Duke | MARGOLIS CENTER for Health Policy

Understanding Priorities for the Use of Digital Health Technologies to Support Clinical Trials for Drug Development and Review

Virtual Public Meeting

March 28, 2023 | 1:00 pm – 4:15 pm ET

March 29, 2023 | 1:00 pm – 4:45 pm ET

Speaker and Panelist Biographies

Wendy Camelo Castillo is Assistant Professor in the Department of Pharmaceutical Health Services Research at the School of Pharmacy, University of Maryland, Baltimore (UMB). Dr. Camelo Castillo is a medical doctor with a MSc degree in physiology, and a PhD in epidemiology. She has expertise in pharmacoepidemiologic and comparative effectiveness research with a focus on multimorbidity in adolescents and young adults. She brings a unique perspective into this work, by integrating the patient perspective into epidemiology and health services research. Her work focuses on three main topics: 1) impact of multimorbidity young cancer survivors and effectiveness of treatments, 2) development of patient-centered methods to improve comparative effectiveness research in the context of multimorbidity and disparities; 3) use of digital health to improve outcome measurement in mental health and comparative effectiveness research.

Lucy Cesnakova is a Program Lead at Digital Medicine Society (DiMe), an organization advancing the ethical, effective, equitable, and safe use of digital medicine to redefine healthcare and improve lives. At DiMe Lucy has led a successful flagship project that applied frameworks and guidances for digital measurement development to a use-case in a specific therapeutic area - digital measurement of nocturnal scratch in atopic dermatitis.

This work included a collection of patient experiences and preferences in a mixed methods study to support development of new digital measurement products targeting scratching. Working with industry, patient organizations, regulators, clinicians and payers, this collaboration resulted in a suite of resources that help operationalize this measure in clinical trials.

In the past, Lucy has led technical development of digital endpoints or other software solutions as a product lead. Using these products in remote clinical trials resulted in both technology and operations understanding of the opportunities and challenges digital technologies can bring to clinical research and healthcare.

Jacqueline Corrigan-Curay is the Principal Deputy Center Director in FDA's Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations. Previously, Dr. Corrigan-Curay was director of CDER's Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and as a practicing attorney in Washington, D.C.

Matthew Diamond is the Chief Medical Officer at FDA's Digital Health Center of Excellence. Serving as the senior clinical expert for digital health medical devices at the Center for Devices and Radiological Health (CDRH), Dr. Diamond provides clinical leadership for policy development on digital health technologies including artificial intelligence. Dr. Diamond represents FDA for national and international digital health initiatives including the International Medical Device Regulators Forum (IMDRF) Artificial Intelligence Working Group. Prior to joining the Agency, Dr. Diamond served on leadership teams of large and small technology companies, including as Chief Medical Officer at Nokia, and as Medical Director at Fossil Group and the startup Misfit Wearables. Dr. Diamond has served on advisory boards including at the Center for Personalized Health Monitoring at UMass Amherst and for the venture firm NGP Capital. As Vice Chair of the Consumer Technology Association (CTA) Health & Fitness Technology Board of Directors, he promoted public health applications of mobile technology and established an ANSI-accredited standardization committee to develop standards in digital health for wellness-related products. Dr. Diamond earned his MD and PhD (biophysics) from the Mount Sinai School of Medicine, and he is board certified in rehabilitation medicine and certified 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.

Danielle Friend received her Ph.D. in neuroscience in 2013 from the University of Utah where her work focused on drug addiction and toxicity. After completing her graduate work, Danielle conducted postdoctoral research on the relationship between obesity and reward circuits in the brain at the National Institutes of Health. In 2016, Danielle was selected as a Science and Technology Policy Fellow with the American Association for the Advancement of Science (AAAS). During her fellowship Danielle developed policies related to genomic and scientific data sharing within the Office of the Director, in the Office of Science Policy at the National Institutes of Health. In 2017, Danielle joined the Biotechnology Innovation Organization (BIO) as a Director of Science and Regulatory Affairs where she covered BIO's work on various topics including rare diseases and orphan drugs, pediatric drug development, cell and gene therapies, decentralized clinical trials, and digital heath technologies. In this role, Danielle also served as an industry negotiator for PDUFA VII. Danielle joined Janssen Research and Development as a Director of Regulatory Policy and Intelligence in August 2021 and much of her work focuses on policy pertaining to digital R&D.

