

TUESDAY, SEPTEMBER 22, 2020 | Symposium 13 | 2:00 – 5:30 PM

Patient-reported Outcomes in Drug Development & Clinical Practice

APPLIED CLINICAL PHARMACOLOGY TECHNIQUES TRACK

Offers both CME & CPE Credit

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ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Barbara Ameer, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

TARGET AUDIENCE:

This Symposium will be useful for individuals with professional degrees (MD, PharmD or PhD) who are involved in drug and device development. The Symposium will inform clinicians who follow evidence-based clinical practice guidelines when making therapeutic decisions on individual patients.

GOALS & OBJECTIVES:

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

1. Understand the challenges of using patient-reported outcomes (PRO) data to assess treatment benefit and/or risk during a clinical trial;
2. Outline the process used by the US Food & Drug Administration in assessing the tools that collect PRO data during a clinical trial for adding a claim to a product label;
3. Explain a lesson learned from incorporation of PRO instruments in the care of patients with a rare disease;
4. Delineate the role of patients in defining values and preferences about treatment for inclusion in practice guidelines.

Introduction to Patient-reported Outcomes (PROs): Capturing & Communicating the Patient Experience for Medical Product Development & Clinical Practice

Barbara Ameer, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

Patient-reported Outcomes in Chronic Heart Failure: Clinical & Regulatory Challenges & Achievements

John A. Spertus, MD, MPH, Adjunct Professor, Medicine, Washington Univ School of Medicine St Louis

Regulatory Perspective on PRO Measures in Product Development for Oncology Drug Labeling

Bellinda King-Kallimanis, PhD, Senior Staff Fellow, US Food & Drug Administration

Patient-reported Outcomes in Pediatric Oncology

Allison Barz Leahy, MD, Attending Physician, Oncology, Cellular Therapy & Transplant Section, Children's Hosp of Philadelphia

Patient-important Input: What's the Impact on Medical Product Labeling & Clinical Practice Guidelines in 2020?

Barbara Ameer, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

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