MULTI-REGIONAL CLINICAL TRIALS

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

2021 REIMAGINING CLINICAL TRIALS: LEARNING FROM COVID-19

16 June 2021

10AM-1PM EDT

Speaker Biographies

Barbara Bierer, MD, is the faculty director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center); 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 Science Center and the 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 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 currently 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), an international organization working in partnership globally to strengthen health care, local capability, and access; and the Edward P Evans Foundation, a foundation supporting biomedical research. Previously she has served as the chair of the Board of Directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP), on the Board of Public Responsibility in Medicine and Research (PRIM&R), and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS. She has authored or co-authored over 240 publications and has served or serves on the editorial boards of a number of journals including *Current Protocols of Immunology, Blood, Therapeutic Innovation and Regulatory Science, Ethics and Human Research*.

Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Esther Krofah is the executive director of FasterCures, a center of the Milken Institute and the Milken Institute Center for Public Health. She has deep experience in the government, nonprofit, and for-profit sectors, where she has led efforts to bring together diverse stakeholder groups to solve critical issues and achieve shared goals that improve the lives of patients. Most recently, Krofah was the director of public policy leading GlaxoSmithKline's engagement with the U.S. Department of Health and Human Services (HHS) and relevant Executive Branch agencies on broad healthcare policy issues, including leadership in improving vaccinations and care for people living with HIV. Prior to GSK, Krofah served as the deputy director of HHS' Office of Health Reform, where she led the development of policy positions for significant regulatory priorities, including the health insurance marketplaces. Prior to HHS, Krofah served as a program director at the National Governors Association (NGA) health-care division, working directly with governors' health policy advisors, state Medicaid directors, and state health commissioners on health insurance, health workforce, and Medicaid coverage issues. Before joining the NGA, Krofah worked in consulting at Deloitte Consulting LLP, where she worked with public sector and commercial clients, including assisting states in developing state-based exchanges. Krofah received a BA from Duke University and a Master of Public Policy from the Harvard University John F. Kennedy School of Government.

Dr. Lindsey Baden is the Director of the Brigham and Women's Hospital (BWH)/Dana-Farber Cancer Institute (DFCI) Infectious Diseases Immunocompromised Host consultative services and the Division's Director of Clinical Research. Dr. Baden's research interests focus on early-stage vaccine development (including for HIV-1 and SARS-CoV-2) and the development of novel diagnostics and therapeutics for fungal and viral diseases that affect transplant and cancer patients disproportionately. He is the Program Director for the Clinical Trial Units of Harvard Catalyst at Harvard Medical School and Directs the Center for Clinical Investigation (CCI) at BWH.

Penny Carlson has nearly 25 years of experience in the pharmaceutical industry and is currently the Head of Global Development Support, which includes multiple clinical trial delivery functions. Prior to this, Penny held various roles of increasing responsibility across several disciplines and multiple therapeutic areas. She started her career working for a small Contract Research Organization supporting NIH sponsored Vaccine and Infectious Disease studies, followed by several years working for Pfizer in various data management roles. During her tenure at Pfizer, Penny moved into Clinical Operations and began managing studies in the Oncology therapeutic area, where she stayed for a number of years. In 2011 Penny joined Takeda (previously Millennium) initially as a Clinical Program Manager and was later responsible for multiple assets in the early development space. In more recent years, Penny has been the Clinical Operations Lead for the Gastroenterology Therapeutic Area and has supported a number of transformative initiatives and projects for Takeda. In addition to her years of traditional development operations experience, Penny also served as the Clinical Scientist for a European submission and multiple publications, and recently supported integration planning efforts prior to recent acquisitions.

Valen Keefer toes the line every day between survival and advocacy. At the age of 37, she is thriving thanks to two lifesaving transplants. Both were needed because of polycystic kidney disease (PKD). Valen was diagnosed with PKD at the age of 10, a genetic kidney disease which she inherited from her mother's side of the family and has deeply impacted and taken the lives of countless family members. Valen endured a challenging childhood full of hospital stays and cyst bleeds. After almost a year in the hospital as a teenager, both of her kidneys were removed, she was on dialysis, endured severe pancreatitis, received more than 70 blood transfusions and at the age of 19 received a life-saving kidney transplant. This second chance restored Valen's health and gifted her the opportunity to find her purpose in life, turn her health challenges into something meaningful and be the role model she wishes shehad. In her early 30s, PKD affected her liver and she became very ill again. Thankfully, at the age of 35 Valen received a life-saving liver transplant and the ability to continue doing what sheloves - helping others and living life to the fullest.

