Agenda

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

Day 1:

7:30am – 8:30am	*Breakfast & Registration*	Regency Randolph
8:30am – 9:00am	Introduction	Roosevelt/Madison

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

Moderator:	**Pina D'Angelo, Novum**	**Roosevelt/Madison**
9:00am – 9:30am	Outliers and Aberrant PK Data in Bioequivalence Studies – Industry Perspective	Keith Gallicano, Novum
9:30am – 10:00am	RLDs with high lot-to-lot variability – Issues and Novel Solutions	Dennis Sandell, S5 Consulting
10:00am – 10:30am	*Networking Coffee Break*	Patio Foyer
Moderator:	**Pina D'Angelo, Novum**	**Roosevelt/Madison**
10:30am – 11:00am	When Even Reference Scaling is Not Enough: Bioequivalence Studies on Extremely Variable Drugs (EVDs)	Charlie DiLiberti, Montclair Bioequivalence Services
11:00am – 11:30am	Baseline Correction for Endogenous Drugs – Getting it Right	Mark Liu, Mylan
11:30am – 12:30pm	Panel Discussion on Extreme Variability and Aberrant Data in BE Studies	All Session 1 speakers & Rob Lionberger, FDA
12:30pm – 1:30pm	*Lunch & Networking*	Regency Randolph

Session 2: *In Vitro* BE Statistical Issues

Moderator:	**Sam Raney, FDA**	**Roosevelt/Madison**
1:30pm – 2:00pm	Statistical Issues with Aberrant IVRT/IVPT Data – FDA Perspective	Elena Rantou, FDA
2:00pm – 2:30pm	Statistical Issues for Low Permeability Compounds in IVPT Studies	Pina D'Angelo, Novum
2:30pm – 3:00pm	Sample Size Calculations for IVPT Studies	Diane Potvin, Excelsus
3:00pm – 3:30pm	*Networking Coffee Break*	Patio Foyer
3:30pm – 4:00pm	Equivalence Criteria for *In Vitro* BE Tests for Locally Acting Drug Products: The Earth Mover's Distance Approach	Meng Hu, FDA
4:00pm – 5:00pm	Panel Discussion on *In Vitro* BE Statistical Issues	All Session 2 speakers & Priyanka Ghosh, FDA Theo Kapanadze, Diteba
5:00pm – 6:00pm	*Networking Cocktail Reception*	Atrium

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Day 2:

7:00am – 8:00am	*Breakfast*	Regency Randolph

Session 3: Practical Issues in BE Statistics

Moderator:	**Charlie DiLiberti, Montclair Bioequivalence Services**	**Roosevelt/Madison**
8:00am – 8:30am	ANOVA Design/Analysis Issues: Nuisance Effects, ANOVA Model Selection, Missing/Unbalanced Data	Chuck Bon, BioStudy Solutions
8:30am – 9:00am	Practical Statistical Issues in Evaluation of Average Bioequivalence	Shein-Chung Chow, FDA
9:00am – 9:30am	The Effect of Adhesion/Detachment on the Pharmacokinetics of Transdermal Delivery Systems (TDS)	Wanjie Sun, FDA
9:30am – 10:00am	*Networking Coffee Break*	Patio Foyer
Moderator:	**Charlie DiLiberti, Montclair Bioequivalence Services**	**Roosevelt/Madison**
10:00am – 10:30am	PK and Statistical Considerations for Steady State BE Studies – Industry Perspective	Julie Szirtes, Apotex Inc.
10:30am – 11:00am	PK and Statistical Considerations for Steady State BE Studies – FDA Perspective	Lanyan (Lucy) Fang, FDA
11:00am – 12:00pm	Panel Discussion on Practical Issues in BE Statistics	All Session 3 speakers & Rob Lionberger, FDA & Walter Hauck, Sycamore
12:00pm – 1:00pm	*Networking Lunch*	Regency Randolph

Session 4: Modeling in Bioequivalence

Moderator:	**Keith Gallicano, PhD, Novum**	**Roosevelt/Madison**
1:00pm – 1:30pm	Dose-Scale (E_{max}) Modeling in Pharmacodynamic BE Studies – Industry Perspective	Murray Ducharme, Learn and Confirm
1:30pm – 2:00pm	Dose-Scale (E_{max}) Modeling in Pharmacodynamic BE Studies – FDA Perspective	Matt Li, FDA
2:00pm – 2:30pm	Use of Modeling and Simulation to Support New BE Approaches	Liang Zhao, FDA
2:30pm – 3:00pm	Panel Discussion on Modeling in Bioequivalence	All Session 4 speakers & Rob Lionberger, FDA