Advancing Childhood Cancer Academic-Industry Collaborative Platform Trials:

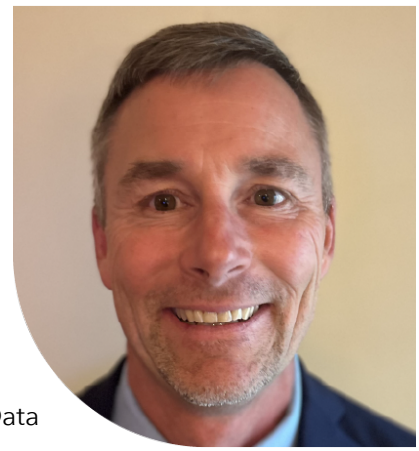
A Multi-Stakeholder Workshop

24–25 July 2025

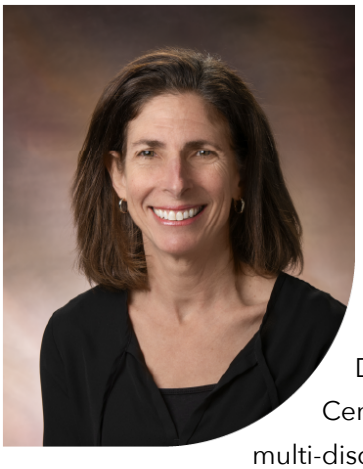
Biographies:

Workshop Attendees

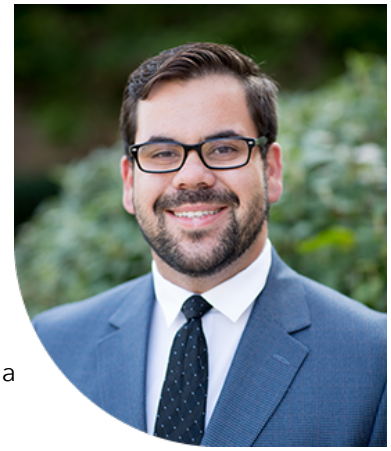
Biographies



Todd A. Alonzo, PhD, is Professor of Research in the Division of Biostatistics at the University of Southern California. Dr. Alonzo is Group Statistician for the Children's Oncology Group (COG) and lead statistician for the COG Myeloid Disease Committee. Dr. Alonzo earned a MS and PhD in Biostatistics from the University of Washington. He has over 290 peer-reviewed publications. In addition, he has been a member of the Editorial Board for *Biometrics*, *Journal of Clinical Oncology*, *Pediatric Blood & Cancer*, and *Biometrical Journal* and has acted as a reviewer for over 30 scientific journals. Dr. Alonzo is also a member of several Data Safety Monitoring Committees. Dr. Alonzo is a Fellow of the American Statistical Association and was President of the International Biometric Society Western Northern America Region (WNAR).



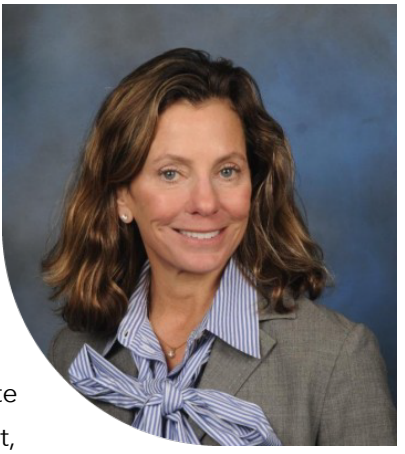
Rochelle "Ro" Bagatell, MD, is a pediatric oncologist at the Children's Hospital of Philadelphia, where she serves as Solid Tumor Section Chief. She is committed to conducting clinical trials designed to develop and optimize new therapies for children with neuroblastoma, particularly those with high-risk and relapsed/refractory disease. She is also committed to incorporating correlative studies into both early phase and late phase trials to learn as much as possible from every study participant. Dr. Bagatell is the chair of the Children's Oncology Group Neuroblastoma Disease Committee, and chair of the National Comprehensive Cancer Center (NCCN) Neuroblastoma Guidelines Committee. She particularly enjoys multi-disciplinary and multi-national collaborations.



Trevor Baker, MS is a Program Manager at the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Trevor primarily focuses on MRCT Center projects involving Artificial Intelligence, Environmental Sustainability, and Platform Studies. Before joining the MRCT center, Trevor worked as a Research Project Manager at Boston Medical Center, implementing a multi-regional trial in the research area of overdose prevention. Trevor graduated from the University of Notre Dame with a Master of Science in Global Health. He earned a Bachelor of Science in Biology from Santa Clara University.

Barbara E. Bierer, MD is the Faculty Director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), a Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston, and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics and the Law Program of the Harvard clinical and translational sciences center. Previously, she served as senior vice president, research, at the Brigham and Women's Hospital for 11 years, and was the institutional official for human subjects and animal research, for biosafety, and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH.

In addition to her academic responsibilities, Dr. Bierer serves on the Board of Directors of Vivli, Inc., a non-profit organization founded by the MRCT Center dedicated to global clinical trial sharing; North Star Research Board; Clinithink, Inc., Generation Patient, and the Edward P Evans Foundation. Previously she has served on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R) and the Association for Accreditation of Human Research Protection Programs (AAHRPP) and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS, among others. She has authored or co-authored over 300 publications. Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.



