SATURDAY, SEPTEMBER 14, 2019 | Pre-meeting Workshop 2 | 8:00 AM – 12:00 PM

Clinical Pharmacology: Statistical Aspects & Methods, an ACCP/ASA Jointly-sponsored Workshop

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-9999-19-018-L04-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CHAIR:

Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC

TARGET AUDIENCE:

This Workshop will be useful for clinical pharmacologists from pharmaceutical/biotechnology companies and regulatory agencies, pharmacometricians, clinical researchers and drug development scientists who have an interest in applying and/or who currently apply principles of data science in clinical pharmacology. The target audience would include clinical and research faculty from schools and colleges of medicine, pharmacy and nursing, pharmacologists, pharmacists, clinicians or graduate/postgraduate trainees wishing to better understand their data and maximize the value of their data through effective communication of results and diagnostics.

GOALS & OBJECTIVES:

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

1. Explain the application of statistical principles to noncompartmental analysis of pharmacokinetic data in a variety of designs and endpoints based an understanding of distributional assumptions behind common pharmacokinetic endpoints derived from concentration-time data (eg, AUC, C_{max}) and understand principles of hypothesis testing for bioequivalence;
2. Distinguish between modeling and simulation;
3. Describe the impact of prospective vs retrospective design and appropriate analysis in drug development/population inference, as well as in individual patient care settings, including the principles of Bayesian and Frequentist inference in these settings;
4. Identify when to use decision support tools vs population analysis;
5. List the different types of models (parametric, semiparametric, nonparametric) and how these relate to pharmacokinetics/pharmacodynamics, drug development and patient/individualized-patient care models;
6. Differentiate between deterministic and Monte Carlo Simulation and how simulation can be used to improve decision making;
7. List ways to analyze, compare and combine multiple retrospective studies from institutional and public databases with clinical pharmacology and safety endpoints.

8:00 – 8:15 AM

Overview: Clinical Pharmacology – Statistical Aspects & Methods

Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC

8:15 – 9:00 AM

Classical Clinical Pharmacology: Bioequivalence, Bioavailability, Dose Proportionality & Noncompartmental Analysis

Robert Bies, PharmD, PhD, Associate Professor of Pharmaceutical Sciences, State Univ of New York at Buffalo School of Pharmacy and Member, Computational & Data Enabled Sciences & Engineering Program and Scott Patterson, PhD, PStat, Sanofi Pasteur, Statistical Innovation

9:00 – 9:30 AM

Modeling & Simulation for Drug Development

Peter Bonate, PhD, Executive Director, Astellas Pharma Inc, Pharmacokinetics, Modeling & Simulation

9:30 – 10:00 AM / **Break**

10:00 – 10:45 AM

Modeling & Simulation for Patient Care/ Individualized Medicine

Robert Bies, PharmD, PhD, Associate Professor of Pharmaceutical Sciences, State Univ of New York at Buffalo School of Pharmacy and Member, Computational & Data Enabled Sciences & Engineering Program

10:45 – 11:30 AM

Data Science & Retrospective Data in Public Databases

Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC

11:30 AM – 12:00 PM

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