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

Advancing international pediatric clinical research:

PART ONE: *Informing the future from COVID-19 lessons learned*

6 & 7 October 2021

Webinar Participant Biographies

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

Conference planning committee members

Albert J "AJ" Allen, MD, PhD, Eli Lilly & Co
Barbara E. Bierer, MD, Faculty Director, Multi-Regional Clinical Trials Center (MRCT Center)
Phaikyeong 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
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 Acknowledgement

Jennifer Ewing, The MRCT Center

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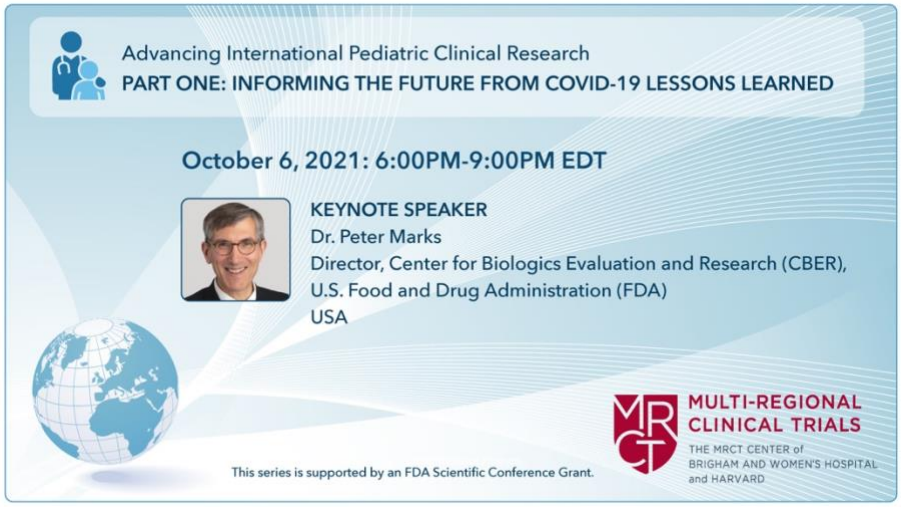
DRAFT Agenda: Day 1 agenda: 6 October 2021, 6-9 PM EDT



Advancing International Pediatric Clinical Research
PART ONE: INFORMING THE FUTURE FROM COVID-19 LESSONS LEARNED

1ST Session: 6 October 2021: 6:00 PM – 9:00 PM EDT

Time	Topic	Speaker
6:00 PM - 6:10 PM EDT	Welcome and introduction	**Dr. Barbara E. Bierer** Faculty Director, The MRCT Center USA
6:10 PM - 6:45 PM EDT	Keynote Address	**Dr. Peter Marks** Director CBER, FDA USA
6:45 PM - 7:45 PM EDT	**Panel 1** Initiating clinical trials in children—*Is there a right time?*	**Moderator:** **Dr. Steven Joffe** University of Pennsylvania USA **Speakers:** **Dr. Robert W. Frenck, Jr.** Cincinnati Children's Hospital Medical Center USA **Dr. Calvin Ho** University of Hong Kong Hong Kong

		Dr. Isao Miyairi Department of Pediatrics, Hamamatsu University School of Medicine Japan
7:45 PM - 7:55 PM EDT	BREAK	
7:55 PM - 8:55 PM EDT	**Panel 2** Infrastructure needs*: How do we create and sustain a network for the conduct of ethical pediatric clinical trials?*	**Moderator:** **Dr. Alysha Croker** Health Canada Canada **Speakers:** **Dr. Mario Alanis** Center for Innovation in Regulatory Science (CIRS) Mexico **Dr. Collin Hovinga** Institute for Advanced Clinical Trials for Children (iACT) University of Texas at Austin USA **Dr. Hidefumi Nakamura** National Center for Child Health and Development Japan **Dr. Min Soo Park** Yonsei University College of Medicine Severance Children's Hospital Korea
8:55 PM – 9:00 PM EDT	Wrap up	

