



**MULTI-REGIONAL
CLINICAL TRIALS**

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Advancing International Pediatric Clinical Research:

Time to Listen: Hearing from Young People in Clinical Research

2 February 2022

The 2nd webinar in a 5-part series

Webinar Participant Biographies



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)

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, The MRCT Center

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

Susan K. McCune, MD, PPD

Walker Morrell, BS, MBe, The MRCT Center

Vasantha Muthuswamy, MD, Forum for Ethics Review Committees in India (FERCI)

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

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

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, The MRCT Center

Katharine Wright, MA, Nuffield Council on Bioethics

Special Acknowledgements

Jennifer Ewing, The MRCT Center

Dr. Gianna “Gigi” McMillan, producer of *“Time to Listen-Hearing from Young People in Clinical Research”* video

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

All the youth who shared their time, expertise and stories with us from iCAN and Kids Barcelona

Advancing International Pediatric Clinical Research
Time to Listen: Hearing from Young People in Clinical Research



Advancing International Pediatric Clinical Research

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH



February 2, 2022

SESSION 1: 9:00 AM - 11:00 AM EST

SESSION 2: 8:00 PM - 10:00 PM EST

Please register for one or both as each will complement the other!

This series is supported by an FDA Scientific Conference Grant.



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Advancing International Pediatric Clinical Research
PART TWO: Time to Listen: Hearing from Young People in Clinical Research

Session One: 2 February 2022: 9:00 AM – 11:00 AM EST

Time	Topic	Speaker
9:00 -9:05 AM EST	Welcome and introduction	Dr. Barbara E. Bierer Faculty Director, The MRCT Center USA
9:05 -9:10 AM EST	Video: "Prioritizing Young People's Voices in Clinical Research"	Produced by iCAN and MRCT Center
9:10-9:45 AM EST	Keynote address	Keynote Speaker Ms. Jennifer Preston University of Liverpool England Youth Guest Speaker Ms. Sophie Ainsworth RAiSE England
9:45-9:55 AM EST	Video: "Time to Listen—Hearing from Young People in Clinical Research"	Produced by Dr. Gianna McMillan and MRCT Center
9:55 – 10:50 AM EST	Panel Discussion: <i>Time to Listen: Responding to young people talking about clinical research</i>	Moderator: Ms. Rhian Thomas-Turner Noah's Ark Children's Hospital Wales



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		<p>Speakers:</p> <p>Ms. Angela Kyalo KEMRI Wellcome Trust Programme Kenya</p> <p>Ms. Begonya Escalera Sant Joan de Déu Children's Hospital Spain</p> <p>Ms. Erin Moore Patient Advocate USA</p>
10:50 – 11:00 AM EST	Introduction of MRCT Center toolkit & pediatric educational materials, and wrap up	<p>Dr. Barbara E. Bierer Faculty Director, The MRCT Center USA</p>



Advancing International Pediatric Clinical Research
PART TWO: *Time to Listen: Hearing from Young People in Clinical Research*

Session two: 2 February 2022: 8:00 PM – 10:00 PM EST

Time	Topic	Speaker
8:00 -8:05 PM EST	Welcome and introduction	Dr. Barbara E. Bierer Faculty Director, The MRCT Center USA
8:05 -8:10 PM EST	Video: “Prioritizing Young People’s Voices in Clinical Research”	Produced by iCAN and MRCT Center
8:10-8:45PM EST	Keynote address	Youth Guest Speaker, Rohit The George Institute for Global Health, India Dr. Sandhya Kanaka Yatirajula The George Institute for Global Health, India
8:45-8:55 PM EST	Video: “Time to Listen—Hearing from Young People in Clinical Research”	Produced by Dr. Gianna McMillan and MRCT Center
8:55 – 9:50 PM EST	Panel Discussion: <i>Time to Listen: Responding to young people talking about clinical research</i>	Moderator: Dr. Thierry Lacaze University of Calgary Canada



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		<p>Speakers:</p> <p>Ms. Sheila Varadan Independent Child Rights Legal Researcher Thailand</p> <p>Dr. Min Soo Park Severance Children's Hospital Korea</p>
9:50 – 10:00 PM EST	Introduction of MRCT Center toolkit & pediatric educational materials, and wrap up	<p>Dr. Barbara E. Bierer Faculty Director, The MRCT Center USA</p>

