

2022 Duke-Margolis Convening on the State of Real-World Evidence Policy

May 12, 2022 | 12:00 pm – 5:00 pm ET

Panelist Biographies

Welcome and Keynote



Jacqueline Corrigan-Curay is the Principal Deputy Center Director in FDA’s Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations. Previously, Dr. Corrigan-Curay was director of CDER’s Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and as a practicing attorney in Washington, D.C.



Mark McClellan is the Robert J. Margolis, M.D., 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.

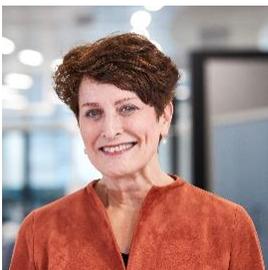
Session 1: Advancing Regulatory Acceptability of RWE



Adam Aten is a Research Associate on the biomedical and innovation team at the Duke-Margolis Center for Health Policy. His work focuses on developing health information systems and data infrastructure in support of evidence generation. Prior experiences to joining Duke-Margolis include the Brookings Institution as a health policy researcher, and the U.S. Department of Health and Human Services as a legislative and regulatory analyst.



Angela Dobes works for the Crohn's & Colitis Foundation. She is the vice president of IBD Plexus, a data platform and biorepository that leverages a patient-centric approach to collect and integrate multimodal, real-world data to accelerate progress towards precision medicine and improve the lives of children and adults affected by inflammatory bowel disease. Ms. Dobes also oversees all direct-to-patient research and engagement initiatives at the Foundation. Ms. Dobes devotes much of her time to advancing patient-centered research and is passionate about ensuring research, care interventions and treatments are meaningful to patients. She is the co-chair of the Trust and Patient-Centeredness Working Group for the Agency for Healthcare Research and Quality Clinical Decision Support Innovation Collaborative. In addition, her work has been funded through organizations such as the Patient-Centered Outcomes Research Institute and The Leona M. and Harry B. Helmsley Charitable Trust. She strives to elevate the important role patient registries and biorepositories play in the pursuit of high-value and high-quality research through volunteering on external committees and initiatives, including The National Academies of Science, Engineering & Medicine project titled, Data Capacity for Patient-Centered Outcomes Research: An Agenda for 2021 to 2030. Prior to her experience at the Foundation, Ms. Dobes worked for clinical technology and pharmaceutical organizations, where she has led implementation of various technology solutions focused on business optimization and accelerating the delivery of new therapies to patients safely.



Nancy Dreyer is Senior Vice President and Chief Scientific Officer for Real World Solutions at IQVIA, and Adjunct Professor of Epidemiology at the University of North Carolina at Chapel Hill. She is responsible for driving innovation in medical product development and commercialization using passive and/or active collection of real-world data to generate evidence for regulators, clinicians, patients and payers. She works with regulators in major markets and has published extensively in a variety of therapeutic areas including elite sports injuries. A Fellow of both the International Society of Pharmacoepidemiology and DIA, she is well-known for her thought leadership. Her work has recently been cited in guidelines from the FDA, EMA and NMPA on regulatory use of RWE. Her substantial executive and field experience have helped hone her pragmatic views.



Trevan Locke 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.



Nicole Mahoney is an Executive Director for Regulatory Policy at Novartis, focused on the use of real-world evidence, artificial intelligence, and digital tools in drug development. In this role, she contributes to a number of collaborative policy efforts, including with the Duke Margolis RWE Collaborative, BIO, PhRMA, EFPIA and TransCelerate. Prior to Novartis, Nicole was the head of Regulatory Policy at Flatiron Health, where she helped advance the use of RWE for regulatory decision making in oncology, and catalyzed the formation of the RWE Alliance. Nicole developed and advanced anti-infectives policies as a Director of

Global Regulatory Policy at Merck, senior officer for the Pew Charitable Trusts' antibiotics and innovation project, and US Food and Drug Administration Commissioner's Fellow. She earned a doctorate in biochemistry from the Albert Einstein College of Medicine, and was a postdoctoral fellow at the University of California, San Francisco.



Jeremy A. Rassen is a pharmacoepidemiologist with 25 years of academic and industry experience. He is Co-Founder and President of Aetion, a healthcare technology company that delivers real-world evidence for life sciences companies, payers, and regulatory agencies. Prior to founding Aetion, Dr. Rassen was Assistant Professor of Medicine at Harvard Medical School, where he focused on methods to improve the quality and validity of real-world data studies. Dr. Rassen received his bachelor's degree in Computer Science from Harvard College and his master's and doctorate degrees in Epidemiology from the Harvard T.H. Chan School of Public Health.



