

**FDA-University of Maryland CERSI Public Workshop:
Development of Antihypertensive Therapies for Use in Pediatric Patients**
Dates: July 15 – 16, 2026
Hybrid/FDA White Oak Campus, Great Room
Silver Spring, MD

Background and Synopsis:

Treatment of chronic hypertension in pediatric patients, particularly children from birth to under 6 years of age, remains an area of unmet medical need, with limited FDA-approved therapies for use in this age group. Products are also being developed for the treatment of uncontrolled and/or resistant hypertension in adults. This public workshop will bring together key stakeholders, including clinicians, academicians, regulators, industry, and patients/caregivers, to discuss the similarities and differences in disease pathophysiology and drug response across age groups, determine the extent to which efficacy can be extrapolated, identify development priorities for both initial therapy and uncontrolled hypertension, and explore feasible strategies to generate evidence for the safe and effective use of antihypertensive treatment(s) in pediatric patients with hypertension.

DAY 1

Welcome & Introduction

Workshop Moderators:	<i>Lily Mulugeta, PharmD</i> <i>Associate Director for Policy and Research</i> <i>Division of Pediatrics and Maternal Health (DPMH), U.S. Food and Drug Administration (FDA)</i> <i>Kirtida Mistry, MD</i> <i>Medical Officer, Division of Cardiology and Nephrology (DCN), FDA</i>
9:00 AM – 9:10 AM	Welcome and Introduction <i>John Alexander, MD, MPH</i> <i>Deputy Director, Division of Pediatrics and Maternal Health (DPMH), FDA</i>
9:10 AM – 9:20 AM	Keynote Talk <i>Hylton Joffe, MD</i> <i>Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, FDA</i>
9:20 AM – 9:35 AM	Regulatory Framework for Drug Development in Children and Extrapolation of Safety and Efficacy Data from a Reference Population <i>Gilbert Burckart, PharmD</i> <i>Associate Director of Pediatrics, Office of Clinical Pharmacology, FDA</i>
9:35 AM – 9:55 AM	Landscape of Drug Development for Management of Hypertension <i>Kirtida Mistry, MD</i> <i>Medical Officer, Division of Cardiology and Nephrology (DCN), FDA</i>

Session 1: Chronic Hypertension

9:55 AM – 10:25 AM	Overview of Pediatric Hypertension and Similarities/Differences in Hypertension in Adults and Pediatric Patients <i>Joshua Samuels, MD (Virtual)</i> <i>Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth</i>
10:25 AM – 10:45 AM	Similarities and Differences in Response to Anti-hypertensive Agents in Adult and Pediatric Patients <i>Joseph T. Flynn, MD (Virtual)</i> <i>Professor, Pediatrics, University of Washington School of Medicine</i>
10:45 AM – 10:55 AM	BREAK
10:55 AM - 11:15 AM	Off-label Prescribing Practices <i>Doug Blowey, MD (Virtual)</i> <i>Medical Director, Chief Clinical Integration Officer, Children's Mercy Integrated Care Solutions</i>

11:15 AM – 11:30 AM	Off-label Prescribing: Medication Errors and Formulation Related Limitations <i>Rachel Meyers, PharmD</i> <i>Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University; Pediatric Clinical Pharmacist, Cooperman Barnabas Medical Center</i>
11:30 AM – 11:45 AM	Considerations for Age-Appropriate Pediatric Formulations—Industry Perspective <i>Lourdes Paola Contreras Chavez, PhD (Virtual)</i> <i>Associate Director, CMC, Paediatric SME, AstraZeneca</i>
11:45 AM – 12:00 PM	Q&A/Clarifying Questions
12:00 PM – 1:00 PM	Panel Discussion Moderator: <i>Mona Khurana, MD</i> <i>Medical Team Leader, Division of Pediatrics and Maternal Health, FDA</i>
	Panelists: <i>Joshua Samuels, MD (Virtual)</i> <i>Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth</i>
	<i>Joseph T. Flynn, MD (Virtual)</i> <i>Professor, Pediatrics, University of Washington School of Medicine</i>
	<i>Doug Blowey, MD (Virtual)</i> <i>Medical Director, Chief Clinical Integration Officer, Children’s Mercy Integrated Care Solutions</i>
	<i>Rachel Meyers, PharmD</i> <i>Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University; Pediatric Clinical Pharmacist, Cooperman Barnabas Medical Center</i>
	<i>Lourdes Paola Contreras Chavez, PhD (Virtual)</i> <i>Associate Director, CMC, Paediatric SME, AstraZeneca</i>
	<i>Fraz Ismat, MD</i> <i>Clinical Development, Mineralys</i>
	<i>Kirtida Mistry, MD</i> <i>Medical Officer, Division of Cardiology and Nephrology, FDA</i>

1:00 PM – 2:00 PM

LUNCH

Session 2: Extrapolation and Trial Design Considerations—Chronic Hypertension

2:00 PM – 2:15 PM	Dose-Response and Extrapolation of Efficacy from Older Pediatric Patients <i>Sudharshan Hariharan, PhD</i> <i>Master Pharmacokineticist, Office of Clinical Pharmacology, FDA</i>
2:15 PM – 2:30 PM	Safety Assessment and Pediatric Specific Considerations <i>Ricardo Fonseca Martins, MD</i> <i>Senior Medical Manager, Pharmacovigilance, E. Lilly and Company</i>

2:30 PM – 3:00 PM

Moderator:

