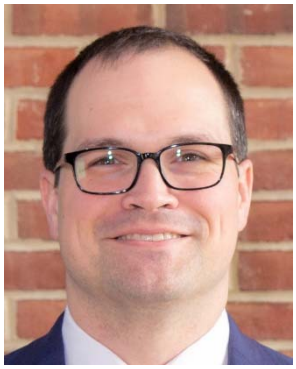
FDA/CERSI IMPACT Bootcamp

Navigating the Journey from Digital Health Technologies to Meaningful Patient Outcomes

Instructor Biographies



Fraser Bocell, PhD

Clinical Outcome Assessment (COA) Reviewer, Patient Science and Engagement Program, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Fraser Bocell, PhD is a Psychometrician and Clinical Outcome Assessment Reviewer with the Patient Science and Engagement Team in CDRH at the FDA. He earned a M.Ed. and Ph.D in Measurement and Statistics from the University of Washington. At CDRH he provides expertise and training, as well as develops policy on the evaluation and use of COAs in regulatory decision-making. Prior to joining the FDA, he published on the quantitative and qualitative development and evaluation of PROMs, as well as providing statistical expertise to other projects. Dr. Bocell is an expert in psychometric methods and an applied statistician by training, specializing in latent variable models. He continues to explore new methods for developing and evaluating COAs and seeks to improve the relevance and utility of COAs in regulatory decision making.

Allen Chen, PhD

Program Manager, Patient Science and Engagement Program, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Allen Chen is Program Manager for the Patient Science and Engagement Program (PSE) in the Office of Strategic Partnerships and Technology Innovation (OST) within FDA's Center for Devices and Radiological Health (CDRH). As Program Manager, Dr. Chen manages PSE's operations and patient science research portfolio, and leads special projects towards ensuring that the patient voice can be seamlessly integrated in the medical device ecosystem. Dr. Chen joined PSE in 2019 after serving as Lead Reviewer and Biomedical Engineer in the Division of Renal, Gastrointestinal, Obesity, and Transplant Devices (DRGOT) in CDRH's Office of Product Evaluation and Quality (OPEQ). As a Lead Reviewer, Dr. Chen led review teams comprised of subject matter experts in the evaluation of medical device investigational and marketing submissions, postmarket signals, and compliance matters, in order to ensure the safety and effectiveness of medical devices. Dr. Chen previously served as an American Institute for Medical and Biological Engineering (AIMBE) Scholar in CDRH's Office of the Center Director, where he co-led the Patient-Reported Outcomes (PRO) Working Group and coordinated related strategic initiatives. Allen received a BS in Bioengineering and Business, and a PhD in Bioengineering from Rice University.

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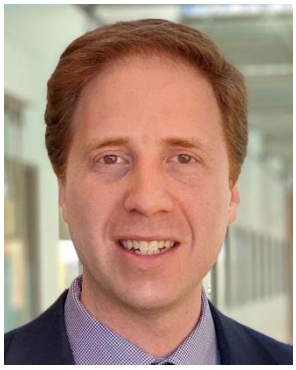


Matthew Diamond, MD, PhD

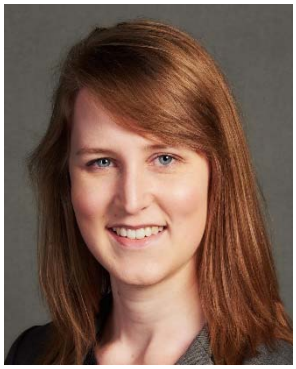
Medical Officer and Senior Clinical Expert for Digital Health, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Matthew Diamond, MD, PhD is the medical officer and senior clinical expert for digital health at FDA's Center for Devices and Radiological Health. Dr. Diamond oversees digital health policy development and implementation for emerging technologies in including artificial intelligence and medical device software, and he leads numerous initiatives in these areas. Serving on center, agency, and international working groups, he regularly provides consultation within and outside of the agency on digital health. Dr. Diamond has also been serving on the CDRH COVID-19 response leadership team.

