



MULTI-REGIONAL CLINICAL TRIALS

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

2021 REIMAGINING CLINICAL TRIALS: LEARNING FROM COVID-19

24 June 2021

10AM-1PM EDT

Speaker Biographies



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.



Fergus Sweeney is Head, Clinical Studies and Manufacturing Taskforce at the European Medicines Agency since March 2020, covering Clinical Studies (Clinical Trial Information System), Biological Health Threats and Vaccine Strategy and supports strategy development in manufacturing and personal data protection in health research on medicines. He joined the EMA Inspections Service in 1999 and became Head of Compliance and Inspections (2009) and Head of Division Inspections and Human Medicines Pharmacovigilance in 2013 (including Scientific Committee Services from 2016). He has a BA (Physiology 1979) a Dr de 3eme Cycle (cancer biology 1982), and PhD (Pharmacology 1986). Fergus worked in clinical research mainly in QA from 1982 to 1999.



Ginny Beakes-Read is Executive Director, Global Regulatory and R&D Policy at Amgen. She leads the GRR&D policy group, which works to shape the regulatory environment in ways that support innovative drug development and patient access to new therapies. The team works with Development, Commercial, Health Policy, Government Affairs, and other departments on a variety of regulatory and policy matters. Ginny joined Amgen from Eisai, where she led the Global Regulatory Policy team for 8 years. For her last 2 years at Eisai, Ginny was the Executive Director/Special Counsel, Regulatory Strategy and Law, where she was a member of the Global Regulatory Affairs and Legal Departments.

Ginny previously worked at Genentech, Inc., as Director, Regulatory Policy and Strategy, in the Washington, D.C. Office. Prior to her work at Genentech, Ginny was at FDA where she was the Director, Division of Regulatory Policy II, Office of Regulatory Policy in CDER for 8 years. In

that position she was responsible for the development of regulations affecting CDER, and was involved with crafting policy positions in areas such as follow-on biologics. Before her tenure at FDA, Ginny was a US Army JAG, working as a prosecutor and appellate attorney. Ginny is also an RN and started her career as an intensive care nurse in the US Air Force. Ginny holds B.S.N. and J.D. degrees from the University of Virginia.



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.



Taras Carpiac leads the Innovation & Process Improvement organization within Amgen Global Development Operations. In this role, he oversees transformation efforts in the clinical trial domain, including risk-based & statistical monitoring, decentralized trial execution, and patient-centered drug development. Prior to this role, Taras has held leadership roles within study operations, clinical data management, and information management. Taras is excited about the potential for new trial execution models to accelerate the pace at which high quality medicines can be brought to patients.



Lauren Hartsmith is Director of Regulatory Affairs at Advarra. She previously served as a Policy Analyst for the Department of Health and Human Services' Office for Human Research Protections (OHRP). In that position, she led scientific, regulatory, and legal experts to develop and revise policies and regulations. Lauren was a key analyst involved in all aspects of the revised Common Rule rulemaking process, where she developed reports analyzing and summarizing over 2,000 public comments submitted in response to proposed Common Rule revisions. Lauren has also conducted analyses and provided advice for the FDA's human subjects protection regulation. She holds a Juris Doctorate degree from Wake Forest University School of Law, where she was a recipient of the Kilpatrick Stockton and Wake Forest University Law Scholarships. She holds a

bachelor's degree from Vassar College, where she majored in Geography.



Dr. Richard (Rich) A. Moscicki, MD, is the Executive Vice President for Science and Regulatory Advocacy and the Chief Medical Officer at Pharmaceutical Research and Manufacturers of America (PhRMA). Dr. Moscicki came to PhRMA in 2017 after serving as the Deputy Center Director for Science Operations for the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) since 2013. While at FDA, Dr. Moscicki brought executive direction of Center operations and leadership in overseeing the development, implementation, and direction of CDER's programs. Previous positions include serving as Chief Medical Officer at Genzyme Corporation from 1992 to 2011, where he was responsible for worldwide global regulatory and pharmacovigilance matters, as well as all aspects of clinical research and medical affairs for the company. He served as

the senior vice president and head of Clinical Development at Sanofi-Genzyme from 2011-2013.

Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency in internal medicine, followed by a fellowship at Massachusetts General Hospital (MGH) in clinical immunology and immunopathology. He remained on staff at MGH and on the faculty of Harvard Medical School from 1979 until 2013.



