



ACCP

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

Symposia

SUNDAY, SEPTEMBER 15, 2019 | Symposium 5 | 3:30 – 5:00 PM

Real-world Data to Real-world Evidence: Opportunities & Challenges for Clinical Pharmacology & Precision Medicine

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers both CME & CPE Credit

UAN #0238-0000-19-005-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Anuradha Ramamoorthy, PhD, Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER

Mark Rogge, PhD, Global Head, Takeda Pharmaceuticals Int'l, Quantitative Translational Sciences

TARGET AUDIENCE:

This Symposium will be useful for regulators, industry scientists, clinicians, pharmacists, scientists from academia and others interested in drug development.

GOALS & OBJECTIVES:

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

1. Describe the regulatory policy framework in the US that is supporting the broad scope of real-world data (RWD) and real-world evidence (RWE) in drug development, approval and patient care;
2. Identify potential roles for RWD and RWE to improve drug development and patient care;
3. Discuss potential roles, opportunities and challenges for clinical pharmacology and precision medicine in generating RWE.

3:30 – 3:45 PM

Real-world Evidence: What is It? What Can It Do for Us?

Anuradha Ramamoorthy, PhD, Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER

3:45 – 4:05 PM

Integrating Clinical & Genomic Data to Improve Patient Care

Sara L. Van Driest, MD, PhD, Assistant Professor, Vanderbilt Univ Medical Ctr, Pediatrics & Medicine

4:05 – 4:25 PM

RWD, RWE & the Need for Collaboration

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

4:25 – 4:45 PM

Real-world Data Will Transform Translational Research & Development

Mark Rogge, PhD, Global Head, Takeda Pharmaceuticals Int'l, Quantitative Translational Sciences

4:45 – 5:00 PM

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