



## **Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies**

*A public meeting to fulfill FDORA Section 3605 requirements and to address the need for advanced planning for clinical study disruptions*

October 18-19, 2023 | 10:00 a.m.—1:30 p.m. EDT

### **Speaker Biographies**

#### **Opening Remarks, Day 1**

**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. 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). Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical assistant professor of medicine. She has continued to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, D.C.

**Janet Woodcock** is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions. Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER). At CBER, she served as Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure. In 2007 Dr. Woodcock was asked to be the therapeutics lead for "Operation Warp Speed" in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19. Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the



Feinberg School of Medicine at Northwestern University Medical School (Chicago). She also completed further training and a fellowship in rheumatology, as well as held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She is board certified in internal medicine.

### **Cross Cutting Industry Perspectives**

**Anina Adelfio** is the Chief Operating Officer for ACRO, the Association of Clinical Research Organizations, a DC-based trade association that represents CROs and technology organizations. She has been with ACRO since 2015 and in her current role since 2022. Anina works closely with ACRO's Risk-Based Quality Management (RBQM) team and leads ACRO's Ukraine Response Team. She runs a four-year long project assessing how RBQM principles are applied and utilized in clinical trials. In 2020, she focused on ACRO's response to the COVID-19 pandemic. In addition, she oversees several collaborations that ACRO has with Regulators and other stakeholder groups in the clinical trial industry. Anina earned a BA from the University of Maryland and is currently pursuing a Masters of Regulatory Affairs from the University of Pennsylvania.

**David Borasky** is Vice President, Compliance for WCG IRB where he is responsible for quality and compliance functions, including maintenance of WCG IRB's AAHRPP accreditation and ISO 9001 certification and serving as liaison to regulatory agencies. He has over two decades of experience managing institutional review boards in multiple settings including research institutes, large academic medical centers, and independent IRBs. David also has experience facilitating training activities on basic research ethics and IRB operations and function for IRBs and investigators and has provided hands-on assistance to IRBs throughout North America, Africa, and Asia. He has served as a consultant for the Office of Human Research Protections, the US Department of Energy, the World Health Organization, and numerous other institutions. David is a Certified IRB Professional and former member of the Board of Directors for PRIM&R. He is Co-Chair of the Subpart A Subcommittee of the HHS Secretary's Advisory Committee on Human Research Protections. David is a frequent presenter on IRB operations and quality and compliance in the IRB setting.

**Janice Chang** is the Chief Executive Officer at TransCelerate BioPharma Inc. Janice has been involved with the organization since its inception. In her current position, Janice works closely with the Board of Directors to shape the long-term strategic vision and priorities for the organization and its 30+ initiatives. Janice defines and guides TransCelerate's overall external engagement strategy with global health authorities, governmental agencies, industry groups, and TransCelerate's country network spanning across 30 countries. She has accountability overseeing TransCelerate's corporate operations and works closely with her team to drive strategic delivery of TransCelerate's portfolio. Janice also actively participates in various cross-stakeholder global discussions to help evolve our R&D paradigm. With a background of 20+ years of experience leading initiatives in large pharma and biotech companies, Janice has experience spanning across regulatory, clinical, and



manufacturing. Janice is passionate in driving meaningful change across our ecosystem and not settling for the status quo. She believes in reimagining the way we advance innovative medicine and advocates for the power of open collaboration across stakeholder groups.

**Karla Childers** is the Head of Bioethics-based Science & Technology Policy, Office of the Chief Medical Officer at Johnson & Johnson. Karla Childers joined Johnson & Johnson (J&J) in October 2013 in the Office of the Chief Medical Officer where her primary responsibility has been leading and coordinating various ethics-based, science and technology policy projects. Her longest running responsibility has been the support and coordination of Johnson & Johnson's Clinical Trial Data Transparency Initiative, including the management of the Yale University Open Data Access (YODA) Project data sharing collaboration. Ms. Childers is the Chair of the J&J Bioethics Committee, which serves as an internal forum providing advice on bioethical questions within J&J. She is responsible for the management and conduct of that committee and relevant bioethics consultations. She serves as a bioethics subject matter expert for various internal and external science and technology policy work and coordinates the internal bioethics educational program sponsored by the Office of the Chief Medical Officer.