Anne E. Borgman, MD is a highly accomplished pharmaceutical executive with over two decades of experience in the drug development landscape, particularly in the fields of hematology and oncology. As an analytical Chief Medical Officer, she has been instrumental in leading teams to achieve nine successful drug filings, demonstrating her extensive expertise in navigating the complexities of Phase 3 and registrational processes.

Dr. Borgman's career has spanned both large pharmaceutical companies and innovative small biotech firms, allowing her to cultivate a deep specialization in oncology and hematology drug development, including applications for pediatric populations. Her proven proficiency spans from early development stages (including leading the early development efforts on Venetoclax and Olaparib) to global Phase 3 trials, with a notable focus on immune-oncology combinations, antibody drug conjugates, proteins, and small-molecule therapeutics.

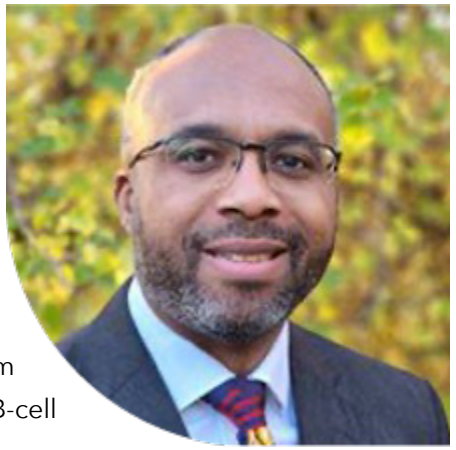
Dr. Borgman is currently a Consulting Attending Physician at Stanford University School of Medicine and the University of Chicago. She possesses significant regulatory expertise in both the U.S. and Europe, having successfully managed multiple drug filings and played a pivotal role on the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC).

As VP and Therapeutic Area Head for Jazz Pharmaceuticals, she led global drug development in oncology and hematology for three marketed products: Defibrotide (veno-occlusive disease), Vyxeos (acute myeloid leukemia), and Zepzelca (relapsed small cell lung cancer), significantly adding to her commercial support experience.

Standout achievements in her career include building a high-functioning department at a biotech firm, where she successfully drove the lead compound to a New Drug Application (NDA) filing for accelerated approval in treating second-relapsed or refractory adult leukemia. She also scaled the organization to one that supports a marketed product from a clinical organization.

With her comprehensive knowledge and leadership capabilities, Dr. Borgman continues to shape the future of oncology-hematology therapeutics, significantly contributing to the field and improving patient outcomes.

Vickie Buenger, PhD taught competitive and cooperative business strategy and project management at the Mays Business School with a joint appointment to the Professional Program for Biotechnology at Texas A&M University for 30 years. Her daughter, Erin, fought neuroblastoma for seven years. After Erin's death in 2009, Vickie continued her academic career while devoting time and energy to launching the Coalition Against Childhood Cancer (CAC2) on behalf of the many dedicated organizations and individuals striving to make a difference for children with cancer. She continues pursuing that vision in a variety of roles, including as the PPIE representative on the GLO-BNHL Clinical Trial Steering Group, as President Emeritus at CAC2, and on the Board of the ACCELERATE Platform.



Amos Burke MB Chb, PhD, MA is Professor of Paediatric Oncology at the University of Birmingham and an Honorary Consultant Paediatric Oncologist at Birmingham, Women and Children's Hospital. He is Head of Department and Director of the University of Birmingham Cancer Research UK Clinical Trials Unit (CRCTU) that delivers a trial portfolio over a wide range of cancers occurring in children, young people and adults. His research is focussed on childhood non-Hodgkin lymphoma and he is Chief Investigator for the innovative platform trial Glo-BNHL for children with relapsed and refractory mature B-cell Non-Hodgkin Lymphoma

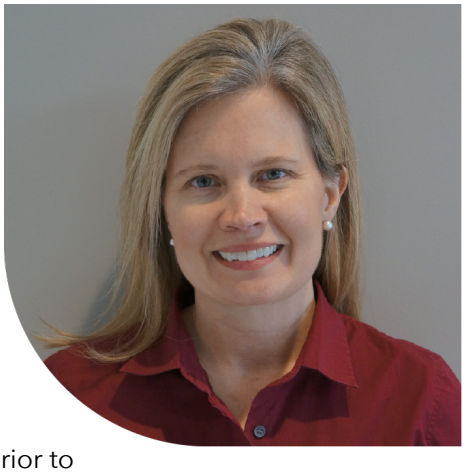
Hubert Caron, MD, PhD, was Group Medical Director at Roche, where he led a cross-functional global pediatric development team for the entire Roche oncology portfolio. He has experience with EU PIP and US iPSP/PPSR design and negotiations. Dr. Caron holds Steering Committee appointments with ACCELERATE and the AACR Pediatric Cancer Working Group.

Todd M. Cooper, DO, is an attending physician at Seattle Children's, professor of pediatrics at the University of Washington School of Medicine and the Evans Family Endowed Chair in Pediatric Cancer. Dr. Cooper is the section head of Oncology in the Seattle Children's Cancer and Blood Disorders Center. Dr. Cooper has led phase 1 studies of new agents for relapsed acute leukemia in a variety of national consortia including the Therapeutic Advances for Childhood Leukemia Consortium, Pediatric Oncology Experimental Therapeutics Investigator Consortium and the Children's Oncology Group (COG) Consortium.

