Advancing the Development of Pediatric Therapeutics (ADEPT) 8 Workshop on Drug Dosing in Pediatric Patients with Renal Impairment

Speaker Biographies

Dr. Adam Levy is Executive Director, Head of the BMS Pediatric Center of Excellence. In his position, Adam is responsible for BMS' strategic approach to Pediatric Development and leads a cross-functional matrix team to ensure BMS is positioned to deliver robust, informed, and timely pediatric plans in response to the evolving pediatric global regulatory and therapeutic environment. Prior to working at BMS he spent 18 years at the Montefiore Health System where he most recently served as Vice Chair of Clinical Affairs and Strategy at the Children's Hospital at Montefiore and Professor of Pediatrics at the Albert Einstein College of Medicine. Over the course of his time at Montefiore/Einstein, Adam directed the pediatric oncology clinical trials program and was a Principal Investigator for the Children's Oncology Group.

Ashish Sharma is the Site Head of Clinical Pharmacology at Boehringer Ingelheim, USA. He is a pharmacist by training (Hamdard University, India) and obtained a Masters in Pharmaceutics at the Memorial University, Canada and a PhD in Clinical Pharmacology at the Laval University in Quebec, Canada in 2003. He has worked in the field of Clinical Pharmacology for almost 20 years of which 18 years were at Boehringer Ingelheim in different roles and locations. He worked as a clinical pharmacologist in Canada – 2 years, Germany – 12 years and USA - 6 years. He is actively involved in the various activities of the IQ organ impairment group and is a member of the IQ Clinical Pharmacology Leadership Group.

Dr. Bakri Alzarka is a pediatric nephrologist and the medical director of Pediatric Nephrology at the University of Maryland Children's Hospital and an Assistant Professor of Pediatrics at The University of Maryland School of Medicine. Dr. Alzarka completed his training in pediatrics at Marshall University and a fellowship in pediatric nephrology at Children's National Medical Center. Dr. Alzarka obtained a Master of Science degree in Clinical and Translational Research at George Washington University School of Medicine and Health Science. His clinical and research interests include inherited renal disorders, chronic kidney disease management and kidney transplantation.

Bradley A. Warady, M.D. is the McLaughlin Family Endowed Chair in Nephrology and Professor of Pediatrics at the University of Missouri-Kansas City School of Medicine. He is also Director, Division of Nephrology and Director, Dialysis and Transplantation at Children's Mercy Kansas City. Dr. Warady serves as Co-Principal Investigator of the NIH-funded Chronic Kidney Disease in Children (CKiD) Study and the International Pediatric Dialysis Network (IPDN). He is Vice President, Board of Directors of the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS), Member, Nephrologists Transforming Dialysis Safety (NTDS) committee of the American Society of Nephrology (ASN), National Board Member for the National Kidney Foundation (NKF), Lead Faculty for the Standardizing Care to Improve Outcomes in Pediatric End-Stage Kidney Disease (SCOPE) Collaborative, and Co-Chairperson of the pediatric component of the Annual Dialysis Conference (ADC). Dr. Warady served on the writing committees for the NKF-KDOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy and Bone Management and the Pediatric Renal Nutrition Task Force and he served as Chair of the writing committees for the KDOQI Guidelines for Nutrition in Children with CKD and for the International Society for Peritoneal Dialysis (ISPD) Pediatric Peritonitis guidelines. He has co-edited the books *CAPD/CCPD in Children, Pediatric Dialysis Case Studies* and three editions of *Pediatric Dialysis*, and he has published more than 700 articles and book chapters. Finally, Dr. Warady has received the J. Michael Lazarus Award from the National Kidney Foundation, the Karl V. Nolph Lifetime Achievement Award in Peritoneal Dialysis from the Annual Dialysis Conference, the Henry L. Barnett Award from the American Academy of Pediatrics and the Founder's Award from the American Society of Pediatric Nephrology.