**Janet Vessotskie** is currently Deputy Vice President of Science and Regulatory Advocacy at PhRMA and is responsible for the International Regulatory portfolio. Dr. Vessotskie is a regulatory affairs professional who has expertise in both leading regulatory strategies as well as regulatory policy and intelligence activities in North America, Latin America, Africa, and Asia. Prior to joining PhRMA, Dr. Vessotskie has over 20 years' experience in the pharmaceutical industry with various pharmaceutical companies, most recently Takeda Pharmaceuticals where she led a Global Regulatory Intelligence and Policy Network for Global Regulatory Affairs. Dr. Vessotskie has a PhD in pharmacology from the University of Pennsylvania and a Master of Public Health from New York University.

### **Patient Experiences and Perspectives**

**Karin Hoelzer** directs Policy and Regulatory Affairs for the National Organization for Rare Disorders (NORD®). In this role, Karin provides strategic direction to advance NORDs federal policy and regulatory priorities. She works closely with key rare disease partners across the pharmaceutical and biological space to ensure the policy landscape supports innovative approaches and new treatments to help rare disease patients, and adequately incorporates patient preferences and perspectives in therapy development. Dr. Hoelzer is a health policy, risk analysis, and biomedical research expert, with extensive intellectual property and regulatory expertise across most FDA-regulated products. Most recently, she worked at Maximus, Inc. where she established and led a new health data analytics division to provide more timely data and better insights to government clients in support of the public health response to the COVID-19 pandemic. Prior to working at Maximus, Inc., Dr. Hoelzer served as Senior Officer for Health Programs at The Pew Charitable Trusts where she led policy and regulatory efforts to improve the federal oversight of a variety of FDA-regulated products. Dr. Hoelzer



joined Pew from the Food and Drug Administration (FDA), where she served as Risk Analyst. In this role, she assessed and quantified the expected impact of changes to FDA policy and regulatory practice.

**Valen Keefer** is a Patient Advocate, Educator, and Consultant for Thermo Fisher Scientific and Otsuka America Pharmaceutical. At 40 years old, she has spent half of her life as a transplant recipient. Diagnosed with polycystic kidney disease (PKD) at the age of 10, Valen needed a kidney transplant at 19 and a new liver at 35. Her experience navigating her health challenges with limited support and resources led her to become a passionate patient advocate for the past 20 years. She is a respected voice in the PKD, organ donation community, and beyond. Valen strives to educate industry and clinicians on the post-transplant needs of recipients, raise awareness of the importance of organ donation, elevate kidney health, and offer hope to chronically ill patients. By sharing her firsthand experiences and creating the resources she wishes she had, Valen has educated millions, helped exemplify the transformative impact of transplantation, and inspires many past her own communities and causes. Her commitment to making the voice of the kidney and transplant community heard has become a beacon of hope for countless people and empowers many to be their own best advocates – taking better charge of their health while pursuing meaningful, purpose-driven lives.

**Neena Nizar** serves as Founder and Executive Director of the Jansen's Foundation, a nonprofit established in 2017 to develop treatments for Jansen's Metaphyseal Chondrodysplasia, an ultra-rare bone disease that affects less than 30 people worldwide. Nizar has a Doctoral degree in Educational Leadership from Creighton University, Nebraska, is a TEDx speaker, a blogger, a disability and inclusion advocate, and Nebraska's Mother of The Year, 2018. Nizar is also a rare disease patient herself and a mother to two boys with Jansen's Disease. She is the Director of Patient Advocacy Strategy at the Center for Rare Disease, at ICON Plc, a world-leading healthcare intelligence and clinical research organization and supports rare disease focused biotech and pharmaceutical companies to develop and implement a strong patient advocacy strategy and to incorporate the patient voice into the clinical development lifecycle. Nizar also serves higher education by teaching English and Leadership Studies.

