2024 Duke-Margolis Convening on the State of Real-World Evidence Policy

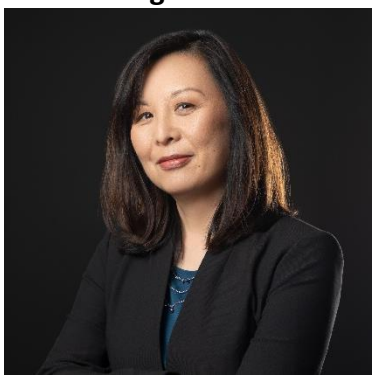
July 25th, 2024 | 12:00pm – 4:45pm ET

Speaker Biographies

Nitzan Arad

Nitzan Arad is an Assistant Research Director with the Duke-Margolis Institute for Health Policy. Her work focuses on drug pricing and payment reforms in Medicare and Medicaid, the legal barriers to value-based payment arrangements for medical products and population-based payment models. Before joining Duke-Margolis, she was a Director of Public Policy at Teva Pharmaceuticals, where she led research and analysis on a variety of government pricing and reimbursement, intellectual property, trade policy and biosimilar issues, in the U.S. and in international markets. She also interacted regularly with different industry associations and developed policy strategies to support company advocacy efforts on various topics.

Stella Chang



Stella Chang, MPH is Senior Vice President of Life Sciences Customer Engagement and Strategic Partnerships at OMNY Health. Stella has extensive experience in developing the strategy, design, and support of real-world evidence and data analytics across the healthcare industry. Prior to joining OMNY Health, Stella was Vice President of Life Sciences Solutions at Veradigm, where she led the development of the largest EHR-sourced real-world data and oversaw a portfolio of clinical registries (PINNACLE, Diabetes Collaborative Registry), SaaS solutions (Evalytica), and point-of-care clinical research services. At Truven Health Analytics, Stella managed several large program evaluation and data strategy initiatives for Federal agencies (CMS, AHRQ, CDC, and state APCDs), and oversaw the MarketScan Database portfolio. Stella was formerly a health outcomes researcher who has published retrospective studies in cancer, metabolic, respiratory, and behavioral health. Stella has an MPH from Yale School of Public Health and a BA in Biology from Johns Hopkins University.

Laura DiAngelo

Laura DiAngelo is the Director of Life Sciences Regulatory Policy and Intelligence at AgencyIQ, a division of POLITICO focused on regulatory intelligence. She has extensive experience in life sciences regulatory policy, focused on the regulation of drugs, medical devices and diagnostics products, as well as in the fields of digital health and data policy in the U.S. and E.U. Laura has worked with life sciences companies and payers on issues related to regulation, market access and reimbursement. Prior to joining AgencyIQ, she worked in regulatory and government affairs consulting at Avalere. She has a Master's in Public Health with a concentration in health policy from the George Washington University (Milken Institute of Public Health).

Hussein Ezzeldin

Dr. Ezzeldin is a Senior Digital Health Expert in the Office of Biostatistics and Pharmacovigilance (OBPV). During the 10 years with OBPV, he has worked on wide range of modeling, risk assessment, policy, and research projects. Currently he is the Lead for the digital health technology review team (DHTRT), supporting the use of DHTs in regulatory submissions. In addition, Dr. Ezzeldin co-leads the Biologics Effectiveness and Safety Innovative Methods Initiative (BEST IM), which aims to develop new and innovative methods for a semi-automated adverse events (AEs) reporting system for CBER-Regulated Biological Products. Also, Dr. Ezzeldin has a passion for advancing the science of patient input, and he is leading the natural history study for metachromatic leukodystrophy, HOME. Dr. Ezzeldin led the development of the open-sourced SHAPE (Survey of Health And Patient Experience) platform, a versatile Data Collection platform for Patient-Centered Studies.

