The Future of Registries in Oncology
Best Practices for Innovation in Drug Development | Public Virtual Workshop – Day 1
Wednesday, August 27, 2025 | 10 AM – 1 PM ET
Biographies

Workshop Co-Chairs (Alphabetically by Last Name)

Martha Donoghue, MD
Associate Director for Pediatric Oncology and Rare Cancers
U.S. Food & Drug Administration, Oncology Center of Excellence

Dr. Martha Donoghue is a pediatric oncologist and serves as the Associate Director for Pediatric Oncology and Rare Cancers in the FDA's Oncology Center of Excellence, Office of the Commissioner and the Acting Associate Director for Pediatric Oncology in the Office of Oncologic Diseases, Center of Drug Evaluation and Research (CDER). In these roles, she oversees the implementation of pediatric regulations designed to facilitate the timely investigation of drugs and biological products for pediatric patients with cancer, supports and promotes consistency of regulatory work relating to pediatric oncology and rare cancer drug development across CDER and the Center for Biologics Evaluation and Research (CBER), and works with members of the oncology community to address challenges and foster development of drugs to treat pediatric and other rare cancers. Areas of special interest include the use of innovative clinical trial designs and real-world data to optimize drug development for rare cancers. Prior to joining FDA in 2009, Dr. Donoghue completed a fellowship in Pediatric Hematology and Oncology at the Children's National Medical Center after working for several years as a general pediatrician in private practice. She received her medical degree from Emory University and completed a residency in general pediatrics at the Georgetown University Medical Center.

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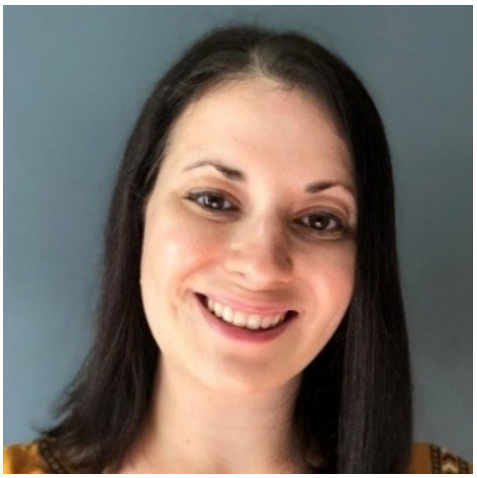

Nicole Drezner, MD
Deputy Director, Division of Oncology 2
U.S. Food & Drug Administration, CDER

Dr. Nicole Drezner is a pediatric oncologist and the Deputy Director of the Division of Oncology 2 (DO2) at the U.S. Food and Drug Administration (FDA). She joined the thoracic and head and neck oncology team in DO2 as a clinical reviewer in 2016, served as team lead of the thoracic and head and neck team from 2020-22, and began her role as Deputy Division Director in 2022. In her current role, Dr. Drezner oversees the development of drugs and biologics for most pediatric solid tumors, central nervous system tumors, and rare tumors. Dr. Drezner completed her residency in pediatrics at Cohen Children's Medical Center of NY and her pediatric hematology/oncology fellowship at Children's National Hospital. She remained at Children's National Hospital for an additional year as a pediatric neuro-oncology fellow prior to joining the FDA.

Elizabeth Duke, MD
Clinical Reviewer, Division of Oncology 2
U.S. Food & Drug Administration, Office of Oncologic Diseases, CDER

Elizabeth Duke is a Pediatric Neuro-Oncologist serving as a Clinical Reviewer in the Division of Oncology 2 (DO2), in the Office of Oncologic Diseases (OOD), at the U.S. Food and Drug Administration (FDA). She received her M.D. from University of Maryland School of Medicine in 2014. She completed Pediatrics and Child Neurology residencies at Boston Children's Hospital/Harvard Medical School, followed by a Pediatric Neuro-Oncology fellowship at Children's National Hospital in Washington, D.C. Since joining FDA in 2020, Dr. Duke's work has centered on the evaluation of investigational new drugs and marketing applications for drugs and biologics for the treatment of neuro-oncologic and pediatric solid tumors. Dr. Duke is an FDA liaison to multiple working groups in the field of neuro-oncology, including National Brain Tumor Society, National Cancer Institute, and Society for Neuro-Oncology. She also continues to see patients in the Brain Tumor Clinic at Children's National Hospital.