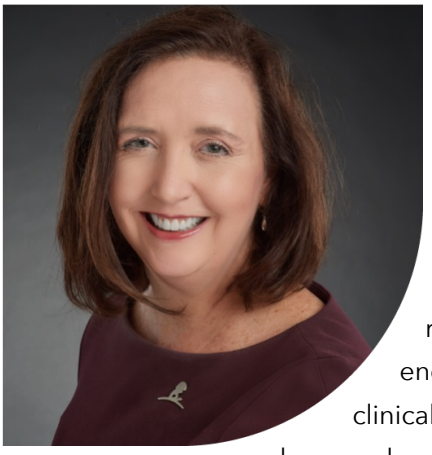
Dr. Cooper serves as the chair of the COG Myeloid Diseases Committee and actively collaborates internationally to help maintain a cohesive strategy for the treatment of children with acute leukemia. Dr. Cooper leads COG AAML1831, a COG phase 3 study for newly diagnosed children with AML. He is the co-lead of The Leukemia & Lymphoma Society's Pediatric Acute Leukemia (PedAL) Initiative, an international effort to develop novel targeted therapies with the goal of providing broad access to new treatment strategies around the globe for children with acute leukemia.

He is intimately involved in the selection of new treatments and in designing and leading clinical trials, all with the goal of bringing positive change to the therapy of children diagnosed with AML, both nationally and internationally.

Laura Danielson, PhD, is the Children's and Young People's Research Lead at Cancer Research UK (CRUK), where she is responsible for developing and driving their research strategy dedicated to transforming outcomes for children and young people affected by cancer. Before joining CRUK, Dr Danielson was a cancer research scientist, most recently in the field of paediatric drug development at the Institute of Cancer Research, London. Dr Danielson has a BSc in Biology from University of Washington, Seattle, and a MSc in Pathobiology and PhD in Biomedical Sciences from New York University School of Medicine, New York.



Martha Donoghue, MD, is a pediatric oncologist and the Associate Director for Pediatric Oncology and Rare Cancers in the FDA Oncology Center of Excellence. She also serves as the Acting Associate Director for Pediatric Oncology in the FDA Office of Oncologic Diseases. In these roles, she oversees implementation of regulations designed to promote timely investigation of drugs and biological products for pediatric patients with cancer, supports work relating to pediatric oncology and rare cancer drug development across FDA, and works with stakeholders to address challenges and foster development of drugs to treat pediatric and other 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.



Elizabeth Fox, MD, leads regulatory and clinical trial operations as well clinical research prioritization and strategy at St Jude Children's Research Hospital. Nationally, she is the chair of Developmental Therapeutics for the Children's Oncology Group and the Pediatric Early Phase Clinical Trials Network. Dr. Fox is a pediatric oncologist with expertise in quantitative clinical and pre-clinical pharmacology, pediatric clinical oncology, and clinical research and trial design including response and toxicity biomarker endpoint development. She applies an integrative approach to clinical drug development utilizing animal models, pre-clinical and clinical pharmacology to evaluate new therapies and novel trial designs and improve outcome for children with catastrophic diseases.

Brian Gadbaw, MD, is the Executive Medical Director of Pediatric Oncology Development in the Pediatric Center of Excellence at Novartis, bringing over 15 years of experience in drug development.

In his current role, Brian leads a cross-functional team tasked with ensuring that Novartis delivers innovative medicines for pediatric oncology patients worldwide. His team addresses the challenges of an ever-evolving global regulatory and therapeutic landscape, integrating considerations for early discovery research through to established products.

Before joining Novartis, Brian completed his pediatric residency and pediatric Hematology/Oncology fellowship at the University of Wisconsin's American Family Children's Hospital and Clinics.

Birgit Geoerger, PhD, HdR, is pediatric oncologist heading the Pediatric Early Drug Development Program in the Department of Pediatric and Adolescent Oncology at Gustave Roussy Cancer Center in Villejuif, France.

Dr. Geoerger has an international career with medical thesis, graduation, pediatrics and hemato-oncology training at the Universities in Mainz, Aachen, Essen and Cologne in Germany, a post-doctorate in Philadelphia, USA, a PhD in Amsterdam, The Netherlands, oncology specialization and Habilitation to Direct Research at the Universities of Paris in France. She is internationally recognized for her expertise in childhood cancer new drug development and was heading the INCa labeled early phase clinical trial center in pediatric hemato-oncology (CLIP²-2015-2024), which regroups Gustave Roussy, Robert Debré and Trousseau Hospitals.

She had developed and contributed to multiple early clinical, first-in-child and first-in-class trials, together with Pharma or academic institutions. Within the precision cancer medicine efforts, she has initiated the MAPPYACTS molecular profiling trial and the AcSé-ESMART molecularly guided therapeutic proof-of-concept platform trial, both sponsored by Gustave Roussy, and is coordinating the pediatric relapse indication of the France Medécine Génomique 2025 program and the MAPPYACTS 2 study.

