Duke | MARGOLIS CENTER for Health Policy

# Fourteenth Annual Sentinel Initiative Public Workshop

November 15, 2022 | 1:00 p.m. – 5:00 p.m. ET
November 16, 2022 | 12:00 p.m. – 4:15 p.m. ET

## Speaker Biographies

**Margaret Anderson, MA** is a Managing Director with Deloitte Consulting where she brings her biomedical program, policy, and patient engagement experience to strategy projects in the Federal Health and nonprofit area. She recently led high-impact COVID-19 projects across the federal health space focused on public-private partnerships, community response, risk mitigation, and overall impacts of the pandemic on our nonprofit sector. Margaret is also leader of the Strategy and Analytics DEI efforts, and Chief Marketing Officer of the Federal Health Sector at Deloitte. She advanced several movements in her career, from patient centricity to women's health research, to HIV/AIDS and genetics, to the COVID-19 response. She joined Deloitte from FasterCures, a Washington DC-based center of the Milken Institute, whose focus is to save lives by speeding up and improving the medical research system by focusing on spurring cross-sector collaboration, cultivating a culture of innovation, and engaging patients as partners. As Executive Director of FasterCures, she oversaw programs advancing the science of patient input, examining the metrics for consortia, and policy related to federal research and regulatory paradigms. She worked on HIV/AIDS strategy and other public health issues at the American Public Health Association and in a consulting capacity for CDC's HIV/AIDS programs in the early part of the epidemic response. She began her career as a Project Director at the Congressional Office of Technology Assessment looking at the impact of biotechnology and genetics on the economy and society.

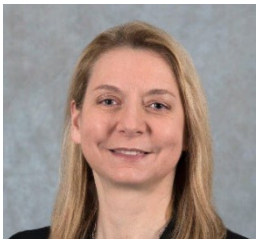
Margaret was a founding board member and past president of the Alliance for a Stronger FDA, as well as the NIH National Center for Advancing Translational Sciences Advisory Council and the Cures Acceleration Network Review Board. She served previously on the boards of the National Health Council, United for Medical Research, the Food and Drug Administration's Science Board, Science Looking Forward Committee, and the National Academy of Medicine's Forum on Drug Discovery, Development and Translation. She currently serves on the Boards of Act for NIH, Allen Institute, FasterCures, and Friends of Cancer Research. She attended University of Maryland and majored in Political Science, and holds her Master's in Science Policy from the George Washington University.

**Steve Anderson, PhD, MPP** is currently the Director of the Office of Biostatistics and Pharmacovigilance (OBPV) at the FDA Center for Biologics Evaluation and Research (CBER). In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER's regulatory processes to improve biologic product safety evaluations and surveillance. In 2018 his office launched the CBER Biologics Effectiveness and Safety (BEST) Initiative to expand and enhance CBER access to new data sources, methods, tools, expertise and infrastructure to conduct surveillance and epidemiologic studies for biologic

products. Dr. Anderson earned a Master's Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens in cattle. Dr. Anderson received his PhD from the University of Cincinnati where he worked on biochemistry, drug resistance, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in biologic product safety, risk assessment, epidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.

**Patricia ("Trish") Bright, PhD, MSPH** earned a Master's Degree and Ph.D. in Epidemiology from the University of North Carolina (Chapel Hill). She was a Faculty Member at the Johns Hopkins School of Medicine from 2003 to 2010, where she helped run clinical trials assessing therapeutic approaches to prevent maternal-to-child HIV transmission in developing countries. She began working at the FDA in 2010 as a Commissioner's Fellow. In 2012, she joined the Division of Epidemiology in the Center for Drug Evaluation and Research (CDER)'s Office of Surveillance and Epidemiology (OSE). She worked in the Division of Epidemiology as both a primary reviewer and as a Team Lead. More recently, she joined the OSE's Regulatory Science and Applied Research (RSAR) Division as the Sentinel System Program Lead.

**David S. Carrell, PhD** is an associate investigator at Kaiser Permanente Washington Health Research Institute (KPWHRI). His research uses clinical natural language processing (NLP) methods to extract information from unstructured clinical text to support precision clinical phenotyping--the automated identification of health conditions and outcomes of interest through the extraction and analysis of rich information available in electronic health records (EHR). Through collaborations with researchers with complementary expertise in the clinical, informatics, and statistical domains, he has applied precision phenotyping methods in the areas of medical product safety surveillance, cardiovascular disease, cancer, substance use disorders, and mental health conditions.



