

WEDNESDAY, SEPTEMBER 23, 2020 | Symposium 17 | 12:00 – 1:30 PM

Innovative Approaches in the Use of Exposure-Response in Therapeutic Proteins to Support Pediatric Extrapolation

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit

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ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Robert M. Nelson, MD, PhD, Senior Director, Pediatric Drug Development, Johnson & Johnson

Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

TARGET AUDIENCE:

This Symposium will be useful for primary care and specialty physicians, pharmacists, clinical pharmacologists, clinical research associates, basic scientists and other healthcare professionals with an interest in learning about the use of extrapolation and Bayesian approaches for pediatric drug development.

GOALS & OBJECTIVES:

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

1. Discuss challenges in the use of extrapolation in drug development for pediatrics;
2. Identify the opportunities for exposure-response analyses in pediatric studies to extrapolate to adult pivotal studies;
3. Identify the utility of the Bayesian Approach to designing pediatric studies;
4. Discuss case studies using extrapolation for pediatric studies.

Introduction to the Use of Extrapolation in Pediatric Drug Development

Robert M. Nelson, MD, PhD, Senior Director, Pediatric Drug Development, Johnson & Johnson

The Pharmacology of Therapeutic Proteins (ADME) in Pediatrics

Bernd Meibohm, PhD, Associate Dean for Research & Graduate Programs, Univ of Tennessee Health Science Ctr

The Use of Exposure-Response With Therapeutic Proteins in Pediatric Drug Development

Marc Gastonguay, PhD, Chief Executive Officer, Metrum Research Group LLC

Bayesian Approaches to Pediatric Pharmacokinetic Studies

Chyi-Hung Hsu, PhD, Scientific Director, Janssen Research & Development LLC and Jian Wang, PhD, Associate Director, Drug Evaluation IV, CDER, US Food & Drug Administration

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