Pediatric Cardiovascular Safety Think Tank: Program Overview

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Pediatric Cardiovascular Safety Think Tank

Preclinical development	Clinical development	Post market surveillance
• Developmental spectrum from neonates to adolescents: impact for drugs and devices • Preclinical models and biomarkers for pediatric safety testing • Regulatory perspective on preclinical assessment • Applicability of TQT studies to pediatric safety	• Lessons learned from pediatric oncology and psychiatric drug trials • Evaluating cardiac safety during pediatric device development • Ethical considerations of pediatric clinical trials • Challenges of pediatric drug clinical trial design	• FDA overview of pediatric cardiovascular drug and device safety in real world practice • Academic/clinical overview of pediatric cardiovascular drug and device safety in real world practice

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Plenary overview presentations

- Special Address by Joshua Sharfstein, MD: Principal Deputy Commissioner, FDA
- Drug Development, Surveillance and Pediatric Cardiovascular Safety
  Dianne Murphy, MD (FDA)
- Device Development, Surveillance and Pediatric Cardiovascular Safety
  Susan Cummins, MD (FDA)
- Pediatric Therapeutics and Cardiovascular Safety- An Academic/Clinical Overview
  Vicki Vetter, MD (Children's Hospital of Philadelphia)

Open Panel Roundtable: Priorities and next Steps