**Patrizia Cavazzoni, MD** is the Director at the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). Dr. Cavazzoni received her medical degree at McGill University and completed a residency in Psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs and safety surveillance.

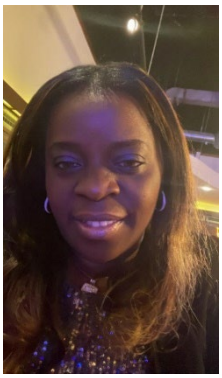
Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, a Fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology and recipient of the American College of Psychiatrists' Laughlin Fellowship

**Yoganand Chillarige, MPA** is a Research Manager at Acumen LLC, and is the Lead of the Acumen BEST Coordinating Center, where he oversees the development, maintenance, and effective use of a distributed data network with multiple data partners to support FDA's surveillance efforts. Mr. Chillarige is an expert in the integrated use of data from a variety of sources including administrative claims, provider databases, surveys, and medical records, and has 10 years of experience conducting studies that monitor and evaluate the uptake, safety, and effectiveness of medical products and procedures.

**Gerald J. Dal Pan, MD, MHS** currently serves as the Director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the Center's programs in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act and other initiatives. He is a member of the World Health Organization Advisory Committee on the Safety of Medicinal Products, and has served on working groups of the Council of International Organization of Medical Sciences (CIOMS) and the International Council on Harmonisation (ICH). He received his MD from Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology from the Johns Hopkins University School of Hygiene and Public Health. He completed residency training in Internal Medicine at the Hospital of the University of Pennsylvania and in Neurology at the Johns Hopkins Hospital. He is board certified in both Internal Medicine and Neurology. He joined FDA in 2000 as a medical reviewer in the Center's Office of New Drugs. Before working at FDA, he was a faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

**Rishi J Desai**, **PhD, MS** is an Assistant Professor of Medicine in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital/Harvard Medical School. Dr. Desai is a nationally recognized researcher in the field of pharmacoepidemiology. His research focuses on generating timely and reliable evidence on the safety and effectiveness of medication among patients with cardio-renal and rheumatic conditions. He has developed highly innovative analytic methods to improve the accuracy of non-randomized studies using large healthcare databases that have gained widespread acceptance in the field. He has a proven record of leading large-scale research activities, including the Food and Drug Administration Sentinel Program's Innovation Center housed at

BWH and a cross-disciplinary multi-center collaborative project on drug repositioning to prevent dementia with the National Institute of Aging.



**Efe Eworuke, PhD** is the Associate Director for Science in the Division of Epidemiology II, Office of Surveillance and Epidemiology, Office of Pharmacovigilance and Epidemiology, US Food and Drug Administration. In her role, she serves as the principal scientific advisor to the Division of Epidemiology on all pharmacoepidemiology, drug safety, RWE and regulatory matters. She trained as a pharmacoepidemiologist and received her PhD from the University of Florida, College of Pharmacy. Prior to completing her PhD, she received her masters from the University of Oxford, United Kingdom and her pharmacy degree from the University of Benin in Nigeria.

Dr. Eworuke's interests are to apply epidemiological methods in every aspect of regulatory science, from drug development through surveillance monitoring of approved drug products. She has been heavily involved in conducting several observational studies using the FDA's Sentinel system, several of which have had significant regulatory impact. Dr. Eworuke has led and served on numerous working groups, contributing to development of guidances and white papers.

**Richard Forshee, PhD** is the Deputy Director of the Office for Biostatistics and Pharmacovigilance. 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, health informatics, 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 4,000 times.

**Eric Heflin** is a 30+ year veteran of the software industry where he has served as an entrepreneur, computer scientist, software architect, and in various leadership roles. Eric was employee #2 at eHealth Exchange where he was the CTO/CISO. In that role he architected, implemented, and helped operate the nation's largest health data sharing network, the eHealth Exchange, which connects approximately 75% of all hospitals in the country. Eric is also the CTO/CISO of the Texas Health Services Authority which is the legislatively created entity charged with fostering secure health data exchange for Texans and being the certifying authority for the Texas security and privacy certification program. He is a current member of the IHE USA standards body Board of Directors, a frequent appointee to Federal Advisory Committee Task Forces as a subject matter expert, and a former Board member for IHE International. Eric is the author of "A Framework for Cross-Organizational Patient Identity Management", co-author of the "IHE IT Infrastructure Handbook - De-Identification", "Advancing a Nationwide Patient Matching Strategy", a co-author of multiple healthcare IT standards used world-wide including XCPD, XDS, and several FHIR resources.

