Integrating Clinical Studies into Health Care Delivery:
Post-Market Evidence Generation for Medical Products
Virtual Public Meeting
Tuesday, November 14, 2023 | 3:30 – 5 pm ET

Speaker Biographies

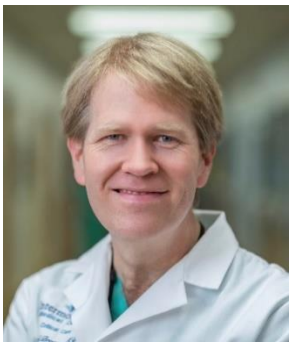
Robert M. Califf, MD, MACC
Commissioner of Food and Drugs, US Food and Drug Administration

Dr. Robert M. Califf was confirmed earlier this year as the 25th Commissioner of Food and Drugs. He also served in 2016 as the 22nd Commissioner, and immediately prior to that as the FDA's Deputy Commissioner for Medical Products and Tobacco. He has spent a good portion of his career affiliated with Duke University, where he served as a professor of medicine and vice chancellor for clinical and translational research, director of the Duke Translational Medicine Institute, and was the founding director of the Duke Clinical Research Institute. He has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

Wanda Brisbane
CEO, The 4 Winds Service, Inc.

Wanda Brisbane is the dedicated CEO of the 4 Winds Services, Inc., a non-profit corporation based in Atlanta, GA, with a mission to promote literacy and education among young people. Ms. Brisbane's visionary approach has transformed the organization into a dynamic force for positive change in the community. Ms. Brisbane is actively involved in every aspect, from overseeing book drives to participating in distribution events. Ms. Brisbane's leadership is marked by empathy, resilience, and a sincere commitment to creating a lasting impact. Through The 4 Winds Services, Inc., she serves as a beacon of hope, fostering a love for learning and literature among the youth and shaping a brighter future for generations to come.

Samuel Brown, MD
Professor of Medicine, Intermountain Medical Center



Dr. Samuel Brown graduated *summa cum laude* from Harvard College in Linguistics with a minor in Russian, then received his MD from Harvard Medical School, where he was a National Scholar and Massachusetts Medical Society Scholar. He completed internal medicine residency at Massachusetts General Hospital and pulmonary/critical care fellowship at the University of Utah. He is Research Professor at Intermountain Health and Professor of Medicine at the University of Utah, and cares for patients in the Shock Trauma ICU at Intermountain Medical Center.

Dr. Brown uses clinical trials and advanced statistical techniques to understand and improve patient-centered outcomes from life-threatening illness and injury. As Vice President for Research at Intermountain Health, he oversees and supports a large research enterprise that focuses on serving patients, communities, and clinicians through the use and understanding of both cutting-edge new treatments and treatments already in broad clinical use. On occasional free weekends, he studies cultural history, with a particular emphasis on questions of embodiment, sickness, and death. He has published widely in medicine, ethics, and history.

Jennifer Byrne
Founder, Board Chair, and Chief Executive Officer, Javara Research

Jennifer Byrne's career has been devoted to leading organizations, building teams, and cultivating partnerships centered on advancing the clinical research enterprise to better connect patients and providers to clinical trials. Ms. Byrne founded Javara with a vision to revolutionize the industry by accelerating access to research – for patients, biopharma companies, and health care systems alike. Her passion and commitment to transforming the clinical research landscape into an integrated component of health care are at the forefront of Javara's mission.

As the former CEO of PMG Research and founder of Greater Gift (501(c)3), Ms. Byrne's involvement in the clinical research enterprise has been vast across collaborations with hundreds of pharma, device, Contract Research Organizations (CROs), technology, site organizations, and other research service providers. Her stellar track record for consistent and excellent quality in patient, provider, and client experiences associated with research trials is but one of many professional accomplishments. Currently, she serves as board chair for Javara Inc. as well the Greater Gift (501(c)3), is an advisory board member for CISCRP and serves as a trustee for the Association of Clinical Research Professionals (ACRP). She is also an advisory chair for the master's in clinical research management with Wake Forest University. Additional advisory roles include Wake Forest Institute of Regenerative Medicine, FCA Health Innovations Fund, and the North Carolina Biotech of the Piedmont Triad. Ms. Byrne is a graduate of Texas A&M University.