Dr. Deepa Chand is a Board-Certified Pediatric Nephrologist with over 20 years of clinical, research, and teaching experience. She obtained her undergraduate Bachelor of Arts and Doctor of Medicine degrees from the University of Missouri at Kansas City. She also holds a Masters in Health Services Administration from Xavier University. After completing a residency in General Pediatrics at The Cleveland Clinic Foundation, she completed a fellowship in Pediatric Nephrology at Cincinnati Children's Hospital Medical Center. She has held prestigious faculty positions at The Cleveland Clinic Foundation, Akron Children's Hospital, and Rush University Medical Center, Washington University School of Medicine & St. Louis Children's Hospital, and currently maintains a clinical practice at the University of Illinois, College of Medicine-Peoria and Children's Hospital of Illinois. She has authored over 50 publications including co-editing "The Clinician's Manual of Pediatric Nephrology". She has received numerous teaching awards and community leadership recognition. Her passion remains the care of children with chronic kidney disease, especially end-stage kidney disease, with an emphasis on pediatric vascular access. She has co-chaired the Pediatric Fistula First Initiative and continues to be champion of optimizing dialysis access.

Deepa joined the pharmaceutical industry approximately 8 years ago and has experience with conducting Phase 1-3 Clinical Trials as a Clinical Development MD, and since as the Global Program Safety Lead for Zolgensma, the only approved systemic gene therapy, and currently serves as the Head of Patient Safety for Immunology at Novartis. She also chairs the Novartis Renal Advisory Group and has recently led the creation of Drug Induced Nephrotoxicity guidelines.

Efthymios Manolis is since 2007 a scientific officer in the European Medicines Agency. He is the EMA lead in the methodology domain M&S specialized interest area, and the modelling and simulation operational expert group. He is also an expert of the ICH M15 EWG. He is the author of multiple articles in peered reviewed journals. Before joining the Agency, Efthymios worked as a modeler in industry. Efthymios obtained his pharmacy degree from the National University of Athens, Greece, in 2002 and his MSc degree in PK/drug metabolism and modelling from Paris XI University, France, in 2003.

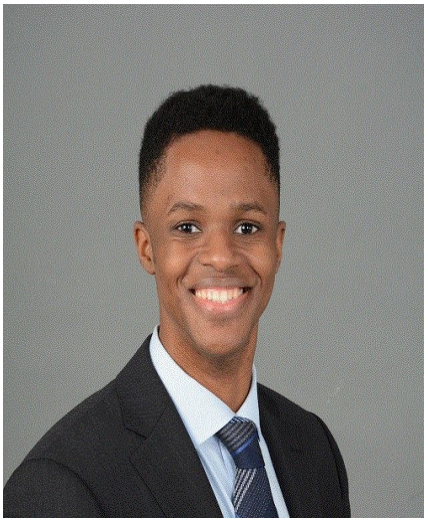
Elimika Pfuma Fletcher, PharmD, PhD, is a Policy Lead in the Office of Clinical Pharmacology (OCP) at the FDA. Her primary areas of focus are pediatrics and maternal pharmacology. She previously served as a Senior Clinical Pharmacology Reviewer supporting Oncology drug products from 2009-2016. She holds a Doctor of Pharmacy (PharmD) degree and a PhD in Pharmaceutical Sciences from the University of Houston College of Pharmacy.

Dr. Guido Filler MD, PhD, FRCPC. Dr. Filler is Professor of Paediatrics, with cross appointments to Medicine and Pathology and Laboratory Medicine at the University of Western Ontario and serves as Division Head of the Division of Paediatric Nephrology at Children's Hospital, London Health Sciences Centre since 2006. He has distinguished himself in all areas of academic life. He is an internationally recognized researcher in pediatric nephrology, he has excelled as a teacher and mentor, and as Chair of the Department of Paediatrics at Western, he has provided service and leadership to the academic community.

Henrietta Abodakpi, PharmD/PhD. Henrietta received her PharmD/PhD from the University of Houston College of Pharmacy in 2018, where her doctoral research focused on optimizing β-lactam/β-lactamase inhibitor dosing using PK/PD modeling. She joined the FDA's Office of Clinical Pharmacology (OCP) as a reviewer in 2019, focusing on traditional anti-infective drug development as well as development of medical countermeasures for chemical, biological or radiological threats under the Animal Rule pathway. Henrietta also currently serves as a representative on the OCP Labeling Initiative Working Group and Technical Evaluation Panel for Antibacterial Breakpoints within the FDA. In her free time, Henrietta enjoys cooking, hiking, dancing and spending time with friends and family.