MULTI-REGIONAL CLINICAL TRIALS
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DRAFT Agenda: Day 2 agenda: 7 October 2021, 8-11 AM EDT

Advancing International Pediatric Clinical Research
PART ONE: INFORMING THE FUTURE FROM COVID-19 LESSONS LEARNED

2nd session: 7 October 2021; 8:00 AM-11:00 AM EDT

Time	Topic	Speaker
8:00 AM -8:10 AM EDT	Welcome and introduction	**Dr. Barbara E. Bierer** Faculty Director, The MRCT Center USA
8:10-AM-8:45 AM EDT	Keynote Address	**Prof. Mojisola Christianah Adeyeye** Director General of the National Agency for Food and Drug Administration and Control (NAFDAC) Nigeria
8:45 AM -9:45 AM EDT	Panel #1: Initiating clinical trials in children-- *When is the right time?*	**Moderator:** **Dr. Angeliki Siapkara** Medicines and Healthcare products Regulatory Agency (MHRA) UK

		Speakers: **Dr. Narendra Kumar Arora** INCLEN Trust International India **Dr. Grace Ku** Institute of Tropical Medicine Belgium **Dr. Tanusha Ramdin** Charlotte Maxeke Johannesburg Academic Hospital South Africa
9:45 PM -9:55 AM EDT	BREAK	
9:55 AM -10:55 AM EDT	Panel #2: Infrastructure needs*: How do we create and sustain a network for the conduct of ethical pediatric clinical trials?*	**Moderator:** **Mrs. Pirkko Lepola** FINPEDMED NORDICPEDMED European Network of Paediatric Research at European Medicines Agency (Enpr-EMA) Finland **Speakers:** **Dr. Lisine Tuyisenge** University Teaching Hospital of Kigali Rwanda **Dr. Vasantha Muthuswamy** Former Senior Deputy DG, ICMR President, FERCI (Forum for Ethics Review Committees in India) India **Dr. Marie Valentin** World Health Organization (WHO) Switzerland
10:55 AM -11:00 AM EDT	Wrap up	

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Webinar speakers

Professor Mojisola Christianah Adeyeye, PhD, is the Director General (DG) of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) where she is leading regulatory and administrative reforms through quality management approach. She is Professor *Emeritus* of Pharmaceutics, Drug Product Development and Evaluation at the College of Pharmacy, Roosevelt University (RU) in Schaumburg, Illinois. She was the Founding Chair of the Department of Biopharmaceutical Sciences at Roosevelt University where she hired new faculty, built research laboratories, and procured research equipment. Professor Adeyeye is celebrated for enhancing the scholastic capacity of the faculty members and engaging community stakeholders (pharmaceutical and biotechnology companies) as advisory board members and collaborators. Her research interest includes pre-formulation, pediatric and adult drug product (solids, liquids, and semisolids) development and evaluation, investigational new drug application-driven bench-to-bedside translational research, preclinical and clinical trials, analytical/bioanalytical assay development, bioavailability and bioequivalence quantitation, fixed dose combination dosage forms for various drug classes including antiretrovirals, anti-malarials and anti-sickling agents. She is Senior William J. Fulbright Scholar and Specialist, 2008 American Association of Pharmaceutical Scientists (AAPS) Fellow, 2016 Nigerian National Academy of Science Fellow and 2017 Nigeria Academy of Pharmacy Fellow. She earned her B.S., and M.S./PhD from the University of Nigeria, Nsukka, Nigeria, and University of Georgia, Athens, GA, respectively. She has 5 patents, 62 peer-reviewed manuscripts, book chapters and books, more than 150 scientific presentations and successfully mentored many MS and PhD candidates. She founded Elim Pediatric Pharmaceuticals Inc. (EPPI), a socially conscious company, to develop drugs for HIV/AIDS children. She was the President/CEO of EPPI until she was appointed as DG of NAFDAC.

