Data Quality and Missing Data in Patient-Centered Outcomes Research Using EMR/Claims Data

PCORI Workgroup Meeting
December 10, 2015
1828 L St. NW #900, Washington, DC 20036

Meeting Participants:

Alan Brookhart is Associate Professor of Epidemiology at the UNC Gillings School of Global Public Health. His research focuses on the development and application of epidemiological methods for observational studies of medications using large healthcare databases. He is particularly interested in two related areas: 1) understanding the determinants of physician prescribing and patient adherence and 2) detecting and controlling confounding bias in comparative effectiveness studies of medications.

Jeff Brown is an Associate Professor and Director of Scientific Systems in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is Research Director of the Therapeutics Research and Infectious Disease program at DPM and Associate Director of the FDA's Mini-Sentinel project. Dr. Brown is a health services researcher with expertise in pharmacoepidemiology and drug safety, with primary research activities involving the development of new methodologies and techniques to facilitate multi-institutional drug and vaccine safety surveillance using automated healthcare administrative and claims data, including the application of sequential analytic and data mining methodologies. Dr. Brown is the lead architect of PopMedNet (www.popmednet.org), an open-source software platform that facilitates the creation and operation of large-scale distributed health data networks. He is co-chair of the Informatics Core of the NCI Cancer Research Network and of the EHR Core of the NIH Health Care System Research Collaboratory. Dr. Brown holds a Master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University.

Michael D. Buck, PhD, is the Senior Director of Biomedical Informatics for the Primary Care Information Project in the NYC Department of Health and Mental Hygiene. He is also an Associate Research Scientist in the Department of Biomedical Informatics at Columbia University. His professional interests include healthcare analytics, health information exchange, clinical research informatics, EHR pay-for-performance initiatives, syndromic surveillance, clinical decision support, and small-practice EHR implementation. Dr. Buck completed his PhD in Biomedical Informatics at the University of Utah, School of Medicine and his postdoctoral fellowship at Columbia University. His work has received a number of awards including the 2012 1st place Innovator Award featured in *Healthcare Informatics* magazine, the 2011 HIMSS Public Health Davies Award of Excellence, and the 2011 Best Application Serving the Public, New York City Excellence in Technology Awards Program.

Elizabeth Chrischilles is Professor and Marvin A. and Rose Lee Pomerantz Chair in Public Health, Director, Health Effectiveness Research Center at the University of Iowa College of Public Health.

Lesley H. Curtis, PhD, is a Professor in medicine at the Duke University School of Medicine and directs the Center for Pragmatic Health Systems Research in the Duke Clinical Research Institute. A health services researcher by training, Dr. Curtis oversees a portfolio of projects that use observational data to address questions related to clinical and comparative effectiveness, pharmacoepidemiology, healthcare delivery, and epidemiological trends across a broad array of clinical conditions and clinical care settings. An expert in the use of Medicare claims data for health services and clinical outcomes research, she has led the linkage of Medicare claims with several large clinical registries and epidemiological cohort studies including the Framingham Heart Study and the Cardiovascular Health Study. Dr. Curtis serves on the American Heart Association/American College of Cardiology Task Force on Practice Guidelines and on the American Heart Association's Task Force on Performance Measures, working to continuously improve the incorporation of evidence into healthcare delivery. Additionally, she serves as Co-Lead of the Data Core for the FDA's Sentinel Initiative, Co-PI of the NIH Health Care Systems Collaboratory, and Co-Lead of the Distributed Research Network Operations Center for PCORI's National Clinical Research Network (PCORnet), working with health systems and patient networks to develop a harmonized data infrastructure for robust observational and interventional research.

