Duke | Robert J. Margolis, MD Center for Health Policy

Measuring Clinical Benefit in Neonatal Randomized Clinical Trials: Challenges and Opportunities

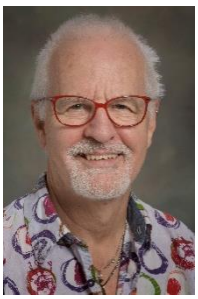
Hybrid Public Workshop
March 23, 2023 | 9:00 am – 4:30 pm ET

Biographies

Gerri Baer, MD, FAAP is a Medical Officer and Team Leader in the Division of Hepatology and Nutrition in the Center for Drug Evaluation and Research (CDER) at the FDA. She currently works with a team managing a portfolio of parenteral nutrition products and drugs to treat liver diseases. Before transferring to CDER in 2022, Dr. Baer was a supervisory team leader for Pharmacovigilance and Neonatology in the Office of Pediatric Therapeutics (OPT) at the FDA.

Dr. Baer began her work at the FDA in 2015 and established OPT's Neonatology Team, with a primary charge of providing Neonatal-Perinatal Medicine consultation services to the product development Centers across the Agency. She also led the OPT Pharmacovigilance Team, working with the Centers to ensure pediatric product safety. Dr. Baer has been involved in developing FDA guidance documents pertinent to neonatology clinical studies and represents the FDA in the International Neonatal Consortium (INC). She has co-authored related publications and book chapters and is involved in regulatory science research projects.

She completed pediatric residency and chief residency at Mount Sinai Medical Center and worked as a NICU hospitalist prior to neonatology fellowship training at the Children's Hospital of Philadelphia. Prior to joining the FDA in September of 2015, she worked for 8 years as an attending neonatologist in a level III NICU in Maryland.



Keith Barrington, MB, ChB is a neonatologist at Ste Justine Hospital in Montreal, and Professor of Pediatrics at the University of Montreal since September 2008.

He received his medical training in England at the University of Liverpool, and his initial post-graduate training in the UK. He moved to Canada in 1983 for a neonatal fellowship in Edmonton Alberta, since then he has been a neonatologist and Professor of Pediatrics at the University of Alberta Hospitals, University of California San Diego, and McGill University.

He has served as chair of the Fetus and Newborn Committee of the Canadian Paediatric Society, and as chair of the Society of Neonatologists of Quebec.

His research interests are in apnea and respiratory control, in cardiovascular adaptations and circulatory support, reducing lung injury, in ethical decision making, and in any clinical research in neonatology which might improve outcomes.

He is an active blogger at neonatalresearch.org, and the father of an extremely preterm baby.

Diana W. Bianchi, MD is the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). Dr. Bianchi oversees an annual budget of approximately $1.6 billion in support of NICHD's mission to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. Dr. Bianchi is also head of the Prenatal Genomics and Therapy Section for the Medical Genetics Branch at the National Human Genome Research Institute.

Dr. Bianchi received her M.D. from Stanford University School of Medicine and her postgraduate training in Pediatrics, Medical Genetics and Neonatal-Perinatal Medicine at Boston Children's Hospital and Harvard Medical School. Dr. Bianchi's research focuses on prenatal genomics with the goal of advancing noninvasive prenatal DNA screening and diagnosis to develop new therapies for genetic disorders that can be administered prenatally.

Prior to coming to NICHD, she spent 23 years at Tufts Medical Center, where she was the founding Executive Director of the Mother Infant Research Institute, as well as the Natalie V. Zucker Professor of Pediatrics, Obstetrics, and Gynecology at Tufts University School of Medicine. Dr. Bianchi also was the Vice Chair for Pediatric Research at the Floating Hospital for Children, Boston, and served for a time on the NICHD advisory council. She is a Past President of the International Society for Prenatal Diagnosis and the Perinatal Research Society. She is a former member of the Board of Directors of the American Society for Human Genetics and a former council member of both the Society for Pediatric Research and the American Pediatric Society. She was elected to membership in the National Academy of Medicine (formerly the Institute of Medicine) in 2013.

