Development of Antihypertensive Products for Use in Pediatric Patients

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration

Public In-Person Workshop
July 15, 2026 | 9:00 AM – 5:00 PM Eastern Time
July 16, 2026 | 9:00 AM – 11:30 AM Eastern Time

Biographies

John Alexander, PhD, MPH
Supervisory Physician
DPMH, ORDPURM, OND, CDER, FDA

Dr. John Alexander is Deputy Director of the Division of Pediatrics and Maternal Health in the Center for Drug Evaluation and Research at FDA. Dr. Alexander is a pediatrician who joined the US Food and Drug Administration in 1995 as part of a joint fellowship in pediatric infectious diseases with FDA and Children's National Medical Center. After completion of his fellowship, he became a full-time medical officer, and subsequently a team leader, in the Division of Anti-Infective Products. Dr. Alexander also obtained a Masters degree in Public Health (MPH) from the George Washington University School of Public Health in 2001. He has been involved in drug regulation and pediatric drug development for more than 30 years.

Carissa Baker-Smith, MD, MPH, FAHA, FACC, FAAP
Professor, Pediatrics
Sidney Kimmel Medical College of Thomas Jefferson University

Director, Pediatric Preventative Cardiology
Nemours Children's Health Delaware

Director
Nemours Cardiac Center for Research and Innovation

Dr. Carissa Baker-Smith is a board-certified (Pediatrics and Pediatric Cardiology) physician and physician-scientist. She is a nationally and internationally recognized Preventive Pediatric Cardiologist who specializes in the management of youth with risk factors for premature cardiovascular disease (CVD), including obesity, dyslipidemia, and hypertension (HTN). She is a Professor of Pediatrics at the Sidney Kimmel Medical College of Thomas Jefferson University, Director of Pediatric Preventive Cardiology at Nemours Children's Health Delaware (NCHD), and director of the Nemours Cardiac Center for Research and Innovation. Her research focuses on the intersection between social/environmental stress/deprivation and traditional risk factors for CVD development throughout childhood and adolescence. She uses mathematical models to evaluate antecedents of CVD risk factors in youth critically. She also leads pragmatic interventions to improve outcomes across populations.

Monica Bengus, MD
Principal Medical Director, Cardiovascular
Roche Clinical Science Lead

Dr. Monica Bengus is a Principal Medical Director Cardiovascular, Roche Clinical Science Lead in the partnership with Alnylam for the Zilebesiran program since 2023.

Monica, a board certified cardiologist, joined Roche in 2008, initially focusing on late-stage cardiometabolic programs and cardiovascular outcome studies.

Over the years Monica worked either in Clinical Science or Medical Affairs as Medical Lead on different stages of development, therapeutic areas (Anemia/Cardiometabolism; Respiratory; Ophthalmology) and molecules with constant contributions to the life cycle teams. Since 2018, Monica has been a co-lead of the internal cardiovascular safety expert group. Monica is a member of the European Society of Cardiology.

Douglas L. Blowey, MD
Associate Professor, Pediatrics and Pharmacology
Director, Hypertension Clinic, Division of Nephrology, Dept of Pediatrics
Medical Director
Children's Mercy Hospital, Kansas City

Chief Clinical Integration Officer
Medical Director
Children's Mercy Integrated Care Solutions

Dr. Douglas L Blowey is an Associate Professor of Pediatrics and Pharmacology; Director of the Hypertension Clinic in the Division of Nephrology in the Department of Pediatrics at Children's Mercy Hospital in Kansas City. He serves as the Medical Director of Children's Mercy Kansas and is also the Chief Clinical Integration Officer and Medical Director for Children's Mercy Integrated Care Solutions.

Dr. Blowey received his medical degree from the University of Kansas School of Medicine and completed a Pediatric residency and pediatric nephrology fellowship at Children's Mercy Hospital. After completing a Pediatric Clinical Pharmacology and Toxicology fellowship at Sick Children's in Toronto, Canada, he returned to the staff at Children's Mercy Hospital, where he focused on pediatric hypertension and pediatric clinical pharmacology. His work with Children's Mercy Integrated Care Solutions is focused on population health.

