Duke | Robert J. Margolis, MD Center for Health Policy

Tenth Annual Sentinel Initiative Public Workshop

Bethesda Hyatt Regency • Bethesda, MD
Wednesday February 7, 2018

Biographies

Steven Anderson

Steve Anderson, PhD, MPP, is currently the Director of the Office of Biostatistics and Epidemiology (OBE) at the FDA Center for Biologics Evaluation and Research (CBER). He provides leadership for all CBER statistical, epidemiological and risk assessment programs. 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 including vaccines, blood products and others. Since his arrival at FDA he has led numerous important risk assessment projects and epidemiological studies. He led the first studies at FDA using Centers for Medicare & Medicaid Services (CMS) data to estimate blood utilization in inpatient and outpatient setting. 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.

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 and ion pumps, 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.

Robert Ball

Robert Ball, MD, MPH, ScM, is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug risks and promoting the safe use of drugs by the American people, including managing the Sentinel System. From 2008 to 2013, Dr. Ball served as the Director, Office of Biostatistics and Epidemiology (OBE), Center for Biologics Evaluation and Research (CBER), FDA. In this role, Dr. Ball was the principal advisor to the CBER director on all matters pertaining to statistical and epidemiological evaluation of regulated biological products and led post-marketing safety programs for vaccines and blood, including the CBER mini-Sentinel pilot. From 1998 to 2008, Dr. Ball monitored and oversaw post-market safety for all US licensed vaccines. Prior to joining the FDA, Dr. Ball served as a US Navy Medical Officer where he led research to improve the safety and efficiency of deep-sea diving, and provided patient care in US Naval hospitals in Subic Bay, Philippines, and Bethesda, Maryland.

Brian Bradbury

Brian D. Bradbury is an Executive Director and Head of the Data & Analytic Center (DAC) within the Center for Observational Research (CfOR) at Amgen, Inc, and is an Adjunct Assistant Professor of Epidemiology at UCLA. He leads a team of epidemiologists, biostatisticians, data scientists and programmers who use real-world data (RWD) to generate evidence for decision-making, both in and outside Amgen. He and his team are responsible for developing and maintaining Amgen's real-world data (RWD) platform, conducting epidemiologic research to characterize patients with target clinical indications, help design clinical studies, conduct post-marketing commitment studies, and operationalize Amgen's Sentinel Analytic Platform, which is used for comparative effectiveness and safety research, predictive analytics and quality of care evaluation. Brian received his D.Sc. in Epidemiology from Boston University and a M.A. in Education & Psychology from Pepperdine University. He has authored or co-authored over 70 peer-reviewed publications in the areas of pharmacoepidemiology, cancer and kidney disease epidemiology and methods for controlling confounding-by-indication in drug safety studies.

Gerald Dal Pan

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 Conference 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 full-time faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

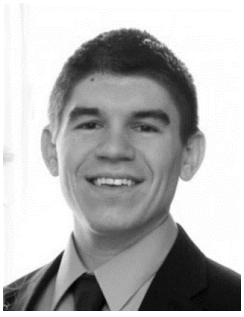
Gregory Daniel

Dr. Gregory Daniel, PhD, MPH, is the Deputy Director of the Duke-Robert J. Margolis, MD Center for Health Policy and a Clinical Professor in Duke's Fuqua School of Business. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio, which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device value-based payment reform. Dr. Daniel is also Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (an Anthem, Inc. company). In addition to health and pharmaceutical policy, Dr. Daniel's research expertise includes real world evidence (RWE) development utilizing electronic health data in the areas of health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.

Richard Forshee

Richard Forshee leads the Analytics and Benefit-Risk Assessment Team for the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of blood and blood products, vaccines, and human cell and tissue products. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.

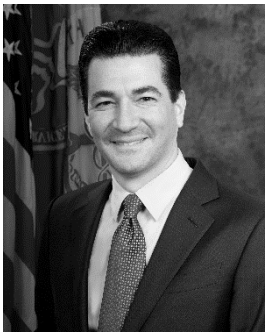
Josh Gagne



Joshua J Gagne, PharmD, ScD, is an Associate Professor of Medicine at Brigham and Women's Hospital and Harvard Medical School and an Associate Professor in the Department of Epidemiology at the Harvard T.H. Chan School of Public Health (Harvard Chan). Josh is Co-Lead of the Methods Core of the US Food and Drug Administration's (FDA's) Sentinel program, Co-Director of the Pharmacoepidemiology Program at Harvard Chan, and Co-Director of the Harvard-Brigham Drug Safety and Risk Management Research Center funded by the FDA. His research centers on methods for generating post-approval comparative safety and effectiveness evidence for new medical products. Josh teaches courses in pharmacoepidemiology and comparative effectiveness research at Harvard Chan and directs a course through Harvard Catalyst, the Harvard Clinical and Translational Science Center. His research is supported by the FDA, the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality, the Reagan-Udall Foundation, and pharmaceutical companies. Josh is a recipient of the International Society for Pharmacoeconomics and Outcomes Research Award for

Excellence in Application of Pharmacoeconomics and Health Outcomes Research. He serves on the editorial boards of Drug Safety and Pharmacoepidemiology and Drug Safety and is an Associate Editor for PCORI.

