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

Developing Real-World Data and Evidence to Support Regulatory Decision-Making

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Biographies

Jeff Allen 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 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 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.

Adam Asare has over 15 years' experience in academia and industry developing clinical and translational research information systems. He has a joint appointment as the Chief Data Officer for Quantum Leap Healthcare Collaborative and as the Director of Technology for the University of California – San Francisco Breast Care Clinic where he leads initiatives for process re-engineering and quality improvement. A key focus is in direct source data capture from Electronic Health Record (EHR) and Patient Reported Outcome systems to improve the quality and efficiency of clinical trial data submissions. He is the lead architect for the OneSource platform supporting the Bayesian adaptive I-SPY2 TRIAL, BreastCancerTrials.org, and the Athena Breast Health Network with over 100K patients.

Robert Ball 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.
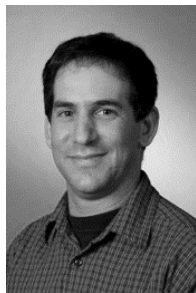
Jeffrey Brown is an Associate Professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. Within DPM, Dr. Brown serves as a member of the Therapeutics Research and Infectious Disease Epidemiology program Executive Committee. His primary research activities involve new approaches to facilitate large-scale multi-institutional research through the use of distributed health data networks to support a learning health system. This research established the basis for several established research networks, including the FDA's Sentinel System and PCORnet. He has leadership roles in FDA Sentinel, PCORnet, the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), the Innovation in Medical Evidence and Development Surveillance (IMEDS) program, and the NIH Health Care Systems Research Collaboratory. Dr. Brown is the inventor of PopMedNet, an open-source software platform that facilitates creation and operation of distributed health data networks. Dr. Brown holds a Master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University. He is an 8-time US national champion and 3-time world champion in Ultimate Frisbee and coached the Tufts Men's Ultimate team for 20 years.

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 and regulatory review processes. OMP is comprised of the Office of Prescription Drug Promotion (OPDP) and the Office of Medical Policy Initiatives (OMPI). OPDP oversees the regulation of prescription drug promotion and advertising. OMPI provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas. Prior to joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI), at National Institute of Health's (NIH) where she focused on developing policies and procedures to enhance the clinical trial enterprise. She also served as the Director of 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. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical assistant professor of medicine. She continues to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, D.C.

William H. Crown is Chief Scientific Officer of OptumLabs. In this role, he is responsible for research activities of the Labs. From 2004-2013, Dr. Crown was President of the health economics, late phase research, data products, and epidemiology business units at Optum Life Sciences. He was Vice President of Outcomes Research and Econometrics at Thomson Reuters Medstat from 1994-2004. From 1982-1995, Dr. Crown was a faculty member of the Florence Heller Graduate School, Brandeis University, where he taught graduate courses in statistics and conducted research on the economics of aging and long-term care policy. He received his doctorate degree in urban and regional studies from the Massachusetts Institute of Technology, and a master of arts in economics from Boston University. The author of two books and co-author of two others, Dr. Crown has published over 160 peer-reviewed journal articles, book chapters, and other scholarly papers. Known for his early application of sample selection bias models in the pharmaceutical outcomes research literature, he is a frequent speaker on statistical methods for the analysis of observational data at professional meetings and conferences. In addition to his CSO role within Optum Labs, Dr. Crown is Affiliate Faculty, Mongon Institute for Health Policy, Harvard University. He was also 2013-14 President of the International Society of Pharmacoeconomics and Outcomes Research.

Angela Dobes works for the Crohn's & Colitis Foundation. She is the senior director of IBD Plexus - a first-of-its-kind research information exchange platform that integrates multi-dimensional real-world data to accelerate progress towards precision medicine, support real-world evidence, and improve the care of patients living with inflammatory bowel diseases. Angela has over 15 years of experience in the health care industry. In addition to her experience at the Foundation, Angela has previously worked for clinical technology and pharmaceutical organizations, where she has led implementation of various technology solutions focused on business optimization and accelerating the delivery of new therapies to patients safely. Angela has also conducted research in the fields of patient-centered outcomes and patient engagement funded by PCORI. Angela holds an undergraduate degree in Chemical Engineering from Lehigh University and she earned her graduate degree in Public Health from the Icahn School of Medicine at Mount Sinai.

