NONMEM and KIWI to run a base structural PK model and assess the influence of potential covariates.

Requirements

Participants are expected to bring a laptop computer, configured with Google Chrome for Internet access. The workshop content is provided as a combination of formal lectures, review of data, code, and data analysis results, in addition to brief 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. To ease the learning curve and ensure that participants are up and running very quickly, access to NONMEM will be provided via the KIWI™ Pharmacometric Communication Platform.