**Mao Hu** is a Policy Researcher at Acumen, LLC, where he manages projects for the BEST Data Coordination Center. His research interests include the assessment of the safety and effectiveness of vaccines, non-vaccine biologics, drugs, and other products using real world data sources from the Centers for Medicare & Medicaid Services and commercial insurance organizations in the BEST Initiative. He also works on the development and application of pharmacoepidemiologic methods for casual inference and analytics in distributed data networks such as the BEST Initiative.

**Lance Jones** is a lead data scientist and technical project manager in the Artificial Intelligence & Analytics Practice in the Data & Technology Transformation service line for IBM Consulting. He currently leads IBM's delivery of the FDA Biologics Effectiveness and Safety (BEST) Innovative Methods Project for the Center for Biologics Evaluation and Research. In the past, he led projects for the IBM North American Analytics Center, delivering rapid prototypes of A.I. solutions across industries. Prior to joining IBM, Lance worked in academia teaching and offering quantitative and methodological consultation to researchers and Ph.D. candidates across multiple disciplines in the social sciences and life sciences. Lance's graduate training was in quantitative psychology with emphasis on applied statistics and research methodology.

**Bradley Layton**, **PhD, FISPE** is a Director of Epidemiology at RTI Health Solutions with considerable experience in the design, conduct, analysis, and reporting of epidemiologic studies. With over 10 years of experience in the field of pharmacoepidemiology, his experience and publications span a wide range of substantive areas, including renal, cardiovascular, men's health, vaccines, and pregnancy, and incorporate multidatabase and multinational studies. Dr. Layton also has experience with epidemiologic methods, lecturing to clinical and public health audiences about observational study design, large database utilization, and propensity score analysis. Dr. Layton received his master's and doctorate degrees in epidemiology from the Department of Epidemiology in the Gillings School of Global Public Health, University of North Carolina at Chapel Hill, focusing in pharmacoepidemiology. Dr. Layton also is an active member of the International Society of Pharmacoepidemiology (ISPE), and recently served as the chair of the ISPE Vaccine Special Interest Group.

**Yun Lu, PhD,** is a Mathematical Statistician and real-world evidence reviewer working for the Food and Drug Administration (FDA)/Center for Biologics Evaluation and Research (CBER)/Office of Biostatistics and Pharmacovigilance (OBPV)/Analytics and Benefit-Risk Assessment Team (ABRA). Dr. Lu received her Ph.D. in Biostatistics from Johns Hopkins Bloomberg School of Public Health. Dr. Lu joined FDA/CBER/OBPV in 2010 and she has extensive experiences with vaccine safety and effectiveness studies using real-world data including Medicare Data from the Centers for Medicare and Medicaid Services (CMS).

**Judith Maro, PhD** is an Assistant Professor in the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. She received her doctorate in Engineering Systems at the Massachusetts Institute of Technology (MIT). Her doctoral work examined practical implementation of prospective sequential database surveillance activities in distributed data networks using modeling and simulation. Dr. Maro's main research interest is implementation of pharmacovigilance techniques, particularly continuous near-real time sequential statistical analysis methods and data-mining / signal identification methods in distributed longitudinal databases. She is also the Operations Lead for the Sentinel Operations Center (housed at Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute) as part of the U.S. Food and Drug Administration's Sentinel System.

**Keith Marsolo, PhD** is an Associate Professor in the Department of Population Health Sciences (DPHS) in the Duke University School of Medicine and a member of the Duke Clinical Research Institute (DCRI). His current research focuses on infrastructure to support the use of electronic health records (EHRs) and other real-world data sources in observational and comparative effectiveness research and public health surveillance, as

well as standards and architectures for multi-center learning health systems. He serves as technical advisor to the PopHealth DataShare Shared Facility and as faculty lead for the Pragmatic Health Services Research functional group within the DCRI. Dr. Marsolo received his PhD in Computer Science from The Ohio State University, with a dissertation on data mining, specifically the modeling and classification of biomedical data. Dr. Marsolo is an active member within the Sentinel Innovation Center with projects on the representation of unstructured text in Common Data Models and on quality metrics to identify and mitigate mapping issues in structured data domains. Dr. Marsolo is also involved with a number of real-world data initiatives including the RADx Underserved Populations Coordination and Data Collection Center as co-PI of the Data Science Core, the NIH Pragmatic Trials Collaboratory as co-chair of the EHR Core, and the Coordinating Center for the National Patient-Centered Clinical Research Network (PCORnet). Within PCORnet, he serves as co-PI for the Common Data Model Core, which is responsible for support and maintenance of the PCORnet CDM, data curation and privacy-preserving record linkage.

