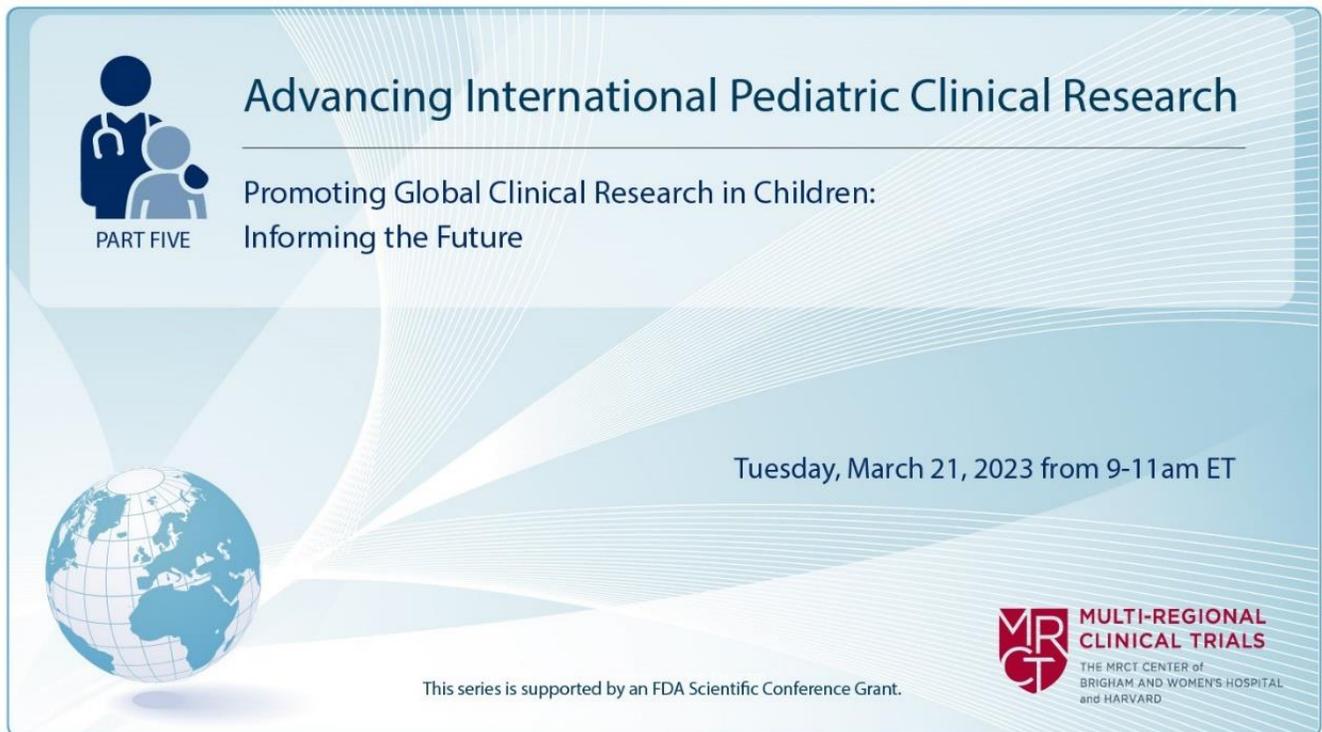


Advancing International Pediatric Clinical Research

Promoting Global Clinical Research in Children: Informing the Future



Advancing International Pediatric Clinical Research

PART FIVE

Promoting Global Clinical Research in Children:
Informing the Future

Tuesday, March 21, 2023 from 9-11am ET

This series is supported by an FDA Scientific Conference Grant.

MRCT MULTI-REGIONAL
CLINICAL TRIALS
THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

The 5th webinar in a 5-part series

21 March 2023

In remembrance of Dr. Vasantha Muthuswamy

We would like to take this opportunity to remember our valued colleague, close collaborator, and friend, Dr. Vasantha Muthuswamy, who passed away in Mumbai, India, in February 2023.



Dr. Vasantha, as she was known by many, was a steadfast, dedicated, and integral member of this webinar series planning group. An obstetrician and gynecologist by training, she was highly respected for her steady wisdom, unwavering dedication to her work, deep knowledge, compassion, and understanding. She worked tirelessly to shape the field of bioethics in India; her influence resonated globally. Her legacy will live on in the substantial body of work she leaves behind and the work of many colleagues she trained. Dr. Muthuswamy will be deeply missed.

We dedicate this webinar to Dr. Vasantha.

