Building Data Capacity for Patient-Centered Outcomes Research:
An Agenda for 2021 to 2030

Workshop 2: Data Standards, Methods, and Policy

Biographical Sketches of Speakers and Moderators

JULIA ADLER-MILSTEIN (NAM) is a Professor of Medicine and Director of the Center for Clinical Informatics and Improvement Research (CLIIR) at the University of California, San Francisco (UCSF). She spent six years on the faculty at University of Michigan prior to joining UCSF. Dr. Adler-Milstein is a leading researcher in health IT policy, with a specific focus on electronic health records and interoperability. She has examined policies and organizational strategies that enable effective use of electronic health records and promote interoperability. She is also an expert in EHR audit log data and its application to studying clinician behavior. Her research – used by researchers, health systems, and policymakers – identifies obstacles to progress and ways to overcome them. She has served on an array of influential committees and boards, including the NHS National Advisory Group on Health Information Technology, the Health Care Advisory Board for Politico, and the Interoperability Committee of the National Quality Forum. Dr. Adler-Milstein holds a Ph.D in Health Policy from Harvard University.

DON EUGENE DETMER (NAM) is Professor of Medical Education at the University of Virginia. He has served as Vice-President for Health Sciences at the Universities of Virginia and Utah, as the Dennis Gillings Professor for Health Management at Cambridge, as President/CEO of the American Medical Informatics Association, and as Medical Director of Policy for the American College of Surgeons. Professorial appointments have included University Professor of Health Policy, Professor of Surgery, Business Administration, Public Health Sciences, Preventive Medicine plus Visiting Professor at University College London. He is past chair of the Board of Regents of the National Library of Medicine, the National Committee on Vital and Health Statistics, the National Academies of Sciences, Engineering, and Medicine Board of Health Care Services, and Blue Ridge Academic Health Group, which he founded. Current boards include the Corporation for National Research Initiatives, the American College of Medical Informatics, and the International Academy of Health Sciences Informatics. Dr. Detmer helped envision the national health information infrastructures of the U.S. and Hong Kong as well as shaped policy for direct electronic communications of health records with patients in the U.S. and Europe. He earned an MA from Cambridge University and an MD from the University of Kansas. He completed post-graduate training at Johns Hopkins University, the National Institutes of Health, Duke Medical Center and Harvard Business School.

DEBORAH ESTRIN (NAE/NAM) is professor of computer science at Cornell Tech, where she also holds the Robert V. Tishman founder's chair. She also serves as associate dean for impact, as an affiliate at Weill Cornell Medicine, and as an Amazon scholar. Dr. Estrin's research activities include technologies for caregiving, immersive health, small data, participatory sensing, and public interest technology. Before joining Cornell University, she was founding

director of the NSF Center for Embedded Networked Sensing at UCLA, pioneering the development of mobile and wireless systems to collect and analyze real-time data about the physical world. She co-founded the non-profit startup, Open mHealth, and has served on several scientific advisory boards for early-stage mobile health startups. Dr. Estrin is an elected member of the National Academy of Engineering and the National Academy of Medicine and was chosen as a 2018 fellow of the MacArthur Foundation. She has M.S. and Ph.D. degrees in electrical engineering and computer science from the Massachusetts Institute of Technology.

EVELYN GALLEGO is the CEO and Founder of EMI Advisors LLC, an 8(a) certified Small Minority-Owned Business, founded to deliver value-driven health data management advisory services to government and commercial clients. Ms. Gallego helps clients bridge the gap between health information technology policy and standards and business requirements. She has a strong ability to work across and build consensus with diverse stakeholder groups to include multidisciplinary providers, policymakers, healthcare payers, researchers, system vendors and implementers, and standard development organizations. Ms. Gallego provides specialized expertise in digital health interoperability and health policy with a focus on alignment of regulatory, technical, and process improvement requirements to enable the effective adoption and use of technology. She is a thought leader in the areas of care coordination, social determinants of health, health IT policy analysis and development, health information exchange and interoperability, and health IT standards development. Ms. Gallego currently serves as the Program Manager and SME for three leading interoperability projects including the HL7 Gravity Project, the ONC STARS HIE Technical Assistance Program, and the NIH/AHRQ Multiple Chronic Care (MCC) electronic Care Plan Project. Ms. Gallego earned her International MBA from the Schulich School of Business in Toronto, Canada, and her MPH in Health Policy from George Washington University.