Dr. Bianchi has received multiple awards, including the 2015 Neonatal Landmark Award from the American Academy of Pediatrics, the 2016 Maureen Andrew Award for Mentorship from the Society for Pediatric Research, and the 2017 Colonel Harland Sanders Award for lifetime achievement in Medical Genetics from the March of Dimes. In 2020, she received an honorary doctorate from the University of Amsterdam and received the Health Public Service Visionary Award from the Society for Women's Health Research. Dr. Bianchi was a finalist for the Samuel J. Heyman Service to America Medal in 2022.

JaNeen Cross, DSW, MBA, MSW is an Assistant Professor at Howard University School of Social Work. She is an expert and leader in maternal child health. She has a mayoral appointment with the District of Columbia, Maternal Mortality Review Committee. She is the former President of the National Association of Perinatal Social Workers (NAPSW) and is on the Board of Directors for the DC Chapter of Postpartum Support International. . Dr. Cross is the former National Association of Social Workers (NASW), Health Education and Leadership Scholars (HEALS), post-doctoral, health policy fellow.

Dr. Cross' research interest includes maternal and child health disparities, mental health, and health policy. She is Co-PI on the Mental Health Awareness Training (MHAT) grant funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). Dr. Cross is co-investigator for Preparing Responsive and Effective School Social Workers (PRESS) a school-based mental health program funded by the Department of Education. Dr. Cross is a Research Fellow with the Center for Financial Security (CFS).

Dr. Cross received her Doctorate of Clinical Social Work from the University of Pennsylvania, Master of Business Administration from Rosemont College, Bachelor and Master of Social Work from Temple University. Dr. Cross is in private practice with clinical licenses in Pennsylvania, Maryland, and the District of Columbia.

Ashley Darcy-Mahoney, PhD, NNP-BC, FAAN a neonatal nurse practitioner and researcher, has worked throughout her career to advance nursing research, education and practice, with a focus on neonatology, infant health and developmental pediatrics. Her research has led to the creation of programs that improve health and developmental outcomes for at-risk and preterm infants.

As a tenured professor of nursing and the director of infant research at George Washington University's Autism and Neurodevelopmental Disorders Institute, Dr. Darcy-Mahoney advances the body of research in infant health and developmental outcomes in high-risk infants with a focus on understanding the early brain and development trajectories in this population. As a Neonatal Nurse Practitioner with PEDIATRIX, she leads a team of advanced practice providers in offering evidence based family centered to neonates and their families.

Dr. Darcy-Mahoney was a Robert Wood Johnson (RWJ) Nurse Faculty Scholar, a 2017 Josiah Macy Scholar, a fellow of the American Academy of Nurses, and recently served as the National Academy of Medicine Nurse Scholar in Residence. She has earned numerous awards, including the 2014 March of Dimes Nurse of the Year (FL) , Florida Association of Neonatal Nurses President's Award and the Lillian Sholtis Brunner Award for Innovation from her alma mater, the University of Pennsylvania.

Deb Discenza created PreemieWorld as the go-to space for patient education for the preemie community including the acclaimed book, The Preemie Parent's Survival Guide to the NICU. When not sought after for speaking engagements, media and news-related spots for the medical and general public, Deb provides public service to her community in the form of being a founding member and steering committee member of the National Premature Infant Health Coalition and a founding member and former Leadership team member of the NICU Parent Network. Additionally, she is a Leadership Team member of the International Neonatal Consortium is also is a regular Column Editor for Neonatal Network Journal, and a columnist for both the quarterly newsletter for the Council of International Neonatal Nurses (COINN) and for Neonatal Intensive Care magazine. In 2020 she was a co-founder of the Alliance for Black NICU Families, a racial and health equity non-profit changing policy and equalizing access with an initial project in the form of a free wearable breast pump to help Mom and baby in the NICU. She is also working on Preemie Crystal Ball as a data portal that can better inform patients and pros through the lifespan.

Daniel Fuentes, PharmD is Director of Medical Affairs and Chair of the Grants Committee for Chiesi USA, leading medical affairs for the Neonatology and Cystic Fibrosis portfolio in the US. Since joining Chiesi USA in 2014, he has made significant contributions to the organization by driving innovation in medical affairs and directing several research initiatives within the neonatal therapeutic area.

