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SAS Silver Partner

COURSE TITLE: Bioequivalence Trials: Concepts, Issues and Pitfalls

Agenda:

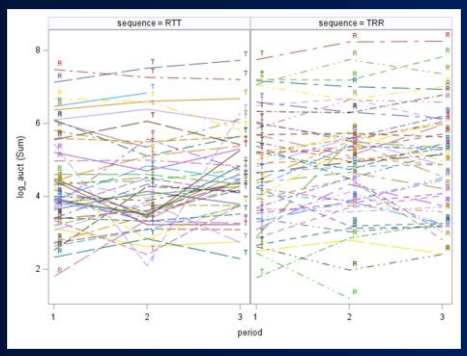
Overview of Key Statistical Concepts

- ☐ Descriptive vs. Inferential Statistics
- ☐ Measures of Central Tendency and Variability, Demo
- ☐ One- and two-sample t-test, Demo
- ☐ Confidence Interval and p-values, Demo
- ☐ ANOVA key concepts
  - ■ Demo

Bioequivalence Trials: Key Concepts, Issues and Pitfalls

- ☐ Test for difference vs. test for equivalence
- ☐ Clinical vs. bioequivalence trials
  - ■ Endpoints
  - ■ Aims
  - ■ Results
  - ■ Demo
- ☐ In-vivo vs. in-vitro bioequivalence trials
- ☐ Parallel vs. paired designs
- ☐ Standard crossover vs. higher-order (replicated) crossover design
  - ■ Some common designs
    - ○ 2 treatment designs
    - ○ 2x2 vs. Higher order/replicated designs
    - ○ 3 treatment designs
    - ○ 4 treatment designs
    - ○ Demo
  - ■ Design evaluation and comparison
    - ○ Uniformity, balance
    - ○ Bias
    - ○ Precision/efficiency
  - ■ Randomization
    - ○ Demo
- ☐ Sample Size and Power for bioequivalence trials
  - ■ Demo
- ☐ Raw vs. log scale
- ☐ Parametric vs. nonparametric analysis
- ☐ Models for the analysis of bioequivalence data
  - ■ Data from a parallel design
    - ○ Demo
  - ■ Data from a non-replicated crossover design
    - ○ Demo
  - ■ Data from a replicated crossover design
    - ○ Demo
  - ■ Fixed factors vs. mixed factors
- ☐ Pitfalls in bioequivalence trials and how to avoid them

Label	LowerCI	Ratio	UpperCI
T-R	86.92	97.38	109.10



Schedule:
4 half-days (2 x 1.5 hours per day)

Timing:
To be agreed

Maximum number of participants:
10

Course format:
On-line via MS-Teams

Presenters:
Vesna Luzar-Stiffler, PhD Statistics/IT
Anja Oberiter-Korbar, PhD Toxicology/IT

Course materials:
PowerPoint Slides