The Future of Registries in Oncology
Advancing Drug Development in Pediatric DMG/DIPG | Public Virtual Workshop – Day 2
Thursday, August 28, 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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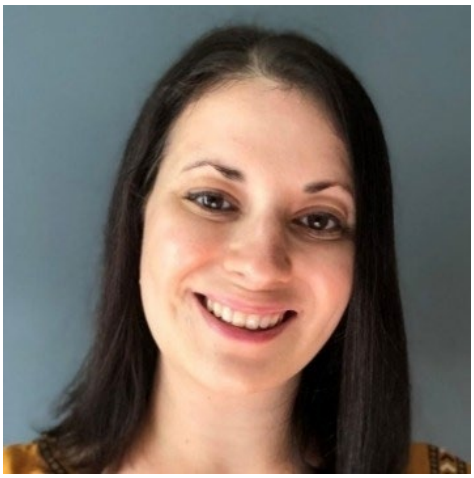


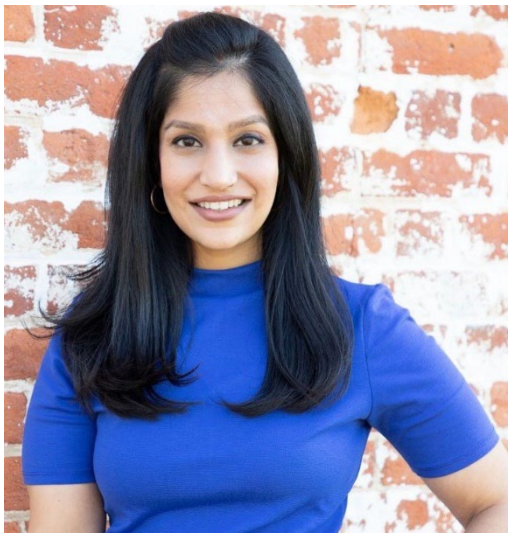
Nicole Drezner, MD
Deputy Director, Division of Oncology 2
U.S. Food & Drug Administration, CDER

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.



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.

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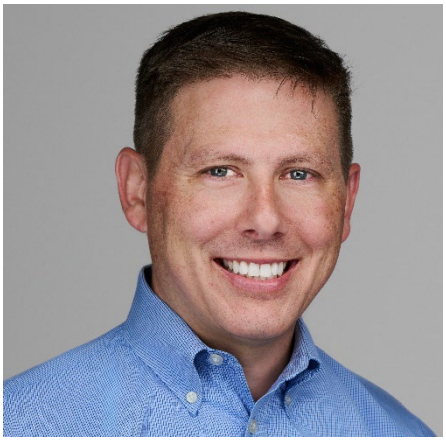

Keith Desserich (Patient Advocate)
The Cure Start Now Foundation

Keith Desserich is a father to Elena, a 6-year-old girl diagnosed with DIPG in 2006 and the subject of the New York Times Bestselling book, "Notes Left Behind". He and his wife Brooke founded The Cure Starts Now Foundation, the largest funder of DIPG/DMG research internationally. Today the efforts of this charity are in 4 countries with over 55 chapters, in partnership with over 900 warrior families and have led to research at over 109 hospitals worldwide. He also founded the DIPG/DMG Collaborative (a group of 27+ independent foundations that work cooperatively to fund research), www.dipg.org, www.medulloblastoma.org and the DIPG/DMG Symposium. He is a steering committee member of the DIPG/DMG International Registry, the SIOPe DIPG Registry, and the Pediatric Brain Tumor Consortium. He is a frequent speaker on patient advocacy and innovative cancer research at conferences worldwide. He and his wife are also Jaqueline Kennedy Onassis Jeffersonian Award recipients for community service. Professionally he has a 27-year background as a private-sector entrepreneur. He and his wife live in Ohio with their adult daughter Grace and youngest daughter Nina.

