2023 Duke-Margolis Convening on the State of Real-World Evidence Policy

September 28, 2023 | 12:30pm – 4:30pm ET

Speaker Biographies

Marc L. Berger

Marc L. Berger, MD, is a semi-retired, part-time consultant and scientific advisor. Until July 2017, he was Vice President, Real World Data and Analytics at Pfizer, Inc. Marc has held senior-level positions in industry including Executive Vice President and Senior Scientist at OptumInsight; Vice President, Global Health Outcomes at Eli Lilly and Company; and Vice President, Outcomes Research and Management at Merck & Co., Inc. He was a temporary employee of CMS from July-December 2022.

Marc is an ISPOR Special Advisor for Real World Evidence and a member of the Duke-Margolis Center for Health Policy Real-World Evidence Collaborative. He has written or co-written more than 130 peer-reviewed articles, book chapters, and other publications on a range of topics including health services research, outcomes research, health economics, and health policy. He received the Donabedian Lifetime Achievement Award from ISPOR in 2019.

Elise Berliner

Elise Berliner, PhD is the Global Senior Principal for Real World Evidence Strategy at Cerner Enviza, an Oracle Company. Before joining Cerner Enviza, Dr. Berliner was the Director of the Technology Assessment Program at the Agency for Healthcare Research and Quality (AHRQ), providing systematic reviews and other scientific analyses to the Centers for Medicare & Medicaid Services (CMS) to inform Medicare coverage decisions and other policy issues. Dr. Berliner has several years of experience in research and development at innovative medical technology companies, was a Fellow at the Office of Technology Assessment in the United States Congress, and received her Ph.D. in biophysics from Brandeis University

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Jeffrey Brown

Jeffrey Brown, PhD, Chief Scientific Officer at TriNetX and Lecturer (part-time) at Harvard Medical School (HMS), is an internationally recognized expert in the use of real-world data to support the evidentiary needs of regulatory agencies and medical product sponsors. He has 25+ years of research experience using real-world data, most recently as an Associate Professor in the Department of Population Medicine (HMS) and a trusted consultant to numerous research groups and pharmaceutical companies. At HMS he served as the Lead Data Scientist for the FDA Sentinel Operations Center and as PI for several multi-site pharmacoepidemiologic studies to support FDA and EMA regulatory requirements.

Dr. Jeffrey Brown, Chief Scientific Officer at TriNetX, is an internationally recognized expert in the use of real-world data to support the evidentiary needs of regulatory agencies and medical product sponsors and an expert in the assessment of data quality of real-world data resources. He focuses on the value of collaborative research with an emphasis on federated networks. He has expertise in assessing the fitness-for-use of real-world data and matching questions to methods to data to generate robust evidence. Dr. Brown has over 15 years of experience facilitating large-scale, multi-institutional observational research through use of distributed health data networks to support a learning health system and the use of electronic health data to support decision-making. In his previous role as Associate Professor at Harvard Medical School he served as the Lead Data Scientist for the FDA Sentinel Operations Center and as a member of the Sentinel Operations Center Executive Committee, Principal Investigator of the analytic coordinating center for Innovation in Medical Evidence Development and Surveillance (IMEDS) program and the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC). While at Harvard he also served as PI of several industry-sponsored multi-site pharmacoepidemiologic studies to support FDA and EMA regulatory requirements. Dr. Brown holds a master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University.

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Gregory Calip

Gregory Calip is a Director, Global Epidemiology (Oncology) at AbbVie and Adjunct Associate Professor, USC Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, Program on Medicines and Public Health. He is an experienced cancer epidemiologist with over a decade of experience in academia and the healthtech industry. After completing his PharmD and MPH in Biostatistics, he received his PhD in Epidemiology from the University of Washington and completed postdoctoral training at the Fred Hutchinson Cancer Center in Seattle. He was previously Associate Professor at the University of Illinois Chicago in the Center for Pharmacoepidemiology and Pharmacoeconomic Research where his NIH-funded research focused primarily on health inequities in multiple myeloma and cancer treatment-related cardiotoxicity. More recently, at Flatiron Health, Greg was Quantitative Sciences Head of Academic Health Systems and Principal Quantitative Scientist in the Flatiron Health Research Unit, where he conducted research focused on the impacts of COVID-19 on oncology real-world evidence, propensity score calibration methods for missing data, and the representativeness of oncology clinical trials. Greg is currently Director of Global Epidemiology (Oncology) at AbbVie and adjunct faculty at the USC Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences in the Program on Medicines and Public Health.

M. Khair ElZarrad

M. Khair ElZarrad, PhD, MPH, is the Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER). He has served as the Deputy Director of OMP since 2017.

As Director of OMP, Dr. ElZarrad leads the development, coordination, and implementation of medical policy programs and strategic initiatives. He works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes.