Panel: Lessons Learned from Conducting Clinical Trials in Pediatric Hypertension

Jennifer S. Li, MD

Professor of Pediatric Cardiology, Duke Department of Pediatrics

Panelists:

Monica Bengus, MD (Virtual)

Principal Medical Director, Cardiovascular, Roche

Joshua Samuels, MD (Virtual)

Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth

Joseph T. Flynn, MD (Virtual)

Professor, Pediatrics, University of Washington School of Medicine; Chief, Division of Nephrology, Seattle Children's

Tammy McLoughlin Brady, MD, PhD

Medical Director, Pediatric Hypertension Program, Children's National Hospital

Fraz Ismat, MD

Clinical Development, Mineralys

3:00 PM – 3:10 PM

BREAK

3:10 PM – 3:25 PM

Dose Prediction and Modeling and Simulation — Industry Perspective

Maria Learoyd, PhD (Virtual)

Clinical Pharmacology & Safety Sciences, AstraZeneca

3:25 PM – 3:40 PM

Innovative Trial Designs and Leveraging Existing Data

Christine Ferrara-Cook, MD, PhD, MAS

Executive Director, Diabetes Clinical Design, Eli Lilly

3:40 PM – 4:40 PM

Moderator:

Panel and Stakeholder Discussion

Lynne Yao, MD

Director, Division of Pediatrics and Maternal Health, FDA

Panelists:

Aliza Thompson, MD, MS

Director, Division of Cardiology and Nephrology, FDA

Sudharshan Hariharan, PhD

Master Pharmacokineticist, Office of Clinical Pharmacology, FDA

Ricardo Fonseca Martins, MD

Senior Medical Manager, Pharmacovigilance, E. Lilly and Company

Jennifer S. Li, MD

Professor of Pediatric Cardiology, Duke Department of Pediatrics

Monica Bengus, MD (Virtual)

Principal Medical Director, Cardiovascular, Roche

Joshua Samuels, MD (Virtual)

*Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program,
McGovern Medical School, UTHealth*

Joseph T. Flynn, MD (Virtual)

Professor, Pediatrics, University of Washington School of Medicine

Tammy McLoughlin Brady, MD, PhD

Medical Director, Pediatric Hypertension Program, Children's National Hospital

Christine Ferrara-Cook, MD, PhD, MAS

Executive Director, Diabetes Clinical Design, Eli Lilly

Maria Learoyd, PhD (Virtual)

Clinical Pharmacology & Safety Sciences, AstraZeneca

4:40 PM – 4:50 PM

Closing Remarks

Lynne Yao, MD

Director, Division of Pediatrics and Maternal Health, FDA

DAY 2

Session 3: Management of Uncontrolled Hypertension

9:00 AM – 9:05 AM	Welcome and Setting the Stage <i>John Alexander, MD, MPH</i> <i>Deputy Director, Division of Pediatrics and Maternal Health, FDA</i>
9:05 AM – 9:20 AM	BaxHTN Baxdrostat Adult Phase 3 Clinical Trial <i>Pamela Zee, MD</i> <i>Head, Pediatric Center of Excellence, Cardiovascular, Renal, Metabolism, AstraZeneca</i>
9:20 AM – 9:35 AM	Uncontrolled Hypertension: Similarities/Differences Adult and Pediatric Patients Across Age Spectrum <i>Carissa M. Baker-Smith, MD, MPH</i> <i>Professor, Cardiologist, Director, Nemours Preventative Cardiology, Program, Nemours Children's Hospital, Professor of Pediatrics</i>
9:35 AM – 9:50 AM	Evaluation of Response—Treatment of Uncontrolled Hypertension in Adults Versus Pediatric Patients Across Age Spectrum <i>Tammy McLoughlin Brady, MD, PhD</i> <i>Medical Director, Pediatric Hypertension Program, Children's National Hospital</i>
9:50 AM – 10:00 AM	BREAK
10:00 AM – 11:20 AM	Panel Discussion
Moderator:	<i>Kirtida Mistry, MD</i> <i>Medical Officer, Division of Cardiology and Nephrology, FDA</i>
Panelists:	<i>Shamir Tuchman, MD, MPH</i> <i>Acting Deputy Director for Safety, Division of Rare Diseases and Medical Genetics</i>
	<i>Carissa M. Baker-Smith, MD, MPH</i> <i>Professor, Cardiologist, Director, Nemours Preventative Cardiology, Program, Nemours Children's Hospital, Professor of Pediatrics</i>
	<i>Tammy McLoughlin Brady, MD, PhD</i> <i>Medical Director, Pediatric Hypertension Program, Children's National Hospital</i>
	<i>Joshua Samuels, MD (Virtual)</i> <i>Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth</i>
	<i>Joseph T. Flynn, MD (Virtual)</i> <i>Professor, Pediatrics, University of Washington School of Medicine; Chief, Division of Nephrology, Seattle Children's</i>
	<i>Gilbert Burckart, PharmD</i> <i>Associate Director of Pediatrics, Office of Clinical Pharmacology, FDA</i>
	<i>Fraz Ismat, MD</i> <i>Clinical Development, Mineralys</i>

Pamela Zee, MD

Head, Pediatric Center of Excellence, Cardiovascular, Renal, Metabolism, AstraZeneca

11:20 AM – 11:30 AM

Closing Remarks

Aliza M. Thompson, MD

Director, Division of Cardiology and Nephrology, FDA
