



ACCP

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY®
Advancing Clinical Care through Pharmacology®

Pre-meeting Workshops

SATURDAY, SEPTEMBER 14, 2019 | Pre-meeting Workshop 4 | 1:30 – 5:30 PM

Decoding the Complexity of Transporter-mediated Drug-Drug Interactions & Recent Advances in Endogenous Biomarkers & Transporter Cocktail Studies

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-0000-19-020-L01-P

ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Ahmed Nader, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

Mohamed Elmeliegy, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology

TARGET AUDIENCE:

This Workshop will be useful for clinical pharmacologists working in academia, the pharmaceutical industry or regulatory settings.

GOALS & OBJECTIVES:

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

1. Explain recent advances using *in vitro*, clinical and *in silico* approaches to define transporter-mediated drug-drug interaction (DDI) potential for new drugs in development;
2. Discuss novel approaches to developing and validating cocktails for transporter substrates to be used in clinical DDI evaluations and evaluations of potential endogenous biomarkers of transporter activity;
3. Describe the implications of transporter-mediated DDI clinical study results in terms of extrapolation to other compounds and informing labeling language.

1:30 – 2:00 PM

Current Challenges & Future State of Transporter-mediated DDIs in Drug Development

Ahmed Nader, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

2:00 – 2:30 PM

Practical Approaches to Evaluate Transporter-mediated DDI Potential & the Interplay With Drug Metabolizing Enzymes

Mohamad Shebley, PhD, Director & Volwiler Research Fellow, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

2:30 – 3:00 PM

Clinical Relevance of Transporter Induction as a Mechanism for Clinical DDIs

Mohamed Elmeliegy, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology

3:00 – 3:30 PM

Perspectives on the Use of Endogenous Metabolites as Biomarkers for Transporter-mediated DDI Evaluation

Kathleen M. Giacomini, PhD, Professor, Univ of California San Francisco, Bioengineering & Therapeutic Sciences

3:30 – 4:00 PM / **Break**

4:00 – 4:30 PM

Recent Advances in the Development of Transporter Substrate Cocktails for Use in Clinical DDI Studies

Peter Stopfer, PhD, Global Head Clinical PK/PD, Boehringer Ingelheim Pharma GmbH & Co KG, Translational Medicine & Clinical Pharmacology

4:30 – 5:00 PM

Regulatory Perspective on Approaches to Predict Transporter-mediated DDIs, Interpretation of DDI Study Results & Implications for Labeling

Shiew-Mei Huang, PhD, Deputy Director, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER

5:00 – 5:30 PM

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