Richard J. Willke is chief science officer of ISPOR, the leading global professional society for health economics and outcomes research. Dr Willke has more than 25 years of experience in the life sciences arena and has specialized in outcomes research in a succession of group leadership roles with Pfizer and its legacy companies. At ISPOR, Dr Willke is responsible for designing and implementing strategic initiatives related to scientific research and content priorities that will advance the Society's mission of promoting health economics and outcomes research excellence to improve decision making for health globally.

Previously, Dr Willke was vice president, Outcomes and Evidence Cluster Lead at Pfizer for its Global Health and Value division. He has also served in a number of leadership roles with affiliated organizations, including the Chair of ISPOR Institutional Council (2010), ISPOR Board of Directors (2007-2009), and Chair of the PhRMA Health Outcomes Committee (2002-2004). Prior to joining industry, Dr Willke served as

department director in the Center of Health Policy Research at the American Medical Association and held research and teaching positions at The Ohio State University. Dr Willke earned a PhD and MA in economics from Johns Hopkins University. He has authored more than 80 scholarly publications that examine the science and methodologies of health economics and outcomes research.

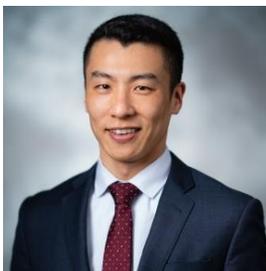
Session 2: Re-imagining Evidence Generation: Opportunities for Developing Shared Evidence and Point of Care Clinical Trials



Marc L. Berger is a semi-retired, part-time consultant and scientific advisor. Until July 2017, he was Vice President, Real World Data and Analytics (RWDnA) 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 currently serves as advisor to a number of pharmaceutical and health data analytics companies. Additionally, Marc is a Special Advisor for Real World Evidence to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) contributing to its ongoing efforts and that of other organizations such as the Duke-Margolis Center for Health Policy to promote best practices in the creation of real-world evidence (RWE). Marc 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.



Rachele Hendricks-Sturup 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.



Dure Kim is an Assistant Research Director for the Biomedical Innovation portfolio, focusing on the Center's Cooperative Agreement with the FDA in the advancement of regulatory science and health policy research. Prior to joining Duke-Margolis, he was a Research Scientist at the National Evaluation System for health Technology Coordinating Center, where he helped manage and develop Real-World Evidence studies with medical device stakeholders and researchers. Dure received his Doctor of Pharmacy from Mercer University in 2016 and completed a fellowship in Comparative Effectiveness Research and Patient-Centered Outcomes Research at the University of Maryland, Baltimore in 2018.



Gracie Lieberman is a Biostatistician with 35+ years of experience in oncology clinical trials. Gracie spent 28+ years at Genentech where she has gained experience in all phases of drug development, from pre-IND to post-marketing, drug/diagnostic co-development, and collection/evaluation of Patient Reported Outcomes (PROs). Gracie was also a panelist, representing Genentech at a clinical conference organized by Friends of Cancer Research and Brookings Institute. The recommendations developed by the specific panel were key to the establishment of the Breakthrough Therapy Designation. During her last 8 years at Genentech, Gracie worked in Regulatory Policy and her focus areas were adoption and acceptance of innovative clinical trials and Real World Evidence in drug development and regulatory decision-making.



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 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. 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.

Session 3: What's Next for the Use for RWE?

Panel 1



Elise Berliner is the Global Senior Principal for Real World Evidence Strategy at Cerner Enviza. 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 also led a portfolio of work in patient registries and led the development of the AHRQ handbook "Registries for Evaluating Patient Outcomes, A User's Guide". 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.



Jeffrey Brown 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. Dr. Brown has more than 25 years of experience in research using real-world data, most recently as an Associate Professor in the Department of Population Medicine at Harvard Medical School and as a trusted consultant to numerous research groups and pharma companies. Dr. Brown holds a master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University. As Chief Scientific Officer at TriNetX Dr. Brown focuses on how to make best use of electronic health data partnerships to optimize clinical development and generate real-world evidence. His research involves 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.



Luca Foschini is the Co-founder and Chief Data Scientist at Evidation Health, responsible for data analytics and research and development. At Evidation he has driven research collaborations resulting in numerous publications in the fields of machine learning, behavioral economics, and medical informatics. Previously, Luca held research positions in industry and academic institutions, including Ask.com, Google, ETH Zurich, and UC Santa Barbara. He has co-authored several papers and patents on efficient algorithms for partitioning and detecting anomalies in massive networks. Luca holds MS and PhD degrees in Computer Science from UC Santa Barbara, and ME and BE degrees from the Sant'Anna School of Pisa, Italy.