CONSTANTINE GATSONIS is the Henry Ledyard Goddard University Professor of Statistical Sciences, Director of Statistical Sciences, and Professor of Biostatistics at Brown University. He was founding director of the Center for Statistical Sciences and the founding chair of the Department of Biostatistics at Brown University. He is a leading authority on the evaluation of diagnostic and screening tests, and has made major contributions to the development of methods for medical technology assessment and health services and outcomes research. He is a world leader in methods for applying and synthesizing evidence on diagnostic tests in medicine and is currently developing methods for Comparative Effectiveness Research in diagnosis and prediction and radiomics. Since 2016 he has served as a statistical consultant for the New England Journal of Medicine. He was the Founding Editor-in-Chief of Health Services and Outcomes Research Methods, and currently serves as Associate Editor of the Annals of Applied Statistics and Academic Radiology. He is an elected fellow of the American Statistical Association (ASA) and received a Long-Term Excellence Award from the Health Policy Statistics Section of the ASA. He has a Ph.D. from mathematical statistics from Cornell University.

SHAUN GRANNIS is the Vice President of Data Analytics and a medical informatics research scientist at the Regenstrief Institute. Dr. Grannis is also the Sam Regenstrief Professor of Medical Informatics and Professor of Family Medicine at the Indiana University School of Medicine. In these roles, he collaborates with national and international health stakeholders

seeking to advance health data technical infrastructure and data-sharing capabilities. He has provided identity management consultancy to organizations, including the World Health Organization and the Office of the National Coordinator for Health Information Technology. Dr. Grannis also supports health information exchange activity among more than 120 hospitals in Indiana for use in clinical research and disease surveillance. His recent research focuses on developing and testing large-scale HIE-based solutions in support of population health and public health informatics; integrating clinical and social determinants of health (SDH) to identify at-risk patients in need of SDH services, which include nutrition counseling, financial planning, and medical-legal partnership assistance; developing and testing novel patient matching methods; and leveraging machine learning-based models to improve discovery and decision support in a variety of contexts. Dr. Grannis holds an MD degree from Michigan State University and bachelor's degree in aerospace engineering from the Massachusetts Institute of Technology.

JOHN HALAMKA (NAM) is the president of Mayo Clinic Platform. Prior to the Mayo Clinic, Dr. Halamka served as the executive director of the Health Technology Exploration Center for Beth Israel Lahey Health in Massachusetts. During his tenure at Beth Israel Lahey Health, Dr. Halamka oversaw digital health relationships with industry, academia, and government worldwide. Previously, he was chief information officer at Beth Israel Deaconess Medical Center for more than 20 years. In his role at Beth Israel Deaconess Medical Center, Dr. Halamka was responsible for all clinical, financial, administrative and academic IT. As a Harvard Medical School professor, he served the George W. Bush administration, the Obama administration and governments around the world planning their health care information (IT) strategies. In addition, he also was the International Healthcare Innovation Professor at Harvard Medical School. He remains chairman of New England Healthcare Exchange Network Inc. and is a practicing emergency medicine physician. Dr. Halamka received his BS in Medical Microbiology and his BA in Public Policy from Stanford, his MD from the University of California, San Francisco, and his MS from Harvard University.

GEORGE HRIPCSAK (NAM) is Vivian Beaumont Allen professor and chair of the Department of Biomedical Informatics at Columbia University. He is also director of Medical Informatics Services for New York-Presbyterian Hospital and a board certified internist. Previously, Dr. Hripcsak led the effort to create the Arden Syntax, a language for representing health knowledge that has become a national standard. His current research focuses on clinical information stored in electronic health records, and by using data mining techniques he is developing the methods necessary to support clinical research and patient safety initiatives. As chair of the American Medical Informatics Association Standards Committee, Dr. Hripcsak coordinated the medical informatics community response to the Department of Health and Human Services for the health informatics standards rules under the Health Insurance Portability and Accountability Act of 1996. He is an elected fellow of the American College of Medical Informatics, a fellow of the New York Academy of Medicine, and a member of the National Academy of Medicine. He has an MD, and an MS degree in biostatistics from Columbia University.

GEORGE J. ISHAM (NAM) is senior fellow at the HealthPartners Institute and senior advisor for the alliance of community health plans. Dr. Isham has been actively involved in health

policy, serving as a member of the Centers for Disease Control and Prevention (CDC) task force on community preventive services, the Agency for Healthcare Research and Quality's United States preventive services task force, as a founding co-chair of the National Committee for Quality Assurance's committee on performance measurement, and as founding co-chair of the National Quality Forum's measurement application partnership. He is also a founding member of the advisory board for the National Guideline Clearinghouse and has served on the advisory board for the National Quality Measures Clearinghouse as well as the advisory committee to the director of the CDC. Dr. Isham is an elected member of the National Academy of Medicine and was recognized as a national associate of the Institute of Medicine for his committee service. He has an M.D. from the University of Illinois, Chicago, and an M.S. degree in preventive medicine and administrative medicine from the University of Wisconsin, Madison.

