2025 Duke-Margolis Convening on the State of Real-World Evidence Policy

July 31st, 2025 | 12:00pm – 4:30 pm ET

Speaker Biographies

Amy Abernethy is cofounder of Highlander Health, an investment firm dedicated to advancing evidence generation and personalized healthcare for a new era of medical innovation. As an oncologist, entrepreneur, and leader in clinical research and health data science, Dr. Abernethy is passionate about breaking down barriers between clinical trials and real-world evidence, seeing both as essential parts of a unified ecosystem that delivers safer, more effective treatments to patients faster. At Highlander, she is bringing together providers, regulators, researchers, tech innovators, and life sciences companies to tackle fragmented health data, build practical solutions for next-generation evidence, and shape a future where data and evidence truly serve patients. Previously, Dr. Abernethy served as principal deputy commissioner of the U.S. Food and Drug Administration, where she led initiatives to modernize clinical evidence generation and advance personalized healthcare, while also serving as the agency's acting chief information officer. This regulatory experience directly informs Highlander Health's work in responsible AI and building modern evidence infrastructures. More recently, Dr. Abernethy served as chief medical officer and president of product development at Verily, Alphabet's precision health business, overseeing efforts to better connect clinical research and care. Prior to that, she was the first chief medical officer and chief scientific officer at Flatiron Health, and held key academic roles at Duke University, including; professor of medicine at Duke University School of Medicine, director of the Center for Learning Health Care at the Duke Clinical Research Institute, and, director of the Duke Cancer Care Research Program at the Duke Cancer Institute. Trained as a hematologist/oncologist and palliative medicine physician, Dr. Abernethy is also an active scholar with more than 500 publications and remains a committed learner and teacher, dedicated to making healthcare work better for all.

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Ivy Altomare is a Medical Oncologist and Senior Medical Director at Flatiron Health, where she serves as the Head of Research Oncology, Clinical Research. At Flatiron, Dr. Altomare interfaces with the Academic Medical Centers and Community Oncology practices that use Flatiron's interoperable digital tools to support and accelerate prospective clinical research. She works with pharma sponsors and NCI-funded cooperative groups to evaluate evidence needs and advocate for pragmatic study design for trials enhanced by Flatiron technology, and assesses the validity and feasibility of running tech-enhanced trials in the Flatiron Research Network. She also maintains an active community oncology practice at the Veteran's Hospital in Durham, NC, having previously served as faculty at Duke University for fifteen years and as the Assistant Medical Director of the Duke Cancer Network prior to joining Flatiron. She is an award-winning medical educator, an established clinical researcher, has authored/co-authored over 50 publications including manuscripts, abstracts and book chapters, and has been an invited speaker at numerous events sponsored by the Clinical Trials Transformation Initiative (CTTI), NCCN, ASCO, ASH, the Cancer Business Exchange, OncLive and OncoDaily.

Robert M. Califf is a physician, researcher, and leader in clinical and regulatory science. He twice served as Commissioner of Food and Drugs (2016–2017, 2022–2025) and is currently an Instructor in Medicine at Duke University. Between his FDA appointments, he led medical policy and strategy at Verily Life Sciences and Google Health within Alphabet, Inc. A nationally recognized expert in cardiovascular medicine and clinical research, Dr. Califf was a long-time professor and vice chancellor at Duke, where he founded the Duke Clinical Research Institute. Throughout his career, Dr. Califf has been a vocal proponent of equitable and high-quality healthcare. He is a member of the National Academy of Medicine and has published over 1,300 peer-reviewed articles.

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Brian Canter is an Assistant Research Director on the Biomedical Innovation team working on policy solutions to improve development, regulatory review, and evidence generation for broadening access and availability to medical products. He manages one of the Biomedical Innovation team's cooperative agreements with the U.S. Food and Drug Administration (FDA). Brian's portfolio of work spans several key areas within the biomedical innovation space. As the lead researcher on regulatory considerations to enable greater competition for biologics, he has evaluated the value of the interchangeability designation and derived strategies to foster future biosimilar development for cell and gene therapies. Supporting the Institute's thought leadership to modernize clinical trials, Brian guides the policy work for the Coalition for Advancing Clinical Trials at the Point of Care. Brian has also managed several projects within the Institute's regulatory science work, including public meetings convened with FDA to advance clinical trial innovation and premarket safety analytics. In addition to biomedical innovation, Brian has done extensive work within the Institute's 21st Century Public Health and Population Health portfolio. He oversaw a project focused on addressing the burden of respiratory viruses through reduction of disease transmission. During the COVID-19 pandemic, Brian led the Institute's work to maximize adoption of therapeutics, with a focus on Test-to-Treat pathways. Prior to joining Duke-Margolis, Brian completed a PhD in Biomedical Sciences with a focus in Biomedical Engineering from Rutgers University. His thesis research focused on utilizing radiation therapy systemically to treat metastatic breast cancer that spread to bone. Brian also graduated with a Bachelor of Science in Biomedical Engineering from Tufts University.

