

Challenges and Opportunities in Pediatric Drug/Device Development for Neuro-Psychiatric Diseases: A Cross-Disciplinary Symposium

Atul R. Mahableshwarkar

Session Objectives

- Understand the unique challenges in pediatric drug and device development by utilizing the following as models
 - Epilepsy
 - Depression
 - Deep brain stimulation and baclofen pump
- Understand regulatory perspectives in issues in pediatric drug and device development
 - FDA
 - PMDA
 - EMA

Participate in interactive workshops and generate specific solutions to

- Specific challenges for PK/PD and potential for longer term adverse effects
- Animal models for pediatric diseases
- Pediatric outcomes and scales
- IRB/ethical issues