OMP is comprised of the Office of Prescription Drug Promotion (OPDP) and the Office of Medical Policy Initiatives (OMPI). OPDP oversees the regulation of prescription drug promotion and advertising. OMPI provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas.

Before joining FDA, he served as senior science policy analyst and Director of the Clinical and Healthcare Research Policy Division at the Office of the Director of the National Institutes of Health (NIH). He also served as a fellow on both the FDA's Interagency Oncology Taskforce, as well as the National Cancer Institute's Cancer Prevention Fellowship Program within the Division of Cancer Control and Population Sciences.

Dr. ElZarrad earned his doctoral degree in medical sciences with a focus on understanding cancer metastases from the University of South Alabama College of Medicine, his Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health, and his bachelor's degree in biochemistry from Samford University.

Andenet Emiru

Andenet Emiru serves as the Director of External Partnerships & Projects at UC Health's Center for Data-driven Insights and Innovation (CDI2). With a passion for utilizing data-driven solutions, Andenet plays a vital role in driving innovation in healthcare. His work involves forging strategic partnerships with external organizations, facilitating collaborative projects, and leveraging data to improve healthcare outcomes. Through his expertise in business development and strategic partnerships, he plays a vital role in promoting the mission of the University of California and driving positive change in the healthcare industry.

Andenet has over 9 years of corporate experience with Target Corp. and has excelled in various areas, including P&L management, consulting, marketing, training, and strategic partnerships. He holds a Bachelor's degree in Management Information Systems and an MBA.

Apart from his work in the industry, Andenet is a mentor to many and an advocate for peace, health, and economic prosperity for all. Andenet finds great fulfillment in being part of a prominent and respected organization dedicated to promoting the public good through research, education, and public service.

Andenet is dedicated to serving with purpose, poised to make a meaningful impact, and committed to driving change by leveraging his gifts and talents to better the lives of others.

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Nora Emmott

Nora Emmott is the Senior Policy Analyst for the Real-World Evidence Collaborative at Duke-Margolis Center for Health Policy. She has a BS in Public Health and Women, Gender, and Sexuality Studies from the University of Massachusetts Amherst. She has an MPH with a concentration in Health Equity, Social Justice, and Human Rights from the University of North Carolina at Chapel Hill. Prior to obtaining her MPH, she worked as a Clinical Research Assistant for the All of Us Research Program at Massachusetts General Hospital in Boston, MA. Previously, she was a Healthcare Innovation and Transformation fellow for the Massachusetts Health Policy Commision.

Josh Fessel

Josh Fessel, MD, PhD is the senior clinical advisor in NCATS' Division of Clinical Innovation, where he serves as a liaison between basic, translational, and clinical scientists and helps build bridges between multiple stakeholders to ensure that the most innovative clinical and translational science moves forward. He works closely with the Clinical and Translational Science Awards (CTSA) consortium, with all of the different components of NCATS, across NIH ICs, and across USG agencies to help streamline existing processes (e.g., single IRB operations, clinical trial metrics, data management and sharing) and to accelerate innovation in clinical and translational research (e.g., novel trial designs and analytical approaches, incorporation of cutting edge real-world data and digital health methods). In addition, Josh has worked on multiple NIH-wide and USG-wide efforts responding to the SARS-CoV-2/COVID-19 global pandemic for both acute COVID and for post-COVID conditions (i.e., long COVID). His clinical background is in adult pulmonary and critical care medicine, and his scientific background is in pharmacology, redox biology, lipid biochemistry, mitochondrial biology, and intermediary metabolism in complex disease phenotypes. Prior to coming to NIH, Josh was a physician-scientist running a basic and early translational lab; seeing patients in the clinic, hospital, bronchoscopy suite, and ICU; and mentoring trainees at all levels.

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Rachele Hendricks-Sturrup

Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Center for Health Policy in Washington, DC, strategically leading and managing the Center's RWE Collaborative. As an engagement expert, 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. She also partners with Duke University faculty, scholars, students, and external health experts to advance the Center's biomedical innovation work.

She is presently adjunct faculty at rural Ohio University, teaching graduate courses in the Department of Interdisciplinary Health Science's Health Policy Certificate program, and has taught graduate courses within the Masters of Health Care Innovation program at the University of Pennsylvania's Perelman School of Medicine. As of January 2023, she serves on the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R) and is part of executive leadership for the National Alliance Against Disparities in Patient Health (NADPH).

Prior to joining Duke-Margolis, Dr. Hendricks-Sturrup was Health Policy Counsel and Lead at the Future of Privacy Forum (FPF), leading the organization's health and genetic data initiatives and workgroup. Prior to FPF, she served in several administrative and scientific roles at various industry, health care, and academic institutions. To date, she has published several commentaries and original research papers in high-quality, peer-reviewed journals. Dr. Hendricks-Sturrup is also an accomplished health and science journalist, having completed a comparative effectiveness research fellowship with the Association of Health Care Journalists in 2017.