ABEL KHO is Professor of Medicine and Preventive Medicine in the Feinberg School of Medicine at Northwestern University and Founding Director of the Center for Health Information Partnerships (CHIP) and the Institute for Augmented Intelligence in Medicine (IAIM). He has served as PI for several regional or national projects including the ONC funded Chicago Health IT Regional Extension Center, the PCORI funded Chicago Area Patient Centered Outcomes Research Network, and the AHRQ funded Health Hearts in the Heartland consortium within the EvidenceNOW initiative. His research focuses on developing regional Electronic Health Record (EHR) enabled data sharing platforms for a range of health applications including high throughput phenotyping, cohort discovery, estimating population level disease burden, and quality improvement. Dr. Kho received his MD from the Medical College of Wisconsin and completed a residency and Chief residency in Internal Medicine at the University of Wisconsin, Madison.

NIROSHA MAHENDRARATNAM LEDERER is Director of Real-World Evidence Strategy at Aetion, where she leads the engagement of federal accounts and advises clients on generating decision-grade evidence. Previously, she was a Managing Associate at the Duke-Margolis Center for Health Policy, where she led the Center's real-world evidence portfolio. Prior to this position, she was a Subject Matter Expert in the Oncology Center of Excellence at FDA. While there, she helped implement patient-focused drug development in cancer products including clinical trial study design and product review, as well as foster consensus across US and ex-US healthcare stakeholders on best practices for patient-reported outcome capture, analysis, and communication. Dr. Lederer has over fifteen years of pharmaceutical policy and health economics and outcomes research experiences, including providing evidence-generation advisory services at Avalere Health, working in commercial and medical roles at Genentech and Bristol-Myers Squibb, respectively, and serving on Capitol Hill during the passage of the Affordable Care Act. She received her Ph.D in Health Outcomes and Policy from the UNC Chapel Hill with a focus on large database analyses and decision-sciences. She received her MSPH in Health Policy & Management from the Johns Hopkins Bloomberg School of Public Health and BA in Public Health from the Johns Hopkins University.

LARA MANGRAVITE is president of Sage Bionetworks, an organization focused on the development and implementation of practices for large-scale collaborative biomedical research. Sage Bionetworks' work is centered on new approaches to scientific process that use open systems to enable community-based research regarding complex biomedical problems.

Previously, Dr. Mangravite served as Director of the Systems Biology research group at Sage Bionetworks where she focused on the application of collaborative approaches to advance understanding of disease biology and treatment outcomes at a systems level with the overriding goal of improving clinical care. Dr. Mangravite obtained a B.S. in physics from the Pennsylvania State University and a Ph.D. in pharmaceutical chemistry from the University of California, San Francisco. She completed a postdoctoral fellowship in cardiovascular pharmacogenomics at the Children's Hospital Oakland Research Institute.

MIGUEL MARINO is associate professor with joint appointments in the School of Public Health Division of Biostatistics and the Department of Family Medicine at Oregon Health and Science University. Dr. Marino's research focuses on: the development and implementation of novel statistical methodology to address complexities associated with the use of electronic health records (EHRs) to study changes in policy; using EHRs to study health disparities; validation of EHRs as a reliable source for observational studies; pragmatic randomized trials; and preventive health maintenance. He currently serves as representative-at-large for the Western North American Region of the International Biometric Society, as the statistical editor for the *Annals of Family Medicine Journal*, and as lead biostatistician for the national evaluation initiative, EvidenceNOW: Advancing Heart Health in Primary Care. Dr. Marino was selected by the National Academy of Medicine as an emerging leader in health and medicine scholar. He has a Ph.D. in biostatistics from Harvard University.

DEVEN MCGRAW is General Counsel and Chief Regulatory Officer for Ciitizen, a consumer health technology start-up. Previously she directed U.S. health privacy and security as Deputy Director, Health Information Privacy at the HHS Office for Civil Rights and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT. Widely recognized for her expertise in health privacy, she directed the Health Privacy Project at the Center for Democracy & Technology 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 advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. She graduated magna cum laude from Georgetown University Law Center and has a Masters of Public Health from Johns Hopkins University.