Névine Zariffa, MMath – a highly accomplished thought leader in the fields of biostatistics and data science with extensive experience across all phases of drug development. Névine had a 25-year career in senior roles at GlaxoSmithKline and AstraZeneca where she also led the Enterprise Data & Analytics initiative. She has been a key contributor to development strategies for over 200 drug projects across oncology, cardiovascular, metabolic, respiratory, inflammation, and renal diseases. She served as a Board member of CDISC for 6 years, has been a reviewer for *The Lancet* and has over 30 peer reviewed publications to her name. She is currently a strategic consultant to select healthcare clients, several scientific data consortia ([ICODA](#) and [ctMoniTR](#)) and to the FDA’s Office of the Commissioner on the application of real-world evidence to COVID19.



Mark Barnes is the faculty co-director of the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center). Mark is also a Partner at Ropes & Gray LLP as well as a Lecturer at Yale School of Medicine and Visiting Lecturer at Yale Law School. Mark’s law practice and his teaching at Yale focus on health care law and finance, human and animal research, stem cell and genetic research, research grants and contracts, research misconduct, and international research. Mark formerly served at Harvard as the Senior Associate Provost and University Senior Research Officer and started and directed Harvard’s HIV/AIDS treatment programs in Nigeria, Tanzania and Botswana. He serves on the Ethics Working Group of the NIH’s HIV Prevention Trials Network (HPTN). Mark has held senior appointed positions in the New York City and State departments of health. In 2019, he was named the “Legal Innovator of the Year” by the *Financial Times*.



M. Khair ElZarrad PhD, MPH., Dr. ElZarrad is the Deputy Director of the Office of Medical Policy (OMP) at FDA’s Center for Drug Evaluation and Research (CDER), where he leads the development, coordination, and implementation of medical policy programs and strategic initiatives. Dr. ElZarrad currently leads multiple projects focused on exploring the potential utility of real-world evidence, innovative clinical trial designs, and the integration of technological advances in pharmaceutical development. Dr. ElZarrad is the rapporteur for the International Council for Harmonisation’s ongoing work to revise the international Good Clinical Practice Guideline (ICH-E6(R2)). Prior to joining the FDA, he served as Acting Director of the Clinical and Healthcare Research Policy Division with the Office of Science Policy at the National Institutes of Health (NIH). At NIH he worked on policies related to human subject protections; the design, conduct, and oversight of clinical research; and enhancing quality assurance programs at pharmaceutical development and production facilities. He earned a doctoral degree in medical sciences with a focus on cancer metastases from the University of

South Alabama, as well as a master's degree in public health from the Johns Hopkins Bloomberg School of Public Health.



Owen Fields received a B.S. in Biochemistry and a minor in mathematics from Wichita State University, and a Ph.D. from the Department of Molecular and Cellular Biology at Berkeley.

Following his graduate education, Owen served in the Policy Development Branch, Center for Food Safety, US FDA, where he helped develop the initial US policy towards agricultural/food biology, led the team that developed the review procedure that still applies to such products, and served as the lead reviewer on 3 of the first 8 products FDA approved in this area.

Following this he moved to Regulatory Affairs at Wyeth in 1995, where he worked on both late and early-stage products. Subsequently Owen became VP for Regulatory Strategy for Pfizer Research and Development and is now responsible for regulatory strategy for the Inflammation and Immunology therapy area at Pfizer.



Steven E. Kern, PhD is Deputy Director of Quantitative Sciences at the Bill and Melinda Gates Foundation. The Quantitative Sciences group is focused on quantitative analysis to support program strategies for therapeutic projects that the foundation funds across multiple disease domains.

Prior to this, he was Global Head of Pharmacology Modeling at Novartis Pharma AG based in Basel Switzerland where he led a team focused on providing model-based drug development support to therapeutics in many disease conditions across all stages of drug development. He joined Novartis in 2010 from the University of Utah in Salt Lake City, Utah where he was Associate Professor of Pharmaceutics, Anesthesiology, and Bioengineering, and served as co-investigator for their NIH funded Pediatric Pharmacology Research Unit. He has designed, conducted, and served as a principal investigator for clinical pharmacology studies in adults and children that spanned the population from preterm infants to elderly adults.

He has a bachelor's degree in Mechanical Engineering from Cornell University, a Master's degree in Bioengineering from Penn State University, and a doctoral degree in Bioengineering from the University of Utah. Dr. Kern has published over 70 papers in areas of pharmacokinetic and pharmacodynamic modeling, applying principles of control systems engineering to drug delivery, and clinical pharmacology.