Mario Alanís, PhD, concluded a Ph.D. in Economics at the University of Pennsylvania and the Bachelor program at the Instituto Tecnológico y de Estudios Superiores de Monterrey Monterrey in Mexico. Dr. Alanis has domestic and international, public-sector experience in health regulation, economic analysis, social policy, and international trade negotiations. He has a proven track record of successfully leading teams working on complex, sensitive issues with governments, multilateral organizations, non-governmental organizations, and the pharmaceutical and medical device industry. Currently he collaborates as a Senior Advisor to the Center for Innovation in Regulatory Science, (CIRS) participating in diverse strategic projects for the Latin American Region.

Narendra Kumar Arora, MD, FAMS, FIAP, FIPHA is Executive Director at the International Clinical Epidemiology Network (INCLEN), New Delhi, India (since 2005), and a former faculty of Paediatric Gastroenterology, Haematology, and Nutrition at the All-India Institute of Medical Sciences (AIIMS), New Delhi, India (1983-2005). As a paediatrician and public health expert, Professor Arora has made major contributions at both national and global levels to the immunization sector (Pulse Polio Immunization Program, vaccine hesitancy, and active & passive AEFI surveillance). Professor Arora served as a Chair/Member of the World Health Organization's (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) from 2010 to 2016 and South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG). Currently, he is serving as a member of the WHO's Global Advisory Committee on Vaccine Safety (GACVS), Strategic and Technical Advisory Group for Maternal, Newborn, Child and Adolescent health and nutrition (STAGE), and is a Member of COVAX Independent Allocation of Vaccines Group (IAVG).

In India, Professor Arora has been involved in numerous national scientific, research, and academic committees constituted under the MoHFW, DBT, BIRAC, DST, ICMR, and UGC. Working towards national centers of excellence in clinical care, research, and training, the Government of India appointed Professor Arora as a President (2018) to two newly established National Institutions of Eminence in India (AIIMS-Patna and AIIMS-Deoghar). He is also currently serving as a Chair, Co-Chair and a Member on various COVID-19 related research activities in India.

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.

Alysha Croker, PhD, joined Health Canada in 2019 as the Manager of the Office of Pediatrics and Patient Involvement, a role which involves developing ways to increase access to safe and effective drugs and medical devices for pediatric populations in Canada, as well as integrating both the patient voice and equity considerations throughout the drug and device lifecycle. Previously, Dr. Croker managed the Canada Excellence Research Chair (CERC) and the Canada First Research Excellence Fund (CFREF) programs for Canada's federal research funders ("tri-agencies"). She also led the development of the Canadian Institutes of Health Research's (CIHR) training and equity strategies where was awarded the CIHR Innovation Award. Dr. Croker has a PhD from Western University where she studied the molecular mechanisms of breast cancer metastasis and therapy resistance.

Robert W. Frenck, Jr, MD, received his undergraduate degree from the University of California at San Diego in 1977 followed by his Doctor of Medicine degree from the University of Texas Health Science Center at Houston in 1981 as part of the Health Professions Scholarship Program. He trained at the National Naval Medical Center in Bethesda, Maryland completing his pediatric residency in 1984. After 3 years as a general pediatrician at the US Naval Hospital, Japan, he entered pediatric infectious disease fellowship training at the University of Texas Health Science Center at Houston which he completed in 1990. After a 27-year career, Dr Frenck retired from the Navy and joined Cincinnati Children's Hospital (CCHMC) in 2006. Dr. Frenck is board-certified in both pediatrics and infectious diseases and maintains an active research portfolio including therapeutic and vaccine clinical trials with special interest in enteric diseases. Dr. Frenck is a Professor of Pediatrics in the Division of Infectious Diseases at Cincinnati Children's Hospital and is the Director for their Center for Vaccine

Research. Additionally, Dr. Frenck is the Executive Chair of the CCHMC IRB and has served on the Secretary's Advisory Committee on Human Research Protections sub-part A sub-committee as well as on the AAHRPP Council.

Calvin Ho, JSD, MSc, LLM, FRSPH, is Associate Professor at the Department of Law and Co-Director of the Centre for Medical Ethics and Law of the Li Ka Shing Faculty of Medicine and the Faculty of Law, the University of Hong Kong. He is also an Ethics Board member of Médecins Sans Frontières (Doctors Without Borders) and a member of the World Health Organization's Ethics and Governance Workgroup of the Access to COVID-19 Tools (ACT)-Accelerator.