With a focus on neonatal respiratory distress syndrome and surfactant therapy, Daniel works in partnership with neonatal clinical experts to identify and address evidence gaps which arise through the continual advancement of clinical practice. He oversees the evaluation of non-registration clinical research, including investigator sponsored research; observational research; and develops data generation strategies for the therapeutic area. Daniel has led his medical team's collaboration across the drug lifecycle, supporting clinical development and regulatory departments on three neonatal development programs at Chiesi USA. Through Daniel's leadership, Chiesi USA has been able to enhance its reputation as a leading pharmaceutical company committed to improving the lives of preterm infants.

Prior to his tenure at Chiesi USA, Daniel contributed to the cytogenetics and microarray programs at LabCorp's Center for Molecular Biology and Pathology, and at the Institute for Pharmacogenomics and Individualized Therapy at the University of North Carolina at Chapel Hill. Daniel received his Pharm.D. degree from the University of North Carolina's Eshelman School of Pharmacy.

Dionna J. Green, MD, FCP is the Director of the Office of Pediatric Therapeutics (OPT) in the Office of the Clinical Policy and Programs in the Office of the Commissioner at the US Food and Drug Administration (FDA). OPT is a congressionally mandated office whose mission is to assure access for children to innovative, safe, and effective medical products. Dr. Green oversees an organization that is responsible for spearheading, coordinating, and facilitating cross-cutting activities of the FDA in the areas of pediatric health and product development, pediatric ethics, neonatology, rare diseases, pharmacovigilance, international collaboration, regulatory science, and education and outreach.

Prior to her current position, Dr. Green served as the Deputy Director of OPT. Dr. Green originally joined the FDA in 2009 and worked in the Office of Clinical Pharmacology (OCP), in the Center for Drug Evaluation and Research (CDER) as a Medical Officer with the Pediatric Clinical Pharmacology Staff where she was engaged in regulatory science research and policy work focused on identifying strategies for improving the design, efficiency, and success rates of pediatric drug development trials. She subsequently became a Medical Officer/Policy Lead with the OCP Guidance and Policy Team, which was charged with the systematic identification, development, and implementation of contemporary clinical pharmacology-related FDA guidances, policies and procedures.

Dr. Green has given numerous invited national and international presentations and published several peer-reviewed articles and book chapters on topics such as pediatric clinical pharmacology, pediatric clinical trial design, and pediatric product development and regulatory considerations. Dr. Green received her medical degree from the Howard University College of Medicine in Washington, D.C., and clinical training in pediatric medicine from the Herman & Walter Samuelson Children's Hospital at Sinai in Baltimore. She completed a clinical pharmacology research fellowship at the Georgetown University

Drug Discovery Program, and a regulatory science fellowship with the FDA Commissioner's Fellowship Program. Dr. Green is currently the President of the American College of Clinical Pharmacology (ACCP), as well as a Fellow of ACCP. She also serves as the ACCP Senior Representative to the Association of American Medical Colleges (AAMC) Council of Faculty and Academic Societies (CFAS)

Kevin Hill, MD, MS is Professor of Pediatrics and Division Chief of Pediatric Cardiology at Duke University Medical Center with a joint appointment at the Duke Clinical Research Institute. His research focus is on improving outcomes for children with heart disease with a specific focus on early and late phase clinical trials.

Erik Jensen, MD, MSCE is a clinician-scientist with a research interest focused on bronchopulmonary dysplasia and the long-term respiratory health of premature infants. His studies aim to (1) develop evidence-based strategies to prevent and treat BPD; (2) develop novel characterizations of disease severity and phenotype in BPD.

Naomi Knoble, PhD is a pediatric psychologist specializing in neuropsychology and is the Associate Director of Rare Disease Measurement Science, Division of Clinical Outcome Assessment (DCOA), Office of Drug Evaluation Science (ODES), Office of New Drugs (OND), Center for Drug Evaluation Research (CDER), with the US Food and Drug Administration (FDA). Dr. Knoble has a PhD in Counseling Psychology from the University of Oregon and completed clinical training in neurodevelopmental conditions at the Oregon Health & Science University and University of Minnesota Medical School. Prior to FDA, Dr. Knoble was a research scientist in patient-centered outcomes and post-market evidence generation. Dr. Knoble is the FDA liaison for the Critical Path Institute's Rare Disease Clinical Outcome Assessment Consortium.

