

Establishing a High-Quality Real-World Data Ecosystem

Duke-Margolis Center for Health Policy | 2-Day Online Workshop

Monday, July 13 | 1:00 – 4:00 pm ET

Tuesday, July 14 | 1:00 – 4:30 pm ET

Speaker Biographies



Amy P. Abernethy is an oncologist and internationally recognized clinical data expert and clinical researcher. As the Principal Deputy Commissioner of Food and Drugs, Dr. Abernethy helps oversee FDA's day-to-day functioning and directs special and high-priority cross-cutting initiatives that impact the regulation of drugs, medical devices, tobacco and food. As acting Chief Information Officer, she oversees FDA's data and technical vision, and its execution. She has held multiple executive roles at Flatiron Health and was professor of medicine at Duke University School of Medicine, where she ran the Center for Learning Health Care and the Duke Cancer Care Research Program. Dr. Abernethy received her M.D. at Duke University, where she did her internal medicine residency, served as chief resident, and completed her hematology/oncology fellowship. She received her Ph.D. from Flinders University, her B.A. from the University of Pennsylvania and is boarded in palliative medicine.



Brian Anderson is a Harvard trained physician-scientist, digital health innovator and clinical systems engineer. Dr. Anderson became a nationally recognized expert on the use of information technology in support of emerging CDS models and the provision of safe, effective, patientcentered care while at athenahealth where he launched a new model of clinical decision support leveraging artificial intelligence. Dr. Anderson has also helped to develop and bring to market nascent technology and clinical workflows to support health system strategies around improved Patient Access. He has served on several national health information technology committees in partnership with the Office of the National Coordinator (ONC). Previously, Dr. Anderson led the Informatics Department at athenahealth where he focused his EHR product development around CDS systems. As MITRE's Chief Digital Health Physician, Dr. Anderson helps to architect, implement, and analyze health information systems for CMS, HHS, the FDA and the VA. Dr. Anderson is also the Co-Principal Investigator of MITRE's largest internally funded R&D project, where he is leading the development of a common data model in Oncology based on FHIR, termed mCODE (minimal Common Oncology Data Elements). Dr. Anderson trained at Massachusetts General Hospital and also practiced at Greater Lawrence Family Medicine. He received his MD with honors from Harvard Medical School, and a BA in Social Anthropology, cum laude from Harvard College.



Monica M. Bertagnolli is the Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School, and a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at Dana-Farber/Brigham & Women's Cancer Center, where she collaborates with colleagues in medical oncology, radiation oncology, and pathology to treat cancer patients in a tertiary care setting. Dr. Bertagnolli has conducted research focusing upon understanding the role of the inflammatory response in epithelial tumor formation. From 1994-2009, she led

gastrointestinal correlative science initiatives within the NCI-funded Cancer Cooperative Groups, where she facilitated integration of tumor-specific molecular markers of treatment outcome into nationwide clinical cancer treatment protocols. Dr. Bertagnoli has had numerous leadership roles in multi-institutional cancer clinical research consortia, and since 2010 has served as the Group Chair of the Alliance for Clinical Trials in Oncology, a US NCI-funded clinical trials group.



Teresa Zayas Cabán is ONC's Chief Scientist and is responsible for developing and evaluating ONC's overall scientific efforts and activities. Her division develops, establishes, or recommends scientific policy to the National Coordinator. She directs ONC's precision medicine initiative (PMI) activities and provides oversight of ONC's patient-centered outcomes research (PCOR) projects. In July 2019, Dr. Zayas Cabán joined the National Library of Medicine on detail from ONC. In her role as Coordinator for FHIR Acceleration, she serves leads National Institutes of Health-funded development efforts that accelerate researcher access to clinical data in the FHIR standard. She is working directly with NLM leadership and the NIH Office of Data

Science Strategy and the NIH Scientific Data Council to coordinate trans-NIH FHIR efforts. Dr. Zayas Cabán was previously the Chief of Health IT research and acting director of the division of health IT at the Agency for Healthcare Research and Quality (AHRQ). While at AHRQ, she set new directions for their funding opportunities and coordinated with federal partners, such as the National Science Foundation. Before joining AHRQ, she served as a post-doctoral trainee in the computation and informatics in biology and medicine program at the University of Wisconsin-Madison. Dr. Zayas Cabán obtained her doctorate in industrial and systems engineering at the University of Wisconsin-Madison where she was a National Science Foundation graduate research fellow in industrial engineering.