Conference Planning Committee Members

Albert J “AJ” Allen, MD, PhD, Eli Lilly & Co (retired)

Barbara E. Bierer, MD, Faculty Director, Multi-Regional Clinical Trials Center (MRCT Center)

Christina Bucci-Rechtweg, MD, Novartis Pharmaceuticals Corporation

Phaik Yeong Cheah, PhD, MORU Tropical Health Network, Bangkok, Thailand and University of Oxford, England

Jonathan M. Davis, MD, Tufts Medical Center and Tufts University School of Medicine, USA

Nilza Diniz, MS, PhD, University of Londrina, Brazil

Steven Joffe, MD, University of Pennsylvania Perelman School of Medicine, USA

Dominik Karres, MD, CPM, European Medicines Agency

Elisa Koppelman, MSW, MPH, MRCT Center

Mariana Kruger, MD, PhD, Stellenbosch University, South Africa

Susan K. McCune, MD, PPD

Gianna McMillan, DBE, Loyola Marymount University, Bioethics Institute

Robert “Skip” Nelson, MD, PhD, Johnson & Johnson

Gary Noel, MD, Institute for Advanced Clinical Trials for Children (iACT)

Lauren Otterman, MBHL, MRCT Center

Carla Saenz, PhD, Pan American Health Organization (PAHO)

Donna Snyder, MD, U.S. Food and Drug Administration

Rhian Thomas-Turner, PhD student, Cardiff and Vale University Health Board, Swansea University, Wales

Mark Turner, MD, PhD, MRCP, FFPM, University of Liverpool, England

Lisine Tuyisenge, MD, University Teaching Hospital of Kigali, Rwanda

Leanne West, MS, Georgia Institute of Technology, USA and International Children’s Advisory Network (iCAN)

Sarah Alicia White, MPH, MRCT Center

Katharine Wright, MA, Nuffield Council on Bioethics and MRCT Center

Special Acknowledgements

Kristin Bartlett, MRCT Center

Gigi McMillan, producer of “Time to Listen: Hearing from Young People in Clinical Research” video series

International Children’s Advisory Network (iCAN), producer of “Prioritizing Young People’s Voices in Clinical Research” video series

Kids Barcelona and **iCAN**, coordinating engagement of young people

All the young people who shared their time, expertise, and stories with us.

Advancing International Pediatric Clinical Research
Part Five: Promoting Global Clinical Research in Children: Informing the Future

21 March 2023, 9-11 am ET

Time	Topic	Speaker
9:00 – 9:20 AM	Welcome and introduction	Dr. Barbara Bierer The Multi-Regional Clinical Trials Center of Brigham & Women’s Hospital and Harvard
9:20 – 9:40 AM	Including Children in Decisions About Research: Towards Consistent Global Standards	Dr. Steve Joffe University of Pennsylvania
9:40 – 10:00 AM	Involving Young People in Research: The Pediatrics Toolbox	Dr. Gianna “Gigi” McMillan Loyola Marymount University Ms. Lisa Koppelman The Multi-Regional Clinical Trials Center of Brigham & Women’s Hospital and Harvard
10:00 – 10:15 AM	Establishing a Model to Integrate Children’s Voices into the Clinical Research Process	Dr. Thierry Lacaze Maternal Infant Child & Youth Research Network (MICYRN)
10:15 – 10:45 AM	Innovations in the Pediatric Regulatory Space: Fireside Chat	Dr. Dominik Karres European Medicines Agency Dr. Robert “Skip” Nelson Johnson & Johnson
10:45 – 10:55 AM	Closing	Dr. Barbara Bierer The Multi-Regional Clinical Trials Center of Brigham & Women’s Hospital and Harvard

Webinar Speaker Biographies



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 (Pediatrics), Harvard Medical School and Brigham and Women's Hospital, 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, and Director of Regulatory Policy, SMART IRB. 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 270 publications and is on the editorial boards of a number of journals including *Ethics and Human Research*. Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.



Steven Joffe, MD, MPH, is a pediatric oncologist and bioethicist who is currently the Art and Ilene Penn Professor of Medical Ethics and Health Policy and Professor of Pediatrics at the University of Pennsylvania Perelman School of Medicine, where he serves as Chair of the Department of Medical Ethics and Health Policy. He is also the Director of the Penn Postdoctoral Training Program in the Ethical, Legal and Social Implications (ELSI) of Genetics and Genomics. Dr. Joffe's research addresses the many ethical challenges that arise in the conduct of clinical and translational investigation and in genomic medicine and science. He has led NIH and foundation grants to study the roles and responsibilities of principal investigators in multicenter randomized trials, accountability in the clinical research enterprise, children's capacity to engage in research decisions, return of individual genetic results to participants in epidemiologic cohort studies, and the integration of whole-exome sequencing technologies into the clinical care of cancer patients. He has coauthored over 200 articles addressing these topics. He served as a member of the NIH's COVID19 Vaccine Trials Data and Safety Monitoring Board, recently completed a term as a member of the US FDA's Pediatrics Ethics Subcommittee, and is immediate past chair of the National Human Genome Research Institute's Genomics and Society Working Group, NIH, USA. He attended Harvard College, received his medical degree from the University of California at San Francisco, and received his public health degree from UC Berkeley. He trained in pediatrics at UCSF and undertook fellowship training in pediatric hematology/oncology at the Dana-Farber Cancer Institute and Boston Children's Hospital.



