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

mHealth as a Source of Real World Data –

Working Group Biographies

Ashish Atreja

Dr. Atreja has received formal training in public health and is board certified in gastroenterology, clinical informatics and internal medicine. Over the last fifteen years, he has led many public health and informatics initiatives at Cleveland Clinic and Mount Sinai Medical Center, NY that includes developing online education modules, leading EHR implementation, performing analytics on healthcare data and developing enterprise-wide mobile apps. As Chief Technology Innovation and Engagement Officer, Medicine, he leads the Sinai AppLab (www.sinaiapplab.org) that is one of the first collaborative hub within academic medical center to build and test disruptive mHealth technologies.

Dr. Atreja leads scientific registries for American Gastroenterology Association and serves in Innovation Advisory Board for American College of Cardiology. As an intrapreneur, Dr. Atreja has won innovation awards at Cleveland Clinic and Mount Sinai, successfully licensed technologies from academic centers and advises startups, accelerators and Fortune 500 companies in digital medicine. Recently, Dr. Atreja established Network of Digital Medicine (www.nodehealth.org) to connect innovation centers worldwide and share best practices for digital medicine innovation and implementation between industry, payers and health systems. Dr. Atreja serves as Scientific Co-founder for Mount Sinai Spinoff, Responsive Health (http://responsivehealth.org) that aims to bring first enterprise-wide app curation, prescription and engagement platform to risk sharing hospitals and payers. Dr. Atreja has published more than 60 papers and has been a keynote speaker globally on topics related to digital medicine and health system transformation.

David Bates

Dr. Bates is an internationally renowned expert in patient safety, using information technology to improve care, quality-of-care, cost-effectiveness, and outcomes assessment in medical practice. He is a Professor of Medicine at Harvard Medical School, and a Professor of Health Policy and Management at the Harvard School of Public Health, where he co-directs the Program in Clinical Effectiveness. He directs the Center for Patient Safety Research and Practice at Brigham and Women's Hospital. He served as external program lead for research in the World Health Organization's Global Alliance for Patient Safety and is the immediate past president of the International Society for Quality in Healthcare (ISQua) and the editor of the Journal of Patient Safety. He has been elected to the Institute of Medicine, the American Society for Clinical Investigation, the Association of American Physicians and the American College of Medical Informatics, and was chairman of the Board of the American Medical Informatics Association. He has published over 700 peer-reviewed papers and has an h-index of 115, which ranks him among the 400 most cited biomedical researchers of any type.

Seth Clancy

Seth has worked in the field of Market Access for more than 13 years – primarily in support of medical device and biopharmaceutical companies. In his current role, Sr. Director, Global Health Economics & Reimbursement at Edwards Lifesciences, he leads the development and implementation of evidence generation and market access strategies for the transcatheter heart valve business. Seth has helped to address a complex and growing set of challenges related to health technology assessment, reimbursement and emerging evidence needs globally. Prior to joining Edwards in 2008, Seth worked at Cerner Lifesciences, where he served as Senior Research Associate, responsible for consultative services to biopharmaceutical companies in the areas of comparative effectiveness research, health technology assessment and health economics.

Seth received a Bachelor of Arts degree from the University of California, Irvine and a Master of Public Health, from the University of California, Los Angeles.

Greg 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 pharmacoeconomics, 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.

Megan Doerr

A former botanist and middle school teacher, Meg Doerr joined the genetic counseling community in 2006. Meg led the clinical development and implementation of Cleveland Clinic's family history and risk assessment tool before joining the Governance team at Sage Bionetworks in 2015. At Sage, Meg's efforts have been concentrated on supporting innovative, participant-centric approaches in open science. Her work has a strong focus on app-based research, including the ELSI issues associated with informed consent, research participation, and data sharing for secondary use in entirely remote, mobile platform-based studies.

