Improving the Efficiency of Outcome Validation in the Sentinel System

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Biographies

Amy Abernethy

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.

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, recent 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.

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.

Steven Anderson

Steve Anderson, PhD, MPP, is currently the Director of the Office of Biostatistics and Epidemiology (OBE) at the FDA Center for Biologics Evaluation and Research (CBER). He provides leadership for all CBER statistical, epidemiological and risk assessment programs. In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products including vaccines, blood products and others. Since his arrival at FDA he has led numerous important risk
assessment projects and epidemiological studies. He led the first studies at FDA using Centers for Medicare & Medicaid Services (CMS) data to estimate blood utilization in inpatient and outpatient setting. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER’s regulatory processes to improve biologic product safety evaluations and surveillance.

Dr. Anderson earned a Master’s Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens in cattle. Dr. Anderson received his PhD from the University of Cincinnati where he worked on biochemistry, drug resistance and ion pumps, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in biologic product safety, risk assessment, epidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.

Robert Ball

Robert Ball, MD, MPH, ScM, 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

Jeffrey Brown, PhD 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.

David Carrell

David Carrell, PhD, is an Investigator at Kaiser Permanente Washington Health Research Institute who applies clinical natural language processing (NLP) and machine-learning methods to the study of problem use of prescription opioids using electronic health record (EHR) data. His recently completed and ongoing research projects include studies developing and using prediction algorithms to identify patients experiencing opioid abuse, addiction, overdose and death, to measure the quality of colonoscopy procedures, to measure clinical conditions and phenotypes to support genetic studies, and to identify patients with recurrent cancer. For over a decade he has developed and applied NLP methods to extract information from unstructured clinical text in a variety of clinical domains and in single- and multi-site settings, and is a recognized expert on approaches to adapting NLP methods for use in multi-site contexts.

Gregory Daniel

Dr. Gregory Daniel, PhD, MPH, is the Deputy Director of the Duke-Robert J. Margolis, MD Center for Health Policy and a Clinical Professor in Duke’s Fuqua School of Business. 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 value-based payment reform. Dr. Daniel is also 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 (an Anthem, Inc. company). In addition to health and pharmaceutical policy, Dr. Daniel’s research expertise includes real world evidence (RWE) development utilizing electronic health data in the areas of health outcomes and pharmacoconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.
Debbie Dean

Debbie Dean is the Vice President of Health Analytics Solutions at GDIT. Debbie oversees large-scale health services research, analytic, and quality programs for federal and state clients. Debbie has more than 23 years of diverse clinical and health information management experience, including data abstraction, collection and reporting; analytics; data management; and development of health analytics solutions. Debbie oversees large scale health data analytics solutions, data-driven health policy-related programs, quality payment programs, and program model implementation and evaluation contracts for federal and state initiatives. She has served in numerous leadership roles for the Centers for Medicare & Medicaid Services programs and related quality initiatives, including oversight of the national Medicare and Medicaid research database (Chronic Condition Warehouse), Health Care Quality Analytics and Reporting program, and Merit-based Incentive Payment System Practice Improvement and Measures Management Support.

Prior to following her work to GDIT, Debbie spent 13 years working for the Iowa Quality Improvement Organization supporting a variety of early data collection, analysis, and reporting programs, as well as quality improvement initiatives for local and national programs. Debbie also supported the American Medical Association Physician Consortium for Performance Improvement with performance measure development. Through local presence as a technology leader, Debbie supports local STEM initiatives to advance the opportunities for Iowa high school students entering STEM fields of study.

Joshua Denny

Dr. Joshua Denny is Professor of Biomedical Informatics and Medicine, Director of the Center of Precision Medicine, and Vice President of Personalized Medicine at Vanderbilt University Medical Center. He is a Fellow of the American college of Medical Informatics and a member of the National Academy of Medicine.

Dr. Denny has substantial experience in the design, development, and implementation of electronic health record (EHR) data mining algorithms, and was the primary author of several natural language processing systems to support phenotype extraction algorithms for genomic research projects, including the development of the phenome-wide association study (PheWAS) method. He is principal investigator (PI) of nodes in the Electronic Medical Records and Genomics (eMERGE) Network, Pharmacogenomics Research Network (PGRN), and the implementing Genomics into Practice (IGNITE) Network. He is also PI of the Data and Research Center of the Precision Medicine Initiative All of Us Research Program (previously called the Precision Medicine Cohort Program), which will eventually enroll at least 1 million Americans in an effort to understand the genetic, environmental, and behavioral factors that influence human health and disease.