Gracy Crane is a cancer biologist by training with a Master in Biomedical Research and a Ph.D. in Cancer Biology. She has also completed post-doctoral training fellowships at Oxford University (UK) and Massachusetts Institute of Technology (USA). She has over 12 years of years of experience in the pharmaceutical industry, in varying roles including medical and scientific affairs, clinical development, health outcomes research and real world data. Currently, she is the RWD & Pragmatic Trials policy lead and Chapter Lead within the Global Regulatory Science team at Roche. She has authored many publications on this topic and has presented in many international conferences. Gracy is also part of a number of external steering/working groups including the ISPOR RWD transparency Initiative, the Duke Margolis RWE Collaborative, and a member of EFPIA IEGU. She is also a co-author on the HARPER work.

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Kate Davidson is the Director of the Learning and Diffusion Group (LDG) at the Center for Medicare and Medicaid Innovation (CMMI), within the Centers for Medicare & Medicaid Services (CMS). In this role, Ms. Davidson leads CMMI's team focused on accelerating healthcare system transformation by leveraging improvement science within and across models, as well as leading the multi-payer alignment strategy for the Center through the Healthcare Payment Learning and Action Network (HCP-LAN). Prior to joining CMS, Ms. Davidson led Policy and Practice Improvement efforts at the National Council for Mental Wellbeing, where she managed payment reform, quality improvement, and workforce development initiatives in mental health and addiction prevention, treatment, and recovery organizations and provided training and technical assistance to human services organizations, counties and states. Ms. Davidson began her career in healthcare as a social worker researching, testing and scaling interventions in primary care, behavioral health and community-based settings. Ms. Davidson has an MSW from Fordham University and a BA from Loyola College in Maryland.

Steven Farmer is a board-certified cardiologist and is co-owner and Senior Partner of ABiG Health. He previously served as Chief Strategy Officer for Coverage at the Centers for Medicare & Medicaid Services (CMS). In that role, he led an effort to streamline and accelerate the development of evidence-based coverage policies. He was the principal architect of the Transitional Coverage for Emerging Technologies (TCET) pathway and led the initiative to incorporate real-world evidence into coverage decision-making. Before his role as CSO, he was a Senior Advisor in the Center for Medicare and Medicaid Innovation, where he assisted with developing and refining value-based payment programs, with a particular emphasis on the Bundled Payments for Care Improvement Advanced model.

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Jennifer C. Goldsack is the founder and CEO of the Digital Medicine Society (DiMe), a 501(c)(3) non-profit dedicated to advancing digital medicine to optimize human health. Her work focuses on practical approaches to the safe, effective, and equitable use of digital technologies to improve health, healthcare, and health research. Jennifer also brings the perspective of a patient navigating late-stage cancer, adding urgency and authenticity to her commitment to reshaping health care. She is a retired elite athlete – a Pan American Games champion, Olympian, and former world record holder. She serves on the boards of the Coalition for Health AI (CHAI) and Sage Bionetworks, is a member of the National Academies of Sciences, Engineering, and Medicine's Roundtable on Genomics and Precision Health, contributes to the World Economic Forum's Digital Health Action Collaborative, and is an Executive Committee Member of the U.S. Department of Health and Human Services' National Committee on Vital and Health Statistics (NCVHS). She earned a master's degree in chemistry from the University of Oxford, a master's in the history and sociology of medicine from the University of Pennsylvania, and an MBA from the George Washington University.

Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Institute for Health Policy in Washington, DC, strategically leading and managing the Institute's RWE Collaborative and RWE policy research portfolio and education. As an engagement expert, biomedical researcher, bioethicist, and policy practitioner with over 18 years of experience, her work centers on addressing implementation, regulatory, and ethical, legal, and social implications (ELSI) at the intersection of health policy and innovation. She presently partners with Duke University faculty, scholars, students, and external practicing experts to advance the Institute's biomedical innovation work. She received a Duke-Margolis Mentor Award in 2023. To date, Dr Hendricks-Sturrup has published impactful commentary and original research in high-quality, peer-reviewed journals and has presented at and served on program committees for several conferences. She presently serves on the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R), Professional Society for Health Economics and Outcomes Research (ISPOR) Steering Committee, has served since 2023 on the Program Committee as both a member and Co-Chair for the Drug Information Association's annual RWE Conference, and was a 2024 AcademyHealth Trust Scholar.