Shaun Grannis is Director of the Regenstrief Center for Biomedical Informatics, Clem McDonald Scholar for Biomedical Informatics, and Associate Professor of Family Medicine at the Indiana University School of Medicine. Dr. Grannis received the American Medical Informatics Association's Martin Epstein Award for developing innovative record linkage methods. Dr. Grannis helped to create the global matching system and serves as the identity management technical advisor for the Indiana Network for Patient Care (INPC), one of the nation's largest and longest running HIE's. The INPC serves as Dr. Grannis's in-vivo patient matching laboratory, linking over two million clinical transactions per day to more than 27 million unique patient registrants and has linked billions of patient identities over the last 17 years. He has provided expert testimony before the Department of Health and Human Services National Committee for Vital and Health Statistics regarding national patient identity management policy; worked with the World Health Organization, United Nations Programme on HIV/AIDS, and the Centers for Disease Control as a subject matter expert developing new approaches, policies, and procedures for identity management; and, has directed multiple patient matching research and innovation initiatives focus on pragmatic, real-world patient matching systems. Dr. Grannis has engaged in Federal IT standards initiatives, collaborating with Office

of the National Coordinator (ONC) and AHRQ to author patient matching position papers. Globally, Dr. Grannis collaborates with developing countries through OpenHIE (www.ohie.org) to implement identity management strategies, including establishing Rwanda's first HIE-related MPI. His recent analyses in conjunction with The Pew Charitable Trusts showed that standardizing matching variables demonstrably improves matching accuracy. Dr. Grannis' current work has focused on applying machine learning, natural language (NLP), and phenotyping methods to improve case identification and population health measurements.

Kevin Haynes is a Principal Scientist at HealthCore, Inc. He is the Principal Investigator on two Patient Centered Outcomes Research Institute (PCORI) awards and the site PI for HealthCore within the FDA Sentinel Initiative as well as a Data Core Co-Lead on Sentinel. At HealthCore, Dr. Haynes is currently responsible for developing responses to proposals and providing clinical pharmacoepidemiology expertise to various projects. Dr. Haynes has more than 14 years of experience in clinical pharmacy, clinical research, epidemiology, pharmacoepidemiology, surveillance, medical informatics, and project management. In addition, he has extensive experience collaborating with the Food and Drug Administration as well as multiple investigators on pharmacoepidemiology projects.

Adrian Hernandez is a cardiologist with extensive experience in clinical research ranging from clinical trials to outcomes and health services research. Before becoming Vice Dean for Clinical Research in 2017, he was a Faculty Associate Director and Director of Health Services and Outcomes Research at the Duke Clinical Research Institute. He is the Coordinating Center Principal Investigator for multiple networks and clinical trials such as the NHLBI's Heart Failure Research Network, PCORI's National Patient-Centered Clinical Research Network (PCORnet) and NIH's Health System Collaboratory all focused on leveraging new methods to improve clinical research and implementation of evidence into clinical practice.

Jonathan Hirsch is the Founder and President of Syapse. Jonathan works closely with healthcare providers and ecosystem partners to create products that improve patient outcomes through precision medicine. Jonathan's work includes catalyzing national cancer data sharing networks, having served on the White House Cancer Moonshot Data Sharing Working Group and the Biden Cancer Initiative Data Sharing Working Group, and chairing the Data Committee for GBM AGILE, a global initiative to find a cure for brain cancer. Before founding Syapse, Jonathan worked in neuroscience commercial development at Abbott Laboratories. Jonathan received an MSci in Neuroscience from Stanford University and an AB in Biology and Political Philosophy from the University of Chicago.

Kristijan (Kris) Kahler is Executive Director, and the Global Head of Outcomes Evidence & Analytics group within the Real World Evidence function at Novartis Pharmaceuticals. He has been at Novartis since 2001, and in his current role, he leads a team of RWE Scientists responsible for real world evidence generation across the organization; largely conducting non-interventional studies with secondary data sources. Kris has a Pharmacy degree from the University of Rhode Island, a Masters in Epidemiology from the Harvard School of Public Health, and received his Ph.D. in Epidemiology from the UMDNJ School of Public Health.

Sean Khozin is a board-certified oncologist and physician-scientist with over a decade of executive experience combining translational and clinical research with data science and health technology to address areas of high unmet need for therapeutic development. Dr. Khozin currently serves as Associate Director at FDA's Oncology Center of Excellence, managing key aspects of the approval and regulation of oncology drugs, biologics, devices, and diagnostics. Areas of focus include novel clinical trial designs, big data analytics, real world evidence, complex phenotyping, and digital biomarker development. Dr. Khozin is also the founding Director of Information Exchange and Data Transformation (INFORMED; www.fda.gov/INFORMED), FDA's first data science and technology incubator focused on developing strategic partnerships and collaborative translational and clinical research opportunities to advance therapeutic development goals consistent with the agency's public health priorities. Previously, Dr. Khozin was founder and Chief Medical Officer of a multidisciplinary healthcare delivery network, and cofounder of a health technology company specializing in building interoperable systems with telemedicine, point-of-care data visualization, and advanced analytics capabilities to optimize patient care and clinical research.

Beth Kunkoski currently works in the FDA's Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP). She oversees several projects involving digital health technologies and electronic records and storage in clinical investigations. She worked for 15 years in the Center for Devices and Radiological Health (CDRH) in guidance document development and as a branch chief overseeing the review of orthopedic devices. She earned a Master's Degree in Biomedical Engineering and a Bachelor's Degree in Chemical Engineering from the University of Michigan.

Jacqueline Law is the VP & Global Head of Personalized Healthcare Data Science at Roche. In this role, Jacqueline is leading a team of data scientists with expertise in Real-World Data (RWD), responsible for RWD strategy and implementation for late stage development, medical affairs and market access across all therapeutic areas including oncology, neuroscience, infectious disease, inflammation and ophthalmology. Jacqueline's team also comprises of imaging data scientists focusing on building imaging capabilities for Roche Pharma. Jacqueline has been with Roche/ Genentech for 16 years, having led quantitative science teams in both Pharma and DIA divisions. Jacqueline received her Ph.D. in Biostatistics from the University of California, Los Angeles.

Nicole Mahoney is the Senior Director of Regulatory Policy at Flatiron Health, helping advance the use of real world evidence for regulatory decision making. Prior to her current role, she was a Director of Global Regulatory Policy at Merck, advocating for incentives to spur antibiotic development and providing strategic input to cross-functional product teams regarding regulatory policy matters. Nicole served as the senior officer for the Pew Charitable Trusts' antibiotics and innovation project and as a U.S. Food and Drug Administration Commissioner's Fellow. She earned her Ph.D. in biochemistry at the Albert Einstein College of Medicine and was a postdoctoral fellow at the University of California, San Francisco.

Keith Marsolo is an Associate Professor in the Department of Population Health Sciences at the Duke University School of Medicine. He was previously a faculty member in the Division of Biomedical Informatics (BMI) at Cincinnati Children's Hospital Medical Center (CCHMC). Dr. Marsolo received his PhD in Computer Science from The Ohio State University. Dr. Marsolo's research interests include architectures for multi-center learning health systems and infrastructure to support the use of real-world data (RWD) sources in research. At CCHMC, Dr. Marsolo served as faculty advisor for BMI Data Services, which developed registry platforms to support learning networks. These included a configurable system for capturing summary or practice-level measures, and a "data-in-once" architecture that allowed information to be collected in the EHR and then be automatically transferred to a registry in order to support chronic care management, quality improvement and research. This architecture was extended to support a pragmatic trial funded by PCORI, and also served as the testbed for an interoperability pilot from the ONC to evaluate the time saved by embedding electronic case report forms in the EHR and pre-populating with data collected during the clinic visit compared with double data entry. Dr. Marsolo is a co-investigator in the Distributed Research Network Operations Center (DRN OC) of the PCORnet Coordinating Center, where he serves as a faculty lead for activities related to the PCORnet Common Data Model and data curation. He was a co-chair of the PCORnet's Data Standards, Security and Network Infrastructure (DSSNI) Task Force, and a member and then chair of the PCORnet Data Committee. He is also a member of the Data Quality Subcommittee of the National Evaluation System for health Technology Coordinating Center (NESTcc).

David Martin is the Associate Director for Real World Evidence Analytics, Office of Medical Policy, FDA Center for Drug Evaluation and Research. He oversees demonstration projects intended to support the agency's evaluation of real world evidence, reviews real world evidence submissions, and contributes to medical policy development mandated by the 21st Century Cures Act. He led the development of the open source FDA MyStudies mobile app. Other key focus areas include FDA-Catalyst and PCORI pragmatic trials as well as replication of clinical trial results with non-interventional study designs. As a former Branch Chief, Division Director, and Acting Deputy Office Director in the Center for Biologics Evaluation and Research, Dr. Martin led analyses of spontaneous reports, formalized risk management planning, and helped develop the Sentinel system. He also served on detail as the FDA Liaison to the European Medicines Agency. Before joining the FDA, Dr. Martin practiced flight and occupational medicine in the U.S. Air Force. He completed his undergraduate degree at the Citadel and his M.D. and M.P.H. at the Johns Hopkins University. He is board certified in occupational medicine and clinical informatics.