David Dore is a pharmacoepidemiologist and Adjunct Assistant Professor, Health Services, Policy and Practice. His full-time position is as Vice President, Epidemiology, and Principal Epidemiologist at Optum. Dore received a PharmD from the University of Rhode Island, a PhD in epidemiology from Brown Medical School, and completed a post-doctoral fellowship at the Center for Gerontology and Health Care Research at Brown University. Dore's main research interest is the study of drug effects, with applications to drug safety and comparative effectiveness research. In most of his work, he has used health plan claims data that have been supplemented through data linkages. His methodological expertise covers topics related to studying medical interventions in the setting of non-randomized treatment groups and incomplete data (i.e., claims data).His clinical areas of interest are diabetes mellitus, cardiovascular disease, aging, and mental health. Recently, Dore has done a number of studies on the safety of newer antidiabetic medications (incretin-based drugs).

Jessica Franklin, PhD, is an Assistant Professor of Medicine at Harvard Medical School and biostatistician in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. Her research focuses on developing and applying statistical methods for the study of medicines, including comparative effectiveness and adverse effects of drugs, the consequences of drug policy, and drug utilization. Her methodological interests are in causal inference and hierarchical modeling. Dr. Franklin received her bachelor's degree in mathematics at the University of Georgia and her doctorate in biostatistics at the Johns Hopkins Bloomberg School of Public Health.

Frank Harrell received his PhD in Biostatistics from UNC in 1979. Since 2003, he has been Professor of Biostatistics, Vanderbilt University School of Medicine, and the department chairman. He is Associate Editor of *Statistics in Medicine*, a member of the Scientific Advisory Board for Science Translational Medicine, a member of the Faculty of 1000 Medicine, and a member of the policy advisory board for the Journal of Clinical Epidemiology. He is a Fellow of the American Statistical Association and winner of the Association's WJ Dixon Award for Excellence in Statistical Consulting for 2014. His specialties are development of accurate prognostic and diagnostic models, model validation, clinical trials, observational clinical research, cardiovascular research, technology evaluation, pharmaceutical safety, Bayesian methods, quantifying predictive accuracy, missing data imputation, and statistical graphics and reporting.

Robert Glynn is Professor in the Department of Biostatistics at Brigham & Women's Hospital and Professor of Medicine (Biostatistics) at Harvard Medical School. Dr. Glynn's research focuses on clinical questions, primarily in aging and vision, and on methodological approaches to address questions in these areas. His recent work in aging has focused on trends in the use of alternative antihypertensive drugs, factors associated with the choice of therapies and clarification of the association of blood pressure with mortality. Methodological issues arising in this research have included problems with missing data and measurement error, which have particular manifestations and are often especially severe in studies of the elderly. Dr. Glynn's research in vision has included studies of contact lenses and corneal ulcers, progression of diabetic retinopathy, determinants of the development of cataract, and utilization and side effects of treatments for glaucoma. His methodological research related to vision has concentrated on methods for the evaluation of paired data and identification of situations when the eye, rather than the patient, is the more appropriate unit of analysis.

Michael Kahn is Professor of Epidemiology (with tenure) in the Department of Pediatrics at the University of Colorado Denver; Co-Director of the Colorado Clinical and Translational Sciences Institute (CCTSI); Biomedical Informatics core director for the CCTSI; and Director of Research Informatics in the Research Institute at Children's Hospital Colorado. Dr. Kahn is responsible for a campus-wide clinical and research data warehouse that combines data from four clinical, financial, and research institutions. Dr. Kahn was the informatics lead for the AHRQ-funded SAFTINet distributed clinical research network and currently is the informatics co-PI for two PCORI national clinical data research networks (PEDSnet and PORTAL). His informatics research focus area is developing well-defined measures of data quality that can be used to evaluate the fitness for use of data from data partners participating in distributed research networks.