Dr. Diamond brings experience from his work at large and small technology companies, including as Chief Medical Officer at Nokia, and as Medical Director at Fossil Group and the startup Misfit Wearables. As Vice Chair of the Consumer Technology Association (CTA) Health & Fitness Technology Board, Dr. Diamond promoted public health applications of mobile technology, and he established an ANSI-accredited standardization committee to develop standards in digital health for wellness-related devices and apps.

Dr. Diamond has served on numerous advisory boards including for the Center for Personalized Health Monitoring at UMass Amherst and for the venture firm NGP Capital. As a wearables expert, he was Chair of the USA Technical Advisory Group to the IEC Wearables Standards Committee TC124. Dr. Diamond earned his MD and PhD (biophysics) from the Mount Sinai School of Medicine, and he is board certified in rehabilitation medicine and sports medicine, with certification in medical acupuncture. A faculty member at NYU, Dr. Diamond is passionate about helping people improve their mobility and performance through a holistic approach to rehabilitation and technology that promotes wellness.

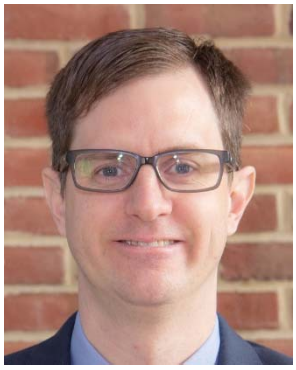


Sonja Fulmer, PhD

Assistant Director for Digital Health Policy, Division of Digital Health, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Sonja Fulmer is Assistant Director for Digital Health Policy in the Division of Digital Health (DDH) in the Office of Strategic Partnerships and Technology Innovation (OST), Center for Devices and Radiological Health (CDRH). In this role, Dr. Fulmer works to help DDH advance and implement new policy approaches to medical device software and digital health technologies to better promote and protect public health. Before joining the DDH in 2020, Dr. Fulmer joined the Center for Devices and Radiological Health (CDRH) in 2014 as an AIMBE Scholar to pursue her interest in science policy after earning her undergraduate degree in Chemistry, with a Biochemistry concentration, from the University of Alabama at Birmingham (UAB) and her doctorate in Chemical and Physical Biology from Vanderbilt University. Dr. Fulmer has held several policy-focused positions in the Office of the Center Director and later as a Policy Advisor in the Office of Policy.



David Gebben, PhD

Health Economist, Patient Science and Engagement Program, Center for Devices and Radiological Health

U.S. Food and Drug Administration

David Gebben, PhD is a research economist focusing on stated preference methods applied within a health care context. Specifically, how stated preference methods can advance regulatory science to inform benefit risk evaluations, clinical trial endpoints, and inform ordering of patient priorities. David has worked at the FDA since June 2018, and prior to joining the Federal government he worked at RTI Health Solutions assisting and helping oversee studies sponsored by industry. Prior to working in a health context, David completed a post-doctorate at Queen's University Belfast studying preferences for invasive plant species management. David completed his PhD at Colorado State University with Dr. John Loomis and completed his MS at Michigan State University with Dr. Frank Lupi. Prior to graduate school David worked in international development, completing a 2.5-year internship in Haiti.

Anupama Govindarajan, PhD

Sr. Advisor to Digital Health, Division of Digital Health, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Dr. Anupama Govindarajan is an Engineer, Nanotechnologist and Medical Device Regulator with a passion for enabling the translation of emerging medical device technologies to safe clinical use – particularly for patients with unmet needs. She received her Ph.D. in Electrical Engineering from the University of Washington in Seattle in the area of micro-and-nano- technologies for biomedical implants.

Her work experiences in the medical-device field over almost two decades have been enriched by closely participating in the diverse viewpoints of different stakeholders across many cultures: the FDA, large companies like Lockheed Martin, startups, academia, research institutions with vast budgets (A*STAR Singapore), funding organizations & non-profits. In these positions, she has held several technical-leadership positions in the development of miniaturized medical devices, active-implantables, paper microfluidics, and point-of-care diagnostics for resource-limited settings.