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Duke-Margolis Center is a university-wide, interdisciplinary initiative that is nationally and internationally recognized for its research, evaluation, implementation, and educational initiatives to improve health and health policy. The Center integrates Duke's expertise in the social, clinical, and analytical sciences with health care leader and stakeholder engagement to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a physician and an economist who has informed and improved a wide range of strategies and policy reforms to advance 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. 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. With highly distinguished record in public service and academic research, Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These reforms 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 previously served as a member of the President's Council of Economic Advisers, senior director for health care policy at the White House, and Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA and a member of the National Academy of Medicine (NAM), where he chairs the Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He is also a Senior Advisor on the faculty of the University of Texas Dell Medical School and co-chair of the Accountable Care Learning Collaborative. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, and Alignment Healthcare. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

Andrew Norden is the Chief Medical Officer of COTA, where he leads COTA's medical and scientific activities. He is responsible for the quality and reliability of COTA's data curation operation and oversees research partnerships with academia, industry, non-profit organizations, and government agencies. Dr. Norden is a neuro-oncologist who practiced clinically for 10 years and was involved in the design and execution of dozens of clinical trials and observational studies. Prior to COTA, he worked for IBM Watson Health as well as Dana-Farber Cancer Institute in several capacities, including Associate Chief Medical Officer. Dr. Norden attended the Yale School of Medicine, conducted his residency training at Massachusetts General and Brigham and Women's Hospitals, and completed a neuro-oncology fellowship at Dana-Farber, Massachusetts General and Brigham and Women's Hospitals. He also earned an MPH degree from Harvard School of Public Health, an MBA from the University of Massachusetts, Amherst, and received his undergraduate degree in neuroscience from Brown University.

Lucinda Orsini is currently Associate Chief Science Officer at ISPOR, the leading professional society for health economics and outcome research. The science office at ISPOR develops, leads, and supports strategic initiatives related to research, scientific, and content priorities. While Lucinda holds a professional medical degree, she has spent most of her ~20-year career in health economics and outcomes research. Starting at The Medstat Group (Truven Health Analytics) Lucinda managed projects using health care claims data for external clients. She has worked in the pharmaceutical industry at Bristol-Myers Squibb and subsidiaries in Global HEOR focused on oncology and immunotherapy leading and publishing on patient reported outcomes, health economic modeling and real-world evidence studies – both prospective and retrospective in many different tumor types. Lucinda has recently led HEOR efforts at PAREXEL a full-service contract research group prior to coming to ISPOR.

Ernesto Ramirez is a Senior Data Scientist 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 data science 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 person-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.

John Reites is the Chief Product Officer at THREAD. Executive intrapreneur turned digital health entrepreneur, his career includes 16+ years leading global drug development and healthcare innovation. As Chief Product Officer at THREAD, he leads their efforts to modernize clinical research for participants, sites and study stakeholders. THREAD was acquired by JLL Partners and Water Street Healthcare in Sep-2019 and continues to focus on decentralizing clinical research via our technology platform and supporting services. Named one of the Top 100 Influencers in Digital Health, he also provides expertise and execution experience in digital health strategy, remote patient research, virtual clinical trials, Phase I - IV clinical research, patient reported outcomes, patient engagement, mobile health and omni-channel experiences. He enjoys being a keynote speaker at global industry events, guest lecturer at Duke University on digital health/innovation and a published author featured in various conferences, journals, articles and media outlets. Let's connect on LinkedIn and Twitter.

Wendy Rubinstein serves as Deputy Medical Director of CancerLinQ® where she leads the genomics strategy and contributes to research oncology, clinical data quality, and strategic vision. CancerLinQ, an initiative of the American Society of Clinical Oncology (ASCO), is a web-based platform that collects and analyzes structured and unstructured real-world cancer data from multiple electronic health record systems to improve care and drive new research. Dr. Rubinstein directed academic cancer genetics programs for 15 years at three NCI-designated Comprehensive Cancer Centers, most recently at the University of Chicago Medical Center. As a Senior

Scientist at the National Institutes of Health, Dr. Rubinstein launched and directed the NIH Genetic Testing Registry (GTR), now the most comprehensive publicly available information resource about genomic tests in the world, for which she received the NIH Director's Award from Dr. Francis Collins. Dr. Rubinstein worked closely with the NIH Office of the Director on interagency issues and served as a representative to the NIH-FDA-CMS Trilateral Genomic Medicine Workgroup. As Chief of Medical Genetics and Human Variation at the National Center for Biotechnology Information (NCBI), she was responsible for flagship resources including ClinVar, dbSNP, dbGaP, and GTR. An NIH Medical Scientist Training Program scholarship awardee, Dr. Rubinstein earned her MD and PhD degrees at the Icahn School of Medicine at Mount Sinai in New York City. She holds dual board certification in clinical genetics and clinical molecular genetics and is a Fellow of the American College of Medical Genetics (FACMG) and the American College of Physicians (FACP). Dr. Rubinstein has authored publications on health information technology, clinical practice guidelines, gene discovery, sequence variant interpretation, genomic population screening, computerized familial risk assessment, pharmacogenomics, genetic risk modifiers, and genomic information resources.