Harold P. Lehmann, Professor and Director of the Division of Health Sciences Informatics, Pediatrics, and Health Policy and Management, is a board-certified general pediatrician from Columbia University and Babies Hospital, with general pediatric fellowship training from Johns Hopkins and doctoral informatics training from Stanford. His research concerns evidence-based medicine (EBM), ranging from authoring reports to researching novel methods of delivering research results to opinion leaders and practitioners. He has served as a methodologist on a number of professional-society guidelines and has demonstrated the use of advanced decision-analytic methods in guideline development. His current work focuses on the informatics infrastructure of research, including research informatics support, ontologies for human studies and for appropriate inference from electronic health records, on sustaining resources for community health workers, and on human (social) services informatics. In addition, he leads the Johns Hopkins efforts in informatics training across all three schools of health sciences, and is the faculty lead for the Informatics Core of the PaTH PCORNet node at Johns Hopkins. He has served as an Associate Editor for the *Journal of the American Medical Informatics Association* since 2011. He was elected a Fellow of the American College of Medical Informatics in 2006.

Rod Little is a Richard D. Remington Distinguished University Professor, Biostatistics Department Professor, and Statistics Department Research Professor at the Institute for Social Research at the University of Michigan.

Laura Qualls is a Senior Research Manager at Duke Clinical Research Institute. She holds a Master's in Health Administration and has more than 15 years of experience in health analytics. She has extensive

experience in using Medicare and private insurance claims data for quality improvement, program evaluation, and health outcomes research, and has recently begun working with electronic health data. In her current role, she supports the data characterization/data quality efforts for the PCORnet Coordinating Center.

Keith Marsolo is an Associate Professor in the Division of Biomedical Informatics (BMI) at the Cincinnati Children's Hospital Medical Center (CCHMC). His research interests include methods to characterize the quality and suitability of electronic health record (EHR) data, approaches to collect and extract research data from the EHR at scale, the design and instantiation of common data models to facilitate distributed research queries, and the development of informatics architectures and standards that can support multi-center learning health systems. Dr. Marsolo serves as faculty advisor for BMI Data Services. This group is heavily involved in supporting the multi-center leaning networks that are affiliated with CCHMC and includes the development of registries that allow data to be collected in the EHR and then reused for improvement, care management, and research. Dr. Marsolo led the implementation of Cincinnati Children's research data warehouse, which utilizes a custom version of the open-source i2b2 framework. He is involved in two projects within the National Patient-Centered Clinical Research Network (PCORnet), a pediatric-focused Clinical Data Research Network (PEDSnet CDRN), and a Patient-Powered Research Network (PPRN) with the ImproveCareNow Network. Dr. Marsolo served as one of the co-chairs of the PCORnet's Data Standards, Security, and Network Infrastructure (DSSNI) Task Force during the first phase of PCORnet. Dr. Marsolo earned a bachelor's in computer science and engineering, a master's in biomedical engineering and in computer and information science, and a PhD in computer and information science, all from The Ohio State University.

Daniella Meeker, PhD, is an Assistant Professor of Preventive Medicine at University of Southern California and Adjunct Information Scientist at the RAND Corporation. She directs the Informatics Program in the Southern California Clinical Translational Sciences Institute and is a Professor at the Pardee RAND Graduate School. Her engineering research focuses on distributed architectures supporting integration of research, data analysis, and practice. Her data policy research includes investigations in how to improve the safety of health information technology and clinical quality measurement. Other projects have included development of collaborative platforms for knowledge management, machine learning, and health and behavioral economics. Dr. Meeker has been actively committed to PCORnet's data and technical infrastructure as a member of the PCORnet Common Data Model Working Group and the Sentinel-PCORnet working group. Along with other members of these groups, she has led PCORnet CDM implementation forums, and co-authored presentations and public commentary on proposed federal rules and the interoperability roadmap. Dr. Meeker earned her PhD in Computation and Neural Systems from the California Institute of Technology.