Collin Hovinga, PharmD, MS, FCCP, completed his Doctor of Pharmacy at Creighton University, after which he pursued a Residency and Fellowship in Pediatric Pharmacotherapy at the University of Tennessee, Memphis, LeBonheur Children's Medical Center. He completed a second Fellowship at the FDA and a Masters of Epidemiology from the University of Tennessee Health Science Center. Dr. Hovinga has additional training in outcomes research from MD Anderson Cancer Center and extensive experience in the leadership and oversight of pediatric clinical trials. He is recognized as an expert in study design, regulatory affairs, pediatric clinical trials, and outcomes research. Currently, Dr. Hovinga is Senior Vice President of Clinical and Scientific Development at the Institute for Advanced Clinical Trials for Children (I-ACT for Children) and is also an Associate Professor at University of Texas at Austin.

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 Interim Chair of the Department of Medical Ethics and Health Policy and Chief of the Division of Medical Ethics. 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 serves as a member of the US FDA's Pediatrics Ethics Subcommittee and the NIH's COVID19 Vaccine Trials Data and Safety Monitoring Board and chair 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.

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Grace Marie V. Ku, MD, MScPH, FPAFP, PhD, is a public health expert, a family and community medicine physician-specialist, a health researcher, and an academician. She has extensive backgrounds in quantitative, qualitative, and mixed methods in research in international health, health systems, and health policy & development; in strategic management and quality management systems; and in bioethics. A graduate of the University of Santo Tomas Faculty of Medicine & Surgery, Philippines, and a Fellow of the Philippine Academy of Family Physicians, she was a practicing clinician and was the Quality Assurance Unit Chief at the 766-bed Veterans Memorial Medical Center in Quezon City. She took her MSc in Public Health at the Institute of Tropical Medicine, Antwerp. Upon receiving her PhD in Medical Sciences (Public Health) from the Vrije Universiteit Brussel, she moved full time to research and academics as an associate professor at the Philippine National Institutes of Health and the University of the Philippines College of Medicine. She later transferred to Médecins Sans Frontières (Doctors Without Borders) where she was the Executive Officer of the MSF-International Ethics Review Board. Currently, she is a senior researcher (public health) and lecturer (health systems; health policy; public health ethics) at the Institute of Tropical Medicine; and a guest lecturer at the Vrije Universiteit Brussel (health systems), at the Université Catholique de Louvain (medical ethics) and at the University Medical Center Utrecht (health systems).

Pirkko Lepola, BSC, MSC, is the Executive Secretary of FINPEDMED, General Secretary of NOZRDICPEDMED at Helsinki University Hospital, Department of Children and Adolescents, Finland and Chair of the Enpr-EMA Coordinating Group. Her broad educational background includes a BSc in Health Care, MSc in Biotechnology, and Teacher/Pedagogical qualification with additional courses in BioMedical Law and Pharmaceutical Medicine.

Mrs. Lepola's Professional Experience from 1995-2006 includes various management positions (Clinical Trials) in Pharma Industry and CRO companies, and University Hospital´s Research Organizations. Since 2007 -present: Executive Secretary of FINPEDMED (Finnish Investigators Network for Pediatric Medicines), 2010-2012: Project Manager of FinnTrials–project (Finland), 2013-2017: Researcher in EU GRiP -project (Global Research in Paediatrics), 2016-present: General Secretary, NordicPedMed (Nordic Investigators Network for Pediatric Medicines), 2017-2021: Consortium Partner in EU PedCRIN (The Paediatric Clinical Research Infrastructure Network)–project; 2018-present: Consortium Partner in the EU/IMI2 c4c (Conect4Children-PanEuropean Pediatric Clinical Research Infrastructure), 2014-2019: Conference creator/co-creator & producer: National Pediatric Drug Therapy Conferences, Nordic Conferences on Pediatric Medicines with Pharma Industry Finland.