Andy Coravos is the CEO/co-founder of Elektra Labs, building a digital medicine platform focusing on digital biomarkers for decentralized clinical trials. She serves as a research collaborator at the Harvard-MIT Center for Regulatory Sciences. Formerly, she served as an Entrepreneur in Residence at the FDA working in the Digital Health Unit (DHU), focusing on the Pre-Cert program and policies around software-as-a-medical-device and AI/ML. Previously, Andy worked as a software engineer at Akili Interactive Labs, a leading digital therapeutic company. Before grad school, Andy worked at KKR, a private equity firm, and at McKinsey & Company, a management consulting firm, where she focused on the healthcare industry. She serves on the

Board of the Digital Medicine Society (DiMe), and she's an advisor to the Biohacking Village at DEF CON.



Jacqueline Corrigan-Curay serves as Director of CDER's Office of Medical Policy (OMP). She leads the development, coordination, and implementation of medical policy programs and strategic initiatives. She works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development. 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 Institute of Health's (NIH) and 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 a practicing attorney in Washington, D.C. Dr. Corrigan-Curay

earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA. and regulatory review processes.



Peter DeVault joined Epic in 1997 with a background in physics and mathematics, working with many of the most prestigious and complex healthcare organizations in the United States and abroad. As these organizations and their clinical systems grew in depth and scope, and with the increased mobility of patients and healthcare provision, it became clear that wide-scale, standards-based interoperability was necessary to achieve the goals of healthcare organizations and health systems. This drove later stages of his career within and outside the growing Epic community. Concurrent with a focus on interoperability and standards development was a complementary focus on developing systems to enable patients and citizens to take charge of their own healthcare and health information. He is also a professional student of world healthcare, traveling extensively, meeting and planning with governments and healthcare organizations around the globe, and helping to share working technology and policy solutions across borders. Cutting across all of these areas is his ongoing work in information technology supporting genomics, oncology, and precision medicine.



Zubin J. Eapen is Chief Medical Officer at HealthCore, an independently operating health outcomes research subsidiary of Anthem with exclusive access to a robust, integrated research environment containing information on nearly 70 million individuals from multiple health plans across the United States. In this role, he is responsible for all prospective studies and is leading the global expansion of a research platform to generate real-world evidence. He actively practices as a cardiologist with CareMore Health, a national care delivery organization serving over 150,000 high-risk members in 11 states across Medicare and Medicaid. In his previous capacity as Chief Medical Officer, he led over 700 clinical associates to the best clinical outcomes in CareMore's history. Becker's Healthcare named him a rising star and one of 90 healthcare leaders under 40 years old. Dr. Eapen is also Adjunct Associate Professor of Medicine at Duke University. He obtained his medical degree and completed his residency and cardiology fellowship at Duke University. During his training, he served as Chief Fellow of both the Duke Cardiology and Duke Clinical Research Institute (DCRI) fellowships. As a faculty member, Dr. Eapen published extensively as a DCRI outcomes researcher and founded Duke Heart Failure Same Day Access, an innovative disease management program that redesigned care for heart failure patients. He is Editor for the 14th edition of Hurst's the Heart, the second most widely circulated cardiovascular textbook in the world.



Laura Esserman is Professor of Surgery and Radiology at the University of California, San Francisco (UCSF) and director of the UCSF Breast Care Clinic. Her work in breast cancer spans the spectrum from basic science to public policy issues, and the impact of both on the delivery of clinical care. Dr. Esserman is recognized as a thought leader in cancer screening and over-diagnosis, as well as innovative clinical trial design. She led the creation of the University of California-wide Athena Breast Health Network, a learning system designed to integrate clinical care and research as it follows 150,000 women from screening through treatment and outcomes. The Athena Network launched the PCORI-funded Wisdom Study, which tests a personalized approach to breast cancer screening in 100,000 women. She is also a leader of the innovative I-SPY TRIAL model,

designed to accelerate the identification and approval of effective new agents for women with high risk breast cancers.