Tammy Brady, MD, PhD
Professor, Pediatrics
George Washington University

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

Dr. Tammy Brady is a Professor of Pediatrics at George Washington University and a pediatric nephrologist at Children's National Hospital where she serves as the Medical Director of the Pediatric Hypertension Program. She is also the Director of Hypertension and Kidney Health Research and the Director of the Grants Enhancement Program within the Center for Health Outcomes Research and Delivery Science.

She has focused her career on improving the care of children at increased cardiovascular disease risk through research and clinical innovation. In addition to her federally funded work aimed at cardiovascular health promotion in youth, she has participated in multiple local and national quality improvement initiatives geared toward improving elevated blood pressure recognition, hypertension diagnosis, and hypertension management in youth.

Gilbert J. Burckart, PharmD
Associate Director for Pediatrics
OCP, CDER, FDA

Dr. Gilbert Burckart is presently Associate Director for Pediatrics, Office of Clinical Pharmacology, US FDA. Dr. Burckart has served on the faculties of four universities (Buffalo, Tennessee, Pittsburgh, Southern California) for 33 years prior to coming to the FDA. He was a Professor of Pharmacy, Pediatrics, and Surgery. In Pittsburgh, he worked in the intensive care unit of Pittsburgh Children's Hospital for 20 years. He moved to the US FDA's Office of Clinical Pharmacology in 2008, where he heads the Pediatric Group in the Immediate Office, and is very involved in pediatric regulatory science and educational programs in the Office. He has been involved in the assessment of the use of pediatric extrapolation since joining the Agency in 2008.

Christine Ferrara-Cook, MD, PhD, MAS
Executive Director, Diabetes, Clinical Design
Eli Lilly, Indianapolis, IN

Dr. Christine Ferrara-Cook is a physician scientist and pediatric endocrinologist with expertise in diabetes, obesity, pediatric endocrine disorders, and disorders of hypoglycemia, spanning academic medicine and the biopharmaceutical industry. She earned a BS in Biology from the University of Notre Dame (2003) and dual MD/PhD degrees (Pharmacology and Cancer Biology) from the Duke University School of Medicine Medical Scientist Training Program (MSTP, 2009). Dr. Ferrara-Cook completed Pediatrics Residency and Pediatric Endocrinology Fellowship training at the Children's Hospital of Philadelphia (2012 and 2015, respectively) and is board certified in both Pediatrics and Pediatric Endocrinology. She subsequently served as Assistant Professor at the University of California, San Francisco, where she obtained a Master of Advanced Studies in Clinical Research (2018) and held an affiliation with the TrialNet Type 1 Diabetes research network, contributing as sub-investigator across multiple Type 1 diabetes trials and leading clinical trial design efforts.

Prior to joining Eli Lilly, Dr. Ferrara-Cook served as Medical Director at Crinetics Pharmaceuticals (2019-2024), where she led clinical development programs as the medical lead, targeting rare endocrine diseases, including pediatric-only indications. At Lilly, she serves within the Clinical Design team in Cardiometabolic Health, a function dedicated to the strategy and design of clinical trials across the full cardiometabolic pipeline, driving efficiencies across indications and accelerating delivery of medicines to patients. Dr. Ferrara-Cook is the medical clinical design lead for the diabetes and pediatrics pillars and leads efforts to advance novel solutions for pediatric clinical trial design challenges.