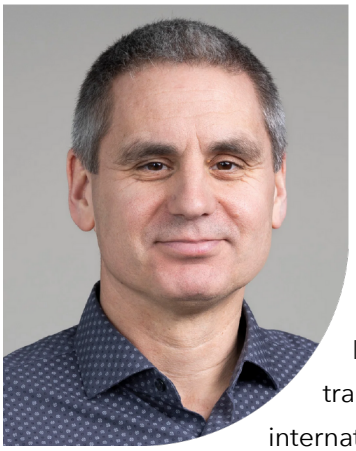
Her laboratory group "Precision Medicine and Experimental Therapeutics" in the INSERM U1015 research laboratory of Prof Laurence Zitvogel aims at developing new therapies for pediatric cancers through the identification of new therapeutic targets in the cancer precision medicine program. Potential targets and their role in oncogenesis or resistance are explored in relevant pre-clinical models. In 2026, she will lead the INSERM research team "Biology for therapeutics in resistant pediatric cancers" in the new pediatric research unit at Gustave Roussy. She is member of the AACR, ASCO, SFCE, SIOPE and SIOP; was chair of the Clinical Trials Committee during 11 years, member of the Biology and the Executive Committee of the European Innovate Therapies for Children with Cancer (ITCC) consortium, member of multiple international scientific committees, editorial boards (Journal of Clinical Oncology and European Journal of Cancer) and advisory boards. She has been Section Editor for Pediatric Oncology of European Journal of Cancer since February 2023.

She trained and mentored more than 20 Master and PhD students in the research laboratory since 2004. Through a fellowship at Gustave Roussy, she trained and mentored 18 young investigators in new drug development since 2010 from all over Europe; most of them are now running the early clinical trials in their center. She initiated the clinical trials workshop within the ITCC clinical trials committee and is Faculty Member of the MCCR Methods in Clinical Research Workshop since 2012 and influenced the development of multiple trial protocols. She is participating to the Juries of PhD students and HDR candidates. In 2006 she received the Gustave Roussy Award from the Chancelleries des Universités de Paris, Sorbonne.

Dr Geoerger has authored more than 160 peer-reviewed publications referenced in Medline.

Douglas S. Hawkins, MD, is the Group Chair of the Children's Oncology Group (COG). COG is the world's largest organization devoted exclusively to childhood and adolescent cancer research. COG unites over 12,000 experts in childhood cancer at more than 200 leading children's hospitals, universities, and cancer centers across North America, Australia, and New Zealand in the fight against childhood cancer. Dr. Hawkins is a clinician at Seattle Children's Hospital and Professor of Pediatrics at the University of Washington School of Medicine.

Prior to becoming COG Group Chair in 2020, he was the Chair of the COG Soft Tissue Sarcoma Committee, overseeing the conduct of biology studies and clinical trials for rhabdomyosarcoma and other soft tissue sarcomas across North America.



David Jenkinson, PhD, with 30 years' experience in oncology research, joined LifeArc in 2023 to lead their efforts in childhood cancer. Following roles in academia and biotech, David joined Cancer Research Technology, introducing several innovative approaches ensuring the progression of discoveries towards patients, including securing orphan designations, industry co-funding and industry-academia drug discovery alliances.

David then moved to The Brain Tumour Charity as CSO, where he transformed the scientific funding for the charity and grew the charity's international networks, establishing the organisation as the pre-eminent funder of research into brain tumours.

Since joining LifeArc, he has established their strategy for delivery of sustainable change in childhood cancers, established C-Further, the children's cancer therapeutic consortium and worked with the community to explore the unmet needs in various cancers through a series of workshops.

Dominik Karres, MD, holds a medical degree in paediatric drug development. He held a training post in paediatric haematology/oncology in Germany, followed by posts in paediatric oncology drug development in the UK. With over 10 years in drug regulation and different scientific roles at the UK's MHRA, he is now Senior Scientific Officer in the Paediatric Medicines Office at EMA.

He oversees scientific evaluations of anti-cancer drug development plans (PIPs) and supports the agency's efforts to foster paediatric global drug development in various roles and responsibilities in line with EU policy initiatives. In that capacity he is, for example, the EMAs nominee to the scientific committee of ACCELERATE and leads the European ICH E11A implementation activities.

Additionally, he has been appointed HTA/payer engagement specialist, supporting the regulatory/HTA interface under the new HTA Regulation.

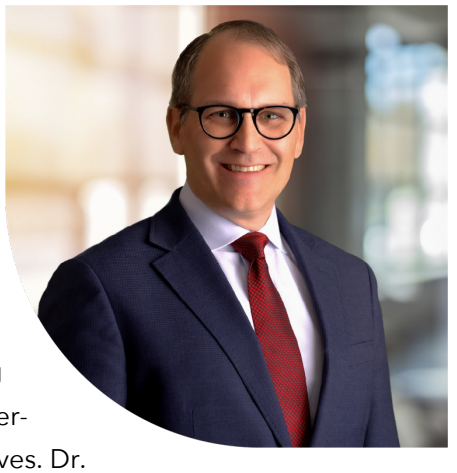
Pam Kearns, PhD, FRCPCH, is Emeritus Professor of Clinical Paediatric Oncology at the University of Birmingham, where she was Director of the Cancer Research UK Clinical Trials Unit 2011-2023 and Director of the Institute of Cancer and Genomic Sciences 2021-2024.

She is President of ITCC and a Founding Board member of ACCELERATE. She was President of SIOPE 2019 -2021 and on the SIOPE Board until December 2024.

She chairs UK's IMPACCT (**I**nitiative for **M**ulti-stakeholder **P**artnership to **A**ccelerate **C**hildren's **C**ancer **T**rials). And chairs the Research Assessment Panel for Great Ormond Street Hospital. She is a member of UK's National Institute for Health Research Invention for Innovation Funding Committee as well as several academic advisory boards. She is a Deputy Chair of the Board of Trustees for Cancer Research UK and Chair of the Board of Trustees for A Child of Mine, a charity dedicated to supporting bereaved parents.