Paul Friedman is a Professor of Medicine and the Norman Blane & Billie Jean Harty Chair, Mayo Clinic Department of Cardiovascular Medicine Honoring Robert L. Frye, M.D. at Mayo Clinic, Rochester, Minnesota. He is ABIM board certified in cardiac electrophysiology, and is an active participant in the MOC process. Dr. Friedman served as Director of the Cardiac Implantable Device Lab, Mayo Clinic. He is a trained electrical engineer, with deep experience in innovation (>40 patents issued, named Minnesota Top Inventor), and scientific research (>250 scientific original publications). He is a committed educator, serving as a director for 5 national and international meetings, editor of 7 textbooks, and author of over 60 book chapters. He is a frequent visiting professor and lecturer at educational meetings. Dr. Friedman received his BA in Plan II liberal arts and BS in Electrical Engineering from the University of Texas at Austin. He received his medical degree from Stanford University, and trained in internal medicine at the University of Washington, Seattle (internship) and Stanford University. He trained in cardiovascular medicine and cardiac electrophysiology at Mayo Clinic, Rochester, MN.



John D. Halamka president of the Mayo Clinic Platform, leads a portfolio of platform businesses focused on transforming health care by leveraging artificial intelligence, connected health care devices and a network of trusted partners. Trained in emergency medicine and medical informatics, Dr. Halamka has been developing and implementing health care information strategy and policy for more than 25 years. Prior to his appointment at Mayo Clinic, Dr. Halamka was executive director of the Health Technology Exploration Center for Beth Israel Lahey Health in Massachusetts, where he oversaw digital health relationships with industry, academia and government worldwide. He had previously served as chief information officer at Beth

Israel Deaconess Medical Center for more than 20 years. He is a practicing emergency medicine physician. As the International Healthcare Innovation Professor at Harvard Medical School, Dr. Halamka helped the George W. Bush administration, the Obama administration and governments around the world plan their health care information strategies. Dr. Halamka completed his undergraduate studies at Stanford University, earned his medical degree at the University of California, San Francisco, and pursued graduate work in bioengineering at the University of California, Berkeley. He completed his residency at Harbor — UCLA Medical Center in the Department of Emergency Medicine.



Leslie R. Harrold is a board certified rheumatologist and Chief Scientific Officer at Corrona LLC as well as Associate Professor in the Department of Medicine at the University of Massachusetts Medical School. Dr. Harrold is a clinician investigator who has used both administrative claims data and registry databases for epidemiologic and health services research in the rheumatic diseases. Her work has focused on treatment patterns, medication adherence, patient safety, comparative effectiveness and quality of care. She has received both federal (NIH, AHRQ, CDC) and foundation funding in the past for these efforts resulting in over 100 manuscripts. In her role at Corrona, LLC she has led the conduct of a cluster randomized trial of a behavioral

intervention to implement the treat to target approach to rheumatoid arthritis care, patient-centered research using patient storytelling to overcome barriers to optimal care and exploration of biomarkers to enable personalized medicine. At Corrona, LLC she leads a team of 50 masters and doctoral level epidemiologists and biostatisticians who work with clients to develop scientific queries, conduct

analyses and develop abstracts and manuscripts for presentation in the public domain based on the proprietary autoimmune registries. Additionally, she has served the American College of Rheumatology in several roles, including as a member of the Quality of Care committee, ACR Guidelines Subcommittee, and a member of the Gout Treatment Guidelines committee.



Aaron Zachary Hettinger is an assistant professor of emergency medicine at Georgetown University of School of Medicine and the director of cognitive informatics of the National Center for Human Factors in Healthcare, MedStar Health. He is a dual board certified in emergency medicine and clinical informatics. In these roles, Dr. Hettinger has the opportunity to translate between the languages of medicine, informatics and human factors with the goal of improving patient safety and healthcare processes. His primary interests include health information technology, adverse event analysis and data visualization as they pertain to reducing hazards in the healthcare environment. He has received funding from the NIH, ONC, AHRQ, FDA and several foundations to pursue these avenues of applied research while practicing clinically in Baltimore at MedStar Union Memorial Hospital.



