

Workshop on Lessons Learned from Failed Pediatric Trials

- **Chairs:**

- Jeffrey Barrett, PhD (Sanofi)
- Lily Mulugeta, PharmD (FDA)

- **Presentations:**

- **Guanfacine for ADHD in adolescents—Utility of Clinical Trial Simulation**--Marc Gastonguay, PhD (Metrum Research)
- **Challenges in Developing Biologics for Pediatric Diseases: Approaches to Dose Selection**--Sameer Doshi, PhD (Amgen)
- **Failed Trials and Design Considerations in Pediatric Oncology**--Brenda Weigel, M.D (Children's Oncology Group, COG)
- **Failed Trials and Design considerations in Pediatric Type 2 Diabetes**--William Tamborlane MD (Yale School of Medicine)

Workshop on Lessons Learned from Failed Pediatric Trials: Questions for the panel

- How is the question of similarity in disease between pediatrics and adults addressed at present? What is lacking (studies, preclinical investigation, natural history understanding)?
- What studies are necessary to ensure appropriate pediatric dose selection?
- Clinical trial simulation (CTS) is routinely used in adult drug development. How can clinical trial simulation be more routinely used in pediatrics to optimize trial design? What areas would benefit most from this approach?