



ACCP

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

Symposia

TUESDAY, SEPTEMBER 22, 2020 | Symposium 10 | 12:00 – 1:30 PM

What's Next in Model-informed Drug Development? Joined Pharmacometrics & Epidemiological (Real-world Data) Approaches

QUANTITATIVE TRACK

Offers both CME & CPE Credit

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ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Yan Xu, MD, PhD, Director, Clinical Pharmacology & Pharmacometrics, Janssen Research & Development LLC

TARGET AUDIENCE:

This Symposium will be helpful for scientists from the pharmaceutical industry and academia with responsibilities or involvement in model-based drug development/pharmacometrics, clinical pharmacology and pharmacoepidemiology, plus medical, PhD and pharmacy students who are interested in those same areas.

GOALS & OBJECTIVES:

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

1. Understand the history and current state of modeling & simulation in drug development and clinical practice;
2. Understand challenges in modeling & simulation and how the knowledge gap can be addressed by an integrated pharmacometric and epidemiologic (real-world data [RWD]) approach;
3. Understand the benefits and risks of the integrated analysis in drug development via case studies (value and lessons learned);
4. Understand the regulatory perspective on how the proposed strategy may facilitate regulatory decision making by adding to 'totality of evidence'.

Introduction: What's Next in Model-informed Drug Development? Joined Pharmacometrics & Epidemiological (RWD) Approaches

Yan Xu, MD, PhD, Director, Clinical Pharmacology & Pharmacometrics, Janssen Research & Development LLC

Integrating Pharmacometrics & Epidemiological Approaches: Why, What and How?

Stephan Schmidt, PhD, Certara Professor, Associate Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Pharmaceutics Lake Nona, Univ of Florida

Interdisciplinary Pharmacometrics Linking Oseltamivir Pharmacology, Influenza Epidemiology & Health Economics to Inform Antiviral Use in Pandemics: A Case Study

Patrick Smith, PharmD, Senior Vice President, Certara

Time to Join Pharmacometrics & Epidemiological Analyses for Real-world Validation of Model-based Projection: A Regulatory Perspective

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

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