David C. Fajgenbaum, MD, MBS, MSc, FCPP
Assistant Professor of Translational Medicine & Human Genetics, University of Pennsylvania School of Medicine

Dr. David Fajgenbaum is an Assistant Professor of Translational Medicine & Human Genetics at the Perelman School of Medicine at the University of Pennsylvania, Founding Director of the Center for Cytokine Storm Treatment & Laboratory (CSTL), Associate Director, Patient Impact of the Penn Orphan Disease Center, and Co-Founder/President of the Castleman Disease Collaborative Network (CDCN). He is also the national bestselling author of 'Chasing My Cure: A Doctor's Race to Turn Hope Into Action' (http://www.ChasingMyCure.com) and a patient battling idiopathic multicentric Castleman disease (iMCD). He is in his longest remission ever thanks to a precision treatment that he identified, which had never been used before for iMCD.

An authority on cytokine storms and their treatment, Dr. Fajgenbaum launched the CORONA project in March 2020 to identify and track treatments for COVID-19. Today, CORONA is the world's largest database of COVID-19 treatments, including more than 500 medications that have been administered to more than 400,000 patients, and a go-to resource for FDA, Google Health, and others. He serves on the treatment selection committee for the NIH's ACTIV-6 trial as well as the Chair of the treatment selection committee for FDA/NIH/C-Path Institute's CURE Drug Repurposing Collaboratory (CDRC) COVID-19 inpatient trial.

One of the youngest individuals ever appointed to the faculty at Penn Medicine and in the top 1 percent youngest awardees of an NIH R01 grant, Dr. Fajgenbaum leads over 20 translational research studies, including the CORONA project and a clinical trial of the drug that is saving his life. He has published scientific papers in high-impact journals such as the New England Journal of Medicine, Blood, and Journal of Clinical Investigation, including one paper selected by STAT News in 2020 as one of the best innovations in science and medicine.

Dr. Fajgenbaum received a bachelor's degree in Human Sciences with Distinction from Georgetown University, where he was USA Today Academic All-USA First Team and a Quarterback on the Division I football team. Dr. Fajgenbaum earned his medical degree from the Raymond & Ruth Perelman School of Medicine at the University of Pennsylvania, where he was a 21st Century Gamble Scholar. Dr. Fajgenbaum joined the Reagan-Udall Foundation for the FDA Board of Directors in 2022.

Robert A. Harrington, MD
Stephen and Suzanne Weiss Dean of Weill Cornell Medicine, Cornell University

Dr. Robert A. Harrington is a cardiologist and the Stephen and Suzanne Weiss Dean of Weill Cornell Medicine and provost for medical affairs of Cornell University. He was previously the Arthur L. Bloomfield Professor and Chairman of the Department of Medicine at Stanford University and Richard Stack Distinguished Professor and the Director of the Duke Clinical Research Institute (DCRI) at Duke University. He has served as a member and the chair of the US Food and Drug Administration Cardiovascular and Renal Drugs Advisory Committee and is a member of the American Heart Association's (AHA's) Board of Directors. He served as AHA President-elect, President, and Immediate Past President during 2019-2021. His research involves building local, national, and international collaborations for the efficient conduct of innovative clinical research and trying to better understand and improve upon the methodology of clinical research, including the use of technologies to facilitate the conduct of clinical trials.

Adrian Hernandez, MD, MHS
Vice Dean for Clinical Research, Duke University School of Medicine

Dr. Adrian Hernandez is a cardiologist who serves as the Executive Director, Duke Clinical Research Institute, and Vice Dean for Clinical Research, Duke University School of Medicine. Dr. Hernandez was previously the Director of Health Services and Outcomes Research at the Duke Clinical Research Institute (DCRI). Dr. Hernandez has devoted his career to research in order to improve population health, focusing on understanding health outcomes, and closing the gap between clinical efficacy and effectiveness. An expert in trial design, use of electronic health data, health services, and regulatory science, Dr. Hernandez has led efforts to create more pragmatic clinical trials that get closer to what patients and clinicians experience every day. Presently, he is the Coordinating Center Principal Investigator for PCORI's National Patient-Centered Clinical Research Network (PCORnet), NIH's Health System Collaboratory, and other pragmatic clinical trials to generate real-world evidence. He is also the Coordinating Center Principal Investigator for the Baseline Health System Consortium which aims to change how clinical research is performed to integrate people in and outside of the health system, accelerate research, and improve efficiency.