Lee Fleisher

Lee A. Fleisher, MD, is Emeritus Professor of Anesthesiology and Critical Care at the University of Pennsylvania Perelman School of Medicine and continues to practice clinically. He is also the Founding Principal and CEO at Rubrum Advising, LLC. He serves as a Senior Advisor of the Bipartisan Policy Center and FasterCures of the Milken Institute, Senior Fellow of the Leonard Davis Institute of Health Economics and Visiting Fellow of the Duke Margolis Center. He is a member of the Steering Committee of CHAI (Coalition of Health AI) and a member of the HITAC of the ONC. From July 2020-July 2023, he was the Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare and Medicaid Services. In this capacity, he was 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. From 2004 through July 2020, he was the Robert D. Dripps Professor and Chair of Anesthesiology and Critical Care and Professor of Medicine at the University of Pennsylvania. His research focuses on measurement of quality of care including quality measures, decision making and decision support, implementation of cultural change and health policy. In 2007, he was elected to membership of the National Academy of Medicine of the National Academy of Sciences and served on Committees including the Board of Health Services of the NAM.

Richard Forshee

Richard Forshee is the Deputy Director of the Office for Biostatistics and Pharmacovigilance at FDA/CBER. He has more than 25 years of experience as a researcher and leader in academia and the Food and Drug Administration. He joined FDA full time in 2008 after working for more than a decade in academia. At FDA, he led the Analytics and Benefit-Risk Assessment Team for the Office of Biostatistics and Pharmacovigilance (OBPV) in CBER and worked extensively to provide quantitative benefit-risk assessment and real-world evidence to ensure the safety and efficacy of biologic products. This work supports OBPV's review, regulatory, and public health missions. Dr. Forshee provides knowledge and expertise on scientific and regulatory matters at Center, Agency, US government, and international meetings, workshops, and conferences. Dr. Forshee has won numerous awards including the FDA Award of Merit, the FDA-CBER Award for Managerial Excellence, and the CBER Hope Hopps Memorial

Award. In 2020, he was awarded the Society for Risk Analysis Outstanding Practitioner Award. He has published more than 100 scientific articles which have been cited more than 5,000 times.

Joe Franklin

Joe Franklin is an attorney at Verily Life Sciences, where he has also had a role overseeing strategy for Verily's clinical research product portfolio. Before joining Verily in 2021, Joe held a variety of positions at FDA, including as senior advisor on data and evidence initiatives in the Commissioner's Office. Joe led the biosimilars policy staff in the Office of New Drugs and served as an attorney in the chief counsel's office for multiple periods during his career at FDA. Joe has a PhD in cell biology from his early career as a bench scientist.

Rachele Hendricks-Sturrup

Dr. 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, and is a 2024 AcademyHealth Trust Scholar.

Inmaculada Hernandez

Inmaculada (Inma) Hernandez is a Professor at the University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences. Dr. Hernandez is a pharmacist and a scholar whose research focuses on improving medication use, outcomes, and equity in access. She has made major contributions to improving transparency in the drug reimbursement system. Dr. Hernandez has authored over than 100 scientific articles and currently serves as the National Academy of Medicine Fellow in Pharmacy. Dr. Hernandez is a pharmacit by training and she earned her PhD in Health Services Research and Policy from the University of Pittsburgh. She was recognized on the Forbes 30 under 30 list in 2018 and in 2021 she became the first pharmacist to be recognized with the Academy Health Alice S. Hersh Emerging Leader Award. She is a Fellow of the American College of Cardiology and the American Heart Association.

Dena Jaffe

Dr. Dena Jaffe is a Lead Real-World Data Strategist at Oracle Health. Her work involves the design, curation, and management of Oracle's EHR RWD for use as HIPAA-compliant, relevant, reliable, and high-quality data for real-world evidence. Dena is the PI on the FDA Sentinel Innovation Center's MOSAIC-NLP study focusing on creating scalable and transportable NLP methodology from clinical notes for use in pharmacoepidemiology analyses. She has over 20 years of experience in epidemiology, quality of care, and RWE studies. Prior to joining Oracle, Dr. Jaffe was the deputy director of the Israel National Program for Quality Indicators in Community Healthcare and a faculty member at the Braun School of Public Health and Community Medicine, Hebrew University-Hadassah, Jerusalem. She has published across numerous therapeutic with a focus on health inequalities. Dena holds a PhD in epidemiology from Case Western Reserve University.