Matthew M. Laughon, MD, MPH is a Professor, with Tenure, in the Division of Neonatal-Perinatal Medicine and Vice Chair for Academic Affairs in the Department of Pediatrics at The University of North Carolina at Chapel Hill (UNC). Dr. Laughon has served as the primary mentor or co-mentor at UNC or Duke for >25 trainees. He has published >160 peer reviewed articles in neonatal epidemiology, pharmacoepidemiology, and clinical pharmacology, including >60% with a trainee as a first author. He receives support from the US government for work in neonatal clinical pharmacology and clinical trials (FDA R01, PI Laughon; NHLBI K24, PI Laughon; NHLBI R33/R61, PI Laughon, and NICHD Pediatric Trials Network, PI Benjamin, Duke) and as the satellite site PI for the NICHD Neonatal Research Network (PI: Cotten, Duke) and is the PI for the NICHD NRN patent ductus arteriosus trial. He is or has been the Protocol Chair of 6 NICHD PTN trials of 10 off-label therapeutics in infants. He also serves as a member of the NICHD PTN Steering committee.

Monica Lemmon, MD is an Associate Professor of Pediatrics and Population Health Sciences at the Duke University School of Medicine, where she also serves as the Associate Dean for Scientific Integrity. Dr. Lemmon is a fetal and neonatal neurologist and co-directs Duke's Neuro-Intensive Care Nursery program alongside colleagues in neonatology. She serves as core faculty within the Duke-Margolis Center for Health Policy and as associate faculty within the Trent Center for Bioethics, Humanities, and the History of Medicine.

Dr. Lemmon's research program centers on prognostic communication, shared decision making, and the caregiver experience of infant illness. In 2021, she was awarded the Philip R. Dodge Young Investigator Award by the Child Neurology Society. Dr. Lemmon's work has been funded by the National Institute of Neurological Disorders and Stroke, American Academy of Neurology, and National Palliative Care Research Center.

Hilary Marston, MD, MPH, Chief Medical Officer of FDA, serves as the primary clinical advisor to the Commissioner and oversees the Office of Clinical Policy and Programs. She leads cross-cutting initiatives that support the FDA's centers in making effective, safe, and innovative medical products available for patients.

Dr. Marston previously served as the Senior Advisor for Global COVID-19 Response on the White House COVID-19 Response Team. Her previous roles also include Director for Medical Biopreparedness and Response at the U.S. National Security Council and Medical Officer and Policy Advisor for Pandemic Preparedness at the National Institute of Allergy and Infectious Diseases, National Institutes of Health. Dr. Marston also served in positions with McKinsey & Company and the Bill & Melinda Gates Foundation.

Dr. Marston trained in Internal Medicine and Global Health Equity at Brigham & Women's Hospital. She completed her M.P.H. at the Harvard T.H. Chan School of Public Health.

An N. Massaro, MD is a pediatrician and neonatologist and her prior research broadly centers on neonatal neurology and neuroprotection. She did her medical training at Weill Medical College of Cornell University and post graduate training in pediatrics and neonatal-perinatal medicine at Children's National in Washington, D.C. She joined the faculty and currently continues part-time as an Adjunct Professor of Pediatrics at The George Washington University School of Medicine and attending in the neonatal intensive care unit at Children's National Hospital. She joined the FDA in August of 2020 and currently serves as a Supervisory Medical Officer overseeing the Neonatology and Rare Pediatric Disease Team in the Office of Pediatric Therapeutics in the Office of the Commissioner.

Susan McCune, MD joined PPD in 2021 from the Food and Drug Administration (FDA) where she was the Director in the Office of Pediatric Therapeutics (OPT) in the Office of the Commissioner. She joined the FDA in 2003 in the Division of Pediatric Drug Development, Office of Counter-Terrorism and Pediatric Drug Development, in the Center for Drug Development and Research (CDER). From 2005 through 2009, Dr. McCune held the positions of Associate Director and team leader in the Office of Counter-Terrorism and Emergency Coordination in CDER. She joined the Office of Translational Sciences in CDER in February, 2010 as the Deputy Director, staying in that position until January, 2017. In addition to the Deputy role, she was the lead for the Translational Medicine Team, the co-director of the Biomarker Qualification Program, and the scientific lead for the Critical Path Innovation Meetings program. In 2015, Dr. McCune worked with the Critical Path Institute to launch the International Neonatal Consortium (INC). Prior to joining the FDA, Dr. McCune was an Associate Professor in the Department of Neonatology at Children's National Medical Center.

