WEDNESDAY, SEPTEMBER 23, 2020 | Symposium 18 | 12:00 – 1:30 PM

Partial Area Under the Curve Analysis in Generic & New Drug Development

BASIC SCIENCE OF CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit

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ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Keith Gallicano, PhD, Chief Scientific Officer, Novum Pharmaceutical Research Svcs

TARGET AUDIENCE:

This Symposium will be helpful for members of industry, academic institutes and government officials who are involved in the development and review of generic and new drugs.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:

1. Understand the approach in deciding when and how to use an appropriate partial area under the curve (pAUC) metric for assessment of bioequivalence and comparative bioavailability;
2. Understand the applicability of pAUC metrics in both generic and new drug development;
3. Understand the regulatory point of view on pAUC and its impact on different therapeutic areas such as hyperactivity disorder, insomnia and pain;
4. Understand an industry perspective on the challenges in study design involving pAUC for bioequivalence purposes.

Introduction to Partial Area Under the Curve (pAUC) Recommendations: A Regulatory Perspective

Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Appropriateness of pAUCs to Evaluate Shape Difference in Pharmacokinetic Profiles

Keith Gallicano, PhD, Chief Scientific Officer, Novum Pharmaceutical Research Svcs

Current Status for pAUC Recommendations in Product-specific Guidance & Case Examples

Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Partial AUC Improved Metrics for Assessing Bioequivalence: An Industry Perspective

Charles DiLiberti, MS, President, Montclair Bioequivalence Svcs LLC

Usage of pAUC for Evaluation of New Drug Applications for the Treatment of Migraine

Sabarinath Nair Sreedharan, PhD, Team Leader, Cancer Pharmacology I, Clinical Pharmacology, Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation