Examining the Impact of Real-World Evidence on Medical Product Development: A Workshop Series

Committee

Gregory E. Simon

Chair

GREGORY SIMON, M.D., M.P.H., is an investigator at Kaiser Permanente Washington Health Research Institute and a psychiatrist in Kaiser Permanente's Behavioral Health Service. He is also a Research Professor in the Department of Psychiatry and Behavioral Sciences at the University of Washington and co-chair of the national scientific advisory board of the Depression and Bipolar Support Alliance. Dr. Simon completed residency training in internal medicine at the University of Washington, residency training in psychiatry at the Massachusetts General Hospital, and fellowship training in the Robert Wood Johnson Clinical Scholars program at the University of Washington. Dr. Simon's research focuses on improving access to and quality of mental health care, especially for mood disorders. Specific areas of research include improving adherence to medication, increasing the availability of effective psychotherapy, evaluating peer support by and for people with mood disorders, identifying and reducing risk of suicidal behavior, cost-effectiveness of treatment, and comorbidity of mood disorders with chronic medical conditions. Dr. Simon currently leads the Mental Health Research Network, a National institute of Mental Health–funded cooperative agreement supporting population-based mental health research across 13 large health systems.

Mark B. McClellan

Co-Chair

MARK MCCLELLAN, M.D., Ph.D., is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including payment reforms to promote better outcomes and lower costs, methods for development and use of real-world evidence, and approaches for more effective drug and device innovation. 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. He was also a Senior Fellow at the Brookings Institution and a professor of economics and medicine at Stanford University.

Jeff Allen

Member

JEFF ALLEN, Ph.D., serves as the President and CEO of Friends of Cancer Research (Friends). During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. As a thought leader on many issues related to the Food and Drug Administration, regulatory strategy and healthcare policy, he is regularly published in prestigious medical journals and policy publications, and has contributed his expertise to the legislative process on multiple occasions. Recent Friends initiatives include the establishment of the new Breakthrough Therapies designation and the development of the Lung Cancer Master Protocol, a unique partnership that will accelerate and optimize clinical trial conduct for new drugs. Dr. Allen received his Ph.D. in cell and molecular biology from Georgetown University, and holds a Bachelors of Science in Biology from Bowling Green State University.

Andrew B. Bindman

Member

ANDREW BINDMAN, M.D., is Professor of Medicine, Health Policy, Epidemiology and Biostatistics, at the University of California San Francisco (UCSF). He is also a senior advisor in the Office of the Assistant Secretary for Planning and Evaluation within the US Department of Health and Human Services where he works on issues related to the health care workforce, graduate medical education, and Medicaid; from May 2016 until January 2017, Dr. Bindman served as the Director of the Agency for Healthcare Research and Quality. He has practiced, taught and performed health services research at UCSF’s affiliated San Francisco General Hospital for over 25 years. Dr. Bindman has published extensively on evaluations of Medicaid health policies with a focus on access to care and health outcomes. During 2009-2010, he served as a Robert Wood Johnson Health Policy Fellow on the staff of the Energy and Commerce Committee within the US House of Representatives where he was intimately involved in the drafting of legislative language for the federal health reform law, the Patient Protection and Affordable Care Act (ACA).

John Graham

Member

John Graham, Pharm.D., is a Senior Vice President at GlaxoSmithKline and leads the Medical Engagement and Value Evidence and Outcomes (VEO) organization within GSK's R&D division. The VEO organization is accountable for providing strategic input into the progression of assets as well as ensuring the value demonstration through evidence generation of the assets that do progress.This evidence includes accountability for real world evidence across GSK products and across all regions globally. In addition, his organization is accountable for GSK's Patient Centered Outcomes and alignment with Patients in Partnership. His interests include real world evidence (RWE), particularly the integration of traditional clinical evidence with non-traditional RWE, to answer questions from patients, providers, and payers. Dr. Graham sits on various Advisory Boards relating to Real World Evidence including the National Academies of Science working group on RWE, OPERAND, as well as the RWE Forum. He has published scientific communications across cardiovascular and metabolic diseases and across both clinical as well as RWE areas. Dr. Graham joined GSK in 2014 as the Vice President, CV/Met, NS, Rare Disease VEO. He is located in the GSK R&D HUB in Collegeville, PA. Prior to GSK, Dr. Graham worked for over 16 years at Bristol-Myers Squibb where he was most recently the Head of the U.S. HEOR group and previously had roles across R&D and commercial with both Global and local accountabilities. Prior to industry, Dr. Graham worked in academia most recently as Assistant Professor of Clinical Pharmacy at St. Louis College of Pharmacy. Dr. Graham holds a Doctorate of Pharmacy degree from Idaho State University and completed a Primary Care Residency at the University of Nebraska Medical Center.