Dr. McCune received her medical degree from George Washington University following her undergraduate degree at Harvard University. She completed her internship, residency, chief residency, and neonatal fellowship at Children's National Medical Center in Washington, D.C. She is Board Certified in Pediatrics and Neonatal/Perinatal Medicine. For 15 years, while practicing academic pediatric and neonatal medicine at Johns Hopkins and Children's National Medical Center, Dr. McCune continued her molecular biology research on adrenergic receptor ontogeny and expression in models of newborn brain injury in the Lab of Developmental Neurobiology, NICHD, NIH. In addition, she has a Masters in Education Technology Leadership from George Washington University, and certificates in Public Health from Georgetown and Regulatory Science from USC.

Martin Offringa, MD, PhD is a is a staff physician in the Division of Neonatology in the Hospital for Sick Children and Professor at the University of Toronto's Institute of Health Policy, Management and Evaluation. He is a Senior Scientist in the Child Health Evaluative Sciences Program in SickKids' Research Institute. Trained in Amsterdam, Rotterdam and at Tufts University in Boston, he is Professor of Clinical Epidemiology at the University of Amsterdam, founding director of the Dutch National Paediatric Pharmacotherapy Expertise Network, the Medicines for Children Research Network, and the Netherlands' paediatric drug prescribing tool Kinderformularium. Since 2009, he chairs the Steering Group of StaR Child Health, an international initiative that aims to enhance the design, conduct and reporting of **clinical trials in children**. He currently leads the Method Core of two CIHR-funded four year project in SPOR Innovative Paediatric Clinical Trials and INFORM RARE, and an international research group that develops, validates and implements a new reporting standards for trial outcomes and for outcome measurement instruments' measurement properties.

Claudia Pedroza, PhD is Professor in Pediatrics at the UT Health Medical School's Center for Clinical Research and Evidenced-Based Medicine. Dr. Pedroza is a biostatistician with expertise in design, implementation, and analysis of Bayesian multicenter trials. During the past 15 years, she has collaborated with clinical investigators in the design and conduct of more than 30 Bayesian adaptive clinical trials on numerous medical fields including traumatic brain injury, stroke, obstetrics and gynecology, and pediatrics. She is currently co-investigator on 4 NIH- and 4 DOD-funded studies, and has served as lead biostatistician on 2 NIH-funded multicenter pediatric surgery trials. Dr. Pedroza has developed Bayesian designs for 3 NICHD Neonatal Research Network hypothermia trials and has participated in 3 other NRN trials. She has co-authored more than 150 peer-reviewed publications including papers in NEJM, JAMA, BMJ, Nature Communications, Pediatrics, and Obstetrics and Gynecology. Her research has focused on application of Bayesian methods in clinical trials to address major therapeutic questions in fields where it has been historically difficult to conduct randomized controlled trials, e.g., pediatrics and surgery. She teaches courses in biostatistics, clinical research methods, clinical trials, and advanced study design. She has mentored more than 20 junior clinical investigators. She has been a scientific reviewer on numerous PCORI panels and has served as Associate Editor for the journals Trials and Cardiovascular Pathology. She received a PhD in Statistics from Harvard University.

Morgan Romine, MPA is Chief of Staff for the Robert J. Margolis, MD, Center for Health Policy at Duke University, and head of the Center's Washington, DC, office. In this role, he guides development and implementation of the Center's strategic priorities across its research and education portfolios by serving as a coordination and communications bridge within the Center and with external collaborators. This includes direct oversight of a number of strategic research projects and policy efforts, development of key public and private sector relationships, and the occasional all-hands hijinks. Since early 2020, Morgan has also served as the Center's internal point of coordination and execution for policy and research efforts focused on the US and international COVID-19 response. Prior to joining the Duke-Margolis Center's founding team in 2016, he held several research positions in the Brookings Institution's Center for Health Policy, with a primary focus on US FDA regulatory policy and medical product development and access challenges. Morgan holds a Masters of Public Administration from Syracuse University's Maxwell School of Citizenship and Public Affairs, and degrees in Molecular Biology and Bioethics from William Jewell College in Liberty, Missouri.

