

MI260: Bayesian Model-Based Meta-Analysis to Support Decision Making in Drug Development (3 CR)

MI260 provides an introduction to meta analysis concepts and methods, with a strong focus on model-based meta-analysis of summary data or a combination of summary and individual data from clinical trials to support decision-making in clinical drug development. Upon completion of the course, participants will be able to write a meta-analysis plan, design a model-based meta-analysis of clinical trial data to address strategic decisions in a clinical drug development program, and implement it using a Bayesian approach executed with WinBUGS and R. Participants will also be able to construct a model for the relationship between an efficacy- or safety-related clinical outcome and independent variables such as dose, time and patient characteristics by analysis of summary data from multiple studies, e.g., treatment means and standard deviations, and construct such a model by analysis of a combination of summary and individual data, as well as execute and interpret population simulations to support decision-making in clinical drug development. Participants may apply the 3 credit hours from this course to the Metrum Institute Certificate Program in Pharmacometrics.

Instructors

Bill Gillespie and Metrum Institute Instructors

Prerequisites

Experience with PK-PD modeling and some familiarity and hands-on experience with nonlinear regression, mixed-effects modeling, Bayesian modeling using WinBUGS, and use of R (or S-PLUS). Applicable MI courses include: MI200, MI205 and MI250, or [contact us](#).

Computer Hardware/Software

This course requires a Windows laptop computer with an available USB 2.0 port. All required software used for hands-on examples will be freeware/open-source software and simple instructions will be provided for users to configure their computers before the course.

Spring 2012 Schedule

TBD

Location

Webcast

Fees

Standard Registration: \$3000 USD / Academic & Government Reduced Registration: \$1500 USD

Course Outline

1. Overview of meta-analysis concepts and methods
 - Why meta-analysis?
 - Different strategies and methods for meta-analysis
 - Problems and limitations of meta-analysis methods
 - Writing a meta-analysis plan
2. Introduction to model-based meta-analysis
 - Rationale and role of model-based meta-analysis in clinical drug development
 - Why do it?
 - What decisions benefit from model-based meta-analysis?
 - Motivating examples
 - Why Bayesian? / Why BUGS?
3. Overview of the model-based meta-analysis process

- Types of data and data sources
 - The process
 - Plan your modeling strategy
 - Identify key information you want to collect
 - Construct a database
 - Construct the modeling and simulation work plan
 - Implementation and application
 - * Model development
 - * Model application, e.g., simulations to support decision-making
4. Database construction
 - Data sources
 - Data types, e.g., mean, mean change from baseline, percent change from baseline, standard deviation, standard error...
 5. Modeling sample mean data
 6. Hands-On Problem 1: Dose response model based on sample means
 7. Modeling sample standard deviations: why and how
 8. Population stimulations
 - Simulating probable ranges of population estimands, e.g., population mean, probability of an event, etc.
 - Using simulation results to support decision-making in a competitive market environment
 9. Hands-On Problem 2: Population stimulations
 10. Issues arising from analysis of summary data
 - Applying models developed to describe responses in individuals to summary data
 - Analysis of longitudinal data
 - Pitfalls of treating treatment arms as "super-patients"
 - Within-arm correlation
 - Approaches for addressing these issues
 11. Modeling other types of summary statistics
 - Number or fraction of patients with a particular outcome or that experience an event
 - Number or fraction of patients within each level of an ordinal scale
 - Number of events per patient
 - Summary statistics for time-to-event measurements
 12. Hands-On Problem 3: Longitudinal dose-response model based on longitudinal summary data
 13. Publication bias
 14. Issues arising from use of LOCF and OC data
 15. Combining summary and individual data
 16. Hands-on Problem 4: Longitudinal dose-response model based on a combination of summary and individual data
 17. Incorporating a broader range of data and knowledge
 - Leveraging the Bayesian framework to incorporate additional quantitative knowledge via informative prior distributions
 - Integrating preclinical, biomarker and clinical outcome data to improve prediction and decision-making in early clinical development
 18. Closing discussion