Patrick Gee is a Healthcare Consultant/Community Activist fighting against systemic issues such as poverty, social and racial injustices, criminal justice reform, health equity, and education reform. Patrick is the Founder and Chief Executive Hope Dealer at iAdvocate, a faith-based health and wellness organization that serves the undervalued, underserved, and disenfranchised communities of color.

Patrick graduated from American University, Washington, DC, with a Doctorate of Philosophy in Justice, Law, & Criminology in 2012. Patrick is a patient advocate living with Diabetic Kidney Disease. He travels the country sharing his lived experience with medical providers, pharmaceutical companies, researchers, and patients to create access to a better quality of life, access to care, treatments, and solutions for those living with diabetes, kidney disease, heart disease, hypertension, and health equity challenges.

Patrick serves in several leadership roles, such as Chair of Kidney Health Initiative's Patient Family Partnership Council, Patient Representative of the American Society of Nephrology's Diabetic Kidney Disease-Collaborative Task Force; Chair of Quality Insights Network 5 Patient Family Advisory Committee; and Patient Representative of World Health Organization's Guideline Development Group for Living Guideline on Therapeutics and COVID-19, Drugs to prevent COVID and Clinical Management Workgroup, to name a few.

Patrick's tagline: **"I am the Voice of the Voiceless and the Face of the Faceless in the fight against kidney disease and health injustice."**

Cindy Geoghegan is a patient advocate, advisor, and activist with over 30 years of health policy and communications experience, having held senior staff and board positions with several leading cancer non-profit organizations including Susan G. Komen, Y-ME National Breast Cancer Organization, and others. She began her advocacy career shortly after her breast cancer diagnosis in 1995. She has provided the patient perspective on research teams and projects funded by Stand Up to Cancer, the National Cancer Institute, the American Association for Cancer Research, the American Society of Clinical Oncology, the Patient-Centered Outcomes Research Institute, and has served on the steering committee of the Clinical Trials Transformation Initiative (CTTI), the Duke University/FDA joint venture focused on more efficient clinical trials. She is currently a member of the Johns Hopkins Kimmel Cancer Center's External Advisory Board, and on the Founding Member Council for the Digital Medicine Society (DiMe), where she also serves on its research committee. She has co-authored more than a dozen publications with researchers focused on patient preferences and improving patient outcomes.

Klaus Gottlieb currently serves as a Vice President at Eli Lilly, overseeing the Immunology Business Unit's Digital Health/AI/ML group. He contributes a wealth of diverse experience from his previous roles in clinical practice, academia, FDA, clinical research, and biopharma. He holds professional doctorates in medicine and law and master's degrees in business administration and biotechnology.

Marianne Hamilton Lopez is the Senior Research Director of Biomedical Innovation, an adjunct associate professor, and core faculty at the Duke-Margolis Center for Health Policy in Washington, DC. She leads the strategic design and direction of the Center's Biomedical Innovation portfolio, with a focus on medical products development and regulation, real world evidence, infectious disease preparedness, and payment, pricing, and coverage of drugs and medical devices. She also oversees the Value for Medical Products Consortium and partners with Duke University faculty, scholars, and external health experts to advance this work. Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a senior program officer with the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System and provided strategic direction and oversight of the Consortium's Science and Technology portfolio and Clinical Effectiveness Research Innovation and the Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community Advisor for the United States Cochrane Center; and the Federal Women's Program Manager and American Indian/Alaska Native Employment Program Manager for the National Institutes of Health.