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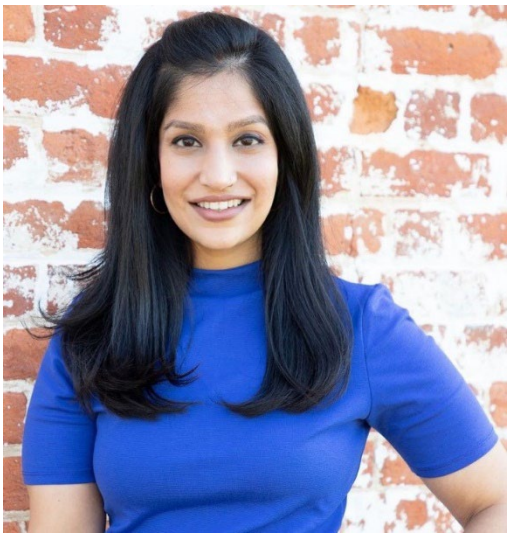
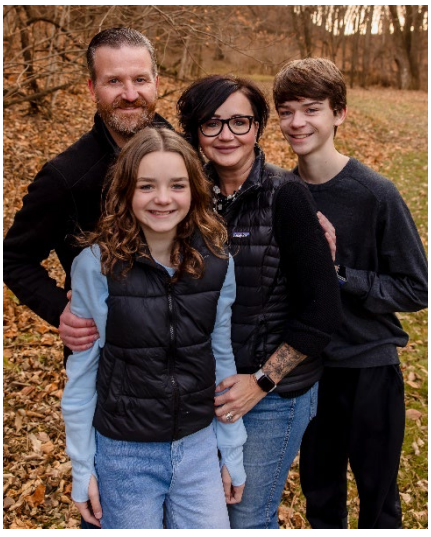


Pallavi Mishra-Kalyani, Biostatistician
Deputy Director, Division of Biometrics V
U.S. Food & Drug Administration, CDER

Pallavi Mishra-Kalyani, Ph.D. is the Deputy Director of the Division of Biometrics V, Office of Biostatistics which supports Office of Oncology Drugs at the Center for Drug Evaluation and Research (CDER). Since joining the FDA in 2015, Dr. Mishra-Kalyani has contributed to the efforts to understand and address the statistical issues in oncology drug development, with a focus on novel and innovative clinical trial design. In particular, she has been a key member of internal and external groups creating guidance and conducting research related to the potential use of external controls, Real World Data, and Real-World Evidence for regulatory purposes. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design. She has organized and participated at several statistics and oncology workshops, conferences, and working groups on these topics. Dr. Mishra-Kalyani received her doctorate in Biostatistics from Emory University, her Master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University, and her Bachelor's degree from MIT.

Speakers and Panelists (Alphabetically by Last Name)



Trish Anderson, Patient Advocate

As the first female diagnosed with a rare childhood cancer back in 1982, Trisha Anderson has lived her life through a lot of unknowns for her health and wellbeing.
Trisha has been married to Jared for 25 years and they have two beautiful kids who also carry the Dicer-1 mutation related to PPB, but have remained free from cancer at the ages of 18 and 14.
As a partner in the research journey for answers and guidelines for rare cancers and genetic predispositions for cancer, Trisha has advocated for other families and spreading awareness for answers to the unknowns that come with rare childhood cancers. She has a strong passion to serve other families going through the unknowns of childhood cancers and will continue to advocate on behalf of all families for more answers and stronger connections to supports for families.

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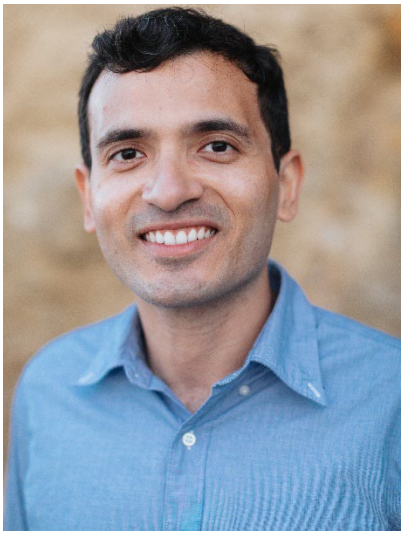

Somak Chatterjee, PhD, Biostatistician
Division of Biometrics V
U.S. Food & Drug Administration, CDER

Somak Chatterjee is a lead statistician in the Office of Biostatistics under the Center for Drug Evaluation and Research at the FDA, supporting the review of drugs and biologic products in malignant hematology and in solid tumors. His regulatory expertise includes specialized areas such as innovative trial designs and use of real-world evidence to support regulatory decision-making. Prior to joining the FDA, he completed his Ph.D. in statistics from The George Washington University.