Maryam Fouladi, MD, MSc, FRCP
Pediatric Neuro-Oncologist
Nationwide Children's Hospital

Maryam Fouladi, MD, MSc, FRCP, is a pediatric neuro-oncologist, co-executive director of the pediatric neuro-oncology program at Nationwide Children's Hospital, Columbus, OH and a Professor of Pediatrics at the Ohio State University College of Medicine. Dr. Fouladi was the founding Chair of the DIPG/DMG Registry. She currently chairs the CNS Committee of the Children's Oncology Group and is the Chair of the Collaborative Network for Neuro-Oncology Clinical Trials (CONNECT) an international clinical trials consortium whose mission is to discover and expand access to novel, promising therapies for high-risk pediatric brain tumors through global, multidisciplinary collaborations.

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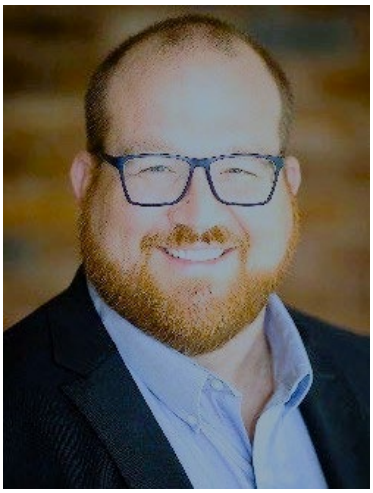

Trent Hummel, MD
Associate Professor of Pediatrics
Cincinnati Children's Hospital Medical Center

Dr. Hummel completed his graduate medical training at the University of Cincinnati College of Medicine, residency training in pediatrics at Children's Hospital Medical Center of Akron, and pediatric hematology/oncology training at Cincinnati Children's Hospital Medical Center. Currently, he serves as an Associate Professor of Pediatrics at Cincinnati Children's within the University of Cincinnati.

Dr. Hummel's clinical and academic interests focus on children and families affected by central nervous system tumors. He is a member of the Central Nervous System (Brain Tumor) Committee in the Children's Oncology Group (COG) and the co-principal investigator for the Pediatric Brain Tumor Consortium (PBTC) at Cincinnati Children's. Dr. Hummel's work is dedicated to developing novel therapeutics to treat children with all central nervous system tumors, including those with neurofibromatosis type 1 and 2 related CNS tumors and very poor prognosis tumors such as high-grade gliomas and diffuse intrinsic pontine gliomas.

Arzu Onar-Thomas, PhD
Lead Biostatistician, COG CNS
St. Jude Children's Research Hospital

Dr. Onar-Thomas completed her PhD in Statistics at the University of South Carolina, Columbia, followed by 2-post docs, the first at the University of Miami, FL, and the second at the University of Surrey, UK. Dr. Onar-Thomas joined the Biostatistics Department at St Jude Children's Research Hospital as an Assistant Member in 2005 where she now serves as a Member (equivalent of a Professor rank). Dr. Onar-Thomas is a clinical trialist with a methodological focus on clinical trial design in rare diseases and a translational focus on pediatric brain tumors. She serves as the primary Biostatistics contact for the Neurobiology and the Brain Tumor Program within the St Jude Comprehensive Cancer Center and is also a faculty member at the St Jude Graduate School. Externally, she leads the Operations, Biostatistics, and Data Management Core of the Pediatric Brain Tumor Consortium (PBTC) and serves as the contact-PI for the grant. Dr. Onar-Thomas is also the Lead

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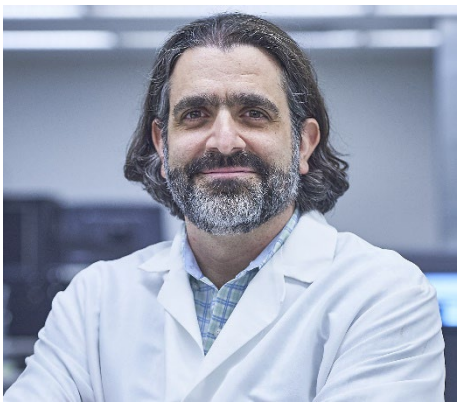
Biostatistician for the Children's Oncology Group Central Nervous System Committee (COG CNS). Currently, Dr. Onar-Thomas is the primary statistician on numerous St Jude, PBTC, and COG CNS trials and collaborates routinely with clinicians as well as with basic and correlative science investigators. Dr. Onar-Thomas is a member of the COG Scientific Council, a member of the NCI Brain Malignancy Steering Committee, and serves as an Associate Editor of Biostatistics for the *Journal of Clinical Oncology*.