Despite life challenging her at nearly every turn, Valen is determined to help others who are fated to walk a similar path. She has taken her new lease on life and is intent on paying it back tenfold. As a passionate patient

advocate since 2004, she works tirelessly to raise awareness of kidney disease, PKD and organ donation and to help educate and empower the 37 million US adults with chronic kidney disease, the 12.5 million people worldwide with PKD and the 114,000 waiting for a life-saving transplant.
Grounded in gratitude, she works directly with countless patients and has shared her journey at 100 events across North America with an authentic optimism that gives people hope and moves them to action. She's done many press interviews, coordinated educational and fundraising events and helped raise over $1,200,000 for polycystic kidney disease research. Valen has written 250 blogs (published by non-profits), painting a genuine picture of the challenges and joys of this journey. Through her collaborations with numerous organizations, she has inspired a combined total of 1.7 million social media followers with her story of hope and resilience that transforms people forever. She proves there is not just life with severe kidney disease, but potentially a great one.

Dr. Isaac R. Rodriguez-Chavez is a biomedical leader with expertise in Infectious Diseases, Viral Immunology, Viral Oncology, and Vaccinology. Currently, he is a Senior Vice President for Scientific & Clinical Affairs, leading the Strategy of the Global Center of Excellence for Decentralized Clinical Trials, PRA Health Sciences. Past positions in the last 33 years include FDA, CDER Senior Officer for Clinical Research Methodology, Regulatory Compliance and Policy Development modernizing clinical research through Decentralized Clinical Trials enabled by Digital Health Technologies; CEO/Founder, 4Biosolutions Biomedical Consulting Firm; Vice President, Research, Texas Biomedical Research Institute; Director of HIV Clinical Research Programs, NIH; Senior Clinical Scientist, Schering Plough Corp.; Scientist, Columbia University; Scientist, Polar Biotechnology Company and Venezuelan Institute for Scientific Research (IVIC). He issued the first U.S. Good Clinical Laboratory Practice (GCLP) Guidelines to improve the consistency of clinical laboratory endpoints supporting trials globally, published numerous scientific and technical articles, and has been an invited speaker in 95 global conferences. He has a PhD in Virology and Immunology; a MS in Microbiology; a MHS in Clinical Research; and a B.S. in Biology. Dr. Rodriguez-Chavez is a Board Member of the Scientific Leadership of the Digital Medical Society (DiME). He is also a co-chair of the DiME's Research Committee, driving digital medicine globally. He is a regulatory Advisor and Vice-Chair of the Institute of Electrical and Electronics Engineers (IEEE) fostering initiatives on DCTs and DHTs. He is a Leadership Council member of the Decentralized Trials & Research Alliance (DTRA); a board member of the Hypertrophic Cardiomyopathy Association (HCMA); and an rare disease health equity board council member of the Global Genes. He is a global content editor for regulatory science at the DIA Global Forum Magazine. He is also an active member is fourteen professional associations, including the American Association of Immunologists, American Society for Virology, American Society of Microbiology, Society of Quality Assurance, Association of Clinical Research Professionals, New York Academy of Sciences, International AIDS Society, International Association for Dental Research, American Association for Dental Research, and Regulatory Affairs Professional Society.

Paul Kluetz, MD, is a medical oncologist and Deputy Director of the Oncology Center of Excellence (OCE) at the U.S. FDA. In addition to assisting in the strategic and operational oversight of the OCE, he has a broad interest in trial design and endpoint selection to expedite drug development and define clinical benefit in oncology trials. Some of his initiatives include creation of the OCE's patient-focused drug development program and expansion and direction of OCE's efforts to advance real-world evidence, decentralized trial designs and digital health technology. He is also active in regulatory review of Oncology products and oversees important oncology drug labeling initiatives. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

Nicholas Brooke is the Founder and Executive Director of The Synergist and CEO of Patient-Focused Medicines Development (PFMD.org). The Synergist is a collaboration platform incubator that brings key players together with the express aim of solving significant societal problems through collective action. Under Nicholas' leadership, The Synergist acts as a backbone, providing vision, strategy, stakeholder alignment and execution on multiple global, multi-stakeholder programs.

Nicholas is the Executive Director of Patient-Focused Medicines Development, a global collaborative platform dedicated to stimulating innovation in medicine development through systematic engagement with patients.

Nicholas Brooke is an economist by training and was previously Chief Executive Officer of an award-winning digital agency, providing cutting-edge digital strategy to global corporations across multiple sectors.
Working with key players from across the public–private spectrum, The Synergist currently manages several collective programs including Motherhood Collective Impact, From Testing to Targeted Treatment, Patient-Focused Medicines Development and Safe Motherhood Week.

Andrea Ferris is President and CEO of LUNGevity Foundation. She became involved with lung cancer advocacy following her mother's death from the disease in 2008. After receiving a diagnosis of stage IV lung cancer in 2006, Andrea's mother underwent numerous treatments and clinical trials at several major academic institutions to no avail. Together with her father, Andrea was her mother's primary caregiver during this time. Determined to drive more money into lung cancer research, Andrea left the successful software company that she helped launch, to found Protect Your Lungs, an organization focused 100% on funding early detection research. In 2010, Andrea merged Protect Your Lungs with LUNGevity, a Chicago based organization, to form the nation's leading lung cancer focused non-profit.