Joseph Flynn, MD, MS
Professor, Pediatrics
University of Washington School of Medicine

Member, Division of Nephrology
Seattle Children's Hospital

Dr. Joseph Flynn is a Professor of Pediatrics at the University of Washington School of Medicine, and a member of the Division of Nephrology at Seattle Children's Hospital. He completed his pediatric nephrology training at St. Christopher's Hospital for Children in Philadelphia, PA, and later received an MS in Clinical Research from the Albert Einstein College of Medicine, Bronx, NY. He is an internationally recognized expert in the treatment of hypertension in children, and in 2017 chaired the American Academy of Pediatrics Subcommittee that developed the updated clinical practice guideline on high blood pressure in children and adolescents. Dr. Flynn has published over 200 peer-reviewed papers and over 150 textbook chapters, invited reviews and editorials. He currently serves as one of the Editors-in-Chief of the journal Pediatric Nephrology. He has trained over 50 pediatric nephrology fellows, most of whom have faculty appointments at academic institutions, and several who currently hold leadership positions within various pediatric nephrology organizations.

Sudharshan Hariharan, PhD
Master Pharmacokineticist
DCEP, OCP, CDER, FDA

Dr. Sudharshan Hariharan is a Team Leader in the Division of Cardiometabolic and Endocrine Pharmacology in the Office of Clinical Pharmacology at the U.S. Food and Drug Administration. In his current role, Dr. Hariharan is involved in the clinical pharmacology review of drugs and biologics in the area of non-malignant hematology, and his past experience include review in the area of drug products for cardiovascular and renal diseases.

Dr. Hariharan received his PhD in Pharmaceutical Sciences from the University of Missouri-Kansas City with an emphasis on drug transporters, pharmacokinetics and ocular microdialysis. Dr. Hariharan's interests are in the areas of biopharmaceutics, drug interactions, pediatric drug development, and use of quantitative approaches to support drug dosing.

Fraz Ahmed Ismat, MD
Clinical Development Consultant
Mineralys Therapeutics, Inc.

Dr. Fraz Ismat is a consultant at FICC, LLC specializing in clinical development in cardiovascular, metabolic, pulmonary, and rare disease, and pediatric indications. He has worked in pharmaceutical development for over 16 years, beginning at Bristol-Myers Squibb where he led their Cardiovascular Advisory Committee on company-wide aspects of cardiovascular safety and was a member of their Pediatric Center of Excellence, training there under Ronald Portman. He later joined Insmed, leading their pulmonary hypertension program from preclinical development to completion of their global Phase 2 program. For the past 2 years Dr. Ismat has been assisting a number of biopharmaceutical companies in clinical development, including Mineralys Therapeutics with their pediatric development program.

Dr. Ismat completed his residency in Internal Medicine & Pediatrics at the Baylor College of Medicine in Houston, TX, followed by a fellowship in Pediatric Cardiology at the Children's Hospital of Philadelphia. He then went on to post-doctoral training in developmental biology in the laboratory of Jonathan A. Epstein at the University of Pennsylvania before starting his own laboratory at the Children's Hospital of Philadelphia.

Hylton Joffe, MD, MSSc
Director
OCHEN, OND, CDER, FDA

Dr. Hylton Joffe joined the FDA more than 20 years ago and has been the director of FDA's Office of Cardiology, Hematology, Endocrinology and Nephrology in CDER's Office of New Drugs for nearly five years. He is also a Part-Time Assistant Professor of Medicine in the Division of Endocrinology, Diabetes, and Metabolism at the Johns Hopkins University School of Medicine.

Over the course of his FDA career, Dr. Joffe has been involved in the regulation of drugs across a broad range of common and rare diseases. In his current role, he oversees more than 120 staff across five review divisions that regulate drugs and therapeutic biologics for cardiovascular, renal, endocrine, and nonmalignant hematologic disorders.

Mona Khurana, MD
Pediatric Team Leader
DPMH, ORDPURM, OND, CDER, FDA

Dr. Mona Khurana is board certified in general pediatrics and in pediatric nephrology. She obtained her undergraduate Bachelor of Science and Doctor of Medicine degrees from the George Washington University in Washington DC. Following her internship at Nicklaus Children's Hospital and residency at Yale New-Haven Children's Hospital, she completed a fellowship in Pediatric Nephrology at Children's Hospital Boston. In 2004, she joined the faculty at Children's National Hospital in Washington DC after her fellowship where she was an Assistant Professor of Pediatrics before joining FDA in 2009. Dr. Khurana initially worked as a Medical Reviewer in the FDA's Division of Nonprescription Drug Products in the Center for Drug Evaluation and Research (CDER). She moved to the Division of Pediatrics and Maternal Health (DPMH) as a Medical Reviewer in 2015 and has been a Pediatric Team Leader in DPMH since 2016 where her efforts have primarily focused on working collaboratively with review divisions in the Office of New Drugs to assist with pediatric drug development in all therapeutic areas.

