WEDNESDAY, SEPTEMBER 23, 2020 | Symposium 21 | 4:00 – 5:30 PM

Beyond Pharmacokinetic Equivalence: Assessment of Pharmacodynamic Similarity in Biologic & Small Molecule Drug Development

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #JA4008220-0000-20-033-H04-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC

Ping Ji, PhD, Biologics Lead, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists, regulatory scientists and clinical researchers who work in or are interested in biologic, biosimilar and small molecule drug development, including those with MD, PharmD or PhD backgrounds.

GOALS & OBJECTIVES:

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

1. Know representative case studies of using pharmacodynamic (PD) similarity to support registration of a biosimilar or to demonstrate similarity of biologics which have undergone major manufacturing changes;
2. Be informed on representative case studies using PD similarity in place of pharmacokinetic equivalence to support the development of locally-administered drugs (e.g., for locally GI-directed treatment);
3. Understand the selection of dose and evaluation of dose-response relationship in study design and be informed on methods for justifying the margins for PD similarity assessment;
4. Be informed about how to properly correct for baselines in PD similarity evaluation and understand the statistical considerations of PD similarity evaluation when assessing baseline-normalized PD endpoint.

Introduction to the Topic of Pharmacodynamic Similarity Assessment in Drug Development

Ping Ji, PhD, Biologics Lead, US Food & Drug Administration and Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC

Pharmacodynamic Similarity Assessment in Biosimilar Development: Reducing the Burden of Comparative Clinical Efficacy Studies

Oliver von Richter, PhD, Director, Sandoz Biopharmaceuticals

Trial Design & Statistical Considerations on the Assessment of Pharmacodynamic Similarity

Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC

Pharmacodynamic Similarity in Biologic & Small Molecule Drug Development: A Regulatory Perspective

Yaning Wang, PhD, Director, Pharmacometrics, Clinical Pharmacology, US Food & Drug Administration

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