Patricia Franklin

Dr. Franklin completed her medical education, Preventive Medicine residency (with MPH), and business training (MBA) at the University of Rochester, Rochester NY. Her training also included a fellowship in Health Services Research emphasizing clinical data warehouse design and cost and outcome analyses. Dr. Franklin has held leadership roles in health system quality improvement (Medical Director for Quality) and outcomes research. She currently serves as Principal Investigator for the national Function and Outcomes Research for Comparative Effectiveness in total joint replacement registry (FORCE-TJR; AHRQ). FORCE-TJR enrolled more than 30,000 TJR patients from over 220 orthopedists in 25 states to evaluate best practices to achieve optimal pain relief and function after TJR. FORCE data include nationally representative patient reported outcomes, adverse events, and implant survivorship; outcomes will be monitored for the next decade. In addition, a new PCORI-funded study is translating the FORCE data to individual outcome predictions to support shared decision making for knee and hip arthritis patients. Franklin's current research is also evaluating physical therapy and post-operative activity support to identify optimal post-TJR care. Finally, her team is developing a mobile App to collect and monitor patient generated arthritis symptom data to guide clinical care decisions. Dr. Franklin is a national leader in patient reported outcome measurement in orthopedics and chronic care and teaches internationally on these topics.

Adrian Hernandez

Dr. Hernandez is a cardiologist with extensive experience in clinical research ranging from clinical trials to outcomes and health services research. He is the Director of Health Services and Outcomes Research and an Associate Director of the Duke Clinical Research Institute. He is the Coordinating Center Principal Investigator for multiple networks and clinical trials such as the NHLBI's Heart Failure Research Network, PCORI's National Patient-Centered Clinical Research Network (PCORnet) and NIH's Health System Collaboratory. Dr. Hernandez has over 400 published articles in high-tier journals including the New England Journal of Medicine, Journal of the American Medical Association, and Lancet.

Martin Ho

Martin Ho is Associate Director for Quantitative Innovation at the Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), U.S. FDA. He is CDRH's methodological lead to incorporate quantitative methods into regulatory decision making. He builds capacity and develops good practices for reviewing patient-reported outcomes data within CDRH. He provides technical leadership to CDRH's regulatory science projects. Mr. Ho participated in developing the Center's patient preferences information guidance document and its final version was released in August. He is the President of the FDA Statistical Association. He is a member of the CDRH Patient Preferences Initiative and co-organized CDRH's inaugural Patient Preferences Workshop. He also serves on the Patient-Centered Benefit-Risk Assessment Project Steering Committee of the Medical Device Innovation Consortium, a public private partnership between the FDA and the industry, the patient advocacy groups, CMS, PCORI, and NIH. Mr. Ho is a voting member of the FDA Research Involved Human Subject Committee, which reviews IRB applications of FDA sponsored clinical studies to protect study participants. Prior to joining the FDA in 2009, Mr. Ho was a senior statistician in various contract research organizations planning and conducting clinical studies for 10 years.

Mohit Kaushal

Dr. Kaushal has had an extensive career within investing, clinical medicine/academia and public policy.

Mohit is a lead investor/board member to numerous transformational companies including Humedica (acquired by Optum Health), Rxante (acquired by Millennium), Change Healthcare (acquired by Emdeon), Gravie, Elation Health, CitiusTech, Oak Street Health and Universal American (NYSE:UAM).

During his time in the Obama administration, he was a member of the White House Health IT task force; a cross agency team implementing the technology aspects of Health Reform. He also built and led the first dedicated health care team at the Federal Communications Commission, where his team initiated collaboration with the Food and Drug Administration for the regulatory streamlining of converged telecommunications, data analytics and medical devices leading to the release of the mobile medical applications guidance by the FDA.

In addition Dr. Kaushal is an Adjunct Professor at Stanford University with a joint position within the newly created Biomedical Data Science Department and the medical school.

Dr. Kaushal continues to be active within public policy and is a Scholar in Residence at the newly created Duke Margolis Center for Health Policy. He was previously a Visiting Scholar at the Brookings Institution. He has also been appointed to the FDASIA Workgroup of the Health IT Policy Committee and to the National Committee on Vital and Health Statistics, advising HHS on Data Access and Use.

Kaushal is an ER physician, holds an MBA from Stanford and an MD with distinction from Imperial College of Science, Technology and Medicine, London.