Maria Learoyd, PhD
Head of Clinical PK Group
Clinical Pharmacology Director
AstraZeneca

Dr. Maria Learoyd is Head of the Clinical PK Group and a Clinical Pharmacology Director at AstraZeneca, with over 20 years of experience in clinical pharmacology and pharmacokinetics. She represents the Clinical Pharmacology function in AstraZeneca's CVRM (Cardiovascular, Renal, and Metabolism) Pediatric Centre of Excellence, providing strategic guidance on pediatric dose selection and regulatory strategy.

Dr. Learoyd has extensive experience leading clinical pharmacology submissions for global regulatory approvals. She led the clinical pharmacology programs for the ongoing submissions and subsequent approvals of Beyfortus (nirsevimab) for the prevention of RSV in pediatric populations. As Global Lead, she directed the clinical pharmacology strategy for the approval of Koselugo (selumetinib) for pediatric patients with neurofibromatosis type 1 and inoperable plexiform neurofibromas. She also led the clinical pharmacology efforts for the approval of Lynparza (olaparib) for oncology indications. Her current work includes leading the pharmacokinetic bridging requirements for oncology products transitioning from intravenous to subcutaneous dosing.

In addition to her project work, Dr. Learoyd leads the AstraZeneca Clinical Pharmacology Training Academy and serves on the Organizing Committee for the PKUK conference. She represents AstraZeneca in the ICH M13 initiative for the harmonization of global bioequivalence study design. She is the primary author of a book chapter on pharmacokinetic studies influenced by extrinsic factors, and her expertise includes applying PBPK and population PK modeling to support pediatric extrapolation. She earned her PhD from The University of Manchester

Jennifer S. Li, MD, MHS
Beverly C. Morgan Professor of Pediatrics (Cardiology)
Professor of Medicine
Duke University.

As a pediatric cardiologist, Dr. Jennifer S. Li has a long-standing research focus in clinical trials and outcomes studies that affect the cardiovascular system in children. She is noted for leading efforts in drug development for children to improve the dosing, safety, and efficacy of pediatric therapeutics, and for developing methods to study patient outcomes in children with heart disease. She has led several clinical trials and outcomes studies sponsored by the NIH and industry evaluating drugs treating hypertension, heart failure, and thrombosis in children with acquired and congenital heart disease. She has regulatory experience and a track record of translating research findings into medical practice and public policy as evidenced by her role as a Special Government Employee providing expertise in the analysis of safety in the pediatric population to the Food and Drug Administration in the Office of Pediatric Therapeutics. She was a member of the FDA Cardiovascular and Renal Drug Advisory Committee and served on an Institute of Medicine committee to evaluate Safe and Effective Medicines for Children.

Ricardo Fonseca Martins, MD
Executive Director, GPS Medical (Drug Safety & Pharmacovigilance)
Eli Lilly and Company

Dr. Ricardo Fonseca Martins is an Executive Director in GPS Medical, Drug Safety and Pharmacovigilance, at Eli Lilly and Company. Board-certified in pediatrics, pediatric cardiology, and pediatric intensive care, he built his clinical career in Brazil, where he coordinated a pulmonary hypertension outpatient unit and managed a cardiothoracic ICU, and completed a pediatric cardiology fellowship at Nationwide Children's Hospital in Columbus, Ohio. He has published on pediatric heart failure and congenital heart disease and spoken widely at national cardiology congresses on topics spanning congenital heart disease, pulmonary hypertension, and pediatric heart failure. Since joining Lilly in 2018, he has worked in pharmacovigilance and regulatory medical writing across FDA, EMA, and other health authorities. His talk, "Safety Assessment and Pediatric Specific Considerations," draws on this clinical and regulatory background to examine the challenges of evaluating antihypertensive therapies in children.

