Achieving Broad Participation in Meaningful Clinical Research at the Point of Care

Public Meeting
June 14, 2022 2:00–5:15 p.m.

Welcome and Overview

John D. Halamka, MD, MS, president of the Mayo Clinic Platform, leads a portfolio of platform businesses focused on transforming health care by leveraging artificial intelligence, connected health care devices and a network of trusted partners. Trained in emergency medicine and medical informatics, Dr. Halamka has been developing and implementing health care information strategy and policy for more than 25 years. Prior to his appointment at Mayo Clinic, he was chief information officer at Beth Israel Deaconess Medical Center, where he served governments, academia and industry worldwide. He is a practicing emergency medicine physician. As the International Healthcare Innovation Professor at Harvard Medical School, Dr. Halamka helped the George W. Bush administration, the Obama administration and governments around the world plan their health care information strategies. Dr. Halamka completed his undergraduate studies at Stanford University, earned his medical degree at the University of California, San Francisco, and pursued graduate work in bioengineering at the University of California, Berkeley. He completed his residency at Harbor — UCLA Medical Center in the Department of Emergency Medicine. Dr. Halamka has written a dozen books about technology-related issues, hundreds of articles and thousands of posts on the Geekdoctor blog. He was elected to the National Academy of Medicine in 2020. He and his wife also run Unity Farm Sanctuary in Sherborn, Massachusetts – the largest animal sanctuary in New England, which includes 300 animals, 30 acres of agricultural production and a cidery.

Trevan Locke, PhD, is a Policy Research Associate on the biomedical innovation team at the Duke-Margolis Center for Health Policy. There he works on a range of regulatory policy topics including real-world data and evidence, clinical trials, and artificial intelligence. He works closely with the Duke-Margolis RWE Collaborative and the Advancing Clinical Trials at the Point of Care Coalition. Prior to Duke-Margolis, he worked in regulatory policy for the American Association for Cancer Research. He earned his PhD from Rutgers University and a Bachelor of Engineering from Vanderbilt University, both in Chemical Engineering.

Keynote Discussion

Mark McClellan, MD, PhD, is the Robert J. Margolis, MD, Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. Dr. McClellan is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Janet Woodcock, MD, is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions. She served as the Acting Commissioner of Food and Drugs from Jan. 20, 2021, until Feb. 17, 2022. Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER) where she served as the Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure. In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), leading the Center's work that is the world's gold standard for drug approval and safety. In 2004, Dr. Woodcock became the FDA's Deputy Commissioner and Chief Medical Officer. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer. In 2007, Dr. Woodcock returned as Director of CDER until she was asked to be the therapeutics lead for "Operation Warp Speed" in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19. Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She is board certified in internal medicine.

Session 1

Kent Thielen, MD, is CEO of Mayo Clinic in Florida and vice president, Mayo Clinic, roles in which he has served since January 1, 2019. Dr. Thielen previously served as chair of the Mayo Clinic Department of Radiology in the Midwest, a position that he held from 2013 to 2018. He also served as the chair of the Division of Neuroradiology in the Department of Radiology at Mayo Clinic in Rochester from 2004 to 2013. Dr. Thielen has a strong personal interest in innovative practice development, including the development of new technologies and delivery of imaged-guided spinal and neuroendovascular therapies. He also spearheaded the development and implementation of multiple innovative image-guided procedures in the cerebrovascular and spinal image-guided interventional practices. He received his bachelor's degree in engineering physics from South Dakota State University and his Doctor of Medicine degree from the University of Minnesota Medical School. Dr. Thielen completed his residency training in diagnostic radiology at the Mayo Clinic School of Graduate Medical Education in Rochester and was chief resident from 1993 to 1994. He subsequently completed a three-year combined fellowship in diagnostic and interventional neuroradiology at the Mayo Clinic School of Graduate Medical Education in Rochester, before joining the Mayo Clinic faculty in 1996. A member of the Mayo Clinic staff for the past 25 years, Dr. Thielen also serves as a professor of radiology at Mayo Clinic College of Medicine and Science. He is a member of the Mayo Clinic Board of Trustees and Board of Governors, and he is a diplomat of the American Board of Radiology with an additional certificate of added qualifications in neuroradiology.