Lauren Silvis serves as Senior Vice President of External Affairs at Tempus, overseeing regulatory, public policy and government affairs. Silvis has held number of senior career public health roles, serving as a Senior Advisor at the Department of Health and Human Services, Chief of Staff of the U.S. Food and Drug Administration and Deputy Center Director for Policy in FDA's Center for Devices and Radiological Health. During her time in government, she advanced policies to promote innovation in precision medicine, real world evidence, clinical

trials, and digital health. Silvis serves as a board member for the Personalized Medicine Coalition and the American Heart Association, Greater Washington Region. She was a partner at the international law firm Sidley Austin LLP, focusing on regulation of pharmaceuticals and medical devices. Silvis graduated from Duke University and earned her law degree from Georgetown University Law Center.

Session 3: What's Next for the Use for RWE?

Panel 2



Solomon Iyasu is a Vice President and Global Head of Epidemiology at Merck and Co. He leads that department that is responsible for the design and conduct of post-approval observational safety and effectiveness studies of pharmaceutical products, real-world data analytics to characterize disease epidemiology, natural history, clinical outcomes to inform clinical trial design, and endpoint strategy. He also plays a key role in leading initiatives to foster patient focused medical product development and to analyze health related big data to produce medical evidence for decision making by policy makers. He serves on Merck's Patient

Innovation Council, the Safety Review Committee, and the steering committees of multiple Strategic Research Partnerships between Merck and Academia. Externally, he serves on the steering committee of the Reagan Udall Foundation's Innovations in Medical Evidence Development (IMEDS), the Duke Margolis Center RWE Collaborative Scientific Advisory Committee and the CIOMS WG XIII RWD/RWE in Regulatory Decision-Making. Prior to joining Merck in 2015, Dr. Iyasu served in positions of various leadership positions in epidemiology, pharmacovigilance and pediatric drug development at the Center for Drug Evaluation and Research (CDER), USFDA for 13 years. Prior to the USFDA, he worked at the US Centers for Disease Control and Prevention (CDC) as a medical team leader leading reproductive and perinatal health epidemiology and health outcomes studies. He has published many research papers and book chapters. Dr. Iyasu received his medical training at the University of Delhi, India and his Master of Public Health at the Johns Hopkins University, and subsequently completed a Preventive Medicine Residency and the Epidemic Intelligence Service Programs at the CDC in Atlanta, USA.



Stephanie Reisinger is the Senior Vice President and General Manager of Real-World Evidence at Flatiron Health. In this role, she leads Flatiron's Real-World Evidence business unit, setting the strategy to drive long term growth and to accelerate Flatiron's leadership in the way real-world oncology data is collected, combined and analyzed to support life sciences research. Steph joined Flatiron in January 2022. She has more than 20 years of experience leading businesses at the intersection of real-world patient data, technology, and analytics within the

life sciences industry. Prior to Flatiron, she served as the General Manager of Life Sciences Data and Analytics at Veradigm, a healthcare analytics subsidiary of Allscripts, one of the largest providers of electronic health records. Steph earned her bachelor's degree at Widener University and is a candidate for her master's in business administration at the Smeal College of Business at Penn State University.



Laura Roe leads policy partnerships and data strategy initiatives for the clinical research business at Verily, an Alphabet company. In this role, Laura advances the team's work on longitudinal data innovation, real-world evidence strategy, and strategic collaborations with data and standard-setting organizations. Throughout her career, Laura has been dedicated to improving the use of data to benefit patient care. Most recently, she served as Sr. Technical Advisor to the Principal Deputy Commissioner at FDA, where she spearheaded public private partnerships focused on the use of real-world data to address the pandemic, including the COVID-19 Evidence Accelerator hosted by the Reagan Udall Foundation, and other research collaborations with data providers. Prior to this, Laura served in multiple roles in the Duke University Cancer Care Research Program and Center for Learning Health care, where her focus was on data innovation for clinical research and to realize a learning healthcare system. Laura has a degree from Duke University School of Medicine in Master of Management in Clinical Informatics (MMCi).



Shirley V Wang is an Associate Professor at Brigham and Women's Hospital, Harvard Medical School and Lead Epidemiologist for the Food and Drug Administration's (FDA) Sentinel Innovation Center. Her research is focused on 1) developing innovative, non-traditional analytic methods to understand the safety and effectiveness of medication use in routine clinical care as well as 2) facilitating appropriate use of complex methods for analyzing large observational healthcare data. She is currently PI on 3 NIH R01s and is also funded by FDA. Her methods work has received 3 awards from international societies. Dr. Wang co- led the 1st and 2nd joint task forces for the International Society of Pharmacoepidemiology (ISPE) and the International Society for Pharmacoconomics and Outcomes Research (ISPOR) focused on real-world evidence for healthcare decision-making. She co-directs the REPEAT Initiative, a non-profit program with projects aimed at improving transparency, reproducibility and robustness of evidence from healthcare databases. She co-leads RCT-DUPLICATE, a series of projects designed to inform when and how real-world data analyses can draw causal conclusions to inform regulatory or other healthcare decision-making.