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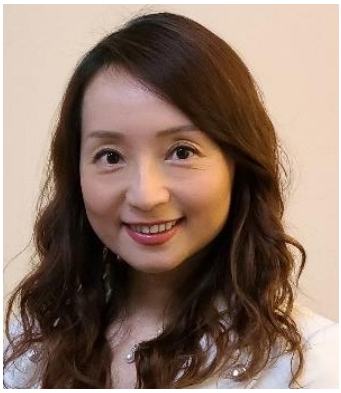
Ashley Jaksa is the Vice President of Evidence Solutions at Aetion, a Datavant Company. Her role focuses on helping Aetion's biopharma clients develop robust real-world evidence to achieve their commercialization goals and improve access to healthcare. She also establishes partnerships with regulatory and HTA agencies to enhance their use of RWE to support their decision-making, and advance methodological guidance for RWE generation. Before Aetion, she led analytic services at Context Matters where she consulted with biopharma clients on designing and executing analytic projects. She also previously worked to curate HTA and regulatory decisions for Context Matters' web based subscription platform. She has presented her research at numerous international conferences including ISPOR, HTAi and AMCP. She holds a bachelor's degree from the University of Michigan and a Master's of Public Health from Yale University.

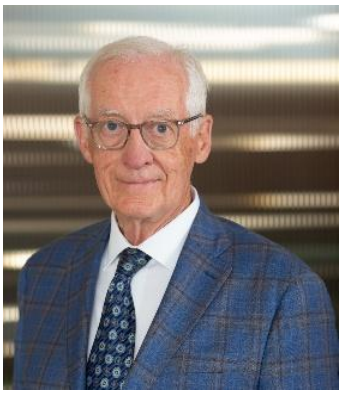
Chris Kim has 10+ years experience as a real world evidence (RWE) scientist/epidemiologist team lead at Amgen in the Center for Observational Research (CfOR) currently serving as a Product Area Lead for the Hematology and Genitourinary oncology product area, leading and managing a team of 5. My team is focused on conducting RWE studies to demonstrate unmet need, to provide context to single arm clinical trials by identifying external controls, designing and executing post-marketing safety commitment studies (PMC/PMR), evaluating risk management minimization plans (RMM/RMP), comparing the effectiveness of drugs/regimens, identify treatment trends, and generating the needed evidence to support the whole drug development lifecycle.

Cate Lockhart is the Chief Science Officer of the Academy of Managed Care Pharmacy (AMCP) and the Executive Director of the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) where she is responsible for all AMCP research programs, including those within the BBCIC multi-stakeholder research collaboration. She is a proven leader in health economics and outcomes research (HEOR), observational research, and managed care pharmacy through experience in the biopharmaceutical sector, experience as a consultant, and her current role at the AMCP. Cate has three undergraduate degrees: Electrical Engineering, Visual

Communications, and Theatre Arts. She also has three advanced degrees: PharmD, M.S. in HEOR, and a Ph.D. in Pharmaceutical Sciences. She has one U.S. Patent.



Julia Luan currently holds the position of Executive Regulatory Science Director at AstraZeneca (AZ). Her responsibilities include overseeing the global regulatory strategy in the cardiovascular, renal, and metabolic disease (CVRM) areas and supporting the research, development, and commercialization of CVRM products across AZ's portfolio. Additionally, she leads the AZ Health Authority Alumni Advisory Group and AZ RWE for Regulatory Purposes Working Group, and drives external engagement initiatives with KEEs, global trade organizations and Health Authorities such as FDA, EMA, PMDA and CDE, particularly in the realm of Real World Data/Real World Evidence. Prior to joining AZ, she gained over 13 years of experience at the FDA CDER Office of Biostatistics, where she served as a Statistical Primary Reviewer, Team Leader, and Acting Deputy Division Director. Preceding her tenure at the FDA, she led a Data Management & Analysis Group at Johns Hopkins University and worked as a Statistical Consultant at the University of Kentucky Medical Center. Dr. Luan has published 10 peer-reviewed journal articles and 3 book chapters, delivered 40+ invited presentations, and taken leadership roles in organizing and chairing 30+ sessions at international conferences. Furthermore, she served on the DIA RWE Annual Conference Program Committee (2020-2023), has been selected for a three-year tenure on the DIA Global Annual Conference Program Committee (2023-2026), and is the President of Chinese Biopharmaceutical Association (2023-2024).