Olga Kholmanskikh, MD, PhD, has extensive experience since 2012 as a clinical assessor at the Federal Agency for Medicines and Health Products (FAMHP), a Belgian National Competent Authority. At the FAMHP, she leads a team of assessors involved in the regulatory clinical assessment of anticancer medicines throughout their lifecycle, including clinical trial applications and marketing authorisation applications. Olga also participates in EMA activities within its working parties, she has been a member of the Oncology Working Party since 2019. Olga initially trained as a medical doctor and continued training as researcher in tumour biology and immunology at Ludwig Cancer Research, Brussels Branch. She received her PhD in Biomedical and Pharmaceutical Sciences from Catholic University of Louvain (UCL) in 2011.

Leona Knox, is Head of Research at Solving Kids' Cancer UK, a non-profit organisation fostering international collaboration to accelerate pioneering clinical research in neuroblastoma. Leona is a passionate advocate dedicated to multi-stakeholder working for the benefit of children with cancer, and actively participates in several academic committees and working groups to help inform research agendas and influence policy. She is founding Chair of the SIOPEN Advocate Committee, a member of the ITCC Advocate Committee, and previously served as a member of the AACR Pediatric Working Group Steering Committee and ACCELERATE Steering Committee. Leona's son Oscar died of neuroblastoma in 2014 following extensive therapy in the UK and US.



E. Anders Kolb, MD, a pediatric hematologist-oncologist and researcher, is the President and CEO of The Leukemia & Lymphoma Society (LLS), where he leads a global organization dedicated to curing blood cancers. Prior to joining LLS, he spent 15 years at Nemours Children's Health, where he led transformative growth in pediatric cancer care and research, including directing the Moseley Foundation Institute and serving as Vice Chair for Research at Sidney Kimmel Medical College. He has held leadership roles at top institutions including Memorial Sloan-Kettering and Montefiore, authored over 150 peer-reviewed articles, and led major clinical trials and research initiatives. Dr. Kolb earned his M.D. from Thomas Jefferson University and completed his fellowship at Memorial Sloan-Kettering Cancer Center.

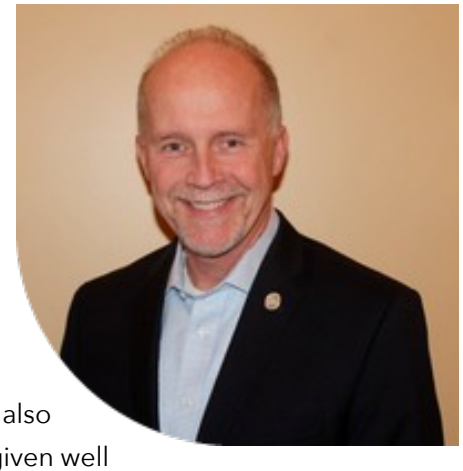
Lisa Koppelman, MSW, LICSW, MPH, joined the MRCT Center in 2019 and has focused on issues related to the global harmonization of pediatric clinical trials, elevating the voices of young people in clinical research, and community engagement. Lisa assumed the position of Team & Program Director in June 2022, incorporating key elements of coaching and professional development into her work that supports the Center's staff. Lisa brings over fifteen years' experience as a public health professional to her work, with a particular focus on qualitative research methods.

Prior to her immersion in the public health realm, Lisa worked for 15+ years as a clinical social worker in a variety of settings. Lisa earned her Bachelor of Arts degree from Tufts University, her Master of Social Work degree from Columbia University School of Social Work, and her Master of Public Health degree in International Health from Boston University School of Public Health. She is a certified yoga teacher, a trained Executive Coach, and conducts professional development trainings focused on emotional intelligence in the workplace.

Carole Lecinse is the current Director of Operations of the Innovative Therapies for Children and Adolescents with Cancer Consortium (ITCC), coordinating the different activities with the ITCC President. She has formerly worked in both pharmaceutical industry and public research. She had gained some specific experience in the field of clinical scales and PROs copyrights in a Danish pharmaceutical company specialised in CNS diseases before joining ITCC in December 2012.

Adam Levy, MD, received his Medical Degree from the New York University School of Medicine, trained in Pediatrics at Mount Sinai Medical Center in New York, and completed fellowship in Pediatric Hematology/Oncology at Memorial Sloan-Kettering and New York Hospital/Weill Cornell Medical Center. Adam joined BMS in March 2022 from the Montefiore Health System where he 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. During his tenure at Montefiore/Einstein, Adam's roles included directing the pediatric oncology clinical trials program and he was a Principal Investigator for the Children's Oncology Group.

As the Head of the BMS Pediatric Center of Excellence, Adam 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. The Pediatric Center of Excellence's mission is to embed pediatrics into the discovery, development and delivery of medicines to help all patients—pediatric and adult—prevail over serious disease.



Joe McDonough, MBA, holds a BA degree from the Univ of Delaware and an MBA from Fordham Univ in NYC. For 40+ years, Joe has held marketing positions in the consumer products, non-profit, and financial services industry. Prior to starting The Andrew McDonough B+ (Be Positive) Foundation, he was a Senior Vice-President in the credit card division of JPMorgan Chase. Joe is the President of The B+ Foundation, an international charity with offices in DE and NYC, with employees around the U.S. The B+ Foundation is the largest provider of financial assistance to families of kids with cancer nationwide and also funds cutting-edge childhood cancer research globally. Joe has given well over 1,600 talks around the country since his son passed away.