John Mattison

John led the largest electronic health record in the US, and founded the international XML standard for healthcare interoperability. He co-leads the national KP virtual care workgroup with oversight of telemedicine, virtual care and remote monitoring. He mentors scores of digital health startups. He consults and keynotes globally on numerous topics in healthcare, IT, and health policy. He has published numerous papers, book chapters (on numerous topics including IOT) and is co-editor of The most current textbook on Health IT. His work has resulted in various national awards and has been cited in WSJ, Forbes, and many others. He is an active innovator in genomics, AI, big data analytics, IOT, blockchain, bioinformatics, mobile healthcare, regulatory policy, telemedicine, privacy, ethics in precision medicine, and is involved in several global not-for-profit initiatives for health and internet access. He is a board member of numerous not-for-profit boards dedicated to improving health, wellness, and resilience of diverse communities. He is passionate about using modern technology to restore ancient wisdom and create a 'behavioral symphony for wellness'. He is faculty at Singularity University and lectures frequently at numerous universities globally, and is a consultant to the X-Prize. Numerous keynote addresses are available on youtube. Full bio available upon request.

Mike McConnell

Michael V. McConnell, MD, MSEE is Head of Cardiovascular Health Innovations at Verily Life Sciences and Professor of Cardiovascular Medicine at Stanford School of Medicine, where he continues to see patients and teach in the Stanford Biodesign program. Dr. McConnell has clinical and research expertise in cardiovascular imaging, prevention, and mobile health. While at Stanford, he led the Cardiovascular MRI program, the Preventive Cardiology Clinic, and the MyHeart Counts cardiovascular mHealth ResearchKit study. Dr. McConnell completed his BS and MS in EE/BioE at MIT, his MD at Stanford, and his Cardiovascular Medicine and Imaging Fellowships at Brigham and Women's Hospital/Harvard Medical School. He has been the PI of multiple grants from the NIH and AHA, and is a Fellow of the AHA and ACC. He serves on the AHA's Health Tech Advisory Board since its founding and is currently co-chair of AHA's 2030 Goals Task Force. He also serves on the Physical Activity Standards working group for the Consumer Technology Association.

Greg Pappas

Gregory Pappas, M.D., Ph.D (FDA) recently joined the FDA as the Associate Director for National Evaluation System for health Technology (NEST) at the Center for Devices and Radiological Health (CDRH). He previously served as the Senior Deputy Director of HAHSTA (HIV/AIDS, Hepatitis, STD, and TB Administration) for the District of Columbia, Department of Health. He has worked professionally in over 30 countries. His consultancies include work with WHO, USAID, and CDC. With InterAction,-- the largest coalition of U.S.-based international nongovernmental organizations (NGOs) focused on the world's poor and most vulnerable people -- he worked on pandemic prepared with 40 African and Asian nations.

Gregory Pappas MD, PhD served as the Noordin M. Thobani Professor at the Aga Khan University (AKU), where he was the Chairman of the Department of Community Health Sciences in Karachi, Pakistan. He has published extensively in international peer reviewed journals on the health of the people of Pakistan and health in other less developed countries. While at AKU he provided university wide leadership for research, training, and service. He also serves as an adviser to the Government of Pakistan on a number of health policy and development areas. Dr. Pappas led the final report of Tawana Pakistan which documented the improvement in education and nutrition of primary school girls in the poorest districts of the country as a result of a school feeding program in over 4000 schools.

Previously he served as Medical Director of the Futures Group, designing and implementing the monitoring and evaluation plan for the antiretroviral program of AIDS Relief, working in nine countries in Africa and the Caribbean. Dr. Pappas assisted in the development of the President's Emergency Plan for AIDS Relief (PEPFAR) including contributing to the PEPFAR Five Year Strategy, a report to Congress. Dr Pappas served in a variety of positions over an 18 year period in the Department of Health and Human Services including his role as Senior Policy Advisor to the Assistant Secretary for Health/Surgeon General, David Satcher. For the Surgeon General, Dr. Pappas worked in a number of areas including disparities in health and global health (HIV/AIDS, other infectious diseases, and health information systems development). Dr Pappas directed the Office of International and Refugee Health, Department of Health and Human Services, serving on the Executive Board of UNICEF and PAHO, and as a delegate to the World Health Assembly. For ORC Macro, as Deputy Director of the Demographic and Health Survey (DHS) he implemented innovative surveys in Uganda, Mali, Uzbekistan, and Dominican Republic.