Sarah Leary, MD
Medical Director, Pediatric Brain Tumor Program
Seattle Children's Hospital

Sarah Leary, MD, is an Attending Physician and Medical Director of the Pediatric Brain Tumor Program in the Cancer and Blood Disorders Center at Seattle Children's Hospital. She is a Professor of Pediatrics at the University of Washington School of Medicine and associate of the Fred Hutch Cancer Research Center. Dr. Leary is the Medical Director of Clinical Research at the Ben Towne Center for Cancer and Blood Disorders and a leader in clinical and translational research with a goal of improving outcomes for children, adolescents and young adults with brain tumors. Locally, she serves as the Medical Director of Clinical Research at the Ben Towne Center for Childhood Cancer and Blood Disorders Research, leads the Seattle Children's Tumor Banking and Biology study, and serves as the Seattle Children's site Principal Investigator for the Children's Oncology Group and CONNECT Clinical trials consortia. Nationally, she is the clinical Vice-Chair of the Central Nervous System Committee of the Children's Oncology Group; the chair of the Data Safety Monitoring Committee of the Pediatric Brain Tumor Consortium; and a member of the Brain Malignancy Steering Committee of the National Cancer Institute. She is leading international data sharing efforts as the lead of the clinical data operations group of the Children's Brain Tumor Network (CBTN) and the Co-Chair of the Executive Committee of the INSPiRE consortium.

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Marcelo Pasquini, MD
Professor of Medicine
Medical College of Wisconsin

Marcelo Pasquini is currently a Professor of Medicine at the Medical College of Wisconsin and Senior Scientific Director of the CIBMTR. He oversees the development and activity of the CIBMTR Cellular Therapy outcomes registry and actively works with the BMT CTN in the design and conduct of clinical trials in transplantation and cellular therapy. His clinical interests are the application of cellular therapies in multiple myeloma and the prevention of toxicities with cellular therapies.

Gregory Reaman, MD
Scientific Director, NCI
Professor Emeritus of Pediatrics, GWU

Gregory H. Reaman, M.D. is the Scientific Director of the NCI's Childhood Cancer Data Initiative (CCDI) and Professor Emeritus of Pediatrics, George Washington University School of Medicine and Health Sciences, Washington, D.C. and Executive Director Emeritus of the Center for Cancer and Blood Disorders at the Children's National Medical Center, which he directed for more than 17 years. He was the Inaugural Chair of the Children's Oncology Group (COG), serving in this capacity from 2000 through 2010. Prior to this, he was the Vice Chair for Scientific Affairs and the Associate Chair for New Agent Studies of the Children's Cancer Group (CCG) for ten years and directed the CCG Phase I Consortium. He joined the FDA in 2011 as the Associate Director for Oncology Sciences in the Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research and, in 2016 served as the Associate Director for Pediatric Oncology in the FDA's Oncology Center of Excellence until 2022 and joining NCI. Dr. Reaman has served on multiple editorial boards; he was an Associate Editor of Cancer and Leukemia and Lymphoma. He served on the Board of Directors of the American Cancer Society and chaired its Task Force on Children

and Cancer and has served on the Board of Directors of the American Society of Clinical Oncology (ASCO) as well as the International Society of Pediatric Oncology (SIOP); he has served on numerous ASCO committees and ad hoc NCI review panels, and the steering committee of the AACR's Pediatric Cancer Working Group. His research interests are the biology and treatment of childhood acute leukemia and new drug development for pediatric cancers. He has authored over 400 peer-reviewed manuscripts, 25 book chapters and textbooks.