Rachel Meyers, PharmD, BCPS, BCPPS, FPPA
Clinical Professor
Ernest Mario School of Pharmacy, Rutgers University

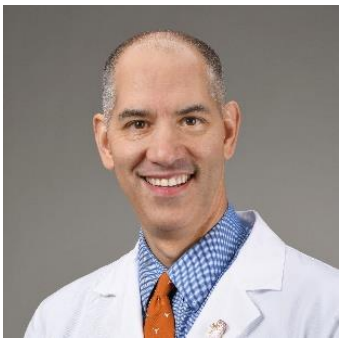
Pediatric Clinical Pharmacist
Cooperman Barnabas Medical Center, Livingston NJ

Dr. Rachel Meyers is a Clinical Professor at the Ernest Mario School of Pharmacy at Rutgers University, and the Pediatric Clinical Pharmacist at Cooperman Barnabas Medical Center in Livingston, New Jersey. Dr. Meyers completed her undergraduate degree at the University of Mary Washington and her Doctor of Pharmacy degree at the University of Connecticut. After graduation she completed a PGY-1 residency at the University of Wisconsin Hospital and Clinics in Madison, Wisconsin, and a PGY-2 residency in Pediatric Pharmacotherapy at the University of North Carolina Children's Hospital in Chapel Hill, North Carolina. In her current position, Dr. Meyers provides both didactic and experiential education in pediatric pharmacotherapy for pharmacy students and residents. She practices in both the Pediatric Intensive Care Unit and General Pediatric Unit at Cooperman Barnabas Medical Center. Dr. Meyers has been a participant in two clinical trials. Her research interests are focused on dosage forms for pediatric patients and medication safety for children.

Kirtida Mistry, MBBCh, DCH, MRCPCH
Senior Physician
DCN, OCHEN, CDER, FDA

Dr. Kirtida Mistry is a senior physician and clinical reviewer in the Division of Cardiology and Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Dr. Mistry is a pediatric nephrologist and board certified in Pediatrics and Pediatric Nephrology. Before joining FDA, Dr. Mistry was a Clinical Associate Professor of Pediatrics at the George Washington University, and an attending physician and Medical Director of Dialysis at the Children's National Health System in Washington, DC. Dr. Mistry completed her training in pediatrics at St. Louis Children's Hospital, Washington University School of Medicine, St. Louis, MO, and in pediatric nephrology at Children's Hospital Boston, Harvard Medical School, Boston, MA.

Joshua Samuels, MD, MPH, FAAP, FASH, FASN
Professor, Pediatrics & Internal Medicine
McGovern Medical School at UTHealth Houston



Dr. Joshua Samuels is a Tenured Professor of Pediatrics and Medicine and Division Chief of Pediatric Nephrology and Hypertension at McGovern Medical School at UTHealth Houston and at Children's Memorial Hermann Hospital. He received his medical degree from Baylor College of Medicine, completed a Medicine and Pediatric Residency at the University of Rochester, and then combined adult and pediatric nephrology fellowships at the University of Texas Health Science Center at Houston. As faculty at UTHealth since 2003, his academic appointment includes clinical care, clinical research, and academic teaching. Currently board certified in General Pediatrics, Nephrology, and Pediatric Nephrology, and a certified Specialist in Clinical Hypertension, he has been site PI for multiple funded multi-center projects including the NIH-funded Chronic Kidney Disease in Childhood (CKiD study) and the AHA-funded Study of Hypertension in Pediatrics: Adult Hypertension Onset in Youth (SHIP AHOY) study. Dr. Samuels has published over 100 peer reviewed scholarly articles, mostly in the field of Pediatric Hypertension. His clinical work focuses on diagnosing and managing hypertension in both children and adults.