Adam Haim

Member

Adam Haim, Ph.D., is the Chief of the Treatment and Preventive Intervention Research Branch within the Division of Services and Intervention Research at the National Institute of Mental Health (NIMH). Dr. Haim manages a broad portfolio of research focused on evaluating the efficacy and effectiveness of pharmacologic, psychosocial and combination interventions on mental and behavior disorders. He is also a thought leader in the development, evaluation and implementation of technology enhanced mental health interventions. Dr. Haim is a licensed clinical psychologist and earned his doctoral degree in clinical psychology from State University of New York at Albany and completed his research fellowship at the NIMH Intramural Program in the Division of Clinical Neuroendocrinology.

Michael A. Horberg

Member

Michael Horberg, M.D., M.A.S, FACP, is Executive Director Research and Community Benefit of Mid-Atlantic Permanente Medical Group (MAPMG) and the director of the Mid-Atlantic Permanente Research Institute (MAPRI). He is also director of HIV/AIDS for Kaiser Permanente. Dr. Horberg has been appointed to serve on the Presidential Advisory Council on HIV/AIDS (PACHA), and co-chairs the Access to Care and Improved Outcomes Committee of PACHA. Dr. Horberg is a Fellow of the American College of Physicians, and he presently serves as Vice-Chair of the Board of Directors of the HIV Medicine Association of the Infectious Disease Society of America. He has co-chaired the NCQA/AMA/HRSA/IDSA sponsored Expert Panel on HIV-related provider performance measures. He is Assistant Clinical Professor at Stanford University Medical School. Dr. Horberg is past-president of the national Gay and Lesbian Medical Association. His HIV research interests are health service outcomes for HIV-infected patients (including HIV quality measures and care improvement, and determinants of optimized multidisciplinary care for maximized HIV outcomes), medication adherence issues in these patients, and epidemiology of the disease. He graduated from Boston University’s College of Liberal Arts and School of Medicine (with honors of Summa cum Laude and Phi Beta Kappa) and completed his internal medicine residency at Michael Reese Hospital in Chicago (University of Chicago affiliate). He received his Master of Advanced Studies (Clinical Research) from University of California San Francisco.

Petra Kaufmann

Member

Petra Kaufmann, M.D., M.Sc., is the director of both the Office of Rare Diseases Research and the Division of Clinical Innovation. Her work includes overseeing NCATS' Rare Diseases Clinical Research Network, Genetic and Rare Diseases Information Center, and Clinical and Translational Science Awards Program as well as the NIH/NCATS Global Rare Diseases Patient Registry Data Repository/GRDR® program. Kaufmann focuses on engaging a broad range of stakeholders to accelerate translation from discovery to health benefits through use of innovative methods and tools in translational research and training. Before joining NCATS, Kaufmann was the director of the Office of Clinical Research at the National Institute of Neurological Disorders and Stroke (NINDS), where she worked with investigators to plan and execute a large portfolio of clinical research studies and trials in neurological disorders, including many in rare diseases. She established NeuroNEXT, a trial network for Phase II trials using a central institutional review board, streamlined contracting, active patient participation in all project phases, and a scientific and legal framework for partnership with industry. Kaufmann also promoted data sharing, working with multiple stakeholders from the academic, patient organization and industry sectors to develop data standards for more than 10 neurological diseases.