Donna R. Rivera, PharmD., MSc

Former Associate Director of Pharmacoepidemiology, Oncology Center of Excellence, FDA; University of Maryland School of Pharmacy Affiliate

Donna R. Rivera, PharmD., MSc., is the former Associate Director for Pharmacoepidemiology in the Oncology Center of Excellence at the U.S. Food and Drug Administration. She led the Oncology Real World Evidence (RWE) Program, which focuses on the use of Real World Data (RWD) and RWE for regulatory purposes, as well as management of the RWD research portfolio strategy and development of regulatory policy to support the OCE mission. As a pharmacist and pharmacoepidemiologist, Dr. Rivera has interests in the use of RWD to advance health equity, observational study designs and methodological approaches, and appropriate uses of RWD for drug development to increase access of effective therapies to patients.

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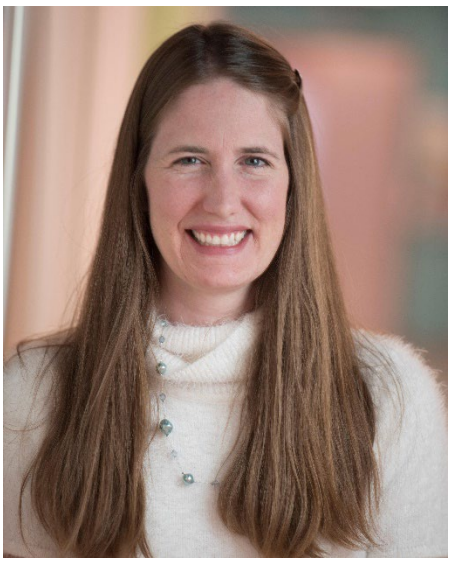

Kris Ann P. Schultz, MD
Scientific Director, Cancer and Blood Disorders
Children's Minnesota

Kris Ann P. Schultz, MD, is a pediatric oncologist and Pine Tree Endowed Chair in Cancer and Blood Disorders Research. Dr. Schultz also serves as Scientific Director of Cancer and Blood Disorders at Children's Minnesota. She graduated summa cum laude from Drake University (B.A.) and summa cum laude from Loyola University (M.D). She completed her pediatric residency and pediatric hematology/oncology fellowship at the University of Minnesota and received a Master of Science degree in clinical research during the course of her fellowship. Dr. Shultz is the Principal Investigator for the International Pleuropulmonary Blastoma (PPB)/DICER1 Registry and the Principal Investigator and founder of the International Ovarian and Testicular Stromal Tumor (OTST) Registry. Her current research focuses on development of novel treatments for DICER1-related tumors. She is a member of the Alpha Omega Alpha Honor Medical Society. Dr. Schultz joined the Hematology Oncology program at Children's Minnesota in 2008 and has particular interest and expertise in the care of children with pleuropulmonary blastoma, ovarian tumors and other rare childhood cancers.

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William A. Wood, MD, MPH
Senior Medical Advisor, ASH Research Collaborative
University of North Carolina, Chapel Hill

Dr. Wood graduated from Harvard college in 1998, Duke University School of Medicine in 2003 (MD), University of North Carolina at Chapel Hill in 2003 (MPH), Harvard Combined Residency in Internal Medicine and Pediatrics (2007), and University of North Carolina fellowship in Hematology and Oncology (2010). Currently, Dr. Wood is a Professor at the University of North Carolina at Chapel Hill in the Division of Hematology in the Department of Medicine and a member of the UNC Cancer Outcomes Research Program.

His work focuses on understanding and improving the experience of patients with cancer and other hematologic diseases and approaches this goal using the tools of real-world evidence development, patient-reported outcomes and patient-generated health data methods and implementation, and patient-centered health care delivery interventions. Currently, Dr. Wood's clinical practice focuses on bone marrow transplantation and cellular therapy and malignant hematology.

His major current efforts include the development of a multi-institutional real-world data network in hematology as the senior medical advisor to the American Society of Hematology Research Collaborative (ASH RC), the development of a multicenter patient navigation program as medical director for patient navigation at the UNC Cancer Center, and the development of a research program studying interventions related to supportive care delivery and optimization of quality of life in patients with cancer and hematologic conditions. Dr. Wood developed the Health Score program, a health coaching program to support patients with cancer and their caregivers, and is also active in the global digital medicine community and conduct projects related to the development of digital biomarkers related to physical and emotional health using patient-generated health data from sensors and PRO's. Dr. Wood has received competitive funding from the NCI, foundations, and industry to support his research efforts.