TUESDAY, SEPTEMBER 22, 2020 | Symposium 7 | 10:00 AM – 12:00 PM

Conducting First-in-Human Studies in the Context of the Concomitant Use of Drug-Drug Interaction Victims & Perpetrators

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

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ACPE – 2 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Olanrewaju Okusanya, PharmD, MS, Team Leader, US Food & Drug Administration

Vadryn Pierre, PharmD, Director, Clinical Pharmacology, EMD Serono Inc

TARGET AUDIENCE:

This Symposium will be useful for drug discovery and development scientists, clinical pharmacologists, preclinical pharmacologists and toxicologists, clinician scientists, systems pharmacology scientists, mathematical biologists and regulatory scientists.

GOALS & OBJECTIVES:

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

1. Explain the challenges in evaluating novel therapies in patients that require therapies known to be either drug-drug interaction victims or perpetrators;
2. Review the challenges in selecting initial doses for First-in-Human evaluation in patients that are on therapies known to be perpetrators of drug-drug interactions;
3. Discuss approaches that allow for the initiation of doses in the presence of interacting concomitant medications;
4. Evaluate the use of quantitative clinical pharmacology and *in vivo*/*in vitro* data to support initial dose selection without compromising safety.

Challenges in Conducting First-in-Human Studies in Patients on Drugs Known to Be a Victim or Perpetrator of Drug-Drug Interactions

Kelly Norsworthy, MD, Medical Officer, US Food & Drug Administration

Applying Clinical Pharmacology Principles to Support Early Dose Selection of Doses in First-in-Human Studies in Patients on Concomitant Interacting Medications

Brian Furmanski, PhD, Senior Director, Clinical Pharmacology & Regulatory Affairs, Nuventra Pharma Sciences

Model-based Approach for Selecting Doses for First-in-Human Studies in Patients on Drugs Known to Be a Victim or Perpetrator of Drug-Drug Interactions

Vadryn Pierre, PharmD, Director, Clinical Pharmacology, EMD Serono Inc

Novel Study Design Approaches to Assess the Impact of Potential Drug-Drug Interactions in First-in-Human Studies

Olanrewaju Okusanya, PharmD, MS, Team Leader, US Food & Drug Administration

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