Jan Marquard, MD, is a board-certified pediatrician and clinician scientist with extensive experience in both academia and the pharmaceutical industry. Notably, he has been involved in pediatric clinical development programs, including the development of the SGLT2 inhibitor empagliflozin for pediatric patients with type 2 diabetes.

Throughout his career, Dr. Marquard has consistently focused on innovative approaches to address evidence gaps and has excelled in designing and conducting clinical trials within a rapidly evolving healthcare landscape. Currently, he serves as the Executive Director and US Clinical Development Leader for Cardio-Renal-Metabolic indications at Boehringer Ingelheim, where he continues to apply his expertise in advancing treatments for these conditions.



Jason Moore, PharmD. Jason received a PharmD from Florida Agricultural & Mechanical University and completed a clinical pharmacology fellowship at Thomas Jefferson University. He joined the US Food and Drug Administration in 2016, and he now serves as a clinical pharmacology team lead in the Division of Cancer Pharmacology II. He supports the Division of Oncology 3, focused on review of drugs for the treatment of gastrointestinal cancer, superficial cutaneous cancers, melanoma, and sarcoma.

Dr. Karim Azer is a drug development leader with over 25 years of experience in pharma, biotech and global health. I have a passion for discovery and development of new drugs that address areas of unmet medical need through the application of advanced computational and systems biology technology. My experience in building cross-disciplinary teams and innovative digital biology platforms that integrate and apply advanced systems biology and pharmacology, computational biology, translational and mechanistic modeling, and cell biology capabilities has led me to work on many research, translational and clinical molecular candidates across a wide variety of rare and complex diseases, two of which are successful drugs on the market to date. Karim received his PhD in Applied Mathematics from the Courant Institute of Mathematical Sciences at NYU, and holds an M.S. in Applied Mathematics from Courant Institute at NYU, and B.S. degrees in Mathematics and Computer Science from Rutgers University.

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 at the Children's National Health System in Washington, DC, where she served as Medical Director of Dialysis. 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.

Liping Zhang, Ph.D, FCP, is a drug developer and clinical pharmacologist with over 20 years of experience, specializing in pediatric drug development. As a Senior Director in the Janssen Pediatric Strategy Team at Johnson and Johnson (JNJ) Innovative Medicine, Liping plays a critical role in providing key insights on dosing strategies and innovative study designs for pediatric clinical trials across JNJ's portfolio. She has designed, conducted, and analyzed numerous trials aimed at investigating the intricate relationship between renal function and its impact on pharmacokinetics, pharmacodynamics, and exposure response in both healthy subjects and patient populations.

Liping obtained her Ph.D. degree in Biological and Medical Informatics from the University of California, San Francisco, and has held various positions at Bristol-Myers Squibb and Eli Lilly & Company prior to joining JNJ.

Liping has published over 50 manuscripts in scientific journals and actively participates in conferences and workshops as a speaker and host. She is an industry representative on the PhRMA Modeling and Simulation Working Group. Committed to serving the scientific community, Liping has served as a member of the Editorial Board for the Journal of Clinical Pharmacology, Chair of the American Conference of Pharmacometrics, and Executive Board Member of the International Society of Pharmacometrics. She was also an instructor at Indiana University, Thomas Jefferson University, and Temple University.

Pieter Colin Pharm.D., Ph.D. Pieter currently works as a seconded national expert in the Scientific Advice Office at EMA, providing specialized expertise in Modelling and Simulation across the Agency. In addition, he is an associate professor of anesthesiology at the University Medical Center Groningen (The Netherlands) where he leads a pharmacometrics group with a focus on treatment individualization in anesthesia, peri-operative and critical care medicine. Pieter has (co-)authored more than 60 publications covering different topics related to pharmacometrics and is frequently involved in teaching principles of pharmacokinetics, pharmacodynamics, and clinical pharmacology to (post-)graduate students and healthcare professionals. Finally, Pieter is a member of the Modelling and Simulation Operation Expert Group at EMA and a consultant for the Belgian Medicines Agency (FAHMP).