To date, Dr. Denny has led >100 genome-wide and candidate gene association studies using EHR data linked to genetic data. He serves on a number of mentoring committees and has trained >30 postdoctoral and predoctoral trainees.
Jon Duke

Dr. Jon Duke is Principal Research Scientist at the Georgia Tech Research Institute and Director of the Center for Health Analytics and Informatics and on faculty in the Georgia Tech College of Computing. He is former Director of Drug Safety Analytics and Advanced Text Mining at the Regenstrief Center for Biomedical Informatics in Indianapolis. He has led over $21 million in funded research for industry, government, and foundation partners. Dr. Duke’s research focuses on advancing techniques for identifying patients of interest from diverse data sources with applications spanning research, quality, and clinical domains. He led the Merck-Regenstrief Partnership in Healthcare Innovation and was a founding member of OHDSI, an open-source international health data analytics collaborative in over 15 countries. In addition to numerous peer-reviewed publications, his work has been featured in the lay media including the New York Times, NPR, and MSNBC. Dr. Duke completed his medical degree at Harvard Medical School and a master's in human-computer interaction at Indiana University.

Nicolle Gatto

Nicolle Gatto, is a Senior Director/Group Lead with the Worldwide Regulatory & Safety Epidemiology Group at Pfizer. In this role, she provides strategic leadership, oversight of comprehensive epidemiology strategies to examine the safety and effectiveness of medicines, consultation on design of pragmatic trials, and expertise on specific methods-related epidemiologic issues. She has designed and implemented primary and secondary data collection observational studies and pragmatic trials, and guides other epidemiologists in research strategy, study design, execution and analysis. She is a Fellow of the International Society for Pharmacoepidemiology.

In addition to her work in pharmacoepidemiology, Nicolle is an Adjunct Assistant Professor of Epidemiology at Columbia University School of Public Health and Tulane School of Public Health and Tropical Medicine, teaching courses in pharmacoepidemiology, causal inference and confounding control methods. Her research interests fall into the general category of causal inference, with a focus on translating theory and concepts to enable application in real-life studies. Nicolle holds a PhD in epidemiology from Columbia University and an MPH from New York University.
Robert Greenlee

Robert Greenlee is a tenured senior scientist at Marshfield Clinic Research Institute (MCRI), with 17 years of experience in clinical epidemiology and population health research, and an adjunct Professor in the department of Population Health Sciences at the University of Wisconsin School of Medicine and Public Health. Dr. Greenlee has served for 11 years as a Governing Board member of the Health Care Systems Research Network (HCSRN), and as a site PI in the NCI-sponsored Cancer Research Network. Dr. Greenlee has led and collaborated on numerous multisite observational studies of health and care delivery within healthcare systems, in cancer and other chronic diseases during this time. Dr. Greenlee is a site PI in the Greater Plains Collaborative, a Clinical Data Research Network within PCORI’s PCORnet, and am involved in expanding patient and system stakeholder engagement activities to support that work. Dr. Greenlee’s doctoral training was in cancer surveillance research, with particular focus on early detection, and he was subsequently a co-investigator for the Marshfield Clinic site in the NCI-sponsored Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial, and the related National Lung Screening Trial. Dr. Greenlee is currently our site PI for the long-term PLCO follow-up study. Dr. Greenlee is also the Cancer Care Delivery Research Lead for the NCI-sponsored Wisconsin National Community Oncology Research Program (WiNCORP). Dr. Greenlee serves as the MCRI lead for the Community and Collaboration Module within the University of Wisconsin Institute for Clinical and Translational Research (UW ICTR), and has had other funded collaborations with the teams from the University of Wisconsin Health Innovation Program and the Wisconsin Collaborative for Healthcare Quality. Dr. Greenlee’s work in this collaboration is focused on health care delivery and health care quality research.

Lisa Herrinton

Lisa Herrinton, PhD, is a senior research scientist and epidemiologist at the Kaiser Permanente Northern California Division of Research. She is Chair of the Healthcare Outcomes and Effectiveness study section at the Agency for Healthcare Research and Quality (AHRQ) and has served on study section for the Centers for Disease Control, National Eye Institute, National Cancer Institute, and other federal agencies. Dr. Herrinton has 25 years of experience using a diverse range of research methods to investigate important questions in public health and health services. Most recently, she is conducting a program in implementation research, working with Kaiser Permanente physicians and health plan leaders to identify high priority topics that enable use of electronic medical records data to be used for integrating care delivery, expanding quality improvement, and enabling research that can be rapidly translated. These efforts cover diverse clinical areas including cataract surgery, oncology, and registry building across medical and surgical specialties. Dr. Herrinton received her doctoral training at the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle, Washington, and her master’s training at Harvard University. She has published 180 reports. In addition, she has led numerous collaborative activities and mentored many scientists and physician-investigators.
Stephan Lanes

Stephan F. Lanes, PhD, MPH, provides scientific oversight and strategic input for a variety of research projects, as well as supporting business development. Dr. Lanes has consulting and industry experience, including having spent 10 years at Boehringer Ingelheim Pharmaceuticals, where he most recently held the position of Distinguished Clinical Scientist. Dr. Lanes serves as Principal Investigator for industry-sponsored and government-sponsored research projects, and he is a longstanding member of the International Society for Pharmacoepidemiology (ISPE), where he has served on the Board of Directors and chaired the committee to update the Guidelines for Good Pharmacoepidemiology Practices (GPP). Dr. Lanes has published many papers on the design, conduct, and interpretation of epidemiologic studies in the peer-reviewed medical literature, and has presented his work at scientific meetings and to regulatory authorities worldwide.