Scott Gottlieb



Dr. Scott Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 10, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner.

He also worked on implementation of the Medicare drug benefit as a Senior Adviser to the Administrator of the Centers for Medicare and Medicaid Services, where he supported policy work on quality improvement and the agency's coverage process, particularly as it related to new medical technologies.

In 2013 Dr. Gottlieb was appointed by the Senate to serve on the Federal Health Information Technology Policy Committee, which advises the Department of Health and Human Services on healthcare information technology.

Dr. Gottlieb was previously a Resident Fellow at the American Enterprise Institute, and a Clinical Assistant Professor at the New York University School of Medicine in Manhattan, where he also practiced medicine as a hospitalist physician.

He completed a residency in internal medicine at the Mount Sinai Medical Center in New York, New York and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University, in Middletown, Connecticut, where he studied Economics.

Chris Granger

Christopher Granger is Professor of Medicine, Professor in the School of Nursing, and Director of the Cardiac Intensive Care Unit at Duke University. His primary research interests are in the coordination of large randomized clinical trials in heart disease and in implementation projects to apply optimal treatments. These projects include the Reperfusion of Acute MI in Carolina Emergency Departments (RACE) projects, North Carolina state-wide programs to improve care for acute myocardial infarction and cardiac arrest, and IMPACT-AF, a randomized trial to improve the care of atrial fibrillation in low and middle income countries. He is co-PI of the Sentinel IMPACT-AFib randomized trial testing patient education to improve anticoagulation care. He has co-authored more than 600 peer-reviewed manuscripts and is a Thomson Reuters Highly Cited Researcher, reserved for the top 1% of cited researchers. He currently serves on three American College of Cardiology/ American Heart Association Guideline Committees. He received an honorary degree at the Carol Davila University in Bucharest Romania. He serves on editorial boards of the American Heart Journal, Journal of the American College of Cardiology and the European Heart Journal, among many others. He is co-author of the Fundamentals

of Clinical Trials, a major textbook of clinical trials. He advises the FDA and serves the National Heart Lung and Blood Institute on a number of committees, including the Board of External Experts.

Mwango Kashoki

Dr. Mwango Kashoki is the Associate Director for Safety in the Office of New Drugs (OND), in the Center for Drug Evaluation and Research (CDER) at FDA. Dr. Kashoki's responsibilities include assisting in the development and ensuring OND's implementation of the policies and procedures related to CDER's various safety initiatives, including the Safety First and Sentinel Initiatives. She also leads OND's implementation of FDA's new authorities to require safety labeling changes, postmarketing investigations, and risk evaluation and mitigation strategies, as provided under the FDA Amendments Act of 2007 (FDAAA).

Dr. Kashoki joined OND in 2002 as a primary medical officer in the former Division of Anesthetic, Critical Care and Addiction Drug Products, and then served as a clinical team leader in that division for several years. As a team leader, she supervised primary medical officers in reviewing investigational and new drug applications, as well as in providing guidance to individual researchers and pharmaceutical companies regarding addiction and analgesic drug development programs. Prior to her current position, Dr. Kashoki served as Associate Director for Special Projects in the former Division of Anesthesia, Analgesia and Rheumatology Products, leading the development and conduct of research projects under FDA's Critical Path Initiative and in collaboration with external groups. Dr. Kashoki is board certified in Preventive Medicine and Public Health. She received her M.D. from the Johns Hopkins School of Medicine, and her M.P.H. degree from Columbia University.

Marianthi Markatou

Dr. Marianthi Markatou is Professor of Biostatistics and Associate Chair of Research and Healthcare Informatics, Department of Biostatistics, School of Public Health and Health Professions. She is also the Assistant Director, Institute of Healthcare Informatics, and holds an Adjunct Professorship in the Department of Computer Science and Engineering, University at Buffalo. Dr. Markatou received a Ph. D. in Statistics from the Pennsylvania State University. Her research interests are broad and include problems at the interface of statistics and machine learning, modeling, surveillance methods, emerging safety sciences, biomedical informatics methods, methods for the analysis of massive (big) data, text mining, and healthcare applications. Her publications appear in both, Statistical Science and Computer Science journals, as well as in medical and biomedical informatics journals. Dr. Markatou is an Elected Fellow of the American Statistical Association, an Elected Member of the International Statistical Institute, and a Faculty Fellow of the Institute of Social and Economic Research and Policy, Columbia University. She is an Associate Editor for Theory and Methods Section, Journal of the American Statistical Association, and a permanent (federally appointed) member on the Biostatistical Methods and Research Design (BMRD) study section, NIH.