Aliza Thompson, MD
Director
DCN, OCHEN, CDER, FDA

Dr. Aliza Thompson is Director of the Division of Cardiology and Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). The Division of Cardiology and Nephrology regulates and reviews Investigational New Drug applications and marketing applications for drug and biologic products for the treatment of cardiovascular and kidney diseases. Dr. Thompson joined the FDA in 2007. Prior to her current position, Dr. Thompson served as Deputy Director of the Division. Dr. Thompson received her medical degree from Johns Hopkins Medical School and completed her Internal Medicine and Nephrology training at Columbia University/New York-Presbyterian Hospital. She holds a Master of Science in Biostatistics/Patient Oriented Research Track from Columbia University Mailman School of Public Health.

Shamir Tuchman, MD, MPH
Acting Deputy Director
DRDMG, ORPURM, OND, CDER, FDA

Dr. Shamir Tuchman is the Acting Deputy Director for Safety for the Division of Rare Disease and Medical Genetics (DRDMG) within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In his current role, he works to facilitate development, review, and approval of drug and biologic products for the treatment of rare diseases. Prior to joining DRDMG, Dr. Tuchman served as a Senior Physician in the Division of Pediatrics and Maternal Health providing pediatric consultative expertise to CDER review divisions. Prior to joining the FDA, Dr. Tuchman worked as an Academic Pediatric Nephrologist in the Division of Pediatric Nephrology at Children's National Hospital where he directed the Pediatric Nephrology Fellow Program and was an Associate Professor of Pediatrics at The George Washington University School of Medicine. His research and clinical areas of interest during his time in academic medicine focused on bone and mineral metabolism abnormalities in pediatric patients with Chronic Kidney Disease.

Lynne Yao, MD
Director
DPMH, OND, CDER, FDA

Dr. Lynne Yao is the Director, Division of Pediatric and Maternal Health (DPMH) in the Office of New Drugs, Center for Drug Evaluation and Research. Dr. Yao received a BS degree in Biology from Yale University, and an MD degree from the George Washington University School of Medicine. She is board certified in both Pediatrics and Pediatric Nephrology. Prior to joining FDA, Dr. Yao was the Director of Dialysis and Associate Pediatric Residency Program Director at the Inova Fairfax Hospital for Children in Fairfax, VA. She has been with the FDA since 2008 and has been DPMH Director since 2012. As DPMH Director, Dr. Yao oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve collection of data to support the safe use of drugs and biological products in pregnant and lactating individuals. She collaborates with numerous stakeholders both inside and outside of FDA to advance development of safe and effective therapies for children, and pregnant and lactating women.

Pamela Zee, MD
Head, Pediatric Center of Excellence, Cardiovascular Renal and Metabolism Division
AstraZeneca

Dr. Pamela Zee heads AstraZeneca's Pediatric Center of Excellence (PCoE) within the Cardiovascular Renal and Metabolism (CVRM) division. This cross functional matrix team advocates for children through the optimization of pediatric drug development and strive to advance the field of pediatric medicine by enabling CVRM development teams to deliver impactful data while upholding the highest standards of integrity, compassion, innovation and scientific rigor. Additionally, she is a founding member of the AstraZeneca Paediatric Council, an enterprise level team under the Chief Medical Office whose mission is to drive efficiency and consistency where needed in a connective business environment to improve children's health.

Prior to joining AstraZeneca to establish and lead the novel business unit, CVRM PCoE in 2021, Pamela enjoyed 13 years at Bristol Myers Squibb (BMS). While at BMS, she served as medical lead of the Pediatric Center of Excellence.

Dr. Zee earned her BA and MD degrees at Vassar College and the University of Medicine and Dentistry of New Jersey (UMDNJ), respectively. After an internal medicine residency, she built an academic clinical practice as Assistant Professor of Medicine at UMDNJ where she operated as the Head of Clinical Research within Internal Medicine at Cooper University Hospital before joining the pharmaceutical industry.