Dr. Pappas received his MD and PhD (Anthropology) from Case Western Reserve in Cleveland, Ohio. After doing his clinical training, he came to Washington DC, first as a fellowship in Epidemiology, then continuing as a scientist at the National Center for Health Statistics/CDC. Dr. Pappas is author of numerous articles, including his work in the New England Journal of Medicine "The increasing disparity in mortality between socioeconomic groups in the United States "and his book with Cornell University Press, The Magic City: unemployment in a working class community. Dr. Pappas is on the faculty of the Bloomberg School of Public Health in the Department of Health Policy and Management, and is on the faculty of Howard Medical School. Dr. Pappas served as Chair of the Science Board and member of the Executive Board of the American Public Health Association. His Megacities and Global Health (APHA Press) with Omar Khan was published in 2012.

Bakul Patel

BAKUL PATEL is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.
Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort.

Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations.

Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

Ravi Ramachandran

Ravi Ramachandran, PhD, is Senior Director, Digital Health Strategy, at PatientsLikeMe Inc. Ravi brings over a decade of experience in digital health strategy, and hands-on implementation of wearables and smartphone apps and medical devices in clinical trials and in the pharmaceutical industry. He has been singularly focused on incorporating and digitizing the "patient voice" using meaningful digital health data, and developing actionable insights into helping patients managing their health and wellness. In his various professional roles, he has led a digital health practice, by building cross-functional teams and has hands-on implementation expertise in clinical trials; and helped establish and nurture collaborations, partnerships, and creating IP.

John Reites

Executive intrapreneur turned digital health entrepreneur, John's career includes over 14 years leading global drug development and healthcare innovation. Named one of the Top 100 Influencers in Digital Health, John provides expertise and execution experience in digital health strategy, remote patient research and care, virtual clinical trials, Phase I - IV clinical research, patient reported outcomes, patient engagement, mobile health, omni-channel experience and virtual reality. John is a keynote speaker at global industry events, guest lecturer at Duke University on digital health/innovation and a published author featured in various conferences, journals, articles and media outlets. As Chief Product Officer, Partner at THREAD, John leads THREAD's digital health platform enabling remote patient research conducted by biopharmaceutical companies, CROs and academic researchers.

Annie Saha

Anindita (Annie) Saha is the Director of External Expertise and Partnerships (EEP) in the FDA's Center for Devices and Radiological Health (CDRH). Ms. Saha leads CDRH's Patient Preference Initiative to incorporate patient perspectives on benefits and risk in regulatory decision-making. She is also a part of larger Strategic Priority to Partner with Patients to incorporate patient engagement and the science of patient input and patient-generated data in device design, assessment, and review. EEP also manages the Network of Experts Program, public-private partnerships including the Medical Device Innovation Consortium (MDIC), the Critical Path and Regulatory Science Initiatives, fellowship programs including the Medical Device Fellowship and AIMBE Scholars programs, and technology transfer and collaboration efforts for the Center. Ms. Saha began her FDA career as a researcher in the CDRH's Office of Science and Engineering Laboratories in the Division of Imaging and Applied Mathematics in the area of imaging display technologies before moving to EEP to coordinate Critical Path and Regulatory Science activities for the Center. Ms. Saha has a Bachelor of Science in Bioengineering and Minor in History from the University of Pittsburgh. She was a student researcher at the McGowan Institute for Regenerative Medicine working in tissue engineering and wound healing.

Kevin Weinfurt

Kevin P. Weinfurt, PhD, is a professor in psychiatry and behavioral sciences at the Duke University School of Medicine. He holds a secondary appointment as a professor of psychology and neuroscience. He is co-director of the Clinical Research Training Program.

Dr. Weinfurt conducts research on measuring patient-reported outcomes, medical decision making, and bioethics. In addition to conducting research, Dr. Weinfurt has taught undergraduate courses in introductory psychology, judgment and decision making, the psychology of medical decision making; and graduate courses in multivariate statistics and patient-reported outcomes research.