**Grace Marx, MD, MPH** is a lieutenant commander in the United States Public Health Service and a medical epidemiologist at the CDC. She received her MD from the University of Washington School of Medicine and a Masters in Public Health in epidemiology from the University of Washington School of Public Health. She completed both an internal medicine residency and an infectious disease fellowship at the University of Colorado. She joined CDC as an Epidemic Intelligence Service officer in 2016 and has been in her current position in CDC's Division of Vector-Borne Diseases in Fort Collins, Colorado since 2018. She is an adjunct professor at the University of Colorado and at the Colorado School of Public Health and regularly sees patients at the Denver Health Infectious Diseases Clinic. Her primary research interests include the surveillance and prevention of Lyme disease, tularemia, bartonella, and tickborne relapsing fever.

**Yandong Qiang, MD, PhD, MHS, MPH** is a Lead Epidemiologist in Division of Epidemiology-I (DEPI-I) of the Center for Drug Evaluation and Research (CDER)'s Office of Surveillance and Epidemiology (OSE). She has been working in DEPI-I as both a primary reviewer and a Team Lead. From 2008 to 2015, she was an Epidemiologist in the Analytic Epidemiology Branch of Center for Biologics Evaluation and Research (CBER)'s Office of Biostatistics and Epidemiology, Division of Epidemiology. Prior to joining in FDA, she completed a post-doctoral fellowship at the Clinical Immunization Safety Assessment (CISA) network. She earned a Master of Public Health in Epidemiology, Master of Health Science in Biostatistics, and Ph.D. in Disease Control and Prevention from the Johns Hopkins University, School of Public Health. She received a Medical Doctor and practiced medicine in China.

**Sebastian Schneeweiss, MD, ScD** is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital.
His research focuses on assessing the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed analytic methods to improve the accuracy of estimating causal treatment effects of new drugs using complex digital healthcare databases. His work is published in >500 articles and is used for regulatory and coverage decision making around the globe. He is funded by NIH, PCORI, IMI, and FDA where he is also a voting consultant. He is Principal Investigator of the FDA Sentinel Innovation Center and co-leads the RCT-DUPLICATE initiative to understand when and how real-world evidence studies can reach causal conclusions.

**John D. Seeger, PharmD, MPH, DrPH, FISPE** is a pharmacoepidemiologist and Chief Scientific Officer for Epidemiology at Optum, where he has been employed for more than 20 years. He has conducted dozens of studies addressing regulatory drug safety questions across a wide range of drugs, vaccines, and disease conditions. Most of this work has involved the use of health insurance claims databases, and Dr. Seeger's methodologic expertise focuses on research issues encountered in such settings. He has worked extensively with propensity scores that seek to mitigate confounding by collapsing covariates, and he teaches several courses on propensity scores in pharmacoepidemiology. Throughout this work, Dr. Seeger has remained keenly aware of the limitations of research using administrative data and has supplemented the platform of insurance claims with additional data where appropriate, including laboratory test results, surveys, medical record reviews, and has expanded into research involving electronic health record data.

Dr. Seeger is an Adjunct Assistant Professor of Epidemiology at the Harvard T.H. Chan School of Public Health. He has been active within the International Society of Pharmacoepidemiology (ISPE) and is a Past President and Fellow of the Society.

**Azadeh Shoaibi, PhD, MHS** is the Associate Director for Post-market Surveillance at the FDA Center for Biologics Evaluation and Research (CBER) where she leads the Biologics Effectiveness and Safety (BEST) Initiative which conducts post-market surveillance activities of biologic products. Dr. Shoaibi joined CBER in 2015. Prior to working at CBER, she held the position of the Sentinel Scientific Lead at the Center for Drug Evaluation and Research (CDER) from 2010-2015. She joined the FDA in 2004 at the Center for Devices and Radiological Health (CDRH) as an epidemiologist with expertise in *in vitro* diagnostic devices. Dr. Shoaibi holds a doctorate in epidemiology and a master's degree in molecular microbiology and immunology.