Michael Mack is the Associate Academic Officer, Baylor Scott & White Health and Chairman of the Board, Baylor Scott & White Research Institute. He also serves as Chair of the American Board of Thoracic Surgery, as Co-Chair of the FDA Heart Valve Collaboratory and Senior Vice Chair, NIH Cardiothoracic Surgery Trial Network (CTSN). Dr. Mack has practiced cardiothoracic surgery in Dallas, TX since 1982. He is board certified in Internal Medicine, General Surgery, and Thoracic Surgery and has over 1,000 peer reviewed publications (h-index 152). Dr. Mack was President of the Society of Thoracic Surgeons (STS) 2011 and is Past President of the Thoracic Surgery Foundation for Research and Education (TSFRE) 2009-2011, the Southern Thoracic Surgical Association (STSA) 2009 and the International Society for Minimally Invasive Cardiothoracic Surgery (ISMICS) 2000. He is also a past member of the American College of Cardiology Board of Trustees and is the past Co-Chair

of the STS/ACC National Transcatheter Valve Therapy (TVT) Registry. He was an Associate Editor of the Journal of the American College of Cardiology 2018-2024. He is a Master of the ACC and is the recipient of the Presidential Citation of the American College of Cardiology, the Transcatheter Cardiovascular Therapeutics (TCT) Lifetime Achievement Award and the 2022 American Association for Thoracic Surgery (AATS) Lifetime Achievement Award.

Hilary Marston is the founding principal of Marston Health, advising biotechnology and investors on regulatory and clinical development strategy. Prior to this, Marston served as the inaugural chief medical officer of the U.S. Food and Drug Administration (FDA). In that role, she served as the primary clinical advisor to the commissioner and oversaw the Office of the Chief Medical Officer. The Office oversaw clinical matters that involved several of the FDA's product development centers, including financial incentives (e.g., for rare disease product development); targeted grantmaking; and research participant protection policy. She also led Agency response to health crises, including epidemics and medical product shortages. Marston previously served as senior advisor for global COVID-19 response on the White House COVID-19 Response Team, director for medical biopreparedness and response at the U.S. National Security Council and policy advisor for pandemic preparedness at the National Institute of Allergy and Infectious Diseases. Marston also worked at McKinsey & Company and the Bill & Melinda Gates Foundation. Marston trained in Internal Medicine and Global Health Equity at Brigham & Women's Hospital. She completed her Masters of Public Health at the Harvard School of Public Health.

Mark McClellan is Director and Robert J. Margolis, M.D., Professor of Business, Medicine and Policy at the Duke-Margolis Institute 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.

Anne-Marie Meyer is Vice President of Healthcare Consulting at acc solutions AG, where she advises organizations on clinical data strategies. She collaborates with partners, including NIH, Reagan-Udall Foundation for the FDA, pharmaceutical sponsors, and innovative startups like LindAI, serving on advisory boards as a subject matter expert. As an Adjunct Associate Professor at UNC Chapel Hill's Department of Epidemiology, Dr. Meyer has over 20 years of experience combining epidemiology and health informatics to address challenges in public health, cancer outcomes, and personalized healthcare. At the Lineberger Cancer Center, she led the development of a data platform encompassing 6+ million patients, linking cancer registry, payer, EHR, census, and ecological data sources. Her career spans academia and industry, including roles as Director of RWE at Quintiles and Senior Principal Data Scientist at Roche Personalized Health Care. She applies interdisciplinary approaches to understand complex patient factors and design targeted interventions. A recognized thought leader in healthcare innovation, Dr. Meyer has organized national meetings on data standards and clinical informatics. Her research focuses on developing novel methods for real-world data, improving data quality through technical innovation to drive meaningful improvements in research and patient care.

Valerie J. Parker is an Assistant Research Director at Duke-Margolis, where she manages one of the institute's cooperative agreements with the US Food and Drug Administration as well as oversees a core workstream of the institute's Real-World Evidence Collaborative, focused on international regulatory efforts to harmonize real-world data and real-world evidence standards. During her time at Duke-Margolis, Valerie has collaborated and led projects on a range of topics including artificial Intelligence; digital health and data; rare diseases; and pharmacology. In addition to her work with the institute, Valerie has worked with Amgen Inc. as a manager on their Global Regulatory and R&D team, where she assessed and collated international regulator responses to COVID-19 clinical trial standards and laboratory developed tests. She began her career at Epic Systems Corporation where she worked as an implementation project manager. In

this capacity, she was able to see first-hand health systems in action and how health care data is collected and stored. Valerie holds a master of science in Global Health and a bachelor of arts in Cultural Anthropology from Duke University, and she is an active member of the Duke alumni community.