Duke | MARGOLIS INSTITUTE *for* Health Policy

Annette James

Annette V. James, FSA, MAAA, FCA is a health consulting actuary focusing primarily on providing health actuarial services to state and federal agencies. Annette has devoted many years to public service, serving as lead actuary for the Nevada Division of Insurance for 14 years (2006–2020). Prior to her regulatory role, Annette was an employee benefits consulting actuary. Annette is also an active volunteer in the actuarial profession with many leadership roles. She is currently a member of the American Academy of Actuaries (Academy) Board of Directors, and the nominee for VP of Health at the Academy, the co-chair of the Academy's Health Equity Committee, the chair of the Health Committee of the Actuarial Standards Board, and a former chair of the Academy's Diversity, Equity and Inclusion Committee. She is a frequent speaker on topics relating to health equity, health insurance, regulation, and professionalism and has authored professional articles on topics ranging from the Affordable Care Act to the future of insurance.

Nicholaas Honig

Nicholaas Honig is Head of Regulatory and Senior Counsel at Aetion. In this role he advises clients on regulatory approaches involving real-world evidence and supports the company's legal and compliance efforts. He also serves as the product manager and strategy lead for Aetion's clinical development optimization product. Prior to joining Aetion, Nicholaas worked at Pfizer in the company's Chief Business Office and has had practical experience in FDA's Office of Chief Counsel and the Massachusetts Legislature's Joint Committee on Healthcare Financing. He has a JD from the Boston University School of Law and a BA from Hobart College.

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.

Mark McClellan

Mark McClellan, MD, PhD, 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.

Duke | MARGOLIS INSTITUTE *for* Health Policy

Rodrigo Refoios Camejo

Rodrigo Refoios Camejo is currently the Executive Director, RWE Science & Innovation at GlaxoSmithKline. With nearly 20 years of experience in Health Economics & Outcomes Research, Market Access, and Real-World Evidence, Rodrigo has continuously explored how to bring innovation to these fields. His Industry practice encompasses multiple therapeutic areas, including neurosciences, immunology, vaccines, and rare diseases and spans across all stages of drug development from pre-clinical all the way to post-launch. He also part of NICE, the UK's Health Technology Assessment body, where he was the technical lead for a number of technology appraisals and saw first-hand how decision making happens in the context of complex information. Rodrigo holds a PharmD from the University of Lisbon, an MSc in Health Economics from University of York, and a PhD from Erasmus University where he utilised RWD to study the dynamics of innovation in drug development. Since then, he has consistently focused on leveraging real-world data to inform healthcare decisions and has contributed to advancing methodologies and processes that integrate real-world insights into drug development, market access, and healthcare policy. He is a published author on health economics and pharmaceutical policy and has been an active member of various epidemiology and HEOR associations as well as peer-reviewing for several journals in the field.

David C. Rhew

David C. Rhew, MD is Microsoft's Global Chief Medical Officer & VP of Healthcare. He has served as Microsoft's International Coordinator for the Pandemic Response, working with WHO to develop their World Health Data Hub, CDC to standup their vaccine data lake, and U.S. states to roll-out COVID-19 vaccines. He is Adjunct Professor at Stanford University; holds six U.S. technology patents that enable authoring, mapping, and integration of clinical decision support into electronic health records; and has been recognized as one of the 50 most influential clinician executives by Modern Healthcare. Dr. Rhew received his Bachelors of Science degrees in computer science and cellular molecular biology from University of Michigan. He received his MD degree from Northwestern University and completed internal medicine residency at Cedars-Sinai Medical Center. He completed fellowships in health services research at Cedars-Sinai and infectious diseases at UCLA. He has served as CMO for Samsung and Zynx Health and sat on National Quality Forum's Executive CSAC Board. He is Chair-emeritus

for Consumer Technology Association's Health Technology Board and currently serves on AdvaMed's Digital Health Board; the Governing Committee for NESTcc, the medical device advisory group for FDA, CMS, and NIH; and the Board of Directors for Cedars-Sinai Medical Center.