Dina Katabi is the Thuan and Nicole Pham Professor of Electrical Engineering and Computer Science, and the director of the Center for Wireless Networks and Mobile Computing at MIT. Dr. Katabi is a MacArthur Fellow, a member of the National Academy of Engineering, and a member of the American Academy of Arts and Sciences. She received her PhD and MS degrees from MIT in 2003 and 1999, respectively, and her Bachelor of Science from Damascus University in 1995. Dr. Katabi's research interests include digital health, applied machine learning, Internet of Things, and mobile and wireless systems. She develops new technologies, algorithms, and systems that provide non-invasive health monitoring, generate novel biomarkers, enable smart homes, improve Wi-Fi and cellular performance, and deliver new applications that are currently infeasible. Dr. Katabi has received several prestigious awards, including the ACM Prize in Computing, the ACM Grace Murray Hopper Award, two SIGCOMM Test of Time Awards, a Sloan Fellowship, the IEEE William R. Bennett Prize, and multiple best paper awards. Additionally, several start-ups, such as PiCharging and Emerald, have spun out of Katabi's lab.

Jennifer Mammen is an assistant professor at the University of Rhode Island and a family nurse practitioner. Her mixed-methods research is focused on understanding the perceptions and experiences of people living with chronic illnesses such as Parkinson's disease. Dr. Mammen's primary objective is to enable patient voices to be heard in a clear and compelling manner, and to improve understanding between people living with illness, healthcare providers, researchers, regulators, and policy makers. In particular, her novel methodological work in symptom mapping aims to connect what is qualitatively important to patients to new digital health technologies in a measurable way, in order to support the development of future devices, treatments, and clinical outcome measures that align with patient's needs and values.

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Center is a university-wide Duke initiative that is nationally and internationally-recognized for research, evaluation, implementation, and educational initiatives to improve health policy and health, most recently in its COVID-19 response. Dr. McClellan is a doctor and an economist who has addressed a wide range of strategies and policy reforms to improve 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. At the center of the nation's efforts to combat the pandemic, Dr. McClellan is the co-author of a roadmap that details 8 the steps needed for a comprehensive COVID-19 response and safe reopening of our country. 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. He also has a highly distinguished

record in public service and academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These 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 completed a predoctoral internship with the National Health Service in London, UK, and postdoctoral research training within the Department of Population Medicine at Harvard Pilgrim Health Care Institute and Harvard Medical School.

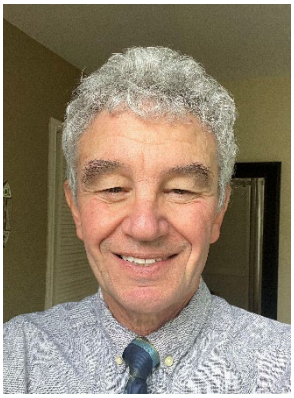
Rebecca Nebel is a Senior Director of Science and Regulatory Advocacy at PhRMA. In this role, she leads advocacy efforts to advance FDA regulatory policy on key issues including digital health, regulatory information and technology, and combination products. Prior to joining PhRMA, Dr. Nebel worked at the Society for Women's Health Research where she led scientific initiatives designed to improve research, diagnosis, treatment, and access to quality care for women, and at the National Institutes of Health's Clinical Center where she managed and implemented strategic initiatives to improve operational processes. She was also a Christine Mirzayan Science & Technology Policy Graduate Fellow at the National Academies of Sciences, Engineering, and Medicine. Dr. Nebel received her PhD in biomedical sciences from Albert Einstein College of Medicine and her BS in biological sciences from Binghamton University.

Carrie Northcott is a Senior Director and Project Lead within Digital Sciences and Translational Imaging (DSTI) at Pfizer, Inc. She leads a driven and diverse team that is developing, validating, and utilizing digital health technologies (DHTs) and novel digital endpoints (NDEs). These DHTs and NDEs are used to further characterize diseases for patients, health care providers and scientists, as well as demonstrate drug efficacy in clinical trials. Carrie has a diverse scientific background in Pharmacology, Toxicology, and Physiology which provides her unique insight into understanding how these NDEs provide meaningful information to patients, physicians and researchers to better treat and understand diseases.