Jeremy A. Rassen, ScD, is an Assistant Professor of Medicine at Harvard Medical School and Director of Computational Pharmacoepidemiology in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. In 2008, he completed a doctoral program at the Harvard School of Public Health, in which his thesis work centered on methods development and applications of instrumental variables (IV) in pharmacoepidemiology. He also has an extensive background in computer science, large database systems, and systems performance. Dr. Rassen's current research seeks to extend his IV work into specific disease areas, and to continue work on epidemiology-specific extensions to IVs. He also examines questions involving the use of computer science techniques in epidemiology, with particular focus on database integration, preservation of privacy, and epidemiologic analyses that span cohorts and databases. He graduated cum laude in

computer science from Harvard College in 1995, after which he worked for 10 years in Silicon Valley. He received a master's degree in epidemiology from Harvard School of Public Health in 2006, and a doctorate in 2008. His master's program was supported by the Winokur Fellowship.

Shelley Rusincovitch is a Project Leader in Applied Informatics & Architecture with the Duke Translational Research Institute (DTRI). She brings a highly technical background, research expertise, and data-centric perspective from more than 12 years with Duke Medicine. Her experience as a database programmer includes clinical trials, outcomes registries, and health system data warehousing. Rusincovitch's responsibilities include leading development of the PCORnet Common Data Model (CDM), fostering collaborative learning in the PCORnet CDM Implementation Forum, and serving as a technical lead for the Southeastern Diabetes Initiative (SEDI). With these and other collaborations, she works closely with investigators and technical teams to facilitate the translation of research initiatives into methodology, system design, and technical implementation. She received her BM in Music Performance from Miami University of Ohio, her AAS in Computer Programming from Durham Technical Community College, and is a part-time graduate student with the MPS in Biomedical and Health Informatics at the University of North Carolina at Chapel Hill. Her current areas of concentration are data modeling, datamart development, and architectural design for secondary use of EHR data.

John D. Seeger, PharmD, DrPH, is a pharmacoepidemiologist and chief scientist at Ingenix/i3 Drug Safety, where he has conducted dozens of studies that have addressed regulatory drug safety issues across a wide range of drugs and disease conditions. Most of this work has involved the use of health insurance claims databases as platforms for pharmacoepidemiology, so Dr. Seeger's methodologic expertise focuses on research issues encountered in such settings. He has worked extensively with propensity scores and related methods that seek to mitigate confounding by collapsing covariates, and he is a co-instructor in courses on propensity scores and pharmacoepidemiology at Harvard TH Chan School of Public Health. He has authored or co-authored dozens of articles in the peer-reviewed medical literature.

Nigam Shah is Associate Professor of Medicine (Biomedical Informatics) at Stanford University, Assistant Director of the Center for Biomedical Informatics Research, and a core member of the Biomedical Informatics Graduate Program. Dr. Shah's research focuses on combining machine learning and prior knowledge in medical ontologies to enable use cases of the learning health system. Dr. Shah received the AMIA New Investigator Award for 2013 and the Stanford Biosciences Faculty Teaching Award for outstanding teaching in his graduate class on "data driven medicine" (Biomedin 215). Dr. Shah was elected into the American College of Medical Informatics (ACMI) in 2015. He holds an MBBS from Baroda Medical College, India, a PhD from Penn State University, and completed postdoctoral training at Stanford University. More at: https://med.stanford.edu/profiles/nigam-shah

Susan Shortreed's research brings together statistics and machine learning methods to address health science problems, with a special emphasis on analyzing complex longitudinal data and overcoming missing-data challenges. Much of her methodological work is focused on developing and evaluating statistical inference approaches for observational data, such as data from electronic healthcare records or from randomized clinical trials with missing information. Dr. Shortreed is also interested in developing new machine learning methods and extending current best-practice methods, specifically for personalized dynamic treatment strategies, clustering, and model selection methods. Dr. Shortreed earned her PhD in statistics from the University of Washington in 2006. After completing her degree, she spent two years in the Department of Epidemiology and Preventive Medicine at Monash University in Melbourne, Australia, and two years in the School of Computer Science at McGill University.