Mark McClellan

Mark McClellan, MD, PhD, is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Margolis Center for Health Policy at Duke University. He is a physicianeconomist 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.

Vinit Nair

Vinit P. Nair is a trained pharmacist & pharmacoepidemiologist with experience at large national health plans and health outcomes & policy research organizations. Currently the lead for the Government Research & Academic Partnerships at Humana's research organization; his team aims to conduct, build and foster research with government entities and academic institutions across the US. He is engaged with several national multi-site research initiatives including the FDA sponsored Sentinel (Site PI), Regan Udall Foundation IMEDS (Site PI) and Patient Centered Outcomes Research Institute PCORnet -HUMnet (Site PI). In addition, Vinit also held academic appointments and serves as a reviewer & editorial board member for peer-reviewed journals and is a recipient of grants and contract awards.

Michael Nguyen

Michael D. Nguyen, MD, is the FDA Sentinel Program Lead and Deputy Director of the Regulatory Science Staff in the Office of Surveillance and Epidemiology at the Center for Drug Evaluation and Research (CDER). He oversees the day-to-day management of the Sentinel Program for the Agency and coordinates scientific operations, routine safety analyses, and data infrastructure development. He previously served as the Acting Director and Deputy Director of the Division of Epidemiology in the Center for Biologics Evaluation and Research (CBER), where he led CBER's Sentinel Program and was involved in postmarketing safety surveillance of vaccines, blood components, and blood-derived products. Prior to working at the FDA, he completed his training in pediatrics at Washington University in St. Louis, and served as an officer in the Epidemic Intelligence Service at the Centers for Disease Control and Prevention.

Beth Nordstrom

Beth L. Nordstrom, PhD, MPH, is the Executive Director of Evidera's Epidemiology Center of Excellence and a Senior Research Scientist in the Real-World Evidence group at Evidera in Waltham, Massachusetts. In her role at Evidera, she serves as principal investigator on epidemiology and database analytics projects using claims and electronic medical record databases. Her studies have investigated such issues as treatment of chemotherapy-induced anemia, the epidemiology and costs of renal disease in HIV, treatment patterns in multiple sclerosis, and the prevalence of retinal diseases. She has led numerous post-marketing drug safety studies in a wide range of therapeutic areas, including oncology, neurology, rheumatology, and others; outcomes for these studies have also varied widely but include cardiovascular events, renal and hepatic outcomes, and development of cancer.

Prior to her current role, Dr. Nordstrom was an epidemiologist at i3 Drug Safety, a division of Ingenix. At i3, she designed and carried out numerous studies related to drug safety and outcomes, including investigations into treatments for HIV, influenza, glaucoma, and psychotic disorders, as well as studies of disease epidemiology in areas such as anemia, atrial fibrillation, and irritable bowel syndrome. Dr. Nordstrom's previous experience includes working in smoking cessation research at Harvard University, running prospective studies of smokers attempting to quit and retrospective epidemiologic studies using data from the Normative Aging Study at the Boston Veteran's Administration.

Dr. Nordstrom earned her graduate degrees in psychology and public health at Northeastern University and the University of Massachusetts at Amherst, and a Bachelor of Science degree from Massachusetts Institute of Technology.

Allison O'Neill

Allison O'Neill, PhD, MA is an epidemiologist in the Center for Devices and Radiological Health. Dr.

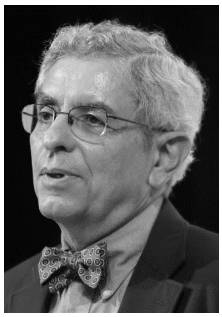
O'Neill received her PhD in Epidemiology from the University of Maryland School of Public Health. She joined the FDA as an ORISE research fellow in 2012, and became a postmarket epidemiological reviewer in 2013. Dr. O'Neill has experience with regulatory review of women's health medical devices and the use of real world evidence to support regulatory decision making.

Gregory Pappas

Gregory Pappas, MD PhD has over 25 years of experience in public health leadership in government, academia, and the private sector, working with multiple stakeholders in the US government, industry, and in communities. Currently he serves as Associate Director for the National Devise Ealuation at the FDA, Center for Devices and Radiological Health. He has worked in over 30 countries.