Russell Rothman, MD, MPP
Senior Vice President for Population and Public Health, Vanderbilt University Medical Center

Dr. Russell Rothman is a primary care physician and an expert in health services research and health communication. Dr. Rothman is Professor of Internal Medicine, Pediatrics and Health Policy, Ingram Professor of Integrative and Population Health, and the Senior Vice President for Population and Public Health at Vanderbilt University Medical Center. He also serves as the Director of the Institute for Medicine and Public Health and Associate Dean for Population Health Sciences. Dr. Rothman served as Chair of the PCORI PCORnet Executive Steering Committee and is currently the Principal Investigator of the STAR (Stakeholders, Technology and Research) Clinical Research Network. Dr. Rothman served as Co-Chair of the Steering Committees of the ADAPTABLE study, a pragmatic clinical trial, and the Healthcare workers Exposure Response and Outcomes (HERO) Study. He is also the past president of the Academy of Communication in Healthcare (ACH).

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Board Chair, Reagan-Udall Foundation for the FDA

Dr. Richard L. Schilsky is the former Chief Medical Officer of the American Society of Clinical Oncology and Professor emeritus at University of Chicago. At the University of Chicago, Dr. Schilsky rose to the rank of Professor of Medicine (tenured) and served as Director of the University of Chicago Cancer Research Center (1991-1999), as Associate Dean for Clinical Research (1999-2007) and as Chief of the Section of Hematology-Oncology (2009-2012). From 1995-2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group. He has served as chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee. Dr. Schilsky also served as a member and chair of the Oncologic Drugs Advisory Committee of the Food and Drug Administration. Dr. Schilsky has served as a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) and of the Conquer Cancer Foundation of ASCO and as ASCO President 2008-2009. He currently serves as Chair of the Board of Directors of the Reagan-Udall Foundation for the FDA.

Ramita Tandon
Chief Clinical Trials Officer, Walgreens Boots Alliance

As the Chief Clinical Trials Officer at Walgreens Boots Alliance, Ramita Tandon is responsible for leading and driving growth for the Company's new clinical trials business. In her role, Ms. Tandon works across the health care and life sciences industries to enable next-generation clinical trials so that breakthrough treatments reach patients faster. Her team is focused on unlocking value and improving access, awareness, and trust by efficiently matching diverse patient populations to sponsor-led trials, reducing trial operational complexities and patient burdens, as well as capitalizing on Walgreens deep patient insights and leveraging real-world data from owned and partner assets.

Ms. Tandon brings more than 25 years of leadership and operational experience across a portfolio of industry-leading businesses and services in real-world evidence and patient-centered health outcomes. Prior to joining Walgreens, she served as the Chief Operating Officer at Trio Health, and prior to that she was the Executive Vice President, Commercialization and Outcomes at ICON. She is a graduate of the University of Michigan and the Boston University School of Public Health.

Joanne Waldsteicher, MD
Independent Board Director and Consultant

Dr. Joanne Waldstreicher was the Chief Medical Officer at Johnson & Johnson with oversight across pharmaceuticals, devices, and consumer products for safety, epidemiology, clinical and regulatory operations transformation, collaborations on ethical science, and technology and R&D policies, including those related to clinical trial transparency and compassionate access. She chaired the R&D Development Pipeline Review Committee for The Janssen Pharmaceutical Companies of Johnson & Johnson and supported the Medical Devices and Consumer Development Committees. Before joining Johnson & Johnson in 2002, she headed endocrinology and metabolism clinical research at Merck Research Laboratories. Dr. Waldstreicher is currently an independent board member of Becton Dickinson and Structure Therapeutics, a consultant for pharmaceutical companies, and a faculty affiliate of the Division of Medical Ethics, Department of Population Health, New York University School of Medicine.

Moderator Biography

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.