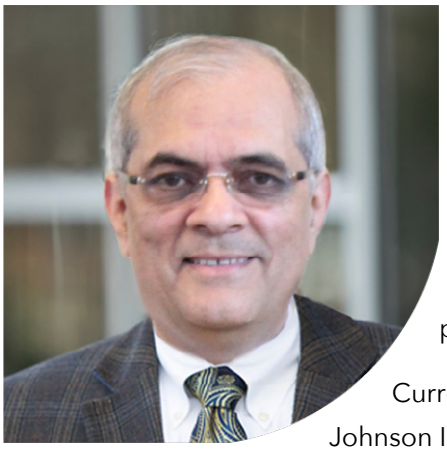
Andrew and The B+ Foundation have been recognized by NASCAR, Major League Baseball, NBA, and NHL teams, the Jefferson Award for Public Service, the Governor of the State of Delaware and numerous other organizations and honors. Andrew was inducted in the News-Journal/Delaware Online 2025 Most Influential Delawareans Hall of Fame. The B+ Foundation was named one of the

"Top 100 Charities" in the country by Chase and Facebook. The B+ Foundation was featured on The Today Show.

Joe was an invited guest at Pres. Obama's 2011 State of the Union Address. He was inducted in the International Blood Bank Hall of Fame, the Mt. Pleasant HS (DE) Hall of Fame and the University of Delaware Wall of Fame.

Amanda Monteiro, LMSW, is patient advocate and leukemia mom recognized as one of Cancer Health Magazine's top patient advocates for 2025. Licensed palliative care social worker and ambassador for the Leukemia and Lymphoma Society's Dare to Dream Project.

Kerri Nottage, MD, MPH, is a Pediatric Hematologist/Oncologist and is currently serving as Senior Director, Pediatric Drug Development within Johnson & Johnson's Child Health Innovation and Leadership Department at Johnson & Johnson. She is currently the Clinical Leader of the Pediatric Oncology Strategy Team and responsible for pediatric strategy for all compounds within the Oncology Therapeutic Area. Prior to this role, Kerri spent 9 years in Hematology Late Development at Johnson & Johnson serving as the Clinical Leader for multiple programs in the myeloid portfolio as well as Tecvayli™, Talvey™, Imbruvica®, and Darzalex®. In addition to these clinical activities, Kerri has been Chair of the Pediatric Working Group for MPAACT – an initiative to establish MRD as an acceptable surrogate endpoint in AML clinical trials to expedite bringing novel therapies to market. Kerri earned her Medical Degree from Brown University and a Master's in Public Heath from the University of Memphis. She completed her residency at Brown University in both Internal Medicine and Pediatrics and subsequently trained in Pediatric Hematology/Oncology at St. Jude Children's Research Hospital in Memphis, TN. She was an academic faculty member in the Department of Hematology at St. Jude prior to coming to Johnson & Johnson.



Hernando Patino, MD, is a pediatrician with a background in critical care from Universidad del Valle (Colombia) and Maimonides Medical Center (USA), Dr. Hernando Patino's career is grounded in real-world patient needs. His journey, which began with bedside care, academics and public health, transitioned into a 30-year career in the pharmaceutical industry, with the last 15 years dedicated exclusively to advancing pediatric drug development.

Currently, Dr. Patino serves as an Executive Director at Johnson & Johnson Innovative Medicines and is a core member of the company's Children Health Innovation Leadership Department (CHILD). He has successfully implemented two Pediatric Drug Development Centers for Cardiology and Oncology, demonstrating his strategic vision and ability to drive impactful pediatric initiatives.

As the leader of the Pediatric Oncology Strategy Team (POST), Dr. Patino is at the forefront of providing strategic guidance for J&J's entire pediatric oncology portfolio. He is central to prioritizing assets, regulatory strategies, and integrating scientific and ethical considerations into pediatric development plans. He has extensive experience with multi-platform trials, having been involved with the NCI-MATCH program and currently exploring opportunities with different consortia.

Dr. Patino's expertise spans a broad range of therapeutic areas, including antimicrobials, antifungals, cardiovascular disease, thrombosis, vaccines, diabetes, and oncology. His background as a general pediatrician and specialist in pediatric critical care is complemented by a data-oriented mindset and a deep passion for clinical pharmacology and pharmacoepidemiology, skills he enhanced at Harvard training in Quantitative Methods in Clinical & Public Health Research. This blend of clinical and quantitative expertise allows him to provide expert opinions across multiple specialty areas. Prior to joining J&J, he held key roles at Merck and Schering-Plough and previously served as a university professor and public health officer in Colombia.

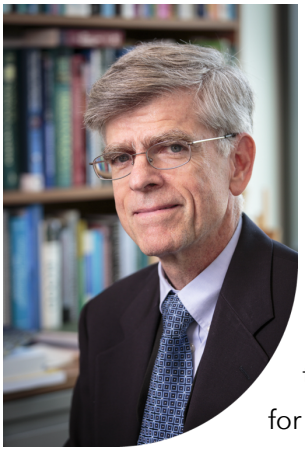
A recognized expert in regulatory strategy, Dr. Patino has broad experience engaging with worldwide health authorities, including the FDA, EMA (CHMP/PDCO), PMDA (Japan), MHRA (UK), and Health Canada. Known for his ethical rigor and scientific innovation, he is committed to expediting pediatric drug development and ensuring that innovative therapies for children are efficiently brought to market through optimized regulatory pathways.