Til Stürmer, MD, MPH, PhD, is Professor, head of the Pharmacoepidemiology Program, and Director of the Center for Pharmacoepidemiology in the Department of Epidemiology at the University of North Carolina at Chapel Hill Gillings School of Global Public Health. He is also the Director of the Comparative Effectiveness Research (CER) Strategic Initiative, NC TraCS Institute, UNC Clinical and Translational Science Award (CTSA). Dr. Stürmer has a dual focus in epidemiologic methods and clinical epidemiology. His research in epidemiologic methods includes the development of more efficient matching strategies in genetic epidemiology; measurement error correction methods in case-control studies; the value of propensity and disease risk scores for pharmacoepidemiologic studies; the use of validation studies for external control for confounding; and the value of active comparator, new user cohort designs to increase validity of nonexperimental studies of medical interventions. His research in clinical epidemiology covers many topics, including nephro- and cardiovascular toxicity of paracetamol and non-steroidal anti-inflammatory drugs; chemoprevention of colorectal cancer and dementia with non-steroidal anti-inflammatory drugs; determinants of antibiotic resistance; hormone therapy, pain, and sub-clinical inflammation in osteoarthritis; and cardiovascular and cancer outcomes in patients treated with antidiabetics. sturmer@unc.edu; til.sturmer@post.harvard.edu

Jessica Sturtevant is a Senior Research Associate in the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. She has over 10 years of experience in epidemiology and research as well as a Master of Science in Epidemiology Methods from the Harvard TH Chan School of Public Health. Sturtevant is experienced in use and implementation of distributed research networks, analytic programming languages, secondary use of healthcare data, and project coordination and documentation.

Zhaohui Su is Senior Director of Biostatistics at Quintiles Real World & Late Phase Research and is responsible for conducting biostatistical activities in support of the design and completion of observational studies of comparative effectiveness and safety, as well as other observational pharmacoepidemiologic and outcomes research. Before Dr. Su joined Quintiles in 2009, he was Head of the Optimization of Antiretroviral Therapy Section, Department of Biostatics, Harvard School of Public Health (HSPH), Chair of the Design and Analysis Review Committee at HSPH, and lead statistician for observational studies and retrospective data analysis of studies conducted by the AIDS Clinical Trials Group. Dr. Su has served as an independent statistical consultant assisting study design, data analysis, grant application, and publication, and has been a statistical reviewer for multiple medical journals. His statistical expertise is in the area of predictive modeling, regression analysis for categorical, continuous and survival data, and applying novel statistical methods to observational studies.

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 comparative safety and effectiveness research of medical products. His research has been focused on 1) assessing the risks and benefits of therapeutics, especially in vulnerable populations such as pregnant women, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks. Darren is Director of Applied Surveillance for the FDA-funded Sentinel program. He received his doctoral degree in epidemiology from the Harvard School of Public Health.

James Topping is an informaticist for the Small Trials Program at the Duke Translational Medicine Institute.

Mark Weiner, MD, works to bridge the gap between health services research, clinical and research operations, and medical informatics. A practicing clinician in General Internal Medicine who completed training as both a VA General Medicine Fellow and a National Library of Medicine fellow in applied informatics, he focuses on adapting routinely collected clinical and administrative data for research purposes and improved quality of care. At Penn, he served as the Director for Information Systems Integration for Research within the Office of Human Research and Co-Chief of the Biostatistics and Informatics Core of the VA Center for Health Equity Research and Promotion. He served as a Data Core Co-Chair for the FDA Mini-Sentinel initiative, where he helped to develop consensus across a wide group of insurance industry data partners on a common data model used by the FDA to detect adverse drug events. He served as a Senior Director for Clinical Research Informatics within the Research and Development Information group at AstraZeneca, where he helped the company leverage clinical and administrative data to design more efficient clinical trials, and understand the landscape of disease and existing therapies to better position its own medications in the marketplace. He is currently the Assistant Dean for Informatics at the Temple University School of Medicine, charged with developing a curriculum to support the needs of the next generation of Clinical and Research Informatics leaders. He is also the Chief Medical Information Officer for the Temple University Health System, overseeing the clinical aspects of the inpatient Epic implementation, ensuring it achieves its goals of supporting the clinical and academic missions of the institution.