DAVID MELTZER (NAM) is Fanny L. Pritzker Professor in the Department of Medicine, chief of the section of Hospital Medicine, and faculty in the Department of Economics and Harris School of Public Policy at the University of Chicago. He is also Director of the Center for Health and the Social Sciences and of the Urban Health Lab 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 hospital care. Since 1997 he has developed the inpatient general medicine services at the University of Chicago as a Learning Health Care System to produce knowledge on how to improve the care of hospitalized patients, mobilizing the clinical care process to generate and learn from diverse data from electronic health records, claims data, patient interviews, and bio-specimens on over 100,000 patients. He is the lead of the University of Chicago network site as part of the Chicago Area Patient Centered Outcomes Research Network. He is the recipient of numerous awards, including the Lee Lusted Prize of the Society for Medical Decision Making, the Health Care

Research Award of the National Institute for Health Care Management, and the Eugene Garfield Award from Research America. Meltzer is a research associate of the National Bureau of Economic Research, elected member of the American Society for Clinical Investigation, and past president of the Society for Medical Decision Making. He is also a member of the National Academy of Medicine. He has an M.D. and Ph.D. in Economics from the University of Chicago.

SHARON-LISE NORMAND is S. James Adelstein Professor of Health Care Policy (Biostatistics) in the Department of Health Care Policy at Harvard Medical School and Professor in the Department of Biostatistics at Harvard School of Public Health. Her research focuses on the development of statistical methods for health services and outcomes research, including the evaluation of medical devices, causal inference, provider profiling, evidence synthesis, item response theory, and latent variables analyses. Her application areas include cardiovascular disease, severe mental illness, medical device safety and effectiveness, and medical technology diffusion. Dr. Normand was the 2010 President of the Eastern North American Region of the International Biometrics Society and inaugural Vice Chair of the Patient Centered Outcomes Research Institute's Methodology Committee (2010-2012). Dr. Normand was awarded the ASA 2011 Health Policy Statistics Section's Long Term Excellence Award; the 2012 American Heart Association's Distinguished Scientist Award; the 2017 American Heart Association Council on Quality of Care and Outcomes Research Outstanding Lifetime Achievement Award; and the 2018 Mosteller Statistician of the Year. She is a Fellow of the American Statistical Association, the American Heart Association, the American College of Cardiology, and the American Association for the Advancement of Science. Dr. Normand earned her Ph.D. in Biostatistics, M.Sc. and B.Sc. in Statistics, and completed a post-doctoral fellowship in Health Care Policy.

RACHEL RICHESSON is a Professor in the Department of Learning Health Sciences, School of Medicine, University of Michigan. She conducts original research on the quality and usability of data from electronic health records (EHRs) for research, and has fostered numerous interdisciplinary research collaborations. She has directed implementation of data standards for a number of multi-national multi-site clinical research and epidemiological studies, including the NIH Rare Diseases Clinical Research Network, Type 1 Diabetes TrialNet, and The Environmental Determinants of Diabetes in the Young (TEDDY) study, and the national distributed Patient Centered Outcomes Research Network (PCORnet). Dr. Richesson currently leads the EHR Core for the NIH Health Systems Research Collaboratory, which is developing standards and quality metrics for clinical phenotyping using EHR data in pragmatic clinical trials. In addition, she and Department of Learning Health Science chair Charles Friedman co-lead the multi-stakeholder "Mobilizing Computable Biomedical Knowledge" (MCBK) community charged with establishing the standards, policies, and governance needed for biomedical knowledge to be widely disseminated and applied. She holds a Ph.D and MS in Health Informatics and a Masters of Public Health from the University of Texas.

PAMELA RILEY is Medical Director of the District of Columbia Department of Health Care Finance, overseeing medical administration and quality of care in the District of Columbia's Title XIX (Medicaid), CHIP and Alliance Programs. Dr. Riley previously served as Vice President for Delivery System Reform at The Commonwealth Fund, developing and managing grants focused on transforming health care delivery systems for vulnerable populations, including low-income groups, racial and ethnic minorities, and uninsured populations. She also

served as program officer at the New York State Health Foundation, where she developed and managed grantmaking programs in the areas of integrating mental health and substance use services, addressing the needs of returning veterans and their families, and diabetes prevention and management. Earlier in her career, Dr. Riley served as clinical instructor in the Division of General Pediatrics at the Stanford University School of Medicine. Dr. Riley served as a Duke University Sanford School of Public Policy Global Health Policy Fellow at the World Health Organization in Geneva, Switzerland, and has served as a volunteer physician in Peru and Guatemala. Dr. Riley received an M.D. from the UCLA David Geffen School of Medicine, and completed her internship and residency in pediatrics at Harbor-UCLA Medical Center in Torrance, California. She received an M.P.H. from the Harvard School of Public Health as a Commonwealth Fund Fellow in Minority Health Policy.