Andrea's strong business background combined with her connections to the worlds of research and advocacy have enabled her to build one of the preeminent patient advocacy organization

in the lung cancer space. LUNGevity funds translational research into both early detection and more effective treatments of lung cancer as well as a highly coveted Career Development Awards program. LUNGevity also fills unmet needs for people diagnosed with lung cancer by providing education, support and survivorship programs. Recognizing the need to build awareness and understanding about lung cancer, LUNGevity has built the largest grassroots network of events and advocates across the country.

Andrew (Andy) Lee is Senior Vice President and Head, Global Clinical Trial Operations (GCTO). In this role, Andy leads and manages all operations related to the conduct of Merck's clinical trials, with particular focus on global in-patient clinical trials that are designed and executed to meet cost, speed and quality standards. Andy is also responsible for the design and study and data management of clinical protocols in all regions and countries, as well as the tools, systems and processes used in clinical trial executions. Andy joined Merck in September 2014 from Sanofi, where he served as Senior Vice President and Deputy Head of Clinical Sciences and Operations (CSO) and Head of the CSO Clinical Operations cluster. In addition to directing the CSO, Andy led the integration of Sanofi with Genzyme, where he had been Senior Vice President, Global Clinical Operations. Earlier in his career, he spent more than 16 years in a range of positions of increasing responsibility at Pfizer.

Andy holds leadership positions in several professional societies, including the role of Treasurer of TransCelerate Biopharma, Inc., a nonprofit organization that comprises the world's leading pharmaceutical and biotech companies. He received his M.S. in bioenergetics and physiology from Ball State University in Indiana, and two undergraduate degrees from Rhodes University in South Africa.

Harpreet Singh, M.D., is director of the Division of Oncology 2 in the Office of Oncologic Diseases, as well the Acting Associate Director for Cancer in Older Adults and Special Populations in the Oncology Center of Excellence at the U.S. Food and Drug Administration (FDA). Dr. Singh received her M.D. degree from the University of Southern California. She completed her Internal Medicine residency and Geriatrics fellowship at USC, followed by a Medical Oncology fellowship at the National Cancer Institute. As Director of the Division of Oncology 2, Dr. Singh oversees drug development for lung cancer, head and neck cancer, neurologic tumors, pediatric solid tumors, and rare cancers. Her scope of expertise includes precision medicine and targeted therapy, novel trial design, innovative regulatory initiatives designed to expedite drug approvals, and use of real-world data in regulatory decision making.

Dr. Singh is co-leading the FDA Oncology Center Excellence's project post Covidity effort, which aims to look at the impact of COVID-19 on patients with cancer. She also sits on a committee of academic investigators who are focusing on lung cancer and COVID-19. Dr. Singh maintains her clinical credentials at the National Cancer Institute.

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Craig is Co-Chair for the Decentralized Trials & Research Alliance, Vice Chair of the MedStar Health Research Institute, Vice President of the Foundation for Sarcoidosis Research and on the Editorial Board for *Therapeutic Innovation & Regulatory Science.* Craig is Adjunct Assistant Professor in Health Informatics at Rutgers University, and Adjunct Instructor in the Center for Health + Technology at University of Rochester.

Craig was the Head of Clinical Innovation and Venture Partner at Pfizer, on the founding Operations Committee for TransCelerate Biopharma, and on the founding management teams for two successful startup ventures.

Sarah White, MPH, joined the MRCT Center as the Executive Director in January of 2018 and is responsible for developing, defining, and implementing the overall strategy and vision for the Center as well as oversee all management aspects of the MRCT Center functions. Sarah has almost 20 years of experience in human subjects' research including experience at both academic medical centers and industry.

Prior to joining the MRCT Center, Sarah was the Director of the Human Research Quality Improvement Program (QI Program) at Partners' Healthcare in Boston, Massachusetts. In this capacity, she was responsible for strategic planning and oversight of the QI Program activities across the human research communities at Partners Healthcare, including Massachusetts General Hospital and Brigham and Women's Hospital. In addition, Sarah oversaw FDA Sponsor-Investigator support and the centralized support of clinical trials registration and disclosure. Sarah is the co-chair of the national Clinical Trials Registration Taskforce, a large consortium of academic medical centers, hospitals and universities that identify best practices, develop tools, and serve as a communication forum associated with the requirements for clinical trials registration and results reporting that affect US academic health centers. Sarah also co-chaired of the Harvard Catalyst Quality Assurance/Quality Improvement Subcommittee from 2010 to 2018. Sarah received her undergraduate degree from Dartmouth College and her MPH from Boston University School of Public Health.