Dominik Karres, MD received his medical degree from the University Erlangen, Germany, followed by a MD in paediatric drug development. He held a training post in paediatric haematology/oncology (University Hospital Muenster) and worked in paediatric oncology and paediatric oncology drug development in Germany and the UK (Royal Marsden Hospital & Institute of Cancer Research UK). In 2014 he joined the UK's medicines regulatory agency (MHRA) with positions in the Licensing and Post-marketing Division. Since 2018 he works as Scientific Officer at the EMA Paediatric Medicines Office. Dominik is supporting the agency's further efforts to foster paediatric oncology drug development. In this capacity, he is also the EMA's nominee to the ACCELERATE Steering Committee, a multi-stakeholder platform aiming to facilitate the acceleration of science-driven developments of paediatric oncology drugs through global cooperation and collaboration.



Lisa Koppelman, MSW, LICSW, MPH joined the MRCT Center in June 2019 as a Program Manager where she focused on issues related to the global harmonization of pediatric clinical trials, elevating the voices of young people in clinical research, and community engagement. Expanding her role, Lisa assumed the position of Program & Team 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, previously overseeing projects on a range of content with a particular focus on qualitative research methods in her work at the Boston University School of Public Health. 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.



Thierry Lacaze, MD, PhD, assumed leadership of MICYRN in May 2018. He received his medical degree from the University Paris 5 - René Descartes in 1993 and a PhD in biological sciences at the University Paris 7 - Pierre et Marie Curie in 1995. Dr. Lacaze completed a fellowship in Neonatology in 1997, a Master in Epidemiology in 2000, and was appointed as Professor of Pediatrics at the University Paris 11 in 1997. Dr. Lacaze moved to Edmonton, Alberta, in 2003 to become the inaugural director of the Women and Children Health Research Institute (WCHRI) in 2006. In 2010, he was recruited as a senior scientist at the Children's Hospital of Eastern Ontario (CHEO) Research Institute and was the scientific director of the Clinical Research Unit at CHEO from 2011 to 2015. From 2016 to 2021, Dr. Lacaze was the section head of Neonatology at the Cumming School of Medicine, University of Calgary, and the regional program director of Neonatology at Alberta Health Services. Since May 2021, he has dedicated most of his time to MICYRN (<https://www.micyrn.ca/>), expanding capacities and providing services of an academic research organization. In addition, he is a Principal Investigator of the CIHR-funded CHEER initiative (The Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (<https://cheerchildhealth.ca/>)).



Gianna "Gigi" McMillan, DBE is the Program Administrator for the Bioethics Institute at Loyola Marymount University in Los Angeles and teaches Research Ethics. In 1996, she co-founded a support network for families whose children have brain cancer. This group evolved into a statewide non-profit organization, serving hundreds of families each year in Spanish and in English, until it became the California chapter of a national organization in 2016. Dr. McMillan has been an advisor to several brain tumor organizations. She has extensive experience as a Subject/Patient Advocate on local and national IRBs, was a member of the Subpart A Subcommittee for SACHRP, and is a patient representative on the FDA's Pediatric Oncology Drug Advisory Committee. Dr. McMillan has served on the board of the American Society for Bioethics and Humanities, has been a faculty member at PRIM&R since 2004, and is the Director of Community Engagement for the academic journal, *Narrative Inquiry in Bioethics*. Her primary interests are consent issues in clinical research and the use of narrative as an educational tool in bioethics.



Robert "Skip" Nelson, MD, PhD is Senior Director, Pediatric Drug Development in the Child Health Innovation Leadership Department at Johnson & Johnson. Previously (2006-2017), Dr. Nelson was the Deputy Director and Senior Pediatric Ethicist in the Office of Pediatric Therapeutics at the U.S. Food and Drug Administration. Prior to joining FDA, Dr. Nelson spent 20 years in the academic practice of pediatric critical care medicine, most recently as Professor of Anesthesiology, Critical Care and Pediatrics at The Children's Hospital of Philadelphia (CHOP) and University of Pennsylvania School of Medicine. Dr. Nelson is a member of the International Council for Harmonisation (ICH) E11A Working Group developing a guideline on the use of extrapolation in pediatric drug development plans. He is a member of the Secretary's Advisory Committee on Human Research Protections (SACHRP) and serves as the Industry Representative to the FDA Pediatric Advisory Committee. After receiving his M.D. degree from Yale University, Dr. Nelson trained in pediatrics (Massachusetts General Hospital), neonatology and pediatric critical care (University of California, San Francisco). He has a Master of Divinity degree from Yale Divinity School and a Ph.D. in The Study of Religion from Harvard University, specializing in ethics.