Webinar speakers



Sophie Ainsworth, Founder and Chief Executive Officer of RAIiSE which stands for Raising Awareness of invisible Illness in Schools and Education. Ms. Ainsworth is a young person with lived experience of an invisible illness, which led her to establish RAIiSE in 2016, following negative experiences in school. She is also a member of several patient advisory groups, and the North West Lupus UK committee. Ms. Ainsworth also has experience being involved in research and has recently completed a degree in English Literature at Durham 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, she serves on the Board of Directors of Vivli, Inc., a non-profit organization founded by the MRCT Center dedicated to global clinical trial sharing; Management Sciences for Health (MSH); North Star Research Board; Clinithink, Inc., 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.



Begonya Nafria Escalera, PhD candidate, is the Patient Engagement Research Coordinator at Sant Joan de Déu Children's Hospital (Spain) with extensive experience in the field of the patient and family involvement in research initiatives. Ms. Escalera also has a personal story as a caregiver and patient advocate as the sister of a young adult with cerebral palsy. Her areas of expertise are focused in paediatric patient involvement in research, specifically in the field of clinical trials. Ms. Escalera is currently a PhD student in paediatric patient involvement.

Other relevant background includes Ms. Escalera's roles as: Fellow of EUPATI (first cohort); Coordinator of eYPAGnet (European Young Patients Advisory Group Network – www.eypagnet.eu); Coordinator of Kids Barcelona (YPAG of Sant Joan de Déu Children's Hospital- www.kidsbarcelona.org); member of Children's Medicines Working Party of EFGCP; volunteer member of the Editorial Board of Center for Information & Study on Clinical Research Participation (CISCRP); member of the Patients and Families working group of EnprEMA (European Network of Paediatric Research of EMA); and coordinator of the cross-cutting theme of patients involvement in Conect4Children project (pan-European paediatric clinical trials network). The main aim of all the activities that

Ms. Escalera either leads or participates in is to achieve a better quality of life for paediatric patients through research related activities and new therapies.



Angela Kyalo, MA, provides leadership, management, and program development for the KWTRP School Engagement Programme (SEP). She draws on her extensive experience from the fields of health research, education, public engagement and youth interventions to support innovation and excellence in the design, implementation, evaluation and dissemination of community and public engagement (CPE) with health research, focusing on children and young people.

Ms. Kyalo has worked closely with educational programs to promote access to quality education for marginalized children in Kenya. She has an interest in inclusive education, particularly gender equality and social inclusion program which includes disability inclusion. Ms. Kyalo is a tireless advocate for action research health promotion and currently supports a school education program to promote interest in science and strengthen understanding of research for young people.



Dr. 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 has been 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. He is also 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/>)).



Erin Moore, B.S., started her work in patient advocacy through a partnership with Cincinnati Children's Hospital Medical Center where she worked as a Healthcare Innovation Consultant and Family Partner. As such, she collaborated with the clinical staff to identify unmet needs, designed and tested innovations to improve care and outcomes, developed solutions to bridge the patient and clinician communities, and ensured the perspective of families and patients were represented. She was and continues to be a leader in the effort to create a Learning Network for the Cystic Fibrosis community, which aims to bring patients, clinicians, and researchers together to test existing and create new solutions and tools to better manage health and care and improve outcomes in the CF community.

In 2014, Erin served as an external innovation advisor with Genentech, a briefer to the JASONs 2014 Data for Individual Health report, and an advisor with The Robert Wood Johnson Foundation's Data for Health initiative. She is as a US Food and Drug Administration Patient Representative and has also worked with the Office of the National Coordinator for Health IT and the White House Office of Science and Technology Policy on the Obama Administration's Precision Medicine initiative.

Ms. Moore joined Eli Lilly and Company in the spring of 2016 as an ePatient advisor, working on their Clinical Innovation Team; her role expanded in 2017 to include managing Lilly's TrialGuide digital recruitment platform and the promotional efforts supporting it. In September of 2016 she was awarded Health 2.0's 10th Anniversary Global Retrospective Award for Patient Activism. At that time she was also serving as an executive board member for Stanford University's MedicineX Conference. Since 2018, Erin has worked as a member of the leadership team at Shift Results to help further shape the inclusion of patient and family voices in improvement efforts across many sectors.