SHERRI ROSE is an Associate Professor at Stanford University in the Center for Health Policy and Center for Primary Care and Outcomes Research. She is also Co-Director of the Health Policy Data Science Lab. Her research is centered on developing and integrating innovative statistical machine learning approaches to improve human health. Within health policy, Dr. Rose works on risk adjustment, comparative effectiveness research, and health program evaluation. She has published interdisciplinary projects across varied outlets, including Biometrics, Journal of the American Statistical Association, Journal of Health Economics, Health Affairs, and New England Journal of Medicine. Dr. Rose is the Co-Editor of Biostatistics and Chair of the American Statistical Association's Biometrics Section. Her honors include an NIH Director's New Innovator Award, the ISPOR Bernie J. O'Brien New Investigator Award, and Mid-Career Awards from the American Statistical Association's Health Policy Statistics Section and Penn-Rutgers Center for Causal Inference. Dr. Rose was also named a Fellow of the American Statistical Association in 2020. In 2011, Dr. Rose coauthored the first book on machine learning for causal inference, with a sequel text released in 2018. Dr. Rose has a B.S. degree in statistics from The George Washington University, and a Ph.D. in biostatistics from the University of California, Berkeley.

PATRICK RYAN is Vice President, Observational Health Data Analytics at Janssen Research and Development, where he is leading efforts to develop and apply analysis methods to better understand the real-world effects of medical products. Dr. Ryan is an original collaborator in Observational Health Data Sciences and Informatics (OHDSI), a multi-stakeholder, interdisciplinary collaborative to create open-source solutions that bring out the value of observational health data through large-scale analytics. He served as a principal investigator of the Observational Medical Outcomes Partnership (OMOP), a public-private partnership chaired by the Food and Drug Administration, where he led methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues. Dr. Ryan has worked in various positions within the pharmaceutical industry at Pfizer and GlaxoSmithKline, and also in academia at the University of Arizona Arthritis Center. He 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 Ph.D in Pharmaceutical Outcomes and Policy from University of North Carolina at Chapel Hill.

NIGAM SHAH is a Professor of Medicine (Biomedical Informatics) at Stanford University, Associate CIO for Data Science at Stanford Healthcare, and a member of the Biomedical Informatics Graduate Program as well as the Clinical Informatics Fellowship. 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". Dr. Shah was elected into the American College of Medical Informatics (ACMI) in 2015 and is inducted into the American Society for Clinical Investigation (ASCI) in 2016. He holds an MBBS from Baroda Medical College, India, a Ph.D from Penn State University and completed postdoctoral training at Stanford University.

PAUL TANG (NAM) is an adjunct professor in the Clinical Excellence Research Center at Stanford University and an internist at the Palo Alto Medical Foundation. He was formerly chief innovation and technology officer at the Palo Alto Medical Foundation and vice president, chief health transformation officer at IBM Watson Health. He has over 25 years of executive leadership experience in health information technology within medical groups, health systems, and corporate settings. He has directed innovation and technology teams in provider organizations, academic institutions, corporate research organizations, and product development organizations. Most recently, he led the creation, development, deployment, and evaluation of the application of artificial intelligence to physician point-of-care solutions integrated within an electronic health record system. He also led a corporate enterprise-wide design team. He has chaired numerous federal and private sector advisory and professional association groups related to health information technology and policy. He is an elected member of the National Academy of Medicine, and has served on numerous NAM study committees, including a patient-safety committee he chaired that published two reports: *Patient Safety: A New Standard for Care, and Key Capabilities of an Electronic Health Record System.* He is a member of the Health and Medicine Division committee of the National Academies of Science, Engineering, and Medicine. He was co-chair of the federal Health Information Technology Policy committee from 2009-2017. He has served as board chair for several health informatics professional associations, including the American Medical Informatics Association. He received an M.S. in Electrical Engineering from Stanford University and his M.D. from the University of California, San Francisco.

VG VINOD VYDISWARAN is an Assistant Professor in the Department of Learning Health Sciences with a secondary appointment in the School of Information at the University of Michigan, Ann Arbor. Dr. Vydiswaran's research focuses on developing and applying text mining, natural language processing, and machine learning methodologies for extracting relevant information from health-related text corpora. This includes medically relevant information from clinical notes and biomedical literature, and studying the information quality and credibility of online health communication (via health forums and tweets). His previous work includes developing novel information retrieval models to assist clinical decision making, modeling information trustworthiness, and addressing the vocabulary gap between health professionals and laypersons. Dr. Vydiswaran received his Ph.D from University of Illinois at Urbana-Champaign and his M.Tech from the Indian Institute of Technology Bombay.