Anne L. Peters is a professor of clinical medicine at the Keck School of Medicine of the University of Southern California. She runs diabetes centers in Beverly Hills and in underserved East Los Angeles. In addition to her clinical work, she has been a principle investigator on multiple grants, has written over 200 articles and 4 books, and has given over 1000 lectures locally, nationally and internationally. She has been on multiple guideline writing committees for the treatment of both type 1 and type 2 diabetes. Her major interests involve translating research findings, from lifestyle interventions to technology, to people with diabetes throughout the socioeconomic spectrum. She is a recipient of the ADA Outstanding Physician Clinician Award, the Bernardo

Houssay Award from the National Minority Quality Forum and an Endocrine Society Laureate Award for Public Service.

Kuldeep Singh Rajput is CEO and Founder of Biofourmis, a global technology-enabled care delivery company, delivering the right care to the right patients at the right time. Biofourmis leverages its proprietary Biovitals® platform and library of biomarkers to predict clinical complications and deliver personalized care for patients at home, across the care continuum. The company is filled with committed, passionate people who care about improving experience, productivity and outcomes for patients and providers; in parallel, Biofourmis is focused on R&D and market access for our pharmaceutical partners. Recognized as a "Forbes 30 Under 30," a PharmaVoice 100 honoree, and a member of the Milken Institute Young Leaders Circle, Rajput has demonstrated strong leadership experience with building teams, developing talent, and successfully growing and managing strategic partnerships with global pharmaceutical manufacturers, health systems and payers. Biofourmis, which was named in 2020 to Forbes' "AI 50: America's Most Promising Artificial Intelligence Companies," became a health tech unicorn in 2022 with a $1.3 billion valuation. The company has raised a total of $465 million from leading venture capital firms, including General Atlantic, CVS Health, Intel Capital, SoftBank, Sequoia Capital, and MassMutual Ventures.



Leonard Sacks received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. He holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences

Abhinav Sharma is a cardiologist, clinician-scientist, and an assistant professor in the division of cardiology at McGill University. His primary research focuses on the use of artificial intelligence and wearable devices to improve diagnosis and identification of cardiovascular disease. The technology he is developing aims to reduce healthcare costs through prevention and early diagnosis thereby improving quality of care for Canadians.

Neeta Sharma serves as the vice president of global regulatory affairs at Dexcom since 2017. She oversees all regulatory affairs activities for Dexcom's continuous glucose sensing technology. Neeta led the regulatory activities for obtaining marketing authorization from the FDA for the G6 Continuous Glucose Monitoring (CGM) system and very recently the G7 CGM system. G6 CGM is the first CGM in the United States to be designated as an integrated CGM (iCGM) permitted by the FDA to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. Neeta has more than 15 years of strategic and executive regulatory leadership experience at leading medical device companies, including Philips, Edward Lifesciences, and Medtronic, and across multiple fields, such as diabetes management and cardiovascular and orthopedic devices. She graduated from the University of Southern California with a dual master's degrees in biomedical engineering and regulatory sciences.

Alicia Staley serves as vice president of Patient Engagement at Medidata. She oversees the Patient Insights Program and the Patient Insights Board. She works to infuse the patient perspective throughout the product development lifecycle and help engage patients in novel ways. She created Patient Centricity by Design (PCbD) in 2018 as a way to provide structure and governance for developing patient-centric technical solutions. Alicia has over 20 years of experience in software design and information systems management. Prior to joining Medidata, Alicia worked at Cure Forward leading their patient engagement and community initiatives to help advance clinical research.

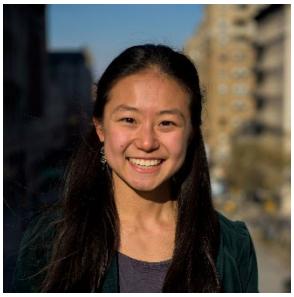
Alicia is also a three-time cancer survivor, first diagnosed with Hodgkin's disease as a sophomore during college. With an extensive network of patient advocates and non-profit organizations, she collaborates with a wide range of stakeholders to help improve processes and policies that impact cancer care. As a champion of patient advocacy and engagement, she understands the critical issues facing patients seeking to engage in clinical research.