Thomas A. Owens, MD, is the President of Duke University Hospital, Senior Vice President of Duke University Health System, and an Associate Professor of Medicine and Pediatrics at the Duke University School of Medicine. Over the past decade, Dr. Owens has made important and varied contributions to the success of DUH and DUHS. He led the work to redesign, realign and in some cases reinvent the way we deliver care in many areas of clinical practice. This work has already resulted in significant improvement in care efficiency, outcomes, and enhanced patient experience. He also served in a critically important leadership role with clinical providers and leaders in the planning, preparation and implementation of Maestro Care, one of the most fundamental transformations across DUHS since its inception in 1998. Dr. Owens' leadership in patient safety and quality management has resulted in marked quantifiable improvements across multiple clinical quality measures and CMS core measures. In addition, Dr. Owens has co-lead local and regional growth of clinical services for DUHS, and under his leadership, Duke Primary Care (DPC) has become the leading primary care network in the greater Triangle area while consistently exceeding quality, growth and financial targets. He has also played a pivotal role in shaping our approach to population health management, and implementing new clinical capabilities in population health improvement. Dr. Owens received his MD with honors from the University at Buffalo School of Medicine & Biomedical Sciences in 1995. He completed an Internal Medicine and Pediatrics internship and residency at Duke in 1999, a General Internal Medicine fellowship in 2000, and served as Chief Resident in 2001. He has held a series of positions of increased responsibility in academic and clinical leadership at Duke over the years including Chief of the DUHS Hospital Medicine Program, Chief Medical Officer for DUH, and Chief Medical and Clinical Officer for DUHS. Tom has received numerous awards and honors including the Eugene A. Stead, Jr. Award for

Outstanding Teaching Faculty (2004, 2008), Samuel L. Katz Faculty Award for Excellence in Teaching (2002) and the Duke University Presidential Award for Executive Leadership (2006).

J.P. Valin, MD, MHA, joined SCL Health as President of Medical Group and Provider Services in September 2016, and assumed the role of Executive Vice President and Chief Clinical Officer in February 2018. Upon the Intermountain Healthcare and SCL Health merger in 2022, Dr. Valin was selected as Chief Clinical Officer for the new Intermountain Healthcare enterprise. Dr. Valin is responsible for integrating and providing direction for all clinical activity across the continuum. All clinical areas have been aligned under Dr. Valin including medical groups across the regions; acute and ambulatory care clinical functions and operations; quality, safety, and risk; and medical informatics. In his role, Dr. Valin provides strategic, clinical, and operational leadership to employed physicians and APPs and medical group caregivers in each region as well as the system-level provider services and support teams. He manages the full scope of the medical group and provider services functions to create a highly attractive practice environment and support structure for physicians and APPs, where teams can best support clinicians as they deliver quality care, thrive professionally, improve performance, and improve value and outcomes. Before joining SCL Health and Intermountain Healthcare, Dr. Valin served in various leadership roles for 10 years at Banner Health in Greeley, Colorado. At Banner, he also practiced clinically for 15 years prior to his leadership tenure, as both a general internist and as a full-time hospitalist. He is a graduate of Georgetown University and New York Medical College and completed his internal medicine residency at New York Presbyterian - Weill Cornell in New York City. Dr. Valin completed the Health Management Academy - GE Fellows Program for Physician Executives in 2015 and holds a Master of Healthcare Administration from the Health Management Academy/University of Providence. He is certified by the American Board of Internal Medicine and is a Fellow of the American College of Physicians. Dr. Valin was a recipient of the Clinician Experience Project's CEO Award of Excellence in December 2020 and received special recognition from the Leapfrog Group for Pandemic Heroism. In August 2021, he received the *What's Right in Health Care® Hero Award*, which is given out by Huron, a global healthcare consultant, to honor individuals who make a positive impact on the healthcare industry.