Peter Margolis is Cincinnati Children's Professor of Pediatrics and Co-Director of the James M. Anderson Center for Health System Excellence at Cincinnati Children's Hospital Medical Center. His work encompasses the application and study of systems improvement methods across a broad range of areas including primary and sub-specialty care, communities and public health settings to improve the health outcomes of children, families and communities. Over the last 20 years, he and his research team have developed innovative approaches that engage patients, their families, clinicians, scientists and communities in developing network-based learning health systems that simultaneously improve care, spawn innovation and accelerate research. This work has repeatedly demonstrated significant impact on the process and outcomes of care. Dr. Margolis was co-PI of an NIH Transformative Research Grant focused on developing learning health systems for children with chronic illness by harnessing the inherent motivation and expertise of all stakeholders involved. Dr. Margolis has extensive experience in large scale comparative effectiveness research, the creation of large scale interoperable data systems, managing large project teams and engaging individuals from diverse backgrounds to co-produce improved care and research. He served as Chair of the PCORnet Council guiding the Patient Centered Outcomes Research Institute's investment in transforming research infrastructure in the US. The ImproveCareNow Network which he leads was awarded the Drucker Prize, the largest non-profit management and innovation award in the US. Dr. Margolis is an elected member of the National Academy of Medicine.



Richard Moldwin has worked in biomedical informatics for over 30 years. His clinical training was in pediatric hematology/oncology, and his biomedical research focused on T cell immunology, leukemia, and stem cell transplantation. His past bioinformatics projects have involved computation of protein structure, development of software for immunologic assay analysis, creation of databases for clinical management and biospecimen research, and the creation of clinical content management software. Since 2006, he has worked at the College of American Pathologists (CAP) on the development of interoperable data representations for the management of cancer data, and he initiated the development and implementation of CAP's "electronic Cancer Checklists" (eCCs). As part of the effort to encourage widespread adoption of the eCC content and interoperability model, he works closely with collaborators from AJCC, ASCO, CDC, HL7/FHIR, IHE,

NAACCR, NCI, NLM, ONC, and others, including many EHR vendors. To further this work, Dr. Moldwin and collaborators have developed an interoperability model called “Structured Data Capture” (SDC). SDC focuses on the technology-agnostic representation of interoperable form-based data sets, which are used for standardizing the content and structure of data entering EHR systems. Thousands of North American pathologists are currently reporting on cancer cases using eCC content delivered in SDC format.



Ryan Moog is the director and solution executive of Research at Cerner and is responsible for setting vision and driving strategy for Cerner’s research solutions, industry partnerships, and client relationships across the provider, academic and life sciences industries. He leads a team focused on evolving HealthIntent as a platform for collaborative research and data science. He makes an impact on Cerner by working across industries to identify and execute innovative partnerships and client relationships that lead to market-leading research solutions. Ryan joined Cerner in 2009 as a Solution Designer for Life Sciences. He has held roles with the company such as strategist, manager, and solution leader where he has progressively led teams focused on research market strategy, solution management and solution delivery. Accomplishments During his time at Cerner, Ryan has created and driven strategic initiatives that advance Cerner’s capabilities for clients worldwide, including the modernization and interoperability of PowerTrials, expanding client use of Cerner Real-World Data, and Cerner Research’s incorporation into numerous client grants and projects. Ryan is a graduate of Butler University, where he earned his Bachelor of Science in biology and chemistry, and the University of Kansas, where he earned a Master’s of Business Administration with an emphasis in strategic management.



Eric Perakslis is a Rubenstein Fellow at Duke University, where his work focuses on collaborative efforts in data science that span medicine, policy, engineering, computer science, information technology, and security, while also contributing to training and mentoring future leaders in the field. Immediately prior to his arrival at Duke, he served as Chief Scientific Advisor at Datavant, Lecturer in the Department of Biomedical Informatics at Harvard Medical School, and Strategic Innovation Advisor to Médecins Sans Frontières.