Diane Stephenson is a neuroscientist by training with 30 years combined experience in academic neuroscience and drug discovery. She is passionate about translational science and has a long-time dedication to the discovery of therapies to treat diseases of the nervous system. Dr. Stephenson received her undergraduate degree in Biochemistry at University of California and her Ph.D. in Medical Neurobiology from Indiana University. She spent the majority of her career as a translational neuroscientist at the largest pharmaceutical companies focusing on disease areas including Alzheimer's, Parkinson's, Stroke, ALS and Autism Spectrum Disorders. Dr Stephenson joined Critical Path Institute in 2011 and has launched several new programs such as the Huntington's Disease Regulatory Science Consortium. She presently leads Critical Path for Parkinson's (CPP), a multinational consortium comprised of academic experts, industry scientists, patient advocacy groups and regulatory experts collectively aimed at accelerating drug development tools for

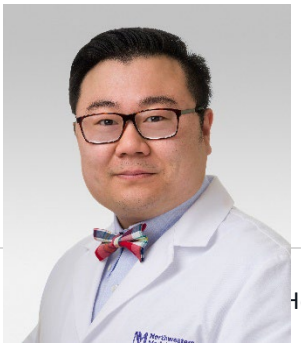
Parkinson's disease. Dr. Stephenson focuses on highlighting the voice of people living with Parkinson's in all CPP's efforts.

Reginald Swift is focused on catalyzing innovation at a grander scale to change how health outcomes can be realized through patient product and service innovation. With a background in mechanical engineering, many research pursuits also involve developing regenerative metals to target specific diseases such as Multiple Sclerosis for Myelin regeneration, ALS, PLS, PKAN, and much more (with a rare and infectious disease focus). With Founding Rubix Life Science, he has devoted his research attention to tackle global health research inequities and to accelerate therapies, through research, to support the patient journey in global underserved communities. With project work conducted in some of the most obscure and remote locations, he has quickly become focused on deploying rapid clinical trial methods that will serve patients in a robust fashion, no matter the level of technologies made available.

Jeremy Wyatt has held progressive leadership roles at ActiGraph since its inception in 2004. He led both the company's hardware engineering and software development teams and served as the Chief Technology Officer until his appointment as Chief Executive Officer in May 2020. With two decades of embedded hardware systems development and related cloud technology expertise, Jeremy has a uniquely well-rounded perspective on the challenges and opportunities of deploying wearable technologies to capture accurate and meaningful patient data. He is considered an industry thought leader and expert in the clinical biosensor space and is a frequent representative and contributor at clinical drug development commercial events, scientific consortiums, and FDA/EMA regulatory meetings. He has an undergraduate degree in electrical engineering from the University of Florida and an MBA from the University of West Florida. Jeremy is a member and contributor to the Digital Medicine (DiMe) Society and participates in various digital biomarker efforts with the Clinical Trial Transformation Initiative (CTTI).



Yuge Xiao is an associate director at the Michael J. Fox Foundation for Parkinson's Research (MJFF) where she oversees the Foundation's portfolio of clinical and digital measures. Prior to her current role, Yuge was a strategy consultant within the life sciences industry.



Steve Xu is a physician-engineer, board certified dermatologist, academic, and entrepreneur. He holds an appointment as the Director of Medical Research at the Querrey Simpson Institute for Bioelectronics at Northwestern University, and the Ruth K. Freinkel, MD, Professorship in the Department of Dermatology at Northwestern University. Dr. Xu has authored more than 140 peer-reviewed publications, which include works in *Nature, Science, The New England Journal*

of Medicine, and the Proceedings of the National Academy of Sciences. Furthermore, he is an inventor on 15 pending and granted patents in the fields of digital health, medical device development, and medical innovation as an MIT 35 Under 35 honoree (Class of 2022). He is currently on leave from his academic position at Northwestern University to serve as the CEO of Sibel Health where he is also a cofounder and board member. To date, Sibel has launched FDA-cleared wearable sensors in more than 20 countries, and monitored more than 14,000 individuals worldwide.