Betsy Pilon is the Executive Director of Hope for HIE, the premiere global nonprofit patient advocacy group dedicated to improving the quality of life for children and families impacted by neonatal and pediatric-acquired Hypoxic Ischemic Encephalopathy (HIE) through awareness, education and support. Hope for HIE connects over 8,000 families, researchers, clinicians and the greater community, worldwide, through a comprehensive support network.

After her own son, Max, was born in 2012 with HIE, it was difficult to find educational resources or connections with other families. Eventually, she found a small group of families gathering on social media. Working with the existing group, she led the efforts to start the grassroots nonprofit foundation in 2013. As a result, Facebook recognized her in 2019 as one of the top community leaders on the platform for building community.

She is an accomplished speaker, writer, advocate, and connector with a background in marketing and corporate communication in healthcare, education and automotive. She serves on the Board of Directors for the Newborn Brain Society, co-chairing the Communication & Networking Committee. In her local community, she serves as the parent co-chair of the Bloomfield Hills School District Special Education Parent Advisory Council.

Barbara Schmidt, MD, MSc is a neonatologist and clinical epidemiologist who led several large international neonatal randomized trials with clinically important, long-term outcomes:

1. Trial of Indomethacin Prophylaxis in Preterms (TIPP)
2. Caffeine for Apnea of Prematurity (CAP) Trial
3. Canadian Oxygen Trial (COT)

These studies were coordinated by the Neonatal Trials Group at McMaster University in Hamilton, Ontario, Canada and supported by the Canadian Institutes of Health Research. The CAP trial was chosen by the Society for Clinical Trials for its inaugural Trial of the Year Award in 2008 (now named the David Sackett Annual Trial of the Year Award). Currently, Dr. Schmidt is a Professor (Part-time) in the Department of Health Research Methods, Evidence, and Impact at McMaster University, and a Professor Emerita at the University of Pennsylvania in Philadelphia. From 2011 until 2018, she was the principal investigator for the University of Pennsylvania and Children's Hospital of Philadelphia in the Neonatal Research Network of the National Institute of Child Health and Human Development. Throughout her career, she has mentored talented neonatal trainees who were enthusiastic about evidence-based neonatal practice and clinical research. Dr. Schmidt has received the highest honors in her specialty, including the Douglas K Richardson Award from the Society for Pediatric Research, the Virginia Apgar Award from the American Academy of Pediatrics, and the Arvo Ylppö Medal from the Finnish Pediatric Research Foundation. She is a member of the Order of Canada.

Kanwaljit Singh, MD, MPH is the Executive Director of C-Path's International Neonatal Consortium (INC) and Director of Pediatric Programs in Tucson, Arizona. Dr. Singh comes to C-Path from University of Massachusetts Medical School (UMass), Worcester, MA, where he worked for more than seven years as Instructor of Pediatric Neurology. At UMass, Dr. Singh's research focused on evaluating novel treatment options for Autism Spectrum Disorders (ASD) and evaluating the safety and efficacy of a small molecule (Sulforaphane) present in broccoli sprouts in the treatment of ASD. Dr. Singh has also done extensive research and has numerous publications in pediatric epilepsy. Before UMass, he worked in ASD research at Lurie Center for Autism at Massachusetts General Hospital/Harvard Medical School in Boston. In addition to his research work, Dr. Singh also served on the IRB committees at Harvard Medical School and interacted with regulatory authorities, including the FDA. His experience also includes the testing of medical devices in hypertension and diabetes mellitus.

Janet Soul, MDCM, FRCPC is the Director of the Fetal-Neonatal Neurology Program where she and her team provide care to fetuses, newborns, and children whose neurologic disorders begin in utero or during the newborn period. This multidisciplinary clinical program provides specialized training for neurology, neonatology and pediatric fellows, residents, and medical students.