A native of Germany, Kaufmann earned her M.D. from the University of Bonn and her M.Sc. in biostatistics from Columbia University's Mailman School of Public Health. She completed an internship in medicine at St. Luke's/Roosevelt (now part of Mt. Sinai) in New York City, training in neurology and clinical neurophysiology at Columbia University, and a postdoctoral fellowship in the molecular biology of mitochondrial diseases at Columbia's H. Houston Merritt Clinical Research Center for Muscular Dystrophy and Related Diseases. Before joining NINDS, Kaufmann was a tenured associate professor of neurology at Columbia, where she worked as a researcher and clinician in the neuromuscular division, the electromyography laboratories and the pediatric neuromuscular clinic. She has served on scientific advisory committees for many rare disease organizations and is a member of the American Academy of Neurology Science Committee, the International Rare Disease Research Consortium Interdisciplinary Scientific Committee and the Clinical Trial Transformation Initiative Steering Committee. Kaufmann is board certified in neurology, neuromuscular medicine and electrodiagnostic medicine. Kaufmann's research focus is on the clinical investigation of rare diseases, such as spinal muscular atrophy, amyotrophic lateral sclerosis and mitochondrial diseases. She currently sees patients in the Muscular Dystrophy Association Clinic at Children's National Medical Center in Washington, D.C.

Richard E. Kuntz

Member

Richard Kuntz, M.D., is Senior Vice President and Chief Scientific, Clinical and Regulatory Officer of Medtronic and serves as a member of the company’s Executive Committee. In this role, which he assumed in August 2009, Dr. Kuntz oversees the company’s global regulatory affairs, health policy and reimbursement, clinical research activities, and corporate technology. Dr. Kuntz joined Medtronic in October 2005, as Senior Vice President and President of Medtronic Neuromodulation, which encompasses the company’s products and therapies used in the treatment of chronic pain, movement disorders, spasticity, overactive bladder and urinary retention, benign prostatic hyperplasia, and gastroparesis. In this role he was responsible for the research, development, operations and product sales and marketing for each of these therapeutic areas worldwide. Dr. Kuntz brings to Medtronic a broad background and expertise in many different areas of healthcare. Prior to Medtronic he was the Founder and Chief Scientific Officer of the Harvard Clinical Research Institute (HCRI), a university-based contract research organization which coordinates National Institutes of Health (NIH) and industry clinical trials with the Food and Drug Administration (FDA). Dr. Kuntz has directed over 100 multicenter clinical trials and has authored more than 250 original publications. His major interests are traditional and alternative clinical trial design and biostatistics. Dr. Kuntz also served as Associate Professor of Medicine at Harvard Medical School, Chief of the Division of Clinical Biometrics, and an interventional cardiologist in the division of cardiovascular diseases at the Brigham and Women’s Hospital in Boston, MA. Dr. Kuntz has served as a member of the Board of Governors of PCORI (Patient Centered Outcomes Research Institute) since it was established in 2010 as part of the Affordable Care Act. Dr. Kuntz graduated from Miami University, and received his medical degree from Case Western Reserve University School of Medicine. He completed his residency and chief residency in internal medicine at the University of Texas Southwestern Medical School, and then completed fellowships in cardiovascular diseases and interventional cardiology at the Beth Israel Hospital and Harvard Medical School, Boston. Dr. Kuntz received his master’s of science in biostatistics from the Harvard School of Public Health.

Elliott Levy

Member

Elliott Levy, M.D., is senior vice president, Global Development, at Amgen. He is responsible for the clinical development of Amgen’s investigative and marketed products. Before joining Amgen, Dr. Levy spent 17 years at Bristol-Myers Squibb (BMS) in clinical development and pharmacovigilance. He has contributed to the development and approval of numerous new therapies for cardiovascular, metabolic, inflammatory, and malignant diseases, and led large organizations through periods of transformative change. Dr. Levy is a graduate of the Yale School of Medicine, where he also trained in internal medicine and nephrology. Dr. Levy was also a member of the Renal Division at Brigham and Women's Hospital in Boston, Massachusetts, where he was an investigator in federally sponsored outcomes research as well as industry-sponsored clinical trials.

David Madigan

Member

DAVID MADIGAN, Ph.D., is Professor of Statistics and Executive Vice President and Dean of the Faculty of Arts & Sciences at Columbia University in New York City. He received a bachelor's degree in Mathematical Sciences and a Ph.D. in Statistics, both from Trinity College Dublin. He has previously worked for AT&T Inc., Soliloquy Inc., the University of Washington, Rutgers University, and SkillSoft, Inc. He has over 180 publications in such areas as Bayesian statistics, text mining, Monte Carlo methods, pharmacovigilance and probabilistic graphical models. He is an elected Fellow of the American Statistical Association, the Institute of Mathematical Statistics, and the American Association for the Advancement of Science. He has served terms as Editor-in-Chief of Statistical Science and of Statistical Analysis and Data Mining – the ASA Data Science Journal.