Session 2

Adrian Hernandez, MD, MHS, was named Vice Dean and Executive Director of the Duke Clinical Research Institute (DCRI) in 2020. In this role, he provides visionary and strategic direction to the DCRI; supports and strengthens its research and teaching agendas; and continues to raise its national and international profile. Among many key responsibilities, Dr. Hernandez oversees the DCRI to ensure the continuance of a broad spectrum of clinical research programs, clinical trials, clinical and pre-clinical education, and shared data and repositories. In his Vice Dean role, Dr. Hernandez provides leadership to the Duke School of Medicine's Dean's Office for clinical research strategy and also provides oversight of the Duke Institute for Health Innovation (DIHI) and participates in the School's leadership team for data science and AI Health. From 2017 to 2020, Dr. Hernandez served as Vice Dean for Clinical Research for the Duke School of Medicine. Prior to that, he served the DCRI as a Faculty Associate Director and the Director of Health Services and Outcomes

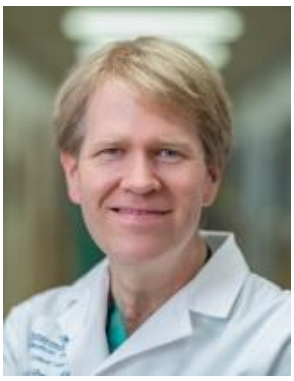
Research. Dr. Hernandez is a cardiologist and an internationally recognized leader in clinical research, ranging from clinical trials to health services and policy research. He has served as the steering committee chair or principal investigator of multiple large studies with goals to improve the health of patients with cardiovascular disease or diabetes. He has published over 600 articles and is an elected member of the American Society for Clinical Investigation and the Association of American Physicians. Dr. Hernandez received his bachelor's degree from Rice University and his medical degree from the University of Texas-Southwestern School of Medicine. He completed his residency in internal medicine at the University of California-San Francisco School of Medicine and then completed a fellowship in cardiology at Duke University. He joined the Duke faculty in 2004 as an assistant professor.

Carrie D. Wolinetz, PhD, is the Deputy Director for Health & Life Sciences for the White House Office of Science and Technology Policy (OSTP), where she advances priority presidential efforts including pandemic preparedness, health systems & health equity, and accelerating innovation to patients. Prior to joining OSTP, she served as Acting Chief of Staff to the Director of the National Institutes of Health, as well as the NIH Associate Director for Science Policy, and Director of NIH's Office of Science Policy. During her time at NIH, Carrie led development of significant agency policies, including data management and sharing, clinical trials stewardship reform, and addressing sexual harassment, and stood up the Novel and Exceptional Technology & Research Advisory Council (NExTRAC). Before entering government service, Carrie worked for the Association of American Universities (AAU) as Deputy Vice President for Federal Relations. She also has served as President of United for Medical Research, and at the Federation of American Societies for Experimental Biology (FASEB) as Director of Scientific Affairs and Public Relations.

Kimberly Sciarretta, PhD is the Launch Office Branch Chief within the Division of Research Innovation and Ventures (DRIVe), Biomedical Advanced Research and Development Authority (BARDA), part of the Assistant Secretary for Preparedness and Response (ASPR), within the United States Department of Health and Human Services (HHS). The DRIVe Launch office is committed to de-risking barriers to implementation and demonstrating clinical impact of medical countermeasure investments. Dr. Sciarretta was one of the inaugural members of DRIVe. Through strategic interagency activities and critical technology investments with external partners, she has led efforts focused on the host response to infection along the entire patient care continuum, including novel diagnostics and host-directed therapeutics, as well as improving patient outcomes for sepsis. Previously Dr. Sciarretta was a Project Officer within the BARDA CBRN Division, and prior to that, was a technical consultant to multiple US Government Agencies. Dr. Sciarretta received her PhD from the University of Chicago in Molecular Genetics and Cell Biology. Her expertise broadly spans diagnostics and devices, medical countermeasure development, biochemistry, synthetic biology, advanced manufacturing and chemical and biological defense technologies.