Judith Maro

Judith C. Maro is an Assistant Professor in the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. She received her doctorate in Engineering Systems at the Massachusetts Institute of Technology (MIT). Her doctoral work examined practical implementation of prospective sequential database surveillance activities in the Sentinel System using modeling and simulation. She works with the Therapeutics Research and Infectious Disease Epidemiology group and acts as the Sentinel Operations Center Operations Lead. Dr. Maro's main research interest is the modeling and simulation of large-scale engineering systems (e.g., observational database networks) with the aim to improve the efficiency of public health activities. She is currently focusing on the implementation of pharmacovigilance techniques, particularly continuous near-real time sequential statistical analysis methods and data-mining. She is also interested in developing these system-based models into teaching tools as simulation-based in silico “microworlds” in which users “practice” testing, adapting, and honing policy/implementation strategies to manage complex public health systems prior to actual implementation in the real world.
Vinit Nair

Vinit P. Nair is a trained pharmacist & pharmacoepidemiologist with experience at large national health plans and health outcomes & policy research organizations. Currently the lead for the Government Research & Academic Partnerships at Humana’s research organization; his team aims to conduct, build and foster research with government entities and academic institutions across the US. He is engaged with several national multi-site research initiatives including the FDA sponsored Sentinel (Site PI), Regan Udall Foundation IMEDS (Site PI) and Patient Centered Outcomes Research Institute PCORnet -HUMnet (Site PI). In addition, Vinit also held academic appointments and serves as a reviewer & editorial board member for peer-reviewed journals and is a recipient of grants and contract awards.

Jennifer Nelson

Jennifer Nelson is Director of Biostatistics and a Senior Investigator at Kaiser Permanente Washington Health Research Institute and an Affiliate Professor of Biostatistics at the University of Washington. Dr. Nelson’s research is focused on methods to quantify post-market safety and effectiveness for drugs and vaccines. She is particularly interested in addressing the statistical challenges of multi-site safety studies that use electronic health record data from large health care systems. She has authored over 80 publications, primarily in this area. Since 2009, Dr. Nelson has provided national leadership as Methods Core Lead and Senior Statistician for the Food and Drug Administration’s (FDA’s) Sentinel Network that is designed to facilitate active and rapid safety surveillance for FDA-regulated medical products. She has also led the Methodology Committee for the Centers for Disease Control and Prevention sponsored Vaccine Safety Datalink (VSD) project, a national collaboration that has involved 10 health care systems and monitored vaccine safety in the U.S. since 1990. Dr. Nelson earned the 2009 VSD Margarette Kolczak Award for outstanding biostatistical and epidemiological contributions in the field of vaccine safety. Her 2013 paper that adapted group sequential monitoring methods to a real-world observational vaccine safety data setting was one of the American Journal of Epidemiology’s Articles of the Year. She received her PhD in Biostatistics at the University of Washington in 1999.

Nigam Shah

Dr. Nigam Shah is Associate Professor of Medicine (Biomedical Informatics) at Stanford University, and an executive member of the Biomedical Informatics Graduate Program. Dr. Shah’s research focuses on combining machine learning and prior knowledge in medical ontologies to enable the learning health system. 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 PhD from Penn State University and completed postdoctoral training at Stanford University.
Jonathan Silverstein

Internationally known for his expertise and research in the application of advanced computing architectures to biomedicine, Dr. Jonathan Silverstein was Vice President and Davis Family Chair of Informatics at NorthShore University HealthSystem and the associate director of the Computation Institute at the University of Chicago and Argonne National Laboratory. He most recently served as Chief Medical Informatics Officer at Tempus. Dr. Silverstein is recognized as one of three founding scientific directors of the Chicago Biomedical Consortium. He was an attending general surgeon for seven years while also serving as the lead physician informatician for enterprise EMR deployments at the University of Chicago and the University of Illinois at Chicago. Dr. Silverstein earned his medical degree from Washington University in St. Louis and his Master of Science from the Harvard School of Public Health. He is a Fellow of both the American College of Surgeons and of the American College of Medical Informatics.

Shirley Wang

Shirley V. Wang has a PhD in epidemiology and an MSc in Biostatistics from Brown University. Her research interests are in 1) developing innovative, non-traditional analytic methods to understand the safety and effectiveness of medication use in clinical care as well as 2) facilitating appropriate use of complex methods for analyzing large observational healthcare data. Her methods work has been recognized with awards from two international research societies.

Shirley has been involved with the Sentinel Initiative since 2011. She recently led a joint task force for the International Society for Pharmacoepidemiology (ISPE) and the International Society for Pharmacoepidemiology and Outcomes Research (ISPOR), which focused on research practice and reporting to improve decision maker confidence in real world evidence. She now leads the REPEAT Initiative, a non-profit program with projects aimed at improving transparency, reproducibility and robustness of evidence from healthcare databases.