Daniel Rosenberg has worked as an epidemiologist in the pharmaceutical industry in both large and small companies for over 20 years. Daniel started his career with a Post Doctoral fellowship under the direction of Prof. Dr. Harry Guess in Pharmacoepidemiology at the University of North Carolina, followed by nearly a decade at GlaxoSmithKline. Daniel founded the Epidemiology group at Actelion Pharmaceuticals Ltd. and led this group until Johnson and Johnson's acquisition of Actelion in 2017. In his present position at J&J within the Global Epidemiology department, Daniel leads a Cross Therapy Area Group of different Disease Area Epidemiology Teams and the Rare Disease/Small and Specialty populations Epicenter team. Daniel continues his work to shape and develop the use of RWE in the regulatory setting including the identification of relevant & reliable, diverse fit-for-use real-world data sources. Daniel served as the EFPIA lead representative to the ICH M14 Expert Working Group who developed harmonized guidance on the use of real-world data in non-interventional studies for safety assessment. Currently, Daniel vice-chairs the Rare Disease Special interest group (SIG) within the International Society of Pharmacoepidemiology.

Heather Rubino is the Head of Safety Surveillance Research (SSR) at Pfizer, Inc.. Heather is responsible for providing strategic and innovative approaches utilizing real world data in the post-approval setting that will support and inform safety signal identification and characterization, assess the effectiveness of additional risk minimization measures, and quantitative benefit risk assessments for marketed products. Additionally, in her capacity she oversees Pfizer's business processes related non-interventional studies and post approval safety studies and represents Pfizer in various external working groups, including, BeCome, COVID R&D Alliance, PhRMA, and ISPE, and IHI/IMI among others. Prior to Pfizer, Heather managed the Surveillance and Surveillance Systems program for the Bureau of Epidemiology at the Florida Department of Health. There, she lead the development of the epidemiology informatics capacity to leverage existing data sources, provided the informatics expertise to inform how to best capture data, and

the epidemiologic methods experience to establish analytic standards and best practices to transform data into meaningful public health action. Heather also deployed to Guinea with the Centers for Disease Control and Health Protection to work for the CDC Guinea country office, WHO, Guinea ministry of health, and other public health partners on Ebola, polio, measles, mumps, rubella, and to establish surveillance infrastructure for 14 priority diseases. Heather has a deep passion for pharmacoepidemiology and innovation!

Heather Stone is a Health Science Policy Analyst at the U.S. Food and Drug Administration, in the Clinical Methodologies Group of the Office of Medical Policy, Center for Drug Evaluation and Research. Ms. Stone joined the FDA upon completing her Master's in Public Health (Concentration: Epidemiology) from the University of Maryland School of Public Health in 2012. Ms. Stone's research focus is on the creation of policies that will encourage drug development for infectious diseases and address the rising challenge of antimicrobial resistance. She applies her policy expertise to issues related to drug repurposing, clinical trial design, and antimicrobial drug development.

Chiho Suzuki is a Deputy Director of Office of Non-clinical and Clinical Compliance I at Pharmaceuticals and Medical Devices Agency (PMDA). She joined PMDA in 2010 as an inspector of Office of Non-clinical and Clinical Compliance. After gaining experiences in conducting document-based inspection and GCP on-site inspection, she worked in Office of Safety II from 2014 to 2017 focusing on safety measures for vaccines. Later, she also supported operation and management of PMDA's original database for electronic medical records called "MID-NET®" from 2017 to 2025. In April 2025, Ms. Suzuki returned to the Office of Non-clinical and Clinical Compliance I to extend her career in the area of compliance inspections by bringing in the knowledge and experience around RWD utilization.

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Shirley Wang is an Associate Professor at Brigham and Women's Hospital, Harvard Medical School. 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 has received several awards from international societies for her methods work and is currently PI on multiple NIH R01s and FDA contracts. She leads the Meta-Research in Pharmacoepidemiology program, with recent projects aimed at improving the transparency, reproducibility and robustness of evidence from healthcare databases (www.repeatinitiative.org) and informing when and how real-world evidence studies can draw causal conclusions to inform regulatory or other healthcare decision-making (www.rct-duplicate.org), through a series of large scale emulation projects offering insights into what types of clinical questions can be answered with real-world data and which methods are the most robust. Dr. Wang co-led the 1st and 2nd joint task forces for the International Society of Pharmacoepidemiology (ISPE) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) focused on real-world evidence for healthcare decision-making.