PCORI Methodology Committee Members:

Cynthia Girman, DrPH, FISPE, is President and sole proprietor of CERobs Consulting, LLC, which provides consulting on study design and methodology for comparative effectiveness research and real-world randomized pragmatic clinical trials as well as the development and validation of patient-reported outcomes. Previously, Dr. Girman was Executive Director and Head of Data Analytics & Observational Methods in the Center for Observational & Real World Evidence at Merck Research Laboratories, from which she retired after 33 years. She founded the Merck Center of Excellence on the development and validation of endpoints for clinical trials, including patient-reported outcomes, and her work has focused on incorporating patient input into clinical trials endpoint identification. With experience in biostatistics, epidemiology, and observational research methods, Dr. Girman has been involved in a range of collaborative methodology research activities with universities in the United States and Europe. She is adjunct Associate Professor and serves on the Scientific Advisory Board for the Center for Pharmacoepidemiology at the University of North Carolina, and a fellow of the International Society for Pharmacoepidemiology. Dr. Girman received an MS in Applied Statistics and Computer Science from Villanova University, and a DrPH. in Biostatistics/Epidemiology from the School of Public Health at the University of North Carolina.

Steven Goodman, MD, MHS, PhD, (Vice Chair), is Associate Dean for Clinical and Translational Research at the Stanford University School of Medicine. Previously, he was Professor of Oncology, Pediatrics, Epidemiology and Biostatistics, Johns Hopkins School of Medicine and Bloomberg School of Public Health. He has been a member of the Division of Biostatistics and Bioinformatics in the Johns Hopkins Sidney Kimmel Cancer Center since 1989. He is Editor-in-Chief of *Clinical Trials: Journal of the Society for Clinical Trials* and is senior statistical editor for *Annals of Internal Medicine*, where he has worked since 1987. He serves as scientific co-advisor of the Medical Advisory Panel of the Blue Cross – Blue Shield Technology Assessment Program. Dr. Goodman is currently co-chair of the Institute of Medicine's Committee on Ethical and Scientific Aspects in Studying the Safety of Approved Drugs. He received an

AB from Harvard University, an MD from New York University School of Medicine, and an MHS in Biostatistics and PhD in Epidemiology from Johns Hopkins Bloomberg School of Public Health.

Sally C. Morton is Professor and Chair of the Department of Biostatistics in the Graduate School of Public Health, and Director of the Comparative Effectiveness Research Center in the Health Policy Institute at the University of Pittsburgh. Previously, she was Vice President for Statistics and Epidemiology at RTI International and Head of the RAND Statistics Group. Her research focuses on evidence synthesis. Dr. Morton is a member of the Patient-Centered Outcomes Research Institute (PCORI) Methodology Committee and a past president of the American Statistical Association. She received a PhD in statistics from Stanford University.

David O. Meltzer, MD, PhD, is Chief of the Section of Hospital Medicine, Director of the Center for Health and the Social Sciences (CHeSS), Chair of the Committee on Clinical and Translational Science, and Associate Professor in the Department of Medicine, Department of Economics and the Harris School of Public Policy Studies at the University of Chicago. His research explores problems in health economics and public policy with a focus on the theoretical foundations of medical cost-effectiveness analysis and the cost and quality of care, especially in teaching hospitals. He is an elected member of the American Society for Clinical Investigation, and serves on the Secretary's Advisory Committee for Healthy People 2020, as an Advisor to the Congressional Budget Office, and on the council of the National Institute for General Medical Studies. He received a BS from Yale, and an MD and PhD in Economics from the University of Chicago.

