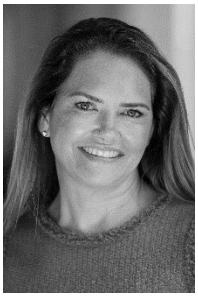
Duke | Robert J. Margolis, MD Center for Health Policy

Unpacking Real-World Data Curation: Principles and Best Practices to Support Transparency and Quality

Biographies



Amy Abernethy serves as chief medical officer, chief scientific officer and senior vice president, oncology, where she leads the research oncology, clinical operations and data science teams, and contributes to the strategic vision of Flatiron Health, a member of the Roche Group. Before joining Flatiron, Amy was professor of medicine at Duke University School of Medicine, and ran the Center for Learning Health Care in the Duke Clinical Research Institute and Duke Cancer Care Research Program in the Duke Cancer Institute. For more than a decade, she has pioneered the development of technology platforms to spur novel advancements in cancer care, including the development of systems by which aggregated clinical data can support personalized medicine, outcomes research, cancer care quality monitoring, and scientific discovery.With over 400 peer-reviewed publications, Amy is an internationally recognized expert in clinical trials, cancer outcomes research, health policy, health services research, patient reported outcomes, clinical informatics and patient-centered care. She maintains a close affiliation with Duke, and is a member of the National Academy of Medicine's National Cancer Policy Forum, past president of the American Academy of Hospice & Palliative Medicine, member of the Board of Directors for the Personalized Medicine Coalition, and recent leader within several federally-funded research networks. She also serves on the Board of Directors for athenahealth (NASDAQ: ATHN) and CareDx (NASDAQ: CDNA) and advises several early-stage health technology companies (SignalPath, Inc; The One Health Company; RobinCare). Amy received her MD at Duke University, where she also did her internal medicine residency, served as chief resident and completed her hematology/oncology fellowship. She has her PhD from Flinders University in Australia, focused on evidence-based medicine and clinical informatics, and her Bachelor's degree from the University of Pennsylvania.

Aylin Altan is Senior Vice President of Research at OptumLabs, an open research and innovation collaborative consisting of more than 27 academic, industry, non-profit, and provider partners. Partners in OptumLabs collaborate to conduct clinical, policy, and population health research in the OptumLabs Data Warehouse, which is comprised of linked administrative claims, electronic health records (EHR), consumer and health behavior data, benefit design information, and other assets.
Altan specializes in the use of real world data and evidence in health services research and health economics. At OptumLabs she works with Partners as a consultant and co-investigator, oversees the OptumLabs team of scientists and research analysts, and leads workshops, issues panels, and training sessions both for OptumLabs Partners and at clinical, policy, and industry conferences and meetings. Most recently, Altan served on a July 2018 panel at the National Academy of Sciences, Engineering, and Medicine in Washington, D.C. focused on the use of real world data and evidence for regulatory decisions. Prior to joining Optum Labs in 2015, Altan led Optum's North American Health Economics and Outcomes Research organization. In this role, she was responsible for working with Life Sciences companies to develop evidence generation strategies in support of their key assets, with the end goal of publication in the peer-reviewed, clinical and policy literature. Altan holds an undergraduate degree from Stanford University and a PhD in Health Services Research from the

University of Minnesota. She was a contributing author to *Managed Care and the Treatment of Chronic Illness*, published by Sage Publications and has more than 30 publications in peer-reviewed journals and more than 90 posters, workshops, podium presentations, and invited speaking engagements.

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 the Research Director of the Therapeutics Research and Infectious Disease Epidemiology program, overseeing a staff of over 100 researchers. 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.

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 is actively involved in Federal IT standards initiatives, collaborating with Office of the National Coordinator (ONC) and AHRQ to author patient matching position papers; he works with Integrating the Healthcare Enterprise (IHE) standards organization, and in 2014 worked with IHE collaborators to validate the first IHE PDQm interoperability profile for patient matching. Globally, Dr. Grannis collaborates with several 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.