Amy Rosenfeld, MD, MSCI, completed her medical training at Tel Aviv University in Israel. She completed her pediatric residency at Children's Mercy in Kansas City, MO and Pediatric Hematology/Oncology and Pediatric Neuro-oncology fellowships at Children's Memorial Hospital in Chicago, IL. She also received a Master's in Clinical Investigation from Northwestern University during her fellowship. She practiced as a Pediatric Neuro-oncologist for 10 years at Phoenix Children's Hospital in Phoenix, AZ where she was the PI for several Phase I clinical trials prior to moving to industry.

Amy has been with AstraZeneca for over 7 years. Her career at AstraZeneca has spanned both Early and Late Oncology as a Senior Director/Clinical Lead, overseeing several Phase I, II, and III assets. Amy has been involved in pediatric drug development since she began her career at AstraZeneca and is currently the Global Clinical Project Lead for the Pediatric Oncology Development team at AstraZeneca.

Nicole Scobie, is the Chair of ACCELERATE and long-serving member of its Scientific Steering Committee, and is a founding member and president-emeritus of Zoé4life, a Swiss non-profit supporting children with cancer, their families, and research. As a parent of a childhood cancer survivor, she advocates for better treatment access and the development of improved therapies. With extensive experience in incorporating patient perspectives into research strategies and clinical trial design, Nicole is a founding member of the ITCC and SIOPEN Advocate Committees. She serves on the board of CAC2, an international childhood cancer umbrella organization, and is a member of CCI-Europe's R&I committee. She is part of Strategic Advisory Boards for LifeArc as well as ITCC P4, and the Canadian ACCESS External Advisory Board. She is also in the TMG for the GLO-BNHL platform trial.

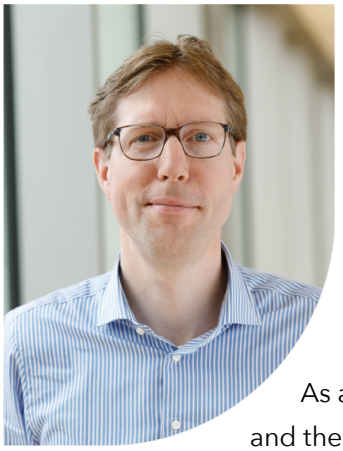
Angeliki Siapkara, MD, is a Senior Regulatory Affairs Director in AstraZeneca and the global regulatory lead for AZ's Paediatric Oncology Development Team. She has been working in paediatric drug development and relative policy activities for over 17 years. She obtained her medical degree from the University of Athens, and completed her postgraduate qualification in Orthopaedic Surgery with a special interest in Paediatrics at hospitals in Athens, Glasgow and at Great Ormond Street Hospital. In 2010 she obtained a MSc in International Child Health from University College London. Between 2008 and 2023 Dr Siapkara led the MHRA Paediatric Unit which delivered the implementation of regulatory activities for innovating paediatric medicines including PIPs, paediatric clinical trials and Marketing authorisations and paediatric pharmacovigilance. During that time, Dr Siapkara was the UK delegate at EMA's Paediatric Committee (PDCO) and member of the CMDh/EMA Working Party on Paediatric Regulation.



Malcolm Smith, MD, PhD, is Associate Branch Chief, Pediatrics, in the Cancer Therapy Evaluation Program (CTEP), NCI. Dr. Smith has been a member of CTEP since 1990 and during his years at CTEP has focused on developing NCI's preclinical and clinical research programs for children with cancer. Dr. Smith serves as an NCI scientific liaison to childhood cancer researchers in the Children's Oncology Group (COG), focusing primarily on hematologic malignancies and brain cancers. He also serves as the Program Director for the Pediatric Early Phase Clinical Trials Network (PEP-CTN) and the Pediatric Brain Tumor Consortium (PBTC). He serves as a project scientist for the Pediatric Preclinical in Vivo Testing (PIVOT) Program. Dr. Smith is the author or co-author of more than 240 publications and 25 book chapters related to childhood cancer research.

Yannick Tanguy, PhD, started his career as a laboratory technician in the pharmaceutical industry before pursuing further studies to obtain a PhD, which allowed me to lead academic research projects in Neuroscience. My thesis focused on investigating a novel gene involved in brain development and its role in pathophysiological conditions such as stroke. Building on my expertise in neuronal death, I continued my career as a postdoctoral researcher at the French Myology Institute, where I worked on developing gene therapy for spinal muscular atrophy. The most severe form of this childhood disease causes progressive muscle weakness, leading to complete paralysis and death around the age of two. We demonstrated that systemic injection of a gene therapy vector could counteract the devastating effects caused by the deletion of the *hSMN1* gene. When administered at birth, the treatment enabled the murine model to avoid disease symptoms and achieve a normal lifespan. However, when administered at or after symptom onset, the therapeutic benefits diminished. I worked on developing combinatorial strategies that showed strong potential and were particularly important in a context where neonatal diagnosis was not yet feasible. Over the years, I had the opportunity to collaborate across various fields—including diabetes, oncology, and cardiomyopathies—and co-authored 11 scientific publications along with a patent.