Moderators

Nancy M. Allen LaPointe is an Adjunct Associate Professor in Medicine at Duke University and Faculty Fellow at the Duke-Margolis Center for Health Policy. She is a researcher and cardiovascular clinical pharmacist with extensive experience in health outcomes research, health services research, evidence synthesis, medication management, and the protection of human research subjects. Her clinical and research work has been focused on patient safety, predominately in patients with cardiovascular disease. This includes work in reducing medication errors, improving medication adherence, safely and effectively translating evidence into clinical practice, comparing safety and effectiveness of therapeutics, evaluating risk communication and mitigation strategies, and exploring the interface between health policy and patient safety. Prior to working with Duke-Margolis, she was an Associate Professor in Medicine at Duke University and the Duke Clinical Research Institute, Director of the Duke Heart Center Distinguished Research Center Program, Chair in the Duke University Health System IRB, Program Director of the Duke Center for Education and Research on Therapeutics, Principal in Applied Research and Analytics at Premier Inc, and Cardiovascular Clinical Pharmacist with the Duke Heart Center. She was also a Clinical Associate Professor at UNC School of Pharmacy and Adjunct Professor of Pharmacy Practice at Campbell University School of Pharmacy and Health Sciences. Dr. Allen LaPointe received her BS in Pharmacy and Doctor of Pharmacy degrees at Purdue University and completed her pharmacy residency at the Duke University Medical Center, Department of Pharmacy, and her clinical pharmacy fellowship in cardiology at the Duke University Medical Center, Division of Cardiology. She then received a MHS with focus on comparative effectiveness research at Duke University**.**

Lola A. Fashoyin-Aje is a medical oncologist and Deputy Director in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Center for Drug Evaluation and Research- Food and Drug Administration (FDA). In this role, she provides clinical, scientific, and regulatory policy guidance and oversight to multidisciplinary teams reviewing drugs and biologics under development for the treatment of solid tumor malignancies. Dr. Fashoyin-Aje is also an Associate Director at the FDA Oncology Center of Excellence at the FDA, where she leads initiatives to address clinical and regulatory science and policy

issues impacting oncology drug development. Prior to joining the FDA, Dr. Fashoyin-Aje completed her undergraduate and graduate training at Columbia University and Yale University, respectively, and received her M.D. degree from the University of Rochester School of Medicine and Dentistry. She completed postgraduate training in internal medicine and medical oncology at Johns Hopkins.

Jennifer C. Goldsack founded and serves as the CEO of the Digital Medicine Society (DiMe), a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. Previously, Jennifer spent several years at the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA. Jennifer spent five years working in research at the Hospital of the University of Pennsylvania, first in Outcomes Research in the Department of Surgery and later in the Department of Medicine. More recently, she helped launch the Value Institute, a pragmatic research and innovation center embedded in a large academic medical center in Delaware. Jennifer earned her master's degree in chemistry from the University of Oxford, England, her masters in the history and sociology of medicine from the University of Pennsylvania, and her MBA from the George Washington University.

Christina Silcox is the Research Director for Digital Health at the Duke-Margolis Center for Health Policy, working on policy solutions to advance innovation in health and health care and improve regulation, reimbursement, and long-term evaluation of medical products, with a focus on digital health. Dr. Silcox's portfolio includes multiple areas in digital health policy and real-world evidence, with an emphasis on medical devices. Currently, she is concentrating on challenges to regulating and adopting of artificial intelligence-enabled software as a medical device, using mHealth to collect real-world data, and characterizing real-world data quality and relevancy. Her projects have included the use of patient-generated health data in medical device evaluations, the exploration of value-based payments for medical devices, and the convening the National Evaluation System for health Technology (NEST) Planning Board.

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).

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