Rebecca E. Wrishko Ph.D. is an Executive Director in Translational Medicine at Merck & Co. with over 20 years of drug development across two large pharmaceutical companies, including model-informed drug development, and global regulatory experience in small molecules and biotherapeutics. Dr. Wrishko has directly contributed to or has oversight of over 100 regulatory filings/approvals, 7 Advisory Committee Meetings with extensive experience across biopharmaceutics, clinical pharmacology and pharmacometric topics supporting global registration of drug candidates. In her current role, Dr. Wrishko leads life cycle development of medicinal products across multiple therapeutic areas including: Neuroscience, Cardiovascular, Endocrine, Infectious Diseases, Respiratory and Oncology, developing strategic plans to improve the quality, compliance and ultimately the outcome of registration activities primarily related to pediatric development. Through these activities, Dr. Wrishko has impacted regulatory decisions and proceedings through application of integrated biopharmaceutics, clinical and PKPD knowledge and model-based methodologies, delivering medicines to patients and prescribers meeting unmet needs. Dr. Wrishko is a co-chair of a Biopharmaceutics Advisory Team within Merck informing formulation and bridging strategies, emphasizing interdependencies between clinical and biopharmaceutics development plans and increasing application of model-based methods driving

development and regulatory decisions. Dr. Wrishko has established a strong record of publication with more than 30 articles and 40 presentations.

Prior to joining the Pharmaceutical industry, Dr. Wrishko completed a B.Sc. (Pharmaceutical Sciences) and M.Sc (Biochemistry) from the University of Alberta followed by a Ph.D (Clinical Pharmacy) at the University of British Columbia. Dr. Wrishko's Ph.D. research focused on Neonatology applying model-based applications to support drug characterization and application to therapeutic drug monitoring in addition to optimizing therapeutic drug monitoring in renal transplantation.

Professor Saskia de Wildt is professor of Clinical Pharmacology and pediatric intensivist at Radboud University, the Netherlands. Her research, largely supported by grants from ZonMW, EU and the Bill and Melinda Gates Foundation, focuses on individualizing drug therapy in children and pregnant women. She is director of the Dutch and International Pediatric Formulary consortium. De Wildt is director and founder of the Dutch pediatric trial network Pedmed-NL and co-lead of the advisory network of Conect4children, a European trial infrastructure. She has more than 200 international peer-review publications and received more than €9 million in research funding as a principal investigator.

Shamir Tuchman, MD, MPH. Shamir Tuchman is a Senior Physician in the Division of Pediatrics and Maternal Health (DPMH) within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In his current role at the FDA, he works within DPMH providing consultation to review Divisions for varied topics relating to drug product and device development for pediatric patients. 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.

Sonya Tang Girdwood, M.D., Ph.D., is a faculty member in the divisions of Hospital Medicine and Clinical Pharmacology at Cincinnati Children's Hospital Medical Center. She obtained her M.D. and Ph.D. at Johns Hopkins University School of Medicine where she studied topoisomerase poisons as potential therapies for malaria and African Sleeping Sickness and was first exposed to the field of Clinical Pharmacology through her mentor, Theresa Shapiro, M.D., Ph.D. She completed pediatric residency and chief residency at Cincinnati Children's Hospital Medical Center. During residency, she conducted her first clinical pharmacology studies in critically ill children under the mentorship of Alexander A. Vinks, Ph.D., Pharm.D., FCP and Jennifer Kaplan, M.D., MS. She stayed in Cincinnati for her Pediatric Hospital Medicine fellowship and her T32 NICHD Clinical Pharmacology fellowship, through which she met many role models in Clinical Pharmacology who have been critical mentors in her career as a pediatrician and clinical pharmacologist. She served as the T32 NICHD-NIGMS Clinical Pharmacology Fellowship Chief Fellow from 2018-2020 and used the opportunity to write white papers about the intersection of pediatrics and clinical pharmacology. During fellowship, she built the infrastructure at her institution to study beta-lactam concentrations in critically ill children to build population pharmacokinetics models to characterize antibiotic variability. In her first year of faculty, she received an NICHD K12 Career Development Award to study the relationship