Following this experience, I transitioned out of academic research and joined Fondation Ipsen as a project manager in scientific communication. I was responsible for organizing numerous seminars and webinars in partnership with prestigious institutions (Mayo Clinic, UCSF, *Science* magazine, etc.). I implemented diverse formats tailored for public outreach to raise awareness about rare diseases and scientific advances. After seven years of collaboration, I joined Imagine for Margo as Head of Research. Founded in 2011, the organization funds ambitious research programs aimed at developing better and more effective treatments for children with cancer. We support projects that systematically screen genes involved in high-risk and relapsed cancers. This program—now backed by the French government—helps identify molecular targets in tumors and guide the prescription of the most appropriate treatments tailored to each child's specific cancer profile. I also serve on several steering committees for international projects (SACHA, InTeREALL, Fight Kids Cancer, Paris Kids Cancer, etc.), act as a passionate advocate for integrating patient and family voices into research, and contribute actively to the organization’s scientific communication.



Cornelis van Tilburg, MD, is a pediatric oncologist from the Netherlands working at the Hopp Children's Cancer Center Heidelberg (KiTZ) in Germany since 2012. In the Netherlands, I received a University degree in Biomedical Sciences and a PhD on Immunity and Infectious Morbidity in Childhood ALL Treatment. After my pediatric trainings in the Netherlands, I received my pediatric oncology training in Heidelberg with a focus on pediatric neuro-oncology. In 2022 I received the Venia Legendi from the medical faculty of the Heidelberg University.

As a consultant I'm responsible for the care for pediatric brain tumor patients and the development of international early phase clinical trials at KiTZ. I am a PI on two biomarker driven pediatric oncology early phase clinical trials. My most important challenge is to translate molecular knowledge of pediatric malignancies into the development of biomarker driven clinical trials in children with cancer.

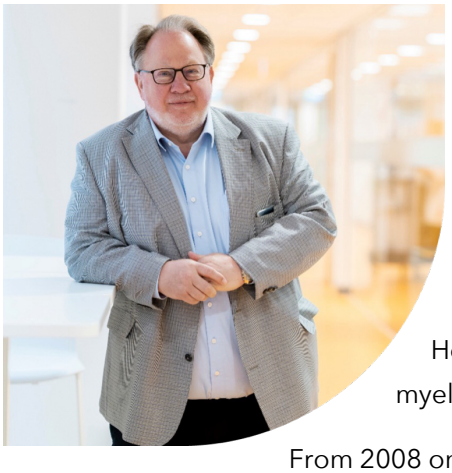
Beate Wulff, MD, has been the Global Development Leader for Roche/Genentech's iPODD (Innovative Pediatric Oncology Drug Development) Team since March 2025, overseeing the global strategy and development of the pediatric hematology-oncology portfolio. Since joining Roche in 2018 as Clinical Science Lead, she has applied her deep expertise in pediatric diseases and drug development, leading transformative initiatives such as the pediatric B-cell Non-Hodgkin Lymphoma (B-NHL) strategy, which secured FDA and EMA approvals for frontline Rituximab in pediatric B-NHL.

Dr. Wulff began her pharmaceutical career at medac GmbH, where she led clinical development in hematology-oncology and autoimmune diseases in adults and children, achieving multiple regulatory approvals in the EU and US.

A board-certified pediatric hematologist-oncologist with almost 30 years of professional experience, her career spans 18 years of clinical care and academic research in pediatrics, and over 12 years in drug development in the pharmaceutical industry. She established a Phase I/II Pediatric Hematology/Oncology Study Center in Germany, served as an investigator in international clinical trials, contributed to the Clinical Trials Committee for Innovative Therapies for Children with Cancer, and acted as Deputy Chair of the University Duisburg-Essen Ethics Committee.

Beyond her academic and industry roles, Dr. Wulff is a Co-Founder and Board Director of aPODD (Accelerating Pediatric Oncology Drug Development), a UK-based non-profit organization. She

leverages her expertise in academic, industry, and ethical dimensions to advance platform trials and accelerate drug development for children with cancer.



Michel Zwaan, PhD, was trained at the VU University medical center in Amsterdam and was registered as a paediatric oncologist in 1999. His PhD focused on drug resistance in paediatric acute myeloid leukaemia (AML) and was defended cum laude in 2003 at the VU Medical Center in Amsterdam.

After working as a consultant paediatric oncologist in Amsterdam in 2005 he moved to Erasmus MC-Sophia Children's Hospital in Rotterdam and focused on translational research on myeloid malignancies and early drug development.

From 2008 onwards he was appointed as associate professor, and in 2014 as 'professor of paediatric oncology, with emphasis on drug development' at Erasmus MC.

From 2014 to 2018 he headed the Paediatric Oncology/Hematology department in Rotterdam before moving to the Princess Máxima Center in Utrecht, where he is appointed as Group Leader for Drug Development/Experimental Therapeutics and medical director of the Trial and Data Center. He also chairs the Clinical Research Committee at the Princess Máxima Center.

He is a member of the Executive Board and Hematological Malignancies committee of ITCC, and he chairs the ethics committee in Utrecht and the Dutch Society of MRECS.

Workshop Sponsorship

The workshop planning committee appreciates the financial support of several organizations, without whom this workshop would not have been possible. The workshop was supported in part by voluntary contributions from: Cancer Research UK, Life Arc, Solving Kids Cancer, Kick Cancer, Andrew McDonough B+ Foundation, Leukemia & Lymphoma Society.