

ACoP 10 Workshop

Title: Practical Methods for Applying Meta-analysis

Course Date and Duration: 20 October 2019; 1-day

Presenter: Dana Nickens (Pfizer)

Course Description and Objectives:

Model-based meta-analysis (MBMA) quantifies clinical trial efficacy, tolerability, and safety information to enable strategic drug development decisions as companies look to benchmark their own compounds with the competition. Further to the immediate role to inform go/no go decisions, MBMA could help optimize trial design through the gained understanding that the impact of study design, demographics, special populations and region could have on treatment effects. In summary, the insights gained via MBMA enable less costly and more effective trials with an eye toward achieving commercial success for both the drug and portfolio.

Going beyond the theory and basic methods of traditional meta-analysis, this course will highlight special topics and practical approaches for situations such as missing data, missing variances, interval calculation and analyzing complex data.

The creation of the appropriate dataset to perform MBMA is not a straight forward exercise. Getting into the real issues one will face when performing MBMA and strategies to deal with them will be the main focus of this course. The analysis platform will be in R.

Objectives:

- (1) Understand the challenges of doing meta-analysis.
- (2) Know how to apply practical approaches to handle data challenges
- (3) Know how to apply R-based code to implement these approaches

Outline:

- A. Introduction to basic meta-analysis & practical issues
- B. Assessing quality of papers
- C. Approaches for deriving or imputing missing data
 - a. Missing variances for median time-to-event data
 - b. Missing hazard ratios & variances
 - c. Incorporating correlation in change-from-baseline
 - d. Missing variances in non-linear models
 - e. Deriving variances for binary responses
- D. Combining Data
 - a. Survival curves (including digitizing issues)

- b. Treatment groups (or not)
 - c. Aggregate and patient level data
- E. Other methods
 - a. Incorporating real world data
 - b. Confidence & Prediction intervals calculations

Materials provided: Syllabus with slides and R code

Attendee requirements: Basic understanding of meta-analysis and experience using R/RStudio

Cost: \$150 for industry; \$75 for academia and students