SAAM*now* Spring 2020 Conference
Cutting Edge Approaches for Demonstrating Bioequivalence
Co-Chaired by Liang Zhao, FDA and Sid Bhoopathy, SAAMnow

Agenda

Day 1: Thursday, April 16, 2020

9:00 – 9:20am	**Keynote: Driving Innovation in Bioequivalence**	**Robert Lionberger, FDA**

Session 1: Advances in Characterization Based Equivalence (CBE); Unit One – Orally Inhaled Drug Products and Long Acting Injectables

Moderators:	**Gur Jai Pal Singh, Cipla & Charles Bon, Biostudy Solutions**	
9:20 – 9:45am	Cutting edge technologies for Q3 determinations of orally inhaled drug products	Hugh Smyth, University of Texas
9:45 – 10:10am	Local and Systemic Absorption Predictions of Orally Inhaled Solutions and Suspensions using CFD and PBPK	Ross Walenga, FDA
10:10 – 10:30am	*Networking Coffee Break*	
10:30 – 10:55am	Model based BE assessment for long acting injectables	Lucy Fang, FDA
10:55 – 11:20am	Complex sameness of injectable long-acting PLGA formulations	Kinam Park, Purdue University
11:20 – 12:00pm	Q&A with moderators, speakers, panel member: Bing Li, FDA	

Session 2: Advances in Characterization Based Equivalence (CBE); Unit Two – Topicals and Ophthalmics

Moderators:	**Darby Kozak, FDA & Sid Bhoopathy, Absorption Systems**	
1:05 – 1:30pm	New technologies to measure skin PK concentrations	Sam Raney, FDA
1:30 – 1:55pm	Building layers and foundations for virtual bioequivalence, “getting under the skin”	Amin Rostami, Certara
1:55 – 2:20pm	Look and see: overcoming challenges in complex ophthalmic drug product CQA equivalence evaluation	Xiaoming Xu, FDA
2:20 – 2:45pm	Prediction of in vivo ophthalmic product performance from product attributes through mechanistic ocular modeling	Andrew Babiskin, FDA
2:45 – 3:15pm	Q&A with moderators, speakers, panel member: Ethan Stier, FDA	

Session 3: Novel Approaches to Assess Compositional and Q3 Deviations for BE Evaluation

Moderators:	**Sam Raney, FDA & Lucy Fang, FDA**	
3:30 – 3:55pm	Compositional and Q3 constraints in demonstrating BE; can we find a pathway for greater tolerance?	Charlie DiLiberti, Montclair Bioequivalence Services
3:55 – 4:20pm	Novel methodologies to mitigate BE risk with compositional and Q3 deviations	Sid Bhoopathy, Absorption Systems
4:20 – 4:45pm	PBPK model applications for BA/BE assessments in drug development	Tycho Heimbach, Novartis
4:45 – 5:25pm	Q&A with moderators, speakers, panel members: Nilufer Tampal, FDA & Rob Lionberger, FDA	

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Day 2: Friday, April 17, 2020

8:15 – 8:35am	**Keynote: Evolution of MIDD for drug development and its potential for BE**	**Carl Peck, NDA Partners**

Session 4: Novel BE Assessment Methods and Designs

Moderators:	**Liang Zhao, FDA & Charles Bon, Biostudy Solutions**	
8:40 – 9:00am	Optimizing study designs for clinical endpoint bioequivalence studies: adaptive/sequential options	Wanjie Sun, FDA
9:00 – 9:20am	Model-based bioequivalence analysis methods for sparse PK data	Andrew Hooker, Upsala University
9:20 – 9:40am	Comparing a Bayesian Approach (BEST) and TOST for clinical BE studies, with focus on when the data are well-behaved and when there are outliers	Greg Campbell, GCStat Consulting
9:40 – 10:30am	Q&A with moderators, speakers, and panel members: Stella Grosser, FDA & Carl Peck, NDA Partners	

Session 5: Use of Model Integrated Evidence (MIE) for Drug Development and Approval; Unit One

Moderators:	**Keith Gallicano, Novum & Stella Grosser, FDA**	
10:50 – 11:10am	Leveraging dermal physiologically-based pharmacokinetic modeling and simulation approaches for the approval of generic diclofenac sodium topical gel	Eleftheria Tsakalozou, FDA
11:10 – 11:30am	Modeling to speed tricky generic development by five times: the case for levonorgestrel IUD	Satish Sharan, FDA
11:30 – 12:00pm	Q&A with moderators, speakers, and panel members: Murray Ducharme, Learn and Confirm, Liang Zhao, FDA, & Amin Rostami, Certara	

Session 6: Use of Model Integrated Evidence (MIE) for Drug Development and Approval; Unit Two

Moderators:	**Keith Gallicano, Novum & Stella Grosser, FDA**	
1:05 – 1:25pm	Model based Q1-3 space determination: case studies and perspectives	Maxime Le Merdy, Simulations Plus
1:25 – 1:45pm	Understanding the needs of pAUC for bioequivalence studies of long acting injectables	Hao Zhu, FDA
1:45 – 2:05pm	BE strategies by leveraging model integrated evidence and potential regulatory-industry landscape	Liang Zhao, FDA
2:05 – 2:50pm	Q&A with moderators, speakers, and panel member: Charlie DiLiberti, Montclair Bioequivalence Services	