

## SAAMnow Spring 2019 Workshop

Challenging Statistical Issues with *In Vitro* and *In Vivo* Bioequivalence Studies: Extreme Variability, Special Study Designs and Novel Approaches

**Day 1: Thursday, April 4, 2019 [8:00 AM – 5:00 PM]**

### Session 1: Extreme Variability and Aberrant Data in BE Studies

- Outliers and Aberrant PK Data in Bioequivalence Studies – Industry Perspective
- Outliers and Aberrant PK Data in Bioequivalence Studies – FDA Perspective
- RLDs with high lot-to-lot variability - Issues and Novel Solutions
- When Even Reference Scaling Is Not Enough: Bioequivalence Studies on Extremely Variable Drugs (EVDs)
- Baseline Correction for Endogenous Drugs – Getting it Right
- Panel Discussion on Extreme Variability and Aberrant Data in BE Studies

### Session 2: *In Vitro* BE Statistical Issues

- Statistical Issues for Low Permeability Compounds in IVPT Studies
- Sample Size Calculations for IVPT Studies
- Statistical Issues with Aberrant IVRT/IVPT Data - FDA Perspective
- Equivalence Criteria for *In Vitro* BE Tests for Locally Acting Drug Products: The Earth Mover's Distance Approach
- Panel Discussion on *In Vitro* BE Statistical Issues

**Day 2: Friday, April 5, 2019 [8:00 AM – 3:00 PM]**

### Session 3: Practical Issues in BE Statistics

- ANOVA Design/Analysis Issues: Nuisance effects, ANOVA Model Selection, Missing/Unbalanced Data
- Practical Statistical Issues in Evaluation of Average Bioequivalence
- The Effect of Adhesion/Detachment on the Pharmacokinetics (PK) of Transdermal Delivery Systems (TDS)
- PK and Statistical Considerations for Steady State BE studies - Industry Perspective
- PK and Statistical Considerations for Steady State BE studies - FDA Perspective
- Panel Discussion on Practical Issues in BE Statistics

### Session 4: Modeling in Bioequivalence

- Dose-Scale ( $E_{max}$ ) Modeling in Pharmacodynamic BE Studies - Industry Perspective
- Dose-Scale ( $E_{max}$ ) Modeling in Pharmacodynamic BE Studies - FDA Perspective
- Use of Modeling and Simulation to Support New BE Approaches
- Panel Discussion on Modeling in Bioequivalence