Mrs. Lepola's various memberships and expert work include: 2010-present: EMA (European Medicines Agency) European Expert, 2010-present: Chair, Enpr-EMA (European Network of Paediatric Research at the European Medicines Agency), 2013-present: Chair, Enpr-EMA Working Group of Ethics. 2013-present: Member of the EFGCP MCWP (European Forum for Good Clinical Practice, Medicines for Children Working Party), 2019-present: Member of the Advisory Board SwissPedNet (The Swiss Research Network of Clinical Pediatric Hubs). Further, Mrs. Lepola has considerable teaching experience: 2007-present: Lecturer at Universities, University Hospitals and Universities of Applied Sciences in Finland. She has published extensively: Articles 10, Book chapters 2, Scientific presentations 50+.

Peter Marks, MD, PhD, received his graduate degree in cell and molecular biology and his medical degree at New York University, and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for Center for Biologics Evaluation and Research (CBER) and became Center Director in January 2016.

Isao Miyairi, MD, PhD, is the Chairman of Pediatrics at the Hamamatsu University School of Medicine in Japan. He is board certified in Pediatrics and Pediatric Infectious Diseases in Japan and the United States. He has been engaged in conducting pediatric research and providing care to children with COVID-19

Vasantha Muthuswamy, MD, is a medical graduate and postgraduate in Obstetrics and Gynaecology and retired as Senior Deputy Director General from the Indian Council of Medical Research (ICMR), New Delhi in 2008 after three decades of service in different capacities. She was Head of the Bioethics Unit in addition to Basic Medical sciences, Traditional Medicine, Maternal and Child Health and Nutrition.

A WHO Fellow at the Kennedy Institute for Ethics, Georgetown University, Washington DC in 1997, she is well recognized for bringing out the ICMR's "Ethical guidelines for biomedical research on human subjects" in 2000 and the revised version "Ethical guidelines for research on human participants" in 2006 and the latest one in 2017. She was also responsible for the Guidance document for Animal experimentation, Guidelines for Stem cell research and therapy, Guidelines for Safety evaluation of food derived from GE plants, Guidelines for Good Clinical laboratory practices, National guidelines for biomedical research in Children etc. She has been member of ethics related committees at WHO TDR, UNAIDS, UNESCO, HPTN, EC etc. Dr. Muthuswamy has also contributed to ethics guidelines in Nepal, Srilanka, Maldives etc. She was the Founder Secretary of Forum for Ethics Review Committees in Asia Pacific (FERCAP) in 2000 and continued as Steering committee member till 2021. She has received Lifetime achievement awards and has many publications and Chapters on research ethics to her credit.

Dr. Muthuswamy is currently President of FERCI (Forum for Ethics Review Committees in India), and Chairperson of the Central Ethics Committee for Human Research (CECHR) under ICMR. She guided release of the Ethical guidelines for EC members in April 2020 for review of research related to COVID 19 pandemic. She is a member of many Institutional Ethics committees and Stem cell research committees.
Dr. Muthuswamy has been continuously involved for the past 25 years in training of EC members and other stakeholders in Research ethics and GCP in India and many countries.

MULTI-REGIONAL CLINICAL TRIALS
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Hidefumi Nakamura, MD, PhD, is the Director for Clinical Research & Development, Department of R&D Supervision, National Center for Child Health and Development, (NCCHD), Tokyo. He is a pediatrician and a pediatric pharmacologist with an experience as a senior reviewer at the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC), former body of the Pharmaceuticals and Medical Devices Agency (PMDA). He is currently the chairman of the Committee on Pharmaceutical Affairs of the Japan Pediatric Society.

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. He served as Vice President of Korea National Enterprise for Clinical Trials (KoNECT) between 2008-2014. And he established the Clinical Trials Center of Severance Hospital and served as Director from 2004 to 2016. He 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 he 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.