Steven Kundrot is Chief Technology Officer and SVP of Engineering at TriNetX. Steve is a technology and business leader with 18 years of experience in clinical research, health analytics, consulting and software development. After joining TriNetX as an early employee 4 years ago, Steve has built and led an engineering team based in Cambridge, MA and overseen the creation of a federated, distributed analytics platform. That platform now powers the world's largest health research network spanning 16 countries, 95 healthcare organizations, and comprised of over 300 million patients. Prior to TriNetX, Steve built and led engineering teams at Perceptive Informatics and PAREXEL with a focus on streamlining clinical endpoint committees, integration between EDC, RTSM, and CTMS systems, and technical advancements in support of using medical images and independently derived data as surrogate endpoints in regulatory submissions. Before that, Steve was a technology consultant for several Fortune 1000 and startup companies and co-founder of an internet infrastructure company. Steve has a BS in Engineering from Cornell University, an MBA from Babson College, and is an avid traveler and fly fisherman.

Keith Marsolo is a faculty member in the Department of Population Health Sciences at the Duke University School of Medicine. He was previously an Associate Professor 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 as a member of the Data Quality Subcommittee of the National Evaluation System for health Technology Coordinating Center (NESTcc).

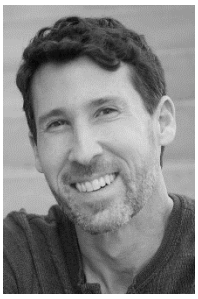
David Martin is the Associate Director for Real World Evidence Analytics, Office of Medical Policy, FDA Center for Drug Evaluation and Research. He oversees demonstration projects intended to support the agency's evaluation of real world evidence, reviews real world evidence submissions, and contributes 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.

Andrew Norden is a neuro-oncologist and physician executive who joined Cota in 2017 as Chief Medical Officer. Prior to joining Cota, Dr. Norden served as Deputy Chief Health Officer and lead physician for oncology and genomics at IBM Watson Health. Previously he worked at Dana-Farber Cancer Institute in Boston in several capacities, including Associate Chief Medical Officer and Medical Director of Satellites and Network Affiliates. Dr. Norden served as physician leader for the Dana-Farber community network for more than 5 years. A talented physician and board-certified neurologist and neuro-oncologist, Dr. Norden cares for patients with brain tumors and neurological complications of cancer. He has also developed many clinical trials for patients with glioma, meningioma, and seizures in brain tumor patients. He is the author of more than 65 peer-reviewed papers primarily involving therapy for high-grade gliomas and meningioma. He is an active member of the American Society of Clinical Oncology, the Society for Neuro-Oncology, and the American Academy of Neurology, and he is an Associate Editor of *JCO-Clinical Cancer Informatics*. Dr. Norden attended medical school at Yale School of Medicine before moving to Boston for residency training at Massachusetts General and Brigham and Women's Hospitals. After serving as Chief Resident, he completed a neuro-oncology fellowship at Dana-Farber. Dr. Norden also earned an MPH degree from Harvard School of Public Health and an MBA from University of Massachusetts, Amherst. His received his undergraduate degree in neuroscience from Brown University. Dr. Norden lives outside Boston with his wife and three young sons. In his free time, he enjoys snow-skiing, running, and watching his sons play sports.

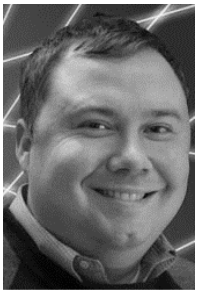
Marc Overhage is the Vice President for Population Health Intelligence Strategy at Cerner and focuses on developing, deploying and evaluating clinical information systems with emphasis on clinical decision support and regional health information exchange. Marc makes an impact on the future of Cerner by conducting research focused on the use of informational interventions to modify provider behavior, including computerized provider order entry, clinical decision support systems and other forms of feedback. He joined Cerner in 2015 as a Chief Medical Informatics Officer, (previously Siemens Health Services). Marc has over 25 years developing and implementing clinical and scientific systems and evaluating their value. Working at the Regenstrief Institute, he created a community wide electronic medical record (called the Indiana Network for Patient Care) containing data from many sources including laboratories, pharmacies and hospitals in central Indiana. Over 104 acute care hospitals and over 22,000 physicians participate in the system, which includes inpatient and outpatient encounter data, laboratory results, immunization data and other selected data. Marc is a graduate of Wabash College and the Indiana University School of Medicine where he earned both his PhD in Biophysics and MD. He completed his residency and fellowships at the Indiana University. Dr. Overhage is a fellow of the American College of Medical Informatics, a Master of the American College of Physicians and a Fellow of the National Academy of Medicine.