Her regulatory career at FDA's Center for Devices and Radiological Health (CDRH) spans scientific review, change management and program building. As lead pre-market reviewer, she has often led the review of several complex and novel first-in-human neurostimulation devices. She detailed as Senior Policy Advisor with CDRH Innovation wherein she helped craft regulatory support strategies promoting early-feasibility, breakthrough and first-in-human studies across several disciplines. She was selected in 2018, to lead the Recall Branch through FDA/CDRH's re-organization. In this capacity, she oversaw medical-device recalls for the United States and re-designed the center's recall review process. In 2019, she joined the Division of Digital Health - to prepare CDRH for the review of emerging digital health technologies.

She looks forward to expanding her expertise to leadership roles in medical device development, regulation, policy, and in the development of a reliable global medical-device ecosystem.

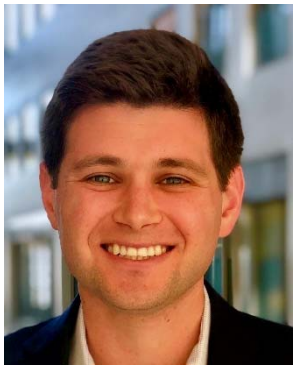
Tracy Gray, MBA, MS

Patient Engagement Lead, Patient Science and Engagement Program, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Tracy Gray is the Patient Engagement Lead in FDA's Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST), Patient Science and Engagement Program. In CDRH, patient engagement refers to the "intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations. These partnerships with patients help CDRH advance the development and evaluation of innovative medical products and monitor the performance of marketed devices". As the Patient Engagement lead, Tracy works with internal and external stakeholders, to foster a culture of patient engagement in CDRH, and in collaboration with other Centers across the agency. Prior to joining the FDA, Tracy held positions in the Health Resources and Services Administration (HRSA), as a Senior Nurse Consultant, Chief of the Nurse Corps Scholarship Branch and Chief of the Advanced Nursing Education Branch, overseeing branch operations, grants management and policy development that resulted in an increased supply of registered and advanced practice nurses, and nurse faculty working in rural and underserved areas across the nation. Tracy served as the Designated Federal Officer (DFO), for the National Advisory Council on Nurse Education and Practice (NACNEP), a council that makes recommendations to the Secretary and Congress, related to the nursing workforce, education and practice improvement. Tracy has worked for the benefit of patients throughout her healthcare career, while providing nursing care, leading grass-roots marketing and business development initiatives in a disproportionate share health system and working in the pharmaceutical industry to increase availability of therapeutic drugs for chronic conditions.

Tracy earned a B.S. in Biological Sciences, with a concentration in microbiology, from the University of Maryland, College Park, and earned a M.B.A. from Marymount University, and a R.N. and M.S. degree from the University of Maryland School of Nursing, Baltimore, MD.

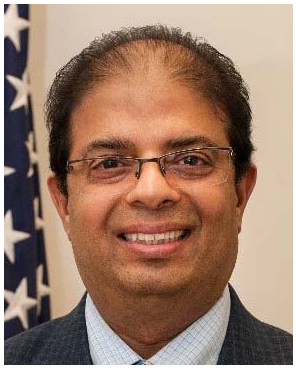


Ian Marcus, MS

Health Scientist, Division of Digital Health, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ian Marcus is a Health Scientist in FDA's Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST), Division of Digital Health (DDH). Ian began his FDA career in 2015 as a Biomedical Engineer / Lead Reviewer in the Office of Neurological and Physical Medicine Devices (OHT5), leading interdisciplinary teams to review 200+ pre-market and post-market medical device submissions, including: digital health technologies, wearable transducers, electrical stimulators, exoskeletons, and brain computer interfaces. Ian received his bachelor's degree in Engineering Science and Mechanics with a Biomechanics Focus from Virginia Tech in 2013 and received his master's degree in Engineering Mechanics from Virginia Tech in 2014. Prior to joining the FDA, Ian worked as a Research Engineer at the Center for Injury Biomechanics at the Wake Forest School of Medicine.