between piperacillin concentrations and the development of acute kidney injury using novel biomarkers under the mentorship of Dr. Vinks, Dr. Kaplan and Stuart Goldstein, M.D. In August 2022, she received the NIGMS R35 Maximizing Investigator Research Award (MIRA) to continue building evidence for precision dosing of antibiotics in critical illness. Through this award, she is currently conducting multiple studies relating renal function and antibiotic pharmacokinetics. She has also published modeling and simulation studies of real-world antibiotic data in children receiving Continuous Kidney Replacement Therapy (CKRT). She is currently a co-director of the CCHMC NICHD-funded T32 Clinical Pharmacology Fellowship, the NICHD0-funded K12 Clinical Pharmacology Training Program and the CCHMC Genetic Pharmacology Service. She is the chair of the CCHMC Graduate Medical Education Research Subcommittee. She also serves on the ASCPT Scientific Programming Committee and in the first Leadership Accelerator Cohort.

Susan R. Mendley, MD. Dr. Mendley is a Senior Scientific Analyst in the Division of Kidney, Urologic and Hematologic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases. Her current portfolio includes research related to acute and chronic kidney diseases that affect children, including the Pediatric Centers of Excellence in Nephrology, as well as basic, translational and clinical research in adult chronic kidney disease, dialysis, and transplantation. She also oversees clinical and translational research in polycystic kidney disease, including the Polycystic Kidney Disease Research Resource Consortium. She is the Executive Secretary of the Kidney Interagency Coordinating Committee which was established by Congress in 1987 to encourage cooperation, communication, and collaboration among all Federal agencies involved in kidney research and other kidney disease-related activities.

Su-Young Choi, Pharm.D., Ph.D is a Master Scientist in the Division of Infectious Disease Pharmacology, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, US Food and Drug Administration. She is primarily responsible for leading scientific and regulatory assessments on clinical pharmacology aspects of antiviral drug development. Particularly, she has been extensively involved in the research and regulation of investigational products being developed for emerging viral infections and counter-terrorism such as HIV, viral hepatitis, COVID-19, influenza, smallpox, or Ebola where clinical pharmacology often plays pivotal role in making critical recommendations for product use in pediatric patients. Dr. Choi obtained her Pharm.D. and Ph.D. at the University of Illinois at Chicago.

Thomas D. Nolin, PharmD, PhD, FCCP, FCP, FASN is Associate Dean for Research and Sponsored Programs, and he is Director of the Small Molecule Biomarker Core mass spectrometry facility at the University of Pittsburgh School of Pharmacy. His research focuses on characterizing the impact of kidney disease and kidney replacement therapy on drug exposure and response, evaluating the functional expression of drug metabolizing enzymes and transporters, developing novel quantitative analytical techniques, and assessing the implications of using various kidney function estimating equations on drug eligibility, selection, and dosing. Dr. Nolin serves on the editorial board of the *Clinical Journal of the American Society of Nephrology*, and as an Editor of *DiPiro's Pharmacotherapy: A Pathophysiologic Approach* textbook. He is a Fellow and current Treasurer of the American College of Clinical Pharmacology, a Fellow of the American College of Clinical Pharmacy, and a Fellow of the American Society of Nephrology.

Dr. Tsuyoshi Fukuda is a Senior Director for Exploratory Medicine and Pharmacology at Eli Lilly and Company. He is currently supporting multiple early-phase clinical trials and bio-pharm/clinical pharmacology studies including renal impairment study and pediatric studies. He is also an active member of the Center of Excellence in Pediatrics, a company-wide pediatric initiative at Lilly.

Before joining Lilly, Dr. Fukuda served as an Associate Professor of Pediatrics at the University of Cincinnati College of Medicine for over a decade and devoted his expertise to numerous translational projects in pediatric clinical pharmacology and pharmacometrics within the Division of Clinical Pharmacology at Cincinnati Children's Hospital Medical Center.

Dr. Fukuda earned his Ph.D. degree from Osaka University in 2000, where he served as an Assistant Professor before moving to the US. His dedicated scientific and educational contributions to the field of clinical pharmacology have resulted in more than 120 peer-reviewed publications and a multitude of awards and recognitions, not only for himself but also for his trainees and colleagues.