Over a 16 year period Dr. Pappas served in a variety of positions in the US Department of Health and Human Services including Senior Policy Adviser to the Assistant Secretary for Health/Surgeon General, David Satcher. Directing the Office of International and Refugee Health (DHHS/OPHS) he served on the Executive Board of UNICEF and PAHO, and on the US delegation to the World Health Assembly. Dr. Pappas received his MD and PhD (Anthropology) from Case Western Reserve University in Cleveland, Ohio.

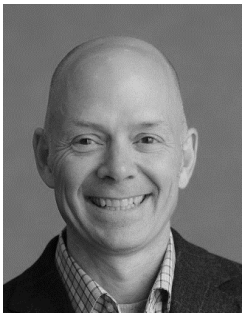
Richard Platt



Richard Platt, MD, MSc, is Professor and Chair of the Harvard Medical School Department of Population Medicine and Executive Director of the Harvard Pilgrim Health Care Institute. He is Principal Investigator of the FDA Sentinel System. He led the development, with the Massachusetts Department of Public Health, of ESPnet, a system for doing real time EHR-based surveillance for both syndromes of interest and individually notifiable conditions. He is also co-Principal Investigator of the National Patient Centered Clinical Research Network (PCORnet) Coordinating Center, which is developing standard methods for extracting and using EHR data for multiple uses.

Dr. Platt also co-leads the coordinating center of the NIH Health Care System Research Collaboratory and leads a CDC Prevention Epicenter. He co-chairs the CER Innovation Collaborative of the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System, and is a member of the American Medical Colleges Advisory Panel on Research.

Robert Platt



Robert Platt is Professor in the departments of Pediatrics and of Epidemiology, Biostatistics, and Occupational Health at McGill University. He holds the Albert Boehringer I endowed chair in Pharmacoepidemiology. Since December 2016, Dr. Platt is the executive co-lead of the Canadian Network for Observational Drug Effect Studies (CNODES); he has led the methods team of CNODES since its inception. In this role he has led a methods research and training program for CNODES and has participated as senior methodologist in several CNODES studies. Dr. Platt received his PhD in Biostatistics from the University of Washington in 1996 and has been on faculty at McGill since then. His research interests are in statistical methods and applications for administrative-data pharmacoepidemiology, and in methods for causal inference from epidemiologic studies. His methodologic interests are in marginal structural

models for analyses of large administrative-data cohorts, in particular with regard to specification and optimization of the propensity score and inverse probability weights.

Claudia Salinas

Dr. Salinas is a Senior Research Scientist in Global Patient Safety at Eli Lilly and Company. She received her doctorate in Epidemiology at the University of Washington in 2009 and completed her dissertation on genetic polymorphisms in IL6 pathway genes and risk of prostate cancer. Since 2013, she has focused on epidemiologic methods relevant to pharmacoepidemiology and conducted observational research studies supporting drug development and assessment of postmarketing drug safety. She currently supports compounds in the Immunology therapeutic area.

Kenneth Sands

Kenneth Sands, MD MPH is Chief Epidemiologist and Patient Safety Officer for HCA Healthcare (HCA), and an Associate Professor of Population Medicine, Part Time, at Harvard Medical School. Dr. Sands attended Dartmouth Medical School and received his MPH from Harvard School of Public Health. Prior to his current position, he was Chief Quality Officer at Beth Israel Deaconess Medical Center in Boston. In his current position, he oversees activities relating to patient safety, clinical analytics, medication management, peer review, infection prevention, and implementation science for more than 300 HCA-affiliated healthcare facilities nationally and internationally.

Azadeh Shoaibi

Azadeh Shoaibi, PhD, MHS is currently the Sentinel Lead at the FDA Center for Biologics Evaluation and Research, Office of Biostatistics and Epidemiology where she leads and directs the CBER Sentinel Program focusing on post-market surveillance of biologics including vaccines, blood and blood products, tissue, and advanced therapies. She previously held the position of the Sentinel Scientific Lead at the Center for Drug Evaluation and Research. Dr. Shoaibi joined the FDA in 2004 at the Center for Devices and Radiological Health Division of Epidemiology 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. Her prior research and public health experience focused on the epidemiology of HIV and other sexually transmitted infections, genomics of malaria parasites, and cell cycle regulation and cancer development.

Darren Toh

Darren Toh, ScD is an Associate 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 has been focused 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 and data-sharing methods to improve the feasibility, efficiency, and validity of multi-center studies.