Bakul Patel, MS, MBA

Director, Division of Digital Health, Center for Devices and Radiological Health

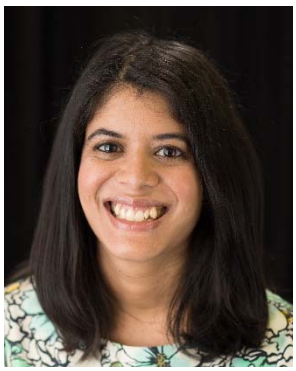
U.S. Food and Drug Administration

Bakul Patel is the Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.

Mr. Patel, in 2013, created the term “software as a medical device” (SaMD) and under his leadership the International Medical Device Regulators Forum (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA.

Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program to reimagine a pragmatic regulatory approach for Digital health that that aims for patients and providers to have timely access to safe and effective digital health products.

Prior to joining FDA, Mr. Patel held key leadership positions in several sectors including 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.

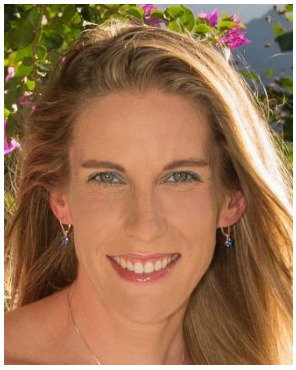


Anindita (Annie) Saha

Director, Partnerships to Advance Innovation and Regulatory Science, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Anindita (Annie) Saha is the Director of Partnerships to Advance Innovation and Regulatory Science (PAIRS) in the FDA’s Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST). PAIRS develops and manages CDRH’s external collaborations and public-private partnerships including the Medical Device Innovation Consortium (MDIC) and the Network of Experts program, fellowship programs including the Medical Device Fellowship and AIMBE Scholars programs, and technology transfer and collaboration efforts for the Center. PAIRS directs and coordinates CDRH’s Regulatory Science, Critical Path, and CERSI activities to facilitate research to promote the development and assessment of high quality, safe, and effective medical devices. Ms. Saha and PAIRS work closely with the Patient Science and Engagement team at CDRH on patient preference information and patient-reported outcomes to foster incorporation of the patient perspective in our decision making. 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 PAIRS 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.

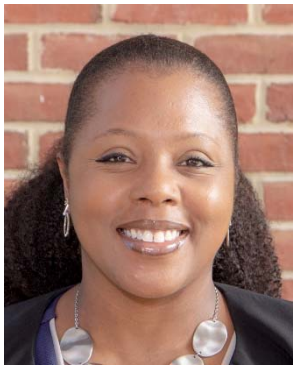


Heike Sichtig, PhD, MS

Pre-Cert Streamlined Review Team Lead, Division of Digital Health, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Heike Sichtig, Ph.D., M.S., is a subject matter expert (SME) and Pre-Cert Streamlined Review Team Lead in FDA's Division of Digital Health. Dr. Sichtig provides technical expertise on artificial intelligence, genomics and other emerging technologies for digital health. She directs, as sole PI, the highly collaborative effort on developing FDA-ARGOS: FDA dAtabase for Reference Grade micrObial Sequences. For her exceptional leadership on this project, Dr. Sichtig was awarded the Commissioners' Special Citation award in 2016. She obtained a B.S. / M.S. in Computer Science/Statistics from Kean University in 2002 and 2003, respectively, and a Ph.D. in Biomedical Engineering from Binghamton University in 2009. Subsequently, Dr. Sichtig completed postdoctoral training at the University of Florida/Genetics Institute in Gainesville FL in pathogen signatures, transcriptional regulation and epigenetics.



