Mobilizing mHealth Innovation for Real-World Evidence Generation

1201 Pennsylvania Ave. NW • Washington, DC 20004
September 15, 2017

Alicyn Campbell

Alicyn Campbell is the Global Head of Patient Centered Outcomes Research for Oncology at Genentech, a member of the Roche Group.

She leads a team of Outcomes Research Scientists to create and implement strategies to quantify the patient's voice to better understand the impact of new treatments.

With over 11 years of experience developing and implementing patient relevant endpoint strategies across all areas of oncology, Alicyn's work includes endpoint development (performance tests, digital health, clinical outcome assessments), qualitative and quantitative research, treatment preference and satisfaction, and burden of illness.

Alicyn is a recognize expert on patience centricity and has presented at: DIA, C-Path, the Brookings Institute, Friends of Cancer Research, ISOQOL, UNC Lineberger Comprehensive Cancer Center, FDA Public workshops, and is ASCO faculty.

Alicyn completed her Masters of Public Health from the University of Connecticut School of Medicine with concentrations in Epidemiology and Outcomes Research.

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.

Martin Entwistle

President of Ares Health Systems; March 2014 – Current Date. Providing services for the design, development and deployment of large-scale personalized care solutions that drive sustained patient engagement, integrate with clinical workflows and advance population health outcomes. Ares Health

services include use of Mpower™, an advanced care-delivery platform that bridges the gap between consumer and population health ecosystems to connect users and care-teams in participatory health that drives bottom-line value.

Executive Director Personal Healthcare Programs, Sutter Health, USA; December 2014 – March 2017. Responsible for building and deploying system of care solutions in Sutter Health, a not-for-profit California health system with 3 million patients, including integrated mHealth capabilities and extensive use of patient generated health data (PGHD) supporting chronic care management, health and wellness (e.g. home tracking BP, glucose, weight, activity)

Executive Director Innovation, Palo Alto Medical Foundation, USA; August 2010 – December 2014. Focus on driving the establishment and development of a department of innovation in one of the USA's largest integrated health systems. Created and deployed two large-scale systems, providing end-to-end patient-care programs, delivering innovative approaches to personalized healthcare and a community model for successful aging.

Subject matter expert on care-management systems. Advanced experience in clinical information systems development and deployment. Regular presenter on these experiences at national-level conferences.

Rachael Fleurence

Rachael L. Fleurence, PhD is the newly appointed Executive Director for the NEST coordinating Center, a joint initiative of the FDA and the medical device industry to improve evidence generation for medical devices. She joins MDIC from the Patient-Centered Outcomes Research Institute (PCORI) where she has led PCORI's initiative to build the National Patient-Centered Clinical Research Network, or PCORnet, sine 2012. PCORnet has been a transformational effort to engage patients and leverage electronic health data to improve the speed and efficiency of clinical research in the United-States. A 330 million dollar investment involving 130 health institutions across the country, 20 patient powered research networks and covering 110 Million patients, PCORnet has just launched as an independent foundation in March 2017. Dr. Fleurence has served on a number of Boards and Steering Committees, including most recently the National Medical Device Evaluation System Planning (NEST) Planning Board, the Medical Device Innovation Consortium (MDIC) Board and the SMART IRB Steering Committee, an effort to streamline IRB reviews across academic research institutions. She was the chair of the PCORnet Executive Committee, and vice-chair of the PCORnet Council.

A health economist and health services researcher by training, Dr. Fleurence previously worked in the private sector in health outcomes research and has authored multiple peer-reviewed publications. Dr. Fleurence received a BA from Cambridge University (United-Kingdom), a MA in business management from ESSEC-Paris (France), and a MSc and PhD in health economics from the University of York (United-Kingdom).

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 28 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.

Cynthia Grossman

Dr. Cynthia (Cyndi) Grossman is associate director, Science of Patient Input at FasterCures, a center of the Milken Institute. Prior to joining FasterCures, Cyndi was Program Chief in the Division of AIDS Research (DAR) at the National Institute of Mental Health (NIMH). She has spent her career conducting and supporting research to address the unmet patient needs related to mental health, stigma, and other social determinants of health. At FasterCures, Cyndi leads projects to advance the science of integrating patient perspectives from early R&D through care delivery to encourage greater alignment of medical products with patients unmet needs. Cyndi holds a doctoral degree in clinical psychology from the University of Vermont and post-graduate training from Brown University.

Mark McClellan

Mark McClellan, MD, PhD, is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Margolis Center for Health Policy at Duke University. He is a physicianeconomist who focuses on quality and value in health care including payment reform, real-world evidence and more effective drug and device innovation. He is former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. He was previously Senior Fellow at the Brookings Institution and a faculty member at Stanford University

Ravi Ramachandran

Ravi Ramachandran, PhD, is Senior Director, Business Partnerships & Solutions, at PatientsLikeMe Inc. Ravi brings over a decade of experience in digital health strategy, and hands-on implementation of wearables, 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 15 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 research, virtual clinical trials, Phase I - IV clinical research, patient reported outcomes, patient engagement,

mobile health and omni-channel experience. 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, John leads THREAD's digital health platform enabling biopharmaceutical companies, CROs and academic researchers to conduct remote patient research.

Jeff Shuren

Jeffrey Shuren, MD, JD is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.

Christina Silcox

Christina Silcox is a Research Associate at the Duke-Margolis Center for Health Policy, working on policy solutions to advance innovation and improve regulation and long-term evaluation of medical products.

Dr. Silcox's work covers multiple areas of policy around real-world evidence, with a concentration on medical devices. She has worked on projects that include the facilitation of the National Evaluation System for health Technology (NEST) Planning Board's recommendations around the collection of real-world data, the use of patient-generated health data collected through mHealth, and value-based payments for medical products.

Before she joined Duke-Margolis, Dr. Silcox was a senior fellow at the National Center for Health Research, focused on federal regulation of and policies for medical products. She earned a M.S. from the Massachusetts Institute of Technology (MIT) in Electrical Engineering and a Ph.D. in Medical Engineering and Medical Physics from the Harvard-MIT Division of Health Sciences and Technology (HST).