Tanusha Ramdin, MD, is the Head of neonatology and paediatric intensive care unit at Charlotte Maxeke Johannesburg Academic Hospital, one of Southern Africa's largest tertiary and academic hospitals. She is the coordinator of the National Neonatal Resuscitation program and has recently embarked on a joint neonatal resuscitation program with Zimbabwe. She is the co-chair of the international COVID-19 mother and child coalition group and member of national COVID-19 task team. She is also the coordinator of the African neonatal fellowship program.

Dr Ramdin completed her MBBCh at the University of the Witwatersrand in 2002, qualified as a Paediatrician in 2010 and as a Neonatologist in 2015 at the College of Medicine South Africa, and is currently developing her PhD proposal. She is involved in various research projects at Charlotte Maxeke and is involved in many aspects of medical education through Wits University Medical School (which is adjacent to the hospital) and the College of Medicine South Africa. Some of her responsibilities include supervising Master of Medicine Students, teaching undergraduate medical students, and examining both undergraduate and postgraduate students. She has published several papers on neurodevelopmental outcome and sepsis in preterm infants.

Dr Ramdin is currently and has for the last 6 years been part of an NGO assisting destitute countries requiring medical assistance.

Angeliki Siapkara, MD, obtained her medical degree from the University of Athens and completed her postgraduate qualification in Orthopedic Surgery with a special interest in Pediatrics at hospitals in Athens, Glasgow and at Great Ormond Street Hospital. In 2010 she undertook postgraduate research leading a MSc in International Child Health from University College London. Dr Siapkara joined the MHRA in 2008 leading the Pediatric Unit which delivers the implementation of regulatory activities for innovating pediatric medicines and improved pediatric pharmacovigilance. She is currently the Group manager for Medicines and Healthcare products Regulatory Agency (MHRA) Benefit Risk Group. She was the United Kingdom (UK) delegate at European Medicines Agency's (EMA) Pediatric Committee (PDCO) and member of the CMDh/EMA Working Party on Pediatric Regulation. Dr Siapkara is an observer at Joint Standing Committee on Medicines of the Royal College of Pediatrics and Child Health.

Lisine Tuyisenge, MD, MMed (Paed), is a Senior Consultant Paediatrician at the University Teaching Hospital of Kigali with more than ten years of clinical experience, a former Head of the Paediatric and child health Department in the same hospital, and currently the Director of Medical services in the University Teaching Hospital of Kigali (CHUK), the biggest public teaching hospital in Rwanda. She is a clinical Associate Professor at the University of Rwanda, College of Medicine and Health Sciences. Dr. Tuyisenge is the former General Secretary of the Rwanda Paediatric Association (RPA) for the last 13 years and is now the Chair of the same Association. She is active member of Rwanda National Ethic Committee.

Dr. Tuyisenge earned her Doctor of General Medicine and Post-Graduate (Paediatrics) degrees from the National University of Rwanda (Butare) Faculty of Medicine and received advanced training in Paediatric Infectious Diseases and Neonatology at Sint Peter Hospital in Brussels, Belgium. She is involved in extensive national and international collaborative research and widely published with a broad interest in Child Health.

Marie Valentin, PharmD, is a pharmacist specialized in drug product regulation with over 20 years of experience in regulatory affairs and product development, acquired both in the private and public sectors.

At The World Health Organization (WHO), Marie works in the Regulatory Convergence and Network Team towards convergence, harmonization and system strengthening activities, supporting different regional regulatory networks, and supporting Member States to strengthen their regulatory systems. She oversees the Secretariat for the WHO paediatric regulatory network, a global network of regulators and other interested stakeholders supporting the availability of quality-assured medical products for children. She is the regulatory lead of the Global Accelerator for Paediatric formulations (GAP-f), a WHO led-network whose goal is to enhance coordination between partners for an optimal development of formulations for children in need.

Before joining the WHO in May 2019, Marie worked for 8.5 years at the European Medicines Agency in London as a Regulatory Affairs Officer where she oversaw providing regulatory and procedural advice in relation to the development, evaluation, and surveillance of medicinal products in the European Union. Before that, she worked in the pharmaceutical industry, contract research organization and consultancies in the United Kingdom, Spain, and France.


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