Dr. Hendricks-Sturrup received her Bachelor of Science in Biology from Chicago State University, her Master's in Pharmacology and Toxicology from Michigan State University, her Master's in Legal Studies from the University of Illinois, and her Doctor of Health Science from Nova Southeastern University. She completed a predoctoral internship with the National Health Service in London, UK, and postdoctoral research training within the Department of Population Medicine at Harvard Pilgrim Health Care Institute and Harvard Medical School.

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Eibhlin Hudson

Eibhlin Hudson is a Global RWE Director at Novartis Global Business Solutions (GBS) where she leads a number of RWE services and is responsible for the GBS RWE strategy. She recently participated in the Duke Margolis RWE sub-group analysis workstream. She has over 15 years of observational data experience. She previously held roles as Group Head, Team Lead and RWE Research Analyst at Novartis. Before joining Novartis Eibhlin held research positions at the University of Galway, UCD Geary Institute and UCD School of Public Health and Trinity College Dublin. She held lectureships at University College Dublin, RMIT Melbourne (Tenured). She earned her PhD in Health Economics/Applied Econometrics from UCD and she earned her BA in Economics and IT (1st) and a MA in Economics (1st) from the University of Galway.

Chris Lindsell

Chris Lindsell is director of Data Science and Biostatistics for Duke Clinical Research Institute, and professor and co-chief of biostatistics in the Department of Bioinformatics and Biostatistics at Duke University. His career has focused on improving clinical research efficiency through better systems, methods, and processes. He has led data coordinating centers for many federal and industry supported clinical trials and epidemiological studies ranging in scale from single center to multi-national studies. The target of Dr. Lindsell's discovery work is in acute and critical care, where he is a recognized expert in biomarker discovery and validation, phenotyping, designing and executing clinical trials, and in health systems and services research. He has published over 350 papers, holds patents for risk stratification in sepsis and septic shock, and also led the development of Vanderbilt's Learning Health System embedded clinical trials platform. Currently, he is an MPI of the ARDS, pneumonia and sepsis phenotyping consortium and of the Trial Innovation Network, he is the incoming Editor in Chief for the Journal of Clinical and translational Science, and he leads the Data Coordinating Center for the ACTIV-6 platform trial studying repurposed medicines for acute Covid-19.

Trevan Locke

Trevan Locke is an Assistant Research Director at Duke-Margolis working on issues related to biomedical innovation. He oversees Duke-Margolis' involvement as a founding member of the Advancing Clinical Trials at the Point of Care Coalition and workstreams on evidence generation for Duke-Margolis' Real-World Evidence Collaborative. Previously, he worked as a Regulatory Science and Policy Analyst at the American Association for Cancer Research on regulatory issues impacting cancer care and the development of cancer therapies, including considerations for equitable clinical trial enrollment. Dr. Locke completed a Bachelor of Engineering in Chemical and Biomolecular Engineering at Vanderbilt University and a PhD in Chemical and Biochemical Engineering at Rutgers University, where his research focused on the development of nanoparticles for the delivery of chemotherapy to treat cancer.

Hilary Marston

Hilary Marston, MD, MPH, is the Chief Medical Officer (CMO) of the FDA. The CMO is the primary clinical advisor to the Commissioner and oversees the Office of Clinical Policy and Programs (OCPP). In this capacity, the CMO leads programs and cross-cutting initiatives that support the FDA's centers in making effective, safe, and innovative medical products available to the American people. These include efforts to ensure timely review of combination products, incentive programs to promote interventions for rare diseases, and dedicated labeling for pediatric patients. OCPP also coordinates and supports patient engagement activities across the medical product centers to foster awareness and collaboration with patients, their advocates, and the FDA, with the goal to strengthen and modernize key functions to enhance communication to stakeholders and further elevate the role of patients in the FDA's work in medical product development.

Before joining the FDA, Dr. Marston was Senior Advisor for Global COVID-19 Response on the White House COVID-19 Response Team, overseeing donations of COVID-19 vaccines to countries in need. Prior to this, Dr. Marston was the Director for Medical Biopreparedness and Response at the U.S. National Security Council, leading policy considerations related to medical countermeasure development and policy matters related to pandemic preparedness. Previously, Dr. Marston served as a Medical Officer and Policy Advisor for

Pandemic Preparedness focusing on emerging infectious disease preparedness and response at the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. In this role, she coordinated NIAID's response to outbreaks including Zika, Ebola and COVID-19.

Dr. Marston trained in Internal Medicine and Global Health Equity at Brigham & Women's Hospital, during which time she worked with Partners in Health and the Clinton Health Access Initiative. She completed her MPH at the Harvard T.H. Chan School of Public Health. Before her medical training, Dr. Marston worked for McKinsey & Company and the Bill & Melinda Gates Foundation as a Program Officer and Special Assistant to the Co-Chair.

