

MI212-W: Advanced Topics in Population PK-PD Modeling & Simulation (3 CR)

MI212 covers intermediate through advanced-level population PK-PD modeling and simulation through lecture and hands-on lab sessions. Topics covered include for nonlinear PK models, modeling PK data with BQL records, models for parent-metabolite data, models for plasma and urine PK data, indirect PK-PD models, disease progression models and clinical trial simulations. This course makes extensive use of NONMEM[®] 7 and R, as well as the Mifuns package. Participants may apply the 3 credit hours from this course to the Metrum Institute Certificate Program in Pharmacometrics.

Instructors

Marc Gastonguay and Metrum Institute staff

Prerequisites

MI210 and related prerequisites, or contact us: info@metruminstitute.org.

Computer Hardware/Software

This course requires a Windows computer with a web browser. Students will be given access to a Metrum Institute web-application server for hands-on examples including all required software. Details on how to access the program are provided at the start of the course.

Fall 2010 Schedule

September	14, 17, 21, 24, 28
October	1, 5, 8, 12, 15, 19, 22, 26, 29
November	2, 5, 9, 12, 16, 19, 30
December	3, 7, 10, 14, 17

Tuesdays 2–4 pm Eastern Time (lecture)

Fridays 2–3 pm Eastern Time (lab)

Location

Live webcast

Fees

Regular registration: \$3000 USD / Academic & government registration: \$1500 USD

Course Outline

1. Advanced pharmaco-statistical topics
 - Inter-occasion variability
 - Mixture models
 - Truncated data distributions (BQL)
2. Advanced pharmacokinetic topics
 - Nonlinear PK models
 - Parent-metabolite models
 - Parameter identifiability
 - Data requirements for urinary excretion data
 - Models for plasma & urine data
 - Exercise: simultaneous analysis of parent metabolite-urine data
3. Advanced pharmacokinetic-pharmacodynamic modeling
 - Indirect PD response models
 - Pharmacodynamic tolerance models
 - Multiple endpoint turnover models
4. Disease progression models
 - Symptomatic effects
 - Disease rate modifying effects
 - Mechanistic models
5. Basics of clinical trial simulation
 - Covariate distributions
 - Multi-level random effects
 - Incorporating parameter and model
 - Uncertainty
 - Sensitivity analysis
6. Population pharmacokinetic study design
 - Controllable and uncontrollable trial design features
 - Information theoretic approaches
 - Simulation-based approaches
- Precursor pool feedback models
- Modeling circadian baseline