Sebastian Schneeweiss, MD, ScD, is Associate Professor of Medicine and Epidemiology at Harvard Medical School and Vice Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital. He is Principal Investigator of the DEcIDE Research Center on Comparative Effectiveness Research funded by AHRQ and PI of the Harvard-Brigham Drug Safety Research Center funded by FDA. His research focuses on the comparative effectiveness and safety of biopharmaceuticals and analytic methods to improve the validity of epidemiologic studies using complex healthcare databases. Dr. Schneeweiss is 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 is voting consultant on the FDA Drug Safety and Risk Management Advisory Committee and member of multiple scientific advisory boards.

Adam Wilcox, PhD, is Director of Medical Informatics at Intermountain Healthcare in Salt Lake City, Utah, where he leads clinical decision support activities and efforts in using health information technology to support primary care and integrated care management. Dr. Wilcox's previous positions include Associate Professor in the Department of Biomedical Informatics at Columbia University and Director of Clinical Databases at New York Presbyterian Hospital, where he was the initial principal investigator for the Washington Heights/Inwood Informatics Infrastructure for Comparative Effectiveness Research Project. He also directed the clinical data warehouse, the clinical data repository, the legacy electronic health record, and a local health information exchange. Dr. Wilcox holds his PhD in Medical Informatics from Columbia University.

PCORI Staff:

Harold (Hal) Sox, MD, is Director of Research Portfolio Development and the Interim Chief Science Officer at the Patient-Centered Outcomes Research Institute (PCORI). Working closely with program directors, he is responsible for the development of PCORI's research portfolio. He also is a Program Officer within the Clinical Effectiveness Research Program.

Jason Gerson, PhD, is the Associate Director for Comparative Effectiveness Research (CER) Methods and Infrastructure team at the Patient-Centered Outcomes Research Institute (PCORI). He is responsible for providing intellectual and organizational leadership in designing and implementing new CER methods and infrastructure initiatives, evaluating proposals, and monitoring programs and grants.

Rachael Fleurence, PhD, is Program Director of the CER Methods and Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORI). In this role, she leads the research prioritization initiative to help identify important patient- and stakeholder-generated questions and establish a rigorous research prioritization process to rank these questions.

Katherine McQueston, MPH, is a Senior Program Associate for CER Methods and Infrastructure at the Patient-Centered Outcomes Research Institute (PCORI).

Andrea Heckert, PhD, MPH, is a Program Officer for the CER Methods and Infrastructure team at the Patient-Centered Outcomes Research Institute (PCORI). Before joining PCORI, Heckert was at The George Washington University, where she directed an NIMH-funded, multi-phased, mixed-methods study investigating individual and neighborhood-level stressors and resilience on the HIV sexual risk and protective behaviors of black men in Washington, DC.

Emily Evans, PhD, MPH, is a Program Officer for the Comparative Effectiveness Research (CER) Methods and Infrastructure team at the Patient-Centered Outcomes Research Institute (PCORI). Before joining PCORI, Evans worked on a number of projects related to research methodology and causal inference. She served as a consultant to the Institute of Medicine (IOM) Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs, where she contributed to the development of recommendations for improved practices in the generation and evaluation of evidence and research ethics.

Thomas Caruso, PhD, MBA, PMP, is Associate Director, Program Operations, for the CER Methods and Infrastructure team at the Patient-Centered Outcomes Research Institute (PCORI). He provides oversight for PCORnet, the National Patient-Centered Clinical Research Network.

Maryan Zirkle, MD, MS, MA, is a Program Officer in the CER Methods and Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORI). She is responsible for providing intellectual and organizational support for the development and regulation of PCORI's National Patient-Centered Clinical Data Research Network.

Yen-pin Chiang, PhD, is the Associate Program Director of the Clinical Effectiveness Research program at the Patient-Centered Outcomes Research Institute (PCORI). His primary responsibilities are to assist the program director in the implementation of strategic objectives and direction, contribute to the program's portfolio development, and identify and build new partnerships in facilitating the execution of all scientific program activities.

Stanley Ip, MD, is a Senior Program Officer for Clinical Effectiveness Research at the Patient-Centered Outcomes Research Institute (PCORI). His primary responsibility is to help implement and manage the Clinical Effectiveness Research program.