Deven McGraw

Member

DEVEN MCGRAW, J.D., M.P.H., is the General Counsel and Chief Regulatory Officer for Ciitizen, a consumer health technology start-up. Prior to joining Ciitizen, she directed U.S. health privacy and security through her roles as Deputy Director, Health Information Privacy at the HHS Office for Civil Rights (the office that oversees HIPAA policy development and enforcement) and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT. Widely recognized for her expertise in health privacy and security, she directed the Health Privacy Project at the Center for Democracy & Technology (a nonprofit civil liberties organization) for six years and led the privacy and security policy work for the HITECH Health IT Policy Committee. She also served as the Chief Operating Officer of the National Partnership for Women and Families. She has also advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. Deven graduated magna cum laude from Georgetown University Law Center and has a Masters of Public Health from Johns Hopkins University.

John D. Nolen

Member

John David Nolen, M.D., P.H.D., MSPH, provides clinical strategic guidance for Cerner Corporation’s solutions in precision medicine, laboratory medicine, behavioral health, and long-term post-acute care. Using his clinical knowledge, analytical skills and engineering talents, he is positioning Cerner’s solutions and clients for the future of medicine. He represents Cerner on boards, working groups, and standards organizations, including HL7, IHE, DICOM, IOM, AMIA, and CLSI. Dr. Nolen joined Cerner in 2010 as the Director of Laboratory Strategy. Since then, he has been instrumental in guiding the incorporation of new solutions around genomics, automation, and technologies into Cerner solutions. He transitioned to the Managing Director of the laboratory business unit in 2013, and expanded his clinical strategic responsibilities in 2015 to solutions beyond laboratory medicine.

Richard Platt

Member

RICHARD PLATT, M.D., M.Sc., 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.

Patrick Vallance

Member

Patrick Vallance, M.D., is President of Research and Development at GlaxoSmithKline (GSK) and a member of the GSK Corporate Executive Team. Prior to joining GSK in 2006, Patrick Vallance was a clinical academic and as Professor of Medicine led the Division of Medicine at University College London and Consultant Physician at UCL. His academic work was in the field of cardiovascular biology and ranged from chemistry through to use of large electronic health records. Patrick Vallance is a Fellow of the Academy of Medical Sciences. He has been on the Board of the UK Office for Strategic Co-ordination of Health Research since 2009. He is also a director of Genome Research Limited.

Joanne Waldstreicher

Member

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, internal and external partnerships and collaborations supporting development of the ethical science, technology and R&D policies, including those related to clinical trial transparency and compassionate access. Joanne also chairs the Pharmaceuticals (Janssen) R&D Development Committee and supports the Device and Consumer Development Committees, which review late stage development programs in the pipeline. She also holds an appointment as a Faculty Affiliate of the Division of Medical Ethics, Department of Population Health, New York University School of Medicine. Among her prior roles in Janssen, the pharmaceutical sector of Johnson & Johnson, Dr. Waldstreicher was responsible for late-stage development spanning the areas of neuroscience, cardiovascular and metabolism including INVOKANA®, XARELTO®, INVEGA SUSTENNA®, and INVEGA TRINZA®. Before joining Johnson & Johnson in 2002, Dr. Waldstreicher was head of the Endocrinology and Metabolism clinical research group at Merck Research Laboratories, and responsible for overseeing clinical development of MEVACOR®, ZOCOR®, PROSCAR® and PROPECIA®, and for clinical development programs in atherosclerosis, obesity, diabetes, urology and dermatology. During that time, she received numerous awards and distinctions, including the Merck Research Laboratory Key Innovator Award. Dr. Waldstreicher received both the Jonas Salk and Belle Zeller scholarships from the City University of New York and graduated Summa Cum Laude from Brooklyn College. Joanne graduated Cum Laude from Harvard Medical School in 1987, and completed her internship and residency at Beth Israel Hospital, and her endocrinology fellowship at MGH. She has won numerous awards and scholarships, and has authored numerous papers and abstracts. In December, 2016, Dr. Waldstreicher was named Healthcare Champion of the Year for Women by the National Association of Female Executives.

Marcus Wilson

Member

MARCUS D. WILSON, Pharm.D., 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 Sciences, Engineering, and Medicine’s 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).

Carolyn Shore

Staff Officer