Ernesto Ramirez is a Design Lead in the Research, Analytica, and Learning team at Evidation Health, a new kind of health and measurement company that provides the world’s most innovative healthcare ecosystem players the technology and expertise they need to understand how everyday behavior and health interact. As part of the multi-disciplinary team at Evidation, Ernesto’s role involves hands-on work with projects that are exploring digital biomarker development and the unique health-related signals present within large-scale longitudinal patient-generated data, primarily for clients in the biopharma space. Ernesto is responsible for driving numerous internal and client-supported projects through ongoing collaborations with experts from industry, academic, and non-profit institutions. He received his PhD in Public Health from the Joint Doctoral Program at San Diego State University and the University of California, San Diego.



Stephanie Reisinger is Vice President and General Manager of Veradigm Life Sciences, a business unit of Allscripts. In this role, she is responsible for commercializing innovative solutions that connect life science researchers and other healthcare stakeholders by leveraging Allscripts core healthcare IT platforms, patient data and provider relationships. Prior to Veradigm, she was President of the Evalyca data & analytics software subsidiary of Evidera, a business that she developed and led from concept through its commercialization and acquisition by Allscripts in February 2018. Steph brings more than 20 years of experience in real-world data analytics leadership and real-world data analytics, and she is a frequent speaker on these topics.



Sam Roosz is a healthcare technology entrepreneur with deep experience in developing and implementing solutions that incorporate RWE and pragmatic methods into clinical development. Most recently, Sam co-founded Datavant, the leading provider of de-identification and linking solutions for health data. He is currently launching a data-driven healthcare non-profit and planning his next venture. Sam received a degree in Molecular and Cellular Biology from Harvard and holds an MBA from the Stanford Graduate School of Business.



Patrick Ryan is Vice President, Observational Health Data Analytics at Janssen Research and Development, where he is leading efforts to develop and apply analysis methods to better understand the real-world effects of medical products. He is an original collaborator in Observational Health Data Sciences and Informatics (OHDSI), a multi-stakeholder, interdisciplinary collaborative to create open-source solutions that bring out the value of observational health data through large-scale analytics. He served as a principal investigator of the Observational Medical Outcomes Partnership (OMOP), a public-private partnership chaired by the Food and Drug Administration, where he led methodological research to assess the appropriate use of observational

health care data to identify and evaluate drug safety issues. Patrick received his undergraduate degrees in Computer Science and Operations Research at Cornell University, his Master of Engineering in Operations Research and Industrial Engineering at Cornell, and his PhD in Pharmaceutical Outcomes and Policy from University of North Carolina at Chapel Hill. Patrick has worked in various positions within the pharmaceutical industry at Pfizer and GlaxoSmithKline, and also in academia at the University of Arizona Arthritis Center.



Chhaya Shadra is Vice President of Product Management for Data and Informatics at Verana Health. She is an epidemiologist-informatician by training, bringing her deep understanding of systems engineering and user workflow to healthcare technology companies like Converge Health by Deloitte, Humedica by Optum, Syapse, Flatiron Health, and Verana Health. Her recent work has focused on product, information architecture and ontology development for integrated precision research data platforms that are sourced from EHR, claims, pharmacy, and medical device data. These platforms are currently being used for real world observational research, health economics and outcomes research (HEOR), and comparative effectiveness research

(CER). Chhaya has focused her informatics career on interoperability and data integrity of routinely captured data that may be used secondarily.



Ian Shakil is the Founding Chairman of Augmedix. Ian has always been passionate about the intersection of science, engineering, and medicine, which drew him to study Biomedical Engineering at Duke University. After graduating in 2006, he worked at Edwards Lifesciences in various engineering, operations, and marketing roles. He left the industry to get his MBA at Stanford University, where he met his soon-to-be Augmedix co-founder, Pelu Tran. After graduating in the spring of 2012, he briefly worked at MC10 before founding Augmedix in late summer 2012. The company was founded with a mission - to rehumanize the doctor-patient interaction and let doctors focus on what matters most - patient care. Ian describes himself as an improv nerd, a foodie, and a regular Burner. He currently lives in San Francisco's Mission District.