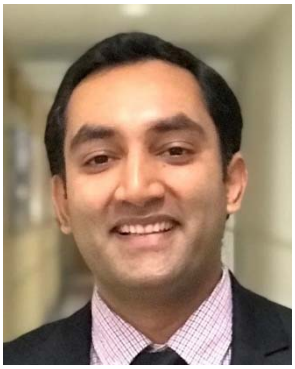
Michelle Tarver, MD, PhD

Director, Patient Science and Engagement Program, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Michelle Tarver is the Director of the Patient Science and Engagement Program at the Center for Devices and Radiological Health (CDRH). The Patient Science and Engagement Program fosters innovative approaches to collecting, analyzing and integrating the patient perspective in the development, evaluation and surveillance of medical devices, including digital health technologies. Under her leadership, CDRH is making the integration of the patients' perspectives throughout the total product lifecycle of medical devices part of its daily business. She also leads the CDRH Patient Engagement Advisory Committee efforts, an advisory panel comprised entirely of patients and caregivers providing their perspectives on general issues related to the regulation of medical devices. In addition to her experience in patient-focused efforts, Dr. Tarver has extensive experience in premarket and postmarket review of various medical devices, developing guidance documents and standards, and fostering external collaborations.

Dr. Tarver attended Spelman College in Atlanta, GA where she received a B.S. in Biochemistry. She completed the M.D./Ph.D. program at The Johns Hopkins University Bloomberg School of Public Health (Ph.D. in clinical epidemiology) and The Johns Hopkins University School of Medicine. Following her internal medicine internship, she completed a residency in ophthalmology with fellowship training in ocular inflammation (uveitis) both at the Wilmer Eye Institute (Johns Hopkins). As an epidemiologist and board-certified ophthalmologist, she has worked on longitudinal epidemiological studies, clinical trials, registries, developing patient-reported outcome measures as well as surveys to capture patient preferences with medical devices. Her research has resulted in numerous peer-reviewed publications and published book chapters. As a dedicated clinician, she continues to evaluate and treat ophthalmology patients at Solomon Eye Associates in Bowie, MD.

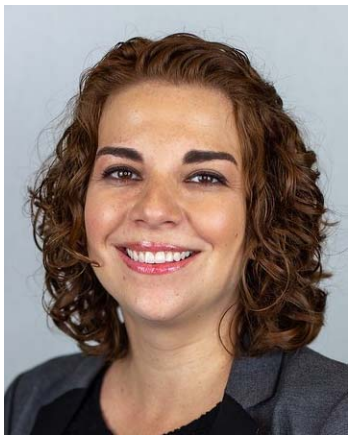


Srikanth Vasudevan, PhD

Regulatory Science Program Manager, Partnerships to Advance Innovation and Regulatory Science, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Dr. Srikanth Vasudevan is a Regulatory Science Program Manager in the Office of Strategic Partnerships and Technology Innovation, Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration (FDA). He received his M.S. and Ph.D. in Biomedical Engineering from the University of Texas at Arlington and the University of Texas Southwestern Medical Center joint program. Since joining the FDA in 2014, Dr. Vasudevan has led research in the area of neuromodulation and neural interfaces, served as a medical device regulatory reviewer, developed project management solutions, and provided digital health policy support. Dr. Vasudevan is a recipient of several awards, including one for the development and implementation of office-wide regulatory science project management solution.



Jessica Weinberg, MPP

Social Science Analyst, Patient Science and Engagement Program, Center for Devices and Radiological Health

U.S. Food and Drug Administration

Jessica Weinberg is a Social Science Analyst in the Center for Devices and Radiological Health, Patient Science and Engagement Program, at the Food and Drug Administration. She is a health researcher with experience in developing surveys, conducting interviews and focus groups, and qualitative analysis. She has spent her career in health research, evaluation, and policy development. She has a Master's in Public Policy with a focus in health policy, and a Bachelors of Arts in Psychology from the University of Maryland, College Park.