Jeremy A. Rassen is a pharmacoepidemiologist with nearly 25 years of academic and industry experience. He is Co-Founder, President and Chief Science Officer at Aetion, Inc., a New York-based healthcare technology company that provides science-driven real-world evidence (RWE) solutions to healthcare companies, regulatory bodies and academic centers. Dr. Rassen leads Aetion's efforts to design, scale and communicate scientific products and methodologies for obtaining valid and timely medical evidence from real-world data. Prior to Aetion, Dr. Rassen was Assistant Professor of Medicine at Harvard Medical School, where he focused on methods for improving the quality and validity of studies based on real-world data, including administrative claims and electronic health records. In peer-reviewed publications and invited talks in the United States, Europe and Asia, he has looked at how real-world data can be used to validly, transparently and reproducibly measure the safety, effectiveness and value of medications and other treatments. Before coming to Harvard, Dr. Rassen worked in Silicon Valley in a variety technology companies, including Hewlett-Packard and Epiphany, Inc. His focus was on high-performance software for the creation and analysis of large databases. Dr. Rassen received his bachelor's degree in Computer Science from Harvard College and his masters and doctorate degrees in Epidemiology from the Harvard T.H. Chan School of Public Health.



Dan Riskin is Founder and Chief Executive Officer of Verantos and previously held positions as Founder and CEO of Health Fidelity and Special Projects Consultant at Apple. He is Adjunct Professor of Surgery and Adjunct Professor of Biomedical Informatics Research at Stanford University. Dr. Riskin is an expert in healthcare artificial intelligence and successful serial entrepreneur. Products he has developed and commercialized influence the care of millions of patients annually. His contributions in data-driven healthcare have been featured in Forbes, The Wall Street Journal, and other leading media. He served on the Obama Healthcare Policy Committee for the 2008 Presidential Campaign and testified before Congress on the 21st Century Cures Initiative. Dr. Riskin is board-certified in four specialties, including surgery, critical care, palliative care, and clinical informatics. He holds degrees and fellowships from University of California, Stanford, and MIT.

Sam Roosz is co-founder and Head of Partnerships at Datavant, a San Francisco-based healthcare technology company. In this capacity he leads a team that supports companies across the healthcare ecosystem to link together disparate real-world datasets while protecting patient privacy. Sam has worked closely with biopharmaceutical, diagnostic, device, and CRO clients in developing the tools and strategies to integrate RWD and RWE into their development approaches. Prior to co-founding Datavant, Sam consulted in the biopharmaceutical industry and held operational roles in product development in the medical device and diagnostics space, helping to bring over 15 products to market. Sam holds a BA in molecular and cellular biology from Harvard University and an MBA from Stanford University.



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.

Cynthia Senerchia serves as Vice President of Clinical Operations for the Optum Digital Research Network, where she leads the operational processes related to innovative digital trial design using all electronic source data, to feed data bases or study specific electronic data capture (EDC) systems for Clinical Research. Her research career began in 1984 at the Beth Israel Hospital in Boston managing multiple interventional cardiovascular research trials, facilitating a career transition in 1994 as a founding member and Director of Clinical Affair's at a Harvard affiliated academic research organization coordinating over 80 trials on medical devices. In 1999, she joined an innovative EDC company (*PhaseForward -subsequently Oracle).* First she headed the clinical services team responsible for InForm Trial Quality Control, and later became the Director of Quality and Regulatory Compliance. She joined Humedica in 2012, which was acquired by Optum in 2013. At Optum she initially focused on HIPAA compliance and her position evolved to working with teams performing data curation, normalization, and statistical de-identification, as well as clinically supporting the Natural Language Processing (NLP) development team that created NLP output from unstructured notes for use by provider organizations as well as life sciences customers. Ms. Senerchia earned a bachelor's and master's degree and an ARNP license from University of South Florida in Tampa.

Duke-Margolis Moderators:

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.

Gregory Daniel is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate

Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes form the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.