

SAAMnow Workshop: Challenges and Strategies for Relative Bioavailability Studies on Drug Products Involving Endogenous Substances

Session 1 (Tuesday April 26, 2022): Design and Conduct of Relative Bioavailability Studies on Drug Products Involving Endogenous Substances		Moderator	Times
Introductory remarks and workshop overview		Charles DiLiberti, Montclair Bioequivalence Services (confirmed)	9:00-9:30 am EDT
Topic 1: Challenges in the planning of pharmacokinetic studies of endogenous substances administered exogenously	Speaker: Keith Gallicano, Keith Gallicano Consulting (confirmed)		9:30-10:15 am EDT
Topic 2: Design and conduct of pharmacokinetic bioequivalence studies on drug products involving endogenous substances: clinical considerations	Speaker: Darin Brimhall, Thermo Fisher Scientific (confirmed)		10:15-11:00 am EDT
Panel Discussion	Panelists: 1. Darin Brimhall, Thermo Fisher Scientific (confirmed) 2. Wei-Jhe Sun, FDA (confirmed) 3. Keith Gallicano, Keith Gallicano Consulting (confirmed)		11:00 am-12:00 pm EDT
Session 2 (Wednesday, April 27, 2022): Data Analysis and Statistical Challenges		Charles Bon, Biostudy Solutions (confirmed)	Times
Topic 1: Baseline measurements and correction issues	Speaker: Charles DiLiberti, Montclair Bioequivalence Services (confirmed)		9:00-9:45 am EDT
Topic 2: PK and statistical issues	Speaker: Mark Liu, Viatrix (confirmed)		9:45-10:30 am EDT
Topic 3: FDA perspectives on data analysis issues	Speakers: 1. Mark Donnelly, FDA (invited) 2. Zhen Zhang, FDA (invited)		10:30-11:15 am EDT
	Panelists: 1. Mark Liu, Viatrix (confirmed)		11:15 am-12:00 pm EDT

	<ul style="list-style-type: none"> 2. Charles DiLiberti, Montclair Bioequivalence Services (confirmed) 3. Mark Donnelly, FDA (invited) 4. Zhen Zhang, FDA (invited) 		
Session 3 (Thursday, April 28, 2022): Bioanalysis of Endogenous Analytes: Overview, Method Validation Considerations, and Case Studies		Nicola Hughes, Biopharma Services (confirmed)	
Topic 1: An overview of bioanalysis of endogenous analytes	<p>Speaker: Rafiq Islam, Somru BioScience Inc. (confirmed)</p>		9:00-9:45 am EDT
Topic 2: Validation of methods for endogenous analytes	<p>Speakers: Yang Lu, FDA (confirmed)</p>		9:45-10:30 am EDT
Topic 3: Challenges in the quantitative analysis of endogenous analytes: case studies	<p>Allan Xu, Keystone (confirmed)</p>		10:30-11:15 am EDT
	<p>Panelists:</p> <ul style="list-style-type: none"> 1. Rafiq Islam, Somru BioScience Inc. (confirmed) 2. Yuyong Ke, Diteba (confirmed) 3. Adrien Musuku, Pharmascience (confirmed) 4. Yang Lu, FDA (confirmed) 5. Allan Xu (confirmed) 		11:15 am-12:00 pm EDT

Contact List

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