Katy Sadowski

Katy Sadowski is a Senior Associate Director on the Real World Evidence Analytics team at Boehringer Ingelheim. Prior to joining Boehringer, she held roles in the data organizations at Formation Bio (fka TrialSpark), Flatiron Health, and the Eastern Cooperative Oncology Group. Throughout her 10+ years in the field of clinical research, Katy has developed a specialization in clinical data quality. She has led initiatives to design and implement data quality frameworks across a variety of use cases, including electronic health record data abstraction, clinical trial recruitment, and real world evidence analytics. Katy is also an active member of the Observational Health Data Science and Informatics (OHDSI) community and the maintainer of the open source OHDSI DataQualityDashboard tool.

Christina Silcox

Christina Silcox is the Research Director for Digital Health at the Duke-Margolis Institute for Health Policy, working on policy solutions to advance innovation in health and health care and improve regulation, reimbursement, and long-term evaluation of medical products, with a focus on digital health and artificial intelligence (AI). Dr. Silcox's portfolio includes multiple areas in digital health policy. Currently, she is concentrating on challenges to regulation, governance, and payment of AI-enabled health tools and other digital health tools (DHTs). Her previous projects have included the use of mHealth and patient-generated health data in regulatory evaluations, characterizing real-world data quality and relevancy, the exploration of value-based payments for medical devices, and the convening the National Evaluation System for health Technology (NEST) Planning Board. During the COVID-19 pandemic, Dr. Silcox also led the Institute's COVID testing work. Before she joined Duke-Margolis, Dr. Silcox was a senior fellow at the National Center for Health Research, focused on federal regulation of and policies for medical products. She earned a MS from the Massachusetts Institute of Technology (MIT) in Electrical Engineering

and a PhD in Medical Engineering and Medical Physics from the Harvard-MIT Division of Health Sciences and Technology (HST).

Jaime Smith

Dr. Jaime Smith is the Global Head of Data Strategy at Parexel, one of the world's largest clinical research organizations (CROs) where she leads innovative strategies for real world data studies. As a real-world evidence strategist and AI/ML thought leader, Dr. Smith has deep expertise in applying emerging digital solutions. Dr. Smith's work addresses complex issues in healthcare such as health disparities/diversity, comparator studies, public health emergencies, regulatory/policy impacts, and outcomes research. Prior to joining Parexel, Dr. Smith led real world data studies at IQVIA and Surecripts for nearly a decade. Dr. Smith serves as a mentor to leadership fellows in the NIH's Artificial Intelligence and Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) Program and is an active member of the American Medical Informatics Association. Dr. Smith holds a Ph.D. in health services research with a concentration in health informatics and data mining from George Mason University and bachelor's degrees in economics and American studies from Tufts University.

Joanne Walker

Jo is the Co-founder and Publishing Director at Becaris Publishing, where she serves as the Executive Editor for both the *Journal of Comparative Effectiveness Research* and The Evidence Base. In this role, Jo oversees the development, writing and creation of content within the integrated fields of real-world evidence, health economics & outcomes research, market access, health technology assessment and health policy. With over 24 years of experience in the STM publishing industry, Jo has worked across various journal and digital platforms. Previously, as the Head of Publishing Solutions at Future Science Group, she initiated the publication of Plain Language Summaries of Publications as peer-reviewed, standalone journal articles. Jo is dedicated to promoting equity in medical publications by ensuring that all content is clear, engaging, and accessible to a broad audience.