Owen Garrick, MD, **MBA,** is Chief Medical Officer of CVS Health Clinical Trial Services. In this role, Dr. Garrick is responsible for the overall medical strategy across the portfolio, overseeing medical compliance, clinical insights, publications and clinical innovation. He will build out the medical affairs function across CTS. Dr. Garrick will continue to be the Executive Sponsor for the CTS-wide equity efforts, including diversity in clinical trials. Dr. Garrick joined CVS Health as Vice President, Conduct Delivery for Clinical Trial Services, in April 2021. He helped build the nationwide, patient-centric clinical trial delivery model currently in expansion, as well as the Commitment on Diversity and Equity (CODE) in clinical trials initiative. Prior to joining CVS Health, Owen was President of Bridge Clinical Research, where he had responsibility for the Clinical Trials, Research Analytics, Health Services Research and Healthcare Communications business units. Which at Bridge Clinical he helped launch multiple collaborative efforts in advancing precision medicine research and data science. His study "Does Diversity Matter for Health? Experimental Evidence from Oakland" won the 2021 Research Paper of the Year by the American Society of Health Economists. Prior to joining Bridge Clinical, Dr. Garrick was Director of Strategy and Business Development at McKesson Corporation. Before joining McKesson, Dr. Garrick was Global Head of M&A Negotiations at Novartis Pharmaceuticals. Dr. Garrick is a nationally recognized leader in the field of research and research ethics. He was confirmed and completed a term with the Department of Health and Human Services Advisory Council on Human Research Protections from 2012-2016. He has co-authored industry advisory documents around biospecimen data security and patient engagement in research and currently serves on the board of Professional Responsibility in Medicine & Research (PRIMR). Dr. Garrick earned his MD from Yale School of Medicine and his MBA from Wharton School of Business. He holds an AB in Psychology from Princeton University.

David Soergel, MD, is the Global Head of Cardio-Renal-Metabolic Development at Novartis, joining in 2017. Prior to this role, Dr. Soergel spent 9 years at biotechnology companies working in a variety of therapy areas, building high-performing development teams and conducting complex multi-stage adaptive trials. He has been involved in development of program strategy and design, execution and reporting of clinical trials in acute and chronic pain, acute heart failure, infectious diseases and renal diseases. Prior to joining biotech, Dr. Soergel worked in early stage clinical development and translational medicine at GlaxoSmithKline, leading programs from the discovery organization into the clinic and through proof of concept. Dr. Soergel originally trained in pediatrics, pediatric cardiology and heart failure and transplant at Johns Hopkins Hospital and Children's Hospital of Philadelphia. During his cardiology fellowship, Dr. Soergel completed an NIH sponsored NRSA post-doctoral fellowship at Johns Hopkins studying myofilament function.



Samuel Brown, MD, MS, is an attending physician in the Shock Trauma ICU at Intermountain Medical Center and assistant professor of pulmonary and critical care at the University of Utah School of Medicine. Board certified in pulmonary and critical care medicine, and a testamur of the National Board of Echocardiography. His clinical interests include life-threatening infection ("sepsis"), acute lung injury, and the function of the heart and blood vessels during life-threatening illness.

Session 3

Brian Anderson, MD, is chief digital health physician at MITRE where he leads research and development efforts across major strategic initiatives in digital health, including several with industry and the United States government during the COVID-19 pandemic. Anderson completed his clinical training at Massachusetts General Hospital and practiced in Greater Lawrence (MA). He completed his BA and MD degrees, both with honors, at Harvard College and Harvard Medical School.