Min Soo Park, MD, PhD, graduated from Yonsei University College of Medicine (YUCM) in Seoul, Korea, and was trained in Pediatrics and Neonatology at Severance Hospital, Yonsei University. He received his MSc in Clinical Pharmacology at University of Aberdeen, UK, and PhD in Medicine at Ajou University, Korea. Dr. Park served as Vice President of Korea National Enterprise for Clinical Trials (KoNECT) between 2008-2014. He established the Clinical Trials Center of Severance Hospital and served as Director from 2004 to 2016. Additionally, he has served as Director of Medical Science Research Affairs & President of University-Industry Foundation, Yonsei University Health System between 2016 and 2018, and as the Chair of Korea Clinical Trials Global Initiative (KCGI), funded by Korea Ministry of Health and Welfare between 2014 and 2019. Currently Dr. Park is Professor in Pediatrics, Head of Clinical Pharmacology at Severance Hospital, Head of Neonatology and NICU at Severance Children's Hospital at YUCM and the Chair of Dept of Pharmaceutical Medicine and Regulatory Science at Yonsei University Graduate School.



Jennifer Preston, PhD Candidate, is a senior Patient and Public Involvement Manager based at the University of Liverpool, UK. Her main role for the last 16 years has been to deliver a strategy for the involvement and engagement of children, young people and families in the design and delivery of paediatric health research. She is involved in a number of UK and European based children and family focused projects, has co-authored over 45 peer-reviewed articles about patient and public involvement, has delivered numerous training sessions, workshops and conference presentations over the years for a variety of audiences including patients and families, health care professionals, and health researchers about the importance and impact of patient involvement in health research. Ms. Preston is currently pursuing her PhD looking at a child-rights based approach to 'meaningful' involvement with children and young people in the design and delivery of paediatric research.



Rohit is a 16-year-old youth speaker from Sultaspuri New Delhi, India where he lives with his family. He is an aspiring classical dancer and is in his 11th year of pre-university education in school.



Rhian Thomas-Turner, NHS, is the Research & Development lead for the Noah's Ark Children's Hospital for Wales based in Cardiff and is the Operational Lead for the Children and Young Adults' Research Unit, Wales' first Paediatric Clinical Research Facility, which she helped to establish in 2017. The hospital has a mixed portfolio of research studies including many commercial drug studies spanning paediatric conditions including early phase paediatric oncology. Ms. Thomas-Turner is also a research student at the Hilary Rodham Clinton School of Law, Swansea University, where she is researching the impact of Research and Development models on drug development for children.



Sheila Varadan, JD, PhD Candidate and Independent Child Rights Legal Researcher, is completing her PhD in Law at the University of Leiden in the Netherlands. Her doctoral research focuses on the evolving capacities of the child in the context of parent-child decision-making in medical research. Ms. Varadan has acted as an independent human rights consultant for UNICEF, UN Women and the ETHOX centre (REACH Project) and has worked as a legal advisor for the International Rescue Committee and the International Commission of Jurists. She also headed the Global Legal Programme at ECPAT International, leading the advocacy for a network of 121 civil society organizations across 103 countries to end the sexual exploitation of children. She holds a Juris Doctor (Distinction) and a Bachelor of Civil Laws (Distinction) from McGill University, and a Master of Laws (Distinction) from the London School of Economics and Political Science in London, United Kingdom. She has published widely on children's rights and recently co-authored the chapter on children's right to parental guidance and the evolving capacities of the child in *The UN Convention on the Rights of the Child, Oxford Commentaries on International Law* (Oxford University Press, 2019). Ms. Varadan is based in Thailand where she has been working for almost 15 years.



Sandhya Kanaka Yatirajula, PhD, is a senior research fellow at The George Institute for Global Health in India where she manages a large cluster randomised control trial that aims to test the effectiveness of a community based anti-stigma campaign co-designed by adolescents to reduce mental health stigma. Dr. Kanaka Yatirajula is a trained qualitative researcher and has extensive experience working with human rights-based approaches, maternal health and rights, youth sexual and reproductive health and rights, and gender justice. She holds a PhD from the Department of Social Medicine and Community Health, Jawaharlal Nehru University.