Frederick Masoudi

Frederick Masoudi, MD, MSPH, MACC, FAHA, 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.

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. He is currently a professor of medicine at the Dell Medical School at the University of Texas at Austin and a clinical professor of medicine at CU Anschutz AMC.

Dr. Masoudi has 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 350 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.

Mark McClellan

Mark McClellan, MD, PhD is Director and Robert J. Margolis, M.D., Professor of Business, Medicine and Policy at the Duke-Margolis Center for Health Policy at Duke University. He is a physician-economist who focuses on quality and value in health care, including payment reform, real-world evidence and more effective drug and device innovation. At the center of the nation's efforts to combat the COVID-19 pandemic, the author of COVID-19 response roadmap, and co-author of a comprehensive set health policy strategies for COVID vaccines, testing, and treatments, Dr. McClellan and his Duke-Margolis colleagues are now focused on health policy strategies and solutions to advance the resilience and interconnectedness of 21st Century public health and health care. Mark is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. Dr. McClellan is an independent board member on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and Prognom IQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and serves as an advisor for Arsenal Capital Group, Blackstone Life Sciences.

Daniela Moga

Daniela Moga, MD, PhD, FISPE is an Associate Professor in the Department of Pharmacy Practice and Science, an affiliated faculty member in the Institute for Pharmaceutical Outcomes and Policy (IPOP), and Larry H. Spears Endowed Chair in Pharmacogenetics in the College of Pharmacy at University of Kentucky. She currently serves as Assistant Dean for Research (Clinical and Translational Programs) in the College of Pharmacy. Dr. Moga is also jointly appointed as Associate Professor in the Department of Epidemiology in the College of Public Health and serves as faculty associate with Sanders-Brown Center on Aging. In 2022, she represented the International Society for Pharmacoepidemiology (ISPE) in the Duke-Margolis Real-World Evidence Collaborative's 2022 workstream on Real-World Efficacy: Patient Subgroups.

Dr. Moga's areas of interest include geriatric pharmacoepidemiology and health outcomes research, and lie at the intersection of aging, multimorbidity and brain health. Dr. Moga's research focuses on using real-world data to evaluate health effects of potentially inappropriate medications, as well as developing and evaluating deprescribing interventions to optimize treatment regimens in older adults at risk.

Sally Okun

Sally Okun 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). She works with CTTI's Executive Committee in the development and execution of strategies 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-focused research network. During her 12-year tenure at PLM she developed the site's medical ontology for curating patient-reported health data and oversaw the development of PLM's fully integrated Drug Safety and Pharmacovigilance Platform. As PLM's Vice President

of Advocacy, Policy, and Ethics she contributed to policy discussions at the national and global level and was PLM's liaison with patient organizations, government and regulatory agencies. She was the Principal Investigator for the Participant Engagement sub-award with Scripps Research Translational Institute for the NIH All of Us Research Program and for a three-year Research Collaboration Agreement with the FDA focused on characterizing patient-generated health data. 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. She earned her Master's degree from the Heller School for Social Policy and Management at Brandeis University and Biomedical Informatics Fellow from the National Library of Medicine.

Donna Rivera

Donna R. Rivera, PharmD, MSc, is the Associate Director for Pharmacoepidemiology in the Oncology Center of Excellence at the US Food and Drug Administration. She leads the Oncology Real World Evidence (RWE) Program, focused on the use of Real World Data (RWD) and RWE for regulatory purposes as well as management of the RWD research portfolio strategy and development of related regulatory policy to support the OCE mission. As a pharmacist and pharmacoepidemiologist, Dr. Rivera has interests in the use of RWD to increase knowledge of unrepresented populations and advance health equity, observational study designs and RWD methodological approaches, and appropriate uses of RWD for drug development to increase access of effective therapies to patients. She is a member of the Scientific Executive Committee for the COVID-19 and Cancer Consortium (CCC19) and leads Project Post COVIDity, a collaborative RWD effort to assess longitudinal sequalae, outcomes, drug safety, vaccination, and immunity.

In her previous role at the National Cancer Institute (NCI), she led a strategic RWD initiative to facilitate large scale, longitudinal treatment data linkages with SEER through collaborative public and private partnerships. She also has previous experience in clinical trials from Stiefel, a GlaxoSmithKline company. Dr. Rivera earned her Doctor of Pharmacy and Master of Science in Pharmaceutical Sciences with a concentration in Pharmaceutical Outcomes and Policy from the University of Florida College of Pharmacy. She completed a postdoctoral fellowship in Pharmacoepidemiology and Pharmacogenomics at the NCI in the Epidemiology and Genomics Research Program.