**Darren Toh, PhD** is the DPM Endowed Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is a pharmacoepidemiologist with an interest in the comparative safety and effectiveness research of medical products. His research focuses on 1) assessing the risks and benefits of medical products using electronic data collected as part of routine healthcare delivery, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks. Darren is Principal Investigator of the Operations Center of the FDA-funded Sentinel System, a congressionally mandated national medical product safety surveillance system. He also leads the Analytic Center of the Medical Evidence and Development Surveillance (IMEDS) program. Darren received his doctoral degree in Epidemiology from the Harvard School of Public Health.

**Colin G. Walsh, MD, MA, FACMI, FAMIA** is an Associate Professor of Biomedical Informatics, Medicine, and Psychiatry at Vanderbilt University Medical Center. He is an internist. He received a degree in Mechanical Engineering from Princeton University and his medical degree at the University of Chicago. He completed residency and chief residency in internal medicine at Columbia University Medical Center. He received a degree in Biomedical informatics in postdoctoral fellowship at Columbia University. He joined the faculty at Vanderbilt University in 2015. His research includes: 1) applied predictive modeling to enable behavioral health and prevention; 2) scalable phenotyping for precision medicine; and 3) population health informatics to combat the overdose crisis.

**Shirley V Wang PhD, ScM** 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 Pharmacoeconomics 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 evidence studies can draw causal conclusions to inform regulatory or other healthcare decision-making.

**Hui-Lee Wong** is Associate Director for Innovation and Development at the Office of Biostatistics and Epidemiology at the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). In this capacity, she is actively engaged in the CBER Surveillance Program efforts aimed at advancing CBER surveillance systems. At the US FDA since 2009, her regulatory experience encompasses post market surveillance of biologics, drugs at Center for Drug Evaluation and Research and

medical devices at Center for Devices and Radiological Health. She also leads projects in building capacity for pharmacovigilance of vaccines in Democratic Republic of Congo and Kenya. She was seconded to the U.S. Centers for Disease Control and Prevention Ebola Response Team in Sierra Leone in 2015. Prior to US FDA, she completed a post-doctoral fellowship at the U.S. National Institutes of Health and received a Ph.D. in Molecular Epidemiology from the University of Southern California.

**Richard Wyss, PhD** is an Assistant Professor of Medicine at Harvard Medical School and Associate Epidemiologist in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. His research lies at the intersection of health informatics, epidemiology, and applied biostatistics. He is interested in advancing semi-automated tools for generating evidence from secondary healthcare databases on the effectiveness and safety of newly marketed medical products in population subgroups that are underrepresented in randomized clinical trials. Specifically, his work has focused on building semi-automated approaches for high-dimensional variable generation and targeted variable selection within healthcare databases to improve large-scale covariate adjustment when evaluating drug effectiveness and safety during the early periods of post-market approval.

## Moderators

**Tanisha Carino, PhD** is a senior corporate affairs and health policy expert with more than 20 years of experience providing strategic counsel in business strategy, government affairs and stakeholder management across the public and private sectors. Most recently, she served as a Visiting Fellow in the White House Office of Science and Technology Policy, focused on pandemic preparedness. Prior to that, she was Executive Vice President and Chief Corporate Affairs Officer at Alexion Pharmaceuticals. Before that, she was Executive Director of FasterCures, a center of the Milken Institute, Vice President of U.S. Public Policy at GlaxoSmithKline and Head of Life Sciences Strategic Advisory Services for Avalere Health. She began her career as an HIV case worker in Atlanta.

**Rachele Hendricks-Sturrup, DHSc, MSc, MA** 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.

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.

**Mark McClellan, MD, PhD** is the Robert J. Margolis Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Center is a university-wide Duke initiative that is nationally and internationally-recognized for research, evaluation, implementation, and educational initiatives to improve health policy and health, most recently in its COVID-19 response. Dr. McClellan is a doctor and an economist who has addressed a wide range of strategies and policy reforms to improve health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical innovation. At the center of the nation's efforts to combat the pandemic, Dr. McClellan is the co-author of a roadmap that details the steps needed for a comprehensive COVID-19 response and safe reopening of our country. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and academic research.

Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. He 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.