Dr. Soul's current research is focused on improving the management and outcome of neonatal seizures and brain injury, particularly hypoxic-ischemic brain injury. She led a randomized, double-blind, controlled trial of bumetanide to treat neonatal seizures (NCT00830531), the first neonatal seizure trial to employ a standard therapy control group. She co-chaired the Seizure Workgroup of the International Neonatal Consortium (Critical Path Institute) to develop consensus recommendations for design of neonatal seizure treatment trials. She has been funded by the NIH, March of Dimes, Hood Foundation, United Cerebral Palsy Foundation, and others, and has served on DSMBs for NIH-funded multicenter trials. Dr. Soul has held leadership roles in the major societies and committees; she serves on the Board of the Newborn Brain Society as the Chair of the QI & Research Committee and was elected to a 2-year term on the Executive Committee of the Child Neurology Society in 2021.

Genny Taylor, MD is an Assistant Professor in the Division of Neonatal-Perinatal Medicine at the University of North Carolina. Her research focuses on neurodevelopment and other longitudinal outcomes of children born preterm or critically ill. The over-arching goal of her research is to incorporate caregiver, former patient, and other key stakeholder perspectives in clinical outcome development.

Michele Walsh, MD, MSc is the Program Scientist for the Eunice Kennedy Shriver National Institute of Child Health and Development overseeing the Neonatal Research Network and the trials focused on improving the outcomes for infants exposed to opioids in utero. Prior to joining the NICHD, Dr. Walsh served as a neonatologist and physician-scientist for over 30 years at Rainbow Babies and Children's Hospital and Case Western Reserve University. At the end of her tenure she served as the Chief of Neonatology and as the inaugural William and Louis Briggs Endowed chair in Neonatology.

With formal training in epidemiology and quality improvement, Dr. Walsh's career focuses at the nexus of generating new knowledge through rigorous clinical trials and implementation of those findings through quality improvement initiatives with the goal of rapidly improving the health of neonates.

Dr. Walsh completed her medical school training at Case Western Reserve University, followed by Pediatric Residency and Neonatal Fellowship at Rainbow Babies & Children's Hospital. She obtained a Masters of Science in Epidemiology with an emphasis on clinical trials and quality improvement at Case Western Reserve University.

Kristi Watterberg, MD is a Professor Emerita of Pediatrics in the Division of Neonatology at the University of New Mexico Health Sciences Center. She served as Chief of the Division from 2006 – 2011, and Director of the UNM Signature Program in Child Health Research from 2011 – 2016. Dr. Watterberg has over 30 years' experience conducting studies exploring newborn adrenal function, its relationship to inflammation and BPD, and long-term outcomes after preterm birth. She is the New Mexico Principal Investigator for the NICHD Neonatal Research Network (NRN, 2006-2023), which has multiple ongoing observational and interventional studies. She also was awarded a grant from NIH to study adrenal function at age six in a cohort of NRN children born extremely preterm (R01HL117764; 2013 – 2019). She has mentored fellows, faculty and other learners in research and academic advancement. Dr. Watterberg has served on NIH peer review panels and is a member of the Society for Pediatric Research and the American Pediatric Society. She has been an AAP member throughout her career and served on its Committee on Fetus and Newborn (COFN) as a member from 2006 – 2012, and as chair (2013 – 2017).

Kanecia Zimmerman, MD, MPH is an Associate Professor with Tenure in the Department of Pediatrics at Duke University School of Medicine, where she specializes in pediatric critical care medicine. She recently served as Chair of the Steering Committee for the Pediatric Trials Network (PTN), a national pediatric clinical research program funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and currently helps to oversee the Network. Dr. Zimmerman also serves as principal investigator for multiple research projects funded by the National Institutes of Health and the US Food and Drug Administration, including a study exploring the pharmacokinetics and safety profiles of anesthetics and analgesics administered to infants and children, the RECOVER Clinical Trials and Data Coordinating Center, and a program to evaluate and validate outcomes and endpoints for trials of acute pain therapeutics in infants and young children. Following completion of Master of Public Health degree from the University of North Carolina at Chapel Hill, Dr. Zimmerman attended Duke University School of Medicine and received residency training in pediatrics, serving as Chief Resident in her final year of residency. Dr. Zimmerman completed fellowships in pediatric critical care medicine and clinical research at the Duke School of Medicine and Duke Clinical Research Institute, respectively. In 2022, she also completed a PhD in Epidemiology at the University of North Carolina Gillings School of Global Public Health.

Funding for this workshop was made possible in part by a cooperative agreement with the U.S. Food and Drug Administration. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.