Michael Vasconcelles is chief medical officer at Flatiron Health, where he is responsible for defining and executing the company's strategic vision for real-world evidence, providing thought leadership and guidance around novel clinical research methods, and partnering with clients and stakeholders across academia, life sciences and government agencies to further the use of real-world data. In this role, Mike works cross-functionally to drive the overall strategy and execution of Flatiron's research business. Prior to joining Flatiron, Mike served as chief medical officer at Unum Therapeutics, a Cambridge, Massachusetts, cell and gene therapy company developing autologous engineered T cell products for the treatment of cancer. Prior to

Unum, Mike spent several years at Takeda/Millennium, where he was senior vice president and head of the oncology therapy area unit. In his role, he was accountable for strategic and operational oversight of the oncology research and development portfolio globally as a member of the Takeda research and development management team. Mike currently serves as a clinical instructor in medicine at Harvard Medical School, where he has taught since 1996, and is an associate physician at the Dana-Farber Cancer Institute and the Brigham & Women's Hospital. Mike completed his postgraduate training in internal medicine at the Beth Israel Hospital and in hematology-oncology at the Brigham and Women's Hospital, and received his BA and MD from Northwestern University.

Duke-Margolis Moderators



Lesley H. Curtis is Professor and Chair of the Department of Population Health Sciences in the Duke School of Medicine. A health services researcher by training, Dr. Curtis is an expert in the use of health care and Medicare claims data for health services and clinical outcomes research, and a leader in national data quality efforts. Dr. Curtis serves as co-PI of the FDA's Sentinel Innovation Center, Co-Investigator of the Data Core for the FDA's Sentinel Initiative to monitor the safety of FDA-regulated medical products, and Chair of the Data Quality Subcommittee for the National Evaluation System for health Technology (NEST) Coordinating Center that generates real-world evidence for health technology and medical devices. She serves as co-

Investigator of the coordinating center for PCORI's National Clinical Research Network (PCORnet), working with health systems and patient networks to develop a harmonized network infrastructure that leverages health systems and electronic health record data for robust observational and interventional research.



Mark McClellan is Director of the Margolis Center for Health Policy at Duke University and the Robert J. Margolis Professor of Business, Medicine, and Policy. 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. He is 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. He was previously Senior Fellow at the Brookings Institution and a faculty member at Stanford University.



Marta E. Wosińska is the Deputy Director, Policy of the Margolis Center for Health Policy at Duke University and Consulting Professor at the Fuqua School of Business. Widely recognized as an expert on health policy, economics, and regulation, Dr. Wosińska leads the Center's Washington, DC office. In her role, she works with Duke-Margolis leadership on developing the Center's strategy and then executes it with support of the roughly 30-person research team based in DC. Dr. Wosińska's experience spans both academia as well as the executive and legislative branches of the federal government. In 2019, Dr. Wosińska served as an economic advisor to the U.S. Senate Finance Committee, providing drug market analysis and expert guidance for the Committee's bipartisan investigative and legislative work on drug pricing. Dr. Wosińska also served for over three years as Chief Healthcare Economist in the Office of Inspector General (OIG) at the US Department of Health and Human Services. Prior to OIG, Dr. Wosińska had a seven-year tenure at the US Food and Drug Administration (FDA) where she headed the Economics Staff at the Office of Strategic Programs in the Center for Drug Evaluation and Research and served as Senior Economic Advisor to FDA's Deputy Commissioner for Medical Products and Tobacco, in both roles advising senior FDA leadership on a wide range of economic issues related to drugs and biologics. Before entering public service, Dr. Wosińska was an Assistant Professor of Marketing at the Harvard Business School, where her academic research focused on prescription drug marketing. She also was a visiting Assistant Professor at the Columbia Business School, where she developed and taught Healthcare Marketing and Marketing of Pharmaceuticals and Medical Devices. Dr. Wosińska received her PhD in economics from University of California at Berkeley and a bachelor's degree from Arizona State University.

Funding for this workshop was made possible in part by a cooperative agreement with the U.S. Food and Drug Administration. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.