Sally Okun, RN, MMHS, is the Executive Director for the Clinical Trials Transformation Initiative (CTTI), a public-private partnership of Duke University and the U.S. Food and Drug Administration (FDA). Okun works with CTTI's Executive Committee in the development and execution of strategies to accomplish the organization's mission to develop and drive adoption of practices that increase the quality and efficiency of clinical trials. She provides senior oversight and management of CTTI operations and organizes efforts to leverage the participation of member organizations and external stakeholders. Prior to joining CTTI, Ms. Okun led a consultancy firm specializing in patient and public involvement in research, care, policy, and socially accountable ethics. In 2008 she joined the digital health technology start up PatientsLikeMe (PLM), an online patient research network. During her 12-year tenure at PLM developed the site's medical ontology for curating patient-reported health data and oversaw the development PLM's Drug Safety and Pharmacovigilance Platform. As PLM's Vice President of Advocacy, Policy, and Ethics she contributed to health policy discussions at the national and global level and was PLM's liaison with patient organizations, government, and regulatory agencies. She oversaw an engagement-focused sub-award with the NIH All of Us Research Program and was the Principal Investigator for Research Collaboration Agreement with the FDA focused on characterizing patient-generated health data. Prior to 2008 Ms. Okun, a registered nurse, practiced as a community-based palliative care specialist and held other clinical leadership positions in hospice and end-of-life care for over three decades.

Marco Schito, PhD is Executive Director of C-Path's CURE Drug Repurposing Collaboratory, Scientific Director of the Inflammatory Bowel Disease Group, and an Adjunct Professor at the University of Arizona, James E. Rogers College of Law. The initiative he leads aims to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need. Prior to joining C-Path, Dr. Schito was a Senior Scientific Officer at the Division of AIDS, NIH where he wrote and managed point-of-care diagnostic contracts for developing HIV viral load assays in low-resource settings, stood up a fully-characterized HIV global viral diversity panel program, and launched a research initiative to standardize the measurement of mucosal immune responses in HIV clinical trials. During his intramural tenure at the National Cancer Institute, Dr. Schito led the in vivo modeling of anti-retroviral zinc finger inhibitors, characterized TCR transgenic murine models, and the immune characterization of mice deficient in p53 phosphatases (PPM1D). Over the past decade, he established data knowledgebase to enable the use of Next Generation Sequencing platforms to quickly and accurately identify efficacious tuberculosis drug regimens. This platform is now being used by the World Health Organization for their global genomic drug surveillance program. Dr. Schito received his PhD from the Ontario Veterinary College at the University of Guelph, Canada in immuno-parasitology.

Pamela Tenaerts, MD, MBA, will direct research to help identify, implement and make ubiquitous responsible decentralized trial strategies. Dr. Tenaerts brings more than 30 years of experience in clinical trials, as a researcher and academic, in medical device research operations, a hospital based site administrator, and physician, most recently serving as executive director of the Clinical Trials Transformation Initiative (CTTI) at Duke University. She sits on the board of the Society of Clinical trials, the Scientific Leadership Council of the Digital Medicine Society, participates on the Good Clinical Trial Collaborative, and is a member of the National Academies of Science and Medicine: Forum on drug discovery, development and translation. She received her MD from the Catholic University in Leuven and her MBA from the University of South Florida.

Session 4

Rachele Hendricks-Sturrup is the Research Director of Real World Evidence at the Duke-Margolis Center for Health Policy. As a researcher, bioethicist, and policy practitioner, her work centers on addressing implementation and ethical, legal, and social implications issues at the intersection of health policy and innovation.

Daniela Bota, MD, PhD, is the Vice Dean for Clinical Research and Medical Director for the UCI Center for Clinical Research. She also serves as the Clinical Director for the Sue & Bill Gross Stem Cell Research Center. Dr. Bota leads the Center for Clinical Research (CCR), UCI's leading-edge clinical research program dedicated to innovating, accelerating, growing and inspiring new ways to address and treat disease. CCR functions as a full-service clinical research unit, connecting the academic and industry partners with UCI physician and scientists, and enabling the development of novel treatments for our local, regional, national and international patients. Dr. Bota's academic research and clinical practice focuses on the innovative treatments for brain malignancies. She currently serves as a principal investigator for numerous studies including novel glioblastoma stem-cell targeted chemotherapy agents, cellular immunotherapy studies, and wearable devices. She consults for multiple companies involved in developing drugs, cellular therapies and devices for human use.

