

MONDAY, SEPTEMBER 21, 2020 | Symposium 5 | 2:00 – 3:30 PM

Clinical Pharmacology in Anti-infective Drug Development

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

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ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Amit Somani, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists from academia and the pharmaceutical industry, industry leaders/decision makers, graduate students, postdoctoral fellows, pharmacists, pharmacometricians, pharmacokinetic/pharmacodynamic scientists and drug development scientists.

GOALS & OBJECTIVES:

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

1. Apply the knowledge of clinical pharmacology's role in anti-infective development programs to enhance ongoing and future drug development programs in this therapeutic area;
2. Compare and assess the value of various preclinical or clinical pharmacology approaches used among the discussed anti-infective drug development programs;
3. Help stakeholders make informed decisions during drug development and facilitate judicious use of available resources (e.g., cross-disciplinary scientific talent, knowledge repository, available guidances unique to the anti-infective area, money or other);
4. Create excellent value for all stakeholders and provide patients with access to the newer anti-infective treatments in a more affordable and timely manner.

Clinical Pharmacology Considerations in Drug Development of Pretomanid

Amit Somani, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

Clinical Pharmacology Considerations in Drug Development of Omadacycline

Sonia Pahwa, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

Future Opportunities for Application of Quantitative Systems Pharmacology or Other Quantitative Pharmacology Approaches to Enhance the Efficiency of Anti-infective Drug Development Programs

Scott Van Wart, PhD, Vice President & Chief Scientific Officer, Enhanced Pharmacodynamics LLC

Clinical Pharmacology Considerations for Anti-infective Products Developed Under the Animal Rule

Kunyi Wu, PharmD, Clinical Pharmacology Reviewer, US Food & Drug Administration

The Current State & Future Prospects for Anti-infective Drugs in Pediatrics

Catherine MT Sherwin, PhD, Professor & Vice Chair for Research, Director, Pediatric Clinical Pharmacology, Pediatrics, Wright State Univ Boonshoft School of Medicine, Dayton Children's Hosp

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