Adam Resnick, MD
Director of Data Driven Discovery **(**Biomedicine)
Children's Hospital of Philadelphia

Adam Resnick is the Director of Data Driven Discovery in Biomedicine (D3b) at Children's Hospital of Philadelphia (CHOP) responsible for leading a multidisciplinary team to build and support a scalable, patient-focused healthcare and educational discovery ecosystem on behalf of accelerated discovery and clinical translation for all children. The D3b Center is comprised of a trans-disciplinary team that spans the clinical research unit, biospecimen research unit, molecular diagnostics research unit, pre-clinical research unit, bioinformatics unit, translational imaging unit, and the advanced data applications and platform technologies unit.

Adam's own laboratory-based research has focused on defining the mechanisms of disordered, central nervous system developmental signaling, oncogenesis and tumor progression in brain tumors, the leading cause of disease-related death in children. Through collaborative, multi-institutional platform-supported research, studies center on cell signaling cascades and their regulation in pediatric brain tumors in order to elucidate the molecular and genetic underpinnings of each tumor in an effort to identify and develop targeted therapies through clinical translation as well as define approaches to prevention and personalized treatments that minimize harm to the developing child.

Adam's efforts extend beyond CHOP in his role as Scientific Chair for several consortia-based efforts, including the Children's Brain Tumor Network (CBTN) and Pacific Pediatric Neuro-Oncology Consortium (PNOC), which include more than 30 pediatric hospitals across the globe. Adam also leads the ongoing development efforts of the NIH Gabriella Miller Kids First Data Resource Center, a platform supporting data sharing and discovery across pediatric cancers and structural birth defects.

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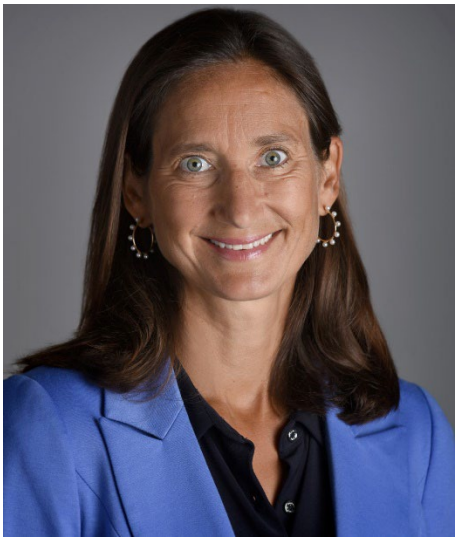
Prior to arriving at CHOP, Adam earned a dual-bachelor's in Neuroscience and English & Literature from the University of Florida before completing a PhD in Neuroscience from Johns Hopkins University in Baltimore, MD.



Giselle Sholler, MD
Chief of Pediatric Hematology/Oncology
Penn State Hershey Children's Hospital

Dr. Sholler is currently the Division Chief of Pediatric Hematology/Oncology/BMT and Director of Pediatric Oncology Research at Penn State Hershey Children's Hospital, Professor of Pediatrics and Pharmacology and Chair of the Beat Childhood Cancer consortium. Research conducted within her laboratory that has led to the opening of 24 clinical trials with a focus on targeted therapies and precision medicine for children with cancer She founded the Beat Childhood Cancer consortium is a collaborative team of over 50 universities, research centers and children's hospitals that have come together to bring new therapies to children in need across the US and Canada. She led the research studying both Precision Medicine approaches to cancer and studying DFMO for children with neuroblastoma to keep children in remission. Working together with the FDA she received FDA approval of DFMO for high-risk neuroblastoma. She has a strong track record of working closely with investigators studying pediatric cancers and this collaborative environment provides the constant availability of innovative perspectives that drives research forward and ultimately makes a difference in the daily lives of children living with cancer.