Darren is Director of Applied Surveillance of the Sentinel Operations Center. In this role, he oversees all the FDA-initiated safety queries and methods projects. He is Principal Investigator of a series of projects funded by the National Institutes of Health (U01EB023683), the Patient-Centered Outcomes Research Institute (ME-1403-11305), and the Food and Drug Administration to further develop and expand the use of privacy-protecting analytic methods in distributed data networks. Darren received his doctoral degree in Epidemiology from the Harvard School of Public Health.

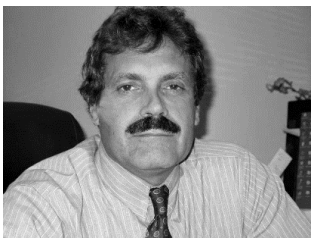
Joanne Waldstreicher

Joanne Waldstreicher, M.D., is Chief Medical Officer, Johnson & Johnson. In this role, she has oversight across pharmaceuticals, devices and consumer products for safety, epidemiology, clinical and regulatory operations transformation, collaborations on ethical science, and technology and R&D policies, including those related to trial transparency and compassionate access. She chairs the Development Committee for Janssen R&D, the pharmaceuticals group of Johnson & Johnson, and supports Device and Consumer Development committees. Joanne is also a Faculty Affiliate of the Division of Medical Ethics, Department of Population Health, New York University School of Medicine.

Among her prior roles, Joanne was responsible for late-stage development in neuroscience, cardiovascular disease and metabolism at Janssen. Before joining Johnson & Johnson in 2002, she headed Endocrinology and Metabolism clinical research at Merck Research Laboratories, overseeing development programs in atherosclerosis, obesity, diabetes, urology and dermatology. She was honored with the Key Innovator Award, among other distinctions.

Joanne received both the Jonas Salk and Belle Zeller scholarships from the City University of New York, and graduated Summa Cum Laude from Brooklyn College. She graduated Cum Laude from Harvard Medical School, completed her internship and residency at Beth Israel Hospital, and her endocrinology fellowship at Massachusetts General Hospital. She has received numerous awards and scholarships, and is an active scientific author. In 2016, the National Association of Female Executives named her Healthcare Champion of the Year. Joanne combines broad experience in science and medicine with a passion for advancing transparency and ethics, with a goal of improving the lives of patients and consumers worldwide.

Alan Williams



Following an 18-year career with the American Red Cross Biomedical Services as a Senior Research Scientist concentrating in blood transfusion safety, Dr. Williams joined FDA in 2001 to manage the regulatory review process in the CBER Office of Blood Research and Review (OBRR), where he remained active in blood safety and regulatory policy development. In early 2017, Dr. Williams became Associate Director for Regulatory Affairs in the CBER Office of Biostatistics and Epidemiology (OBE) where he oversees several large blood-related programs including the Transmissible Infections Monitoring System (TTIMS) and the BEST contract for Development of New, Innovative Methods for Automation of Blood Product Adverse Event Reporting

Dr. Williams is a graduate of Case Western Reserve University and completed his Ph.D. and post-doctoral fellowship at Yale University School of Medicine.

Marcus Wilson

Marcus Wilson is President of HealthCore, Anthem's wholly-owned outcomes research subsidiary. He has been extensively involved in efforts to utilize real-world data environments to accelerate healthcare evidence development and to facilitate clinical decision support for more than 20 years. Prior to co-founding HealthCore in 1996, Dr Wilson spent seven years within an integrated delivery system owned by BCBS of Delaware where he oversaw the physician and patient clinical decision support, pharmacy policy and clinical trials programs.

Dr. Wilson is active on a number of boards and national committees including serving as chair of the Joint Research Committee for the Academy of Managed Care Pharmacy (AMCP) & the AMCP Foundation; member of the FDA Sentinel Initiative Planning Board; Board of Directors for the Center for Medical Technology Policy (CMTP); a member of the Dean's Roundtable, College of Science, Virginia Tech; and member of the Planning Committee for the National Academy of Medicine's upcoming Real-World Evidence Workshop Series that is being conducted for FDA in response to the 21st Century Cures legislation. Dr Wilson is a past member of numerous boards and committees including the Board of Directors for the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), the eHealth Initiative and is former chair of the Innovations in Medical Evidence Development (IMEDS) Steering Committee, Reagan-Udall Foundation for the FDA.

Dr. Wilson received his Bachelor of Science in Biochemistry from Virginia Tech and his Doctor of Pharmacy degree from the Medical College of Virginia. He completed a residency in Family Medicine at the Medical University of South Carolina prior to joining the faculty at the Philadelphia College of Pharmacy (now the University of Sciences in Philadelphia).

Funding for this conference was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written conference 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.