Patrick Ryan is Senior Director of Epidemiology and the Head of Epidemiology 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 currently a 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.

Sebastian Schneeweiss 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 the comparative effectiveness and safety of biopharmaceuticals. He has developed analytic methods to improve the scientific validity of epidemiologic analyses using complex longitudinal healthcare databases for newly marketed medical products. The overarching theme of his research is applying advanced real-world data analytics for regulatory decision making transparently and in rapid cycles. His work is published in more than 400 articles. His work is funded by NIH, PCORI, Arnold Foundation, IMI, and FDA where he is also a voting consultant. Dr. Schneeweiss is Director of the Harvard-Brigham Drug Safety Research Center funded by FDA/CDER and Methods Lead of the FDA Sentinel program. He is Past President of the International Society for Pharmacoepidemiology and is Fellow of the American College of Epidemiology, the American College of Clinical Pharmacology, and the International Society for Pharmacoepidemiology. He received his medical training at the University of Munich Medical School and his doctoral degree in Pharmacoepidemiology from Harvard.

Kristin M. Sheffield is a Research Advisor in the Center of Expertise within the Global Patient Outcomes and Real-World Evidence organization at Eli Lilly and Company. In this role, she develops RWE strategy for oncology, consults with cross-functional partners, advances internal data and analytic capabilities to generate RWE, and leads and supports RWE studies and methods research in oncology. Prior to joining Eli Lilly and Company, Dr. Sheffield was an Assistant Professor in the Department of Surgery at the University of Texas Medical Branch (UTMB) in Galveston, Texas. Her research focused primarily on processes and outcomes of surgical care and the trajectory of cancer care in older adults, and also explored methods to adjust for confounding in comparative effectiveness research studies using observational data. Dr. Sheffield received her PhD in Population Health Sciences, with an emphasis in social epidemiology, from UTMB.
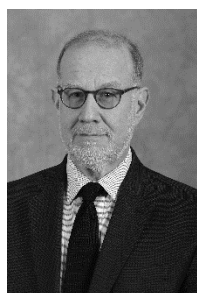
Peter Stein is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters. A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience. Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.
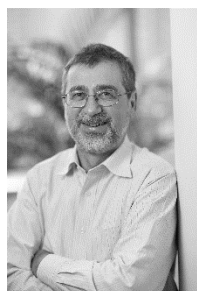
Til Stürmer's career as a medical researcher started with assessing the role of analgesics on kidney function and mortality, which culminated in a paper in the New England Journal of Medicine. After his formal training in epidemiology at Harvard School of Public Health, he continued pharmacoepidemiologic research with analyses of the role of nonsteroidal anti-inflammatory drugs (NSAIDs) and aspirin on cognitive function, risk for colorectal cancer (CRC), and kidney function. Since 2003, he has focused on pharmacoepidemiology, developing and implementing methods to improve validity of nonexperimental research on the effects of medical interventions on clinically relevant outcomes based on real world data (mostly: US Medicare). He is the Nancy A. Dreyer Distinguished Professor and Chair of the Department of Epidemiology, UNC Gillings School of Global Public Health. As former Director of the Center for Pharmacoepidemiology and past President of the International Society for Pharmacoepidemiology, he is very glad to have been able to assemble an outstanding interdisciplinary team of researchers with expertise in epidemiology, pharmacoepidemiology, internal medicine, geriatrics, and biostatistics from within and outside of UNC to advance our methodologic armamentarium to provide valid evidence for relative benefit and harm of clinically relevant treatment alternatives in older adults. Funded by the National Institute on Aging (R01 AG023178, now R01 AG056479) since 2005, the research team published over 100 papers focusing on developing and implementing novel methods to answer clinical questions of importance to older adults in the absence of alternative evidence.

Nancy Yu is the CEO and Co-founder of RDMD, a medical data science company that helps to identify patients & generate data to enable regulatory submissions and real world evidence in rare disease. Prior to RDMD, Nancy was the Head of Corporate Development at 23andme, where she worked on business strategy and operations for the therapeutics and next-generation sequencing divisions. Prior to 23andme, Nancy was a biotechnology investment banker on Wall Street and a consumer healthcare private equity investor. Nancy started her career in research at the University of Pennsylvania, where she received a dual degree in Biology and Finance from the Wharton School of Business.