Frederick Masoudi, MD, MSPH, serves as Chief Science Officer and Vice President, Clinical Research and Analytics for Ascension. In this role, Dr. Masoudi is responsible for planning, developing and implementing the organization's clinical enterprise-wide program to advance Ascension as a national research leader. Dr. Masoudi's priorities include the leadership and delivery of Ascension's research policy and strategy. He also provides academic and administrative leadership in the strategic and tactical development of clinical analytics to support Ascension's clinical performance optimization. Prior to joining Ascension, Dr. Masoudi was a tenured professor in the Department of Medicine at the University of Colorado Anschutz Medical Campus and Chief Scientific Advisor of the American College of Cardiology's (ACC) NCDR, a suite of national quality assessment and improvement platforms for cardiovascular conditions and procedures. He is an internationally recognized clinician scientist who has spent his career dedicated to cardiovascular care in practice, research and education. Dr. Masoudi has also been a mentor to numerous early career health services investigators as a founding member of the Colorado Cardiovascular Outcomes Research consortium. He has co-authored more than 345 peer-reviewed articles published in journals and has contributed to numerous national practice guidelines, scientific statements and policy documents. He has been recognized as a Master of the ACC, a Distinguished Fellow of the ACC, and has been awarded the American Heart Association (AHA) Quality of Care and Outcomes Research (QCOR) Scientific Council Distinguished Service Award and the AHA QCOR Outstanding Lifetime Achievement Award. Dr. Masoudi received his Medical Degree from Johns Hopkins University School of Medicine, Baltimore, was a resident and chief resident in medicine at the University of California, San Francisco, and a fellow in cardiology at the University of Colorado. He has a Master of Science in Public Health from University of Colorado Health Sciences Center, Department of Preventive Medicine and Biometrics, Denver.

John Concato, MD, MS, is the Associate Director for Real-World Evidence Analytics in the Office of Medical Policy (OMP) at the Center for Drug Evaluation and Research (CDER), US Food and Drug Administration. In seeking to enhance policies related to drug development and regulatory review in CDER, his responsibilities include serving as the Chair of RWE Subcommittee, supporting RWE guidance development and demonstration projects, interacting with external stakeholders regarding RWE, and developing internal Agency processes related to RWE. Prior to joining FDA in 2019, his career focused on generating research as an independent investigator and research center director at Yale University School of Medicine and the U.S. Department of Veterans Affairs (VA), including serving as one of two founding principal investigators of the VA Million Veteran Program. He received MD and MS degrees from New York University and an MPH degree from Yale University.

Lee A. Fleisher, MD, was named the Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare and Medicaid Services in July 2020. In this capacity, he is responsible for executing all national clinical, quality, and safety standards for healthcare facilities and providers, as well as establishing coverage determinations for items and services that improve health outcomes for Medicare beneficiaries. He is also Professor of Anesthesiology and Critical Care and Professor of Medicine at the University of Pennsylvania Perelman School of Medicine. Lee received his medical degree from the State University of New York at Stony Brook. His research focuses on perioperative cardiovascular risk assessment and reduction, measurement of quality of care, decision making, implementation of cultural change and health policy. He has received numerous federal, industry and foundation grants related to these subjects and has published 175+ original articles, over 200 editorials, reviews and book chapters, and 9 books and collaborates with anthropologists, sociologists, as well as faculty from law, business and nursing. He is currently an Affiliated Faculty of the Quattrone Center for the Fair Administration of Justice at the University of Pennsylvania Carey Law School and a Senior Fellow of the Leonard Davis Institute of Health Economics. In 2007, he was elected to membership of the National Academy of Medicine (formerly Institute of Medicine) of the National Academy of Sciences and served on Committees of the NAM.