### **Drugs, Biologics, and Device Sponsors' and Investigators' Perspectives**

**Lisa Bennett** is a Principal Lead for Roche Product Development Quality, with interests in clinical trial patient safety and the innovative use of clinical and operational data analytics. Lisa joined the Roche COVID-19 Study Management Task Force to oversee the global impact of pandemic disruption on the quality of patient protection and clinical trial data. The Task Force was instrumental in rapidly incorporating emerging health authority COVID-19 guidance into Roche processes, and Lisa was a key leader in this Task Force.



**Kenneth Getz** is the Executive Director of the Tufts Center for the Study of Drug Development and Professor at the Tufts University School of Medicine. Mr. Getz is an internationally recognized expert on R&D and clinical trial management practices and trends, the global investigative site landscape, site management and patient recruitment and retention practices, and the worldwide market for outsourcing clinical research functions. Mr. Getz's research studies on protocol design complexity and clinical research efficiency and effectiveness, conducted over the past two decades, are considered by many in the research-based life sciences industry to be pioneering work. His 20+ years of original research benchmarking R&D management practices, global outsourcing and the investigative site landscape have contributed to industry-wide understanding of these critical markets and to improvements in management strategy and execution.

**Chris Labaki** is an Internal Medicine resident at Beth Israel Deaconess Medical Center, and a research associate in Genitourinary Oncology and Clinical Computational Oncology at Dana-Farber Cancer Institute and the Broad Institute of Massachusetts Institute of Technology (MIT) and Harvard. He is a co-leader of the COVID-19 and Cancer Outcomes Study (CCOS) group of Dana Farber Cancer Institute and Mount Sinai Hospital, and a co-investigator of the immunotherapy and vaccine working groups within the COVID-19 and Cancer Consortium (CCC19). His work has focused on (1) the impact of the pandemic on oncological clinical trials, as well as (2) the clinical and biological interactions between COVID-19 and cancer, with the aim of improving the outcomes of patients with cancer who are directly or indirectly impacted by COVID-19. His research also leverages clinical, computational, and functional genomic work to study genitourinary cancers, with a particular interest in renal cell carcinoma and urothelial carcinoma.

**Vinny Parthasarathy** is a senior leader who leads the Global Clinical Monitoring and Site management teams within Medtronic. He has been at the forefront of innovation in the space of risk-based monitoring, remote monitoring, and site management practices around the world for the past few years. He leads a team of over 300 site monitors and managers and has over 10 years of experience in clinical research processes. During the COVID public health emergency, Vinny and his team were able to deploy processes and tools that limited disruption in clinical research monitoring and overall site engagement practices across the globe through close collaboration with internal and external stakeholders. Vinny is a certified Master Black Belt in Lean-Sigma practices. Vinny also has a Mechanical Engineering degree from University of East London and Master's degree in management from Harvard Business School.

**Joanne (Jo) Spallone** is clinical quality professional having spent 40+ years working in the Pharma industry. She worked at Ciba-Geigy/Novartis for most of that time in various clinical quality roles including Global Head, Clinical Quality and Global Head, Clinical Quality Audit. Her experience includes managing QA and audit teams, leading global inspections and conducting complex investigations. Joanne retired from Novartis and is currently working as an independent clinical quality consultant.





## Concluding Remarks, Day 1

**Sally Okun** is the Executive Director of the Clinical Trials Transformation Initiative (CTTI). Ms. Okun coordinates with the Executive Committee in the development and execution of strategies to accomplish CTTI's mission. She provides senior oversight and management of CTTI operations and organizes efforts to leverage the participation of member organizations and external stakeholders. Prior to joining CTTI, Ms. Okun led a consultancy firm that specialized in projects related to patient and public involvement in research, care, policy, and socially accountable ethics. From 2013 to 2019, she served as vice president of the online patient research network PatientsLikeMe (PLM) where she was responsible for the company's patient advocacy initiatives, contributed to health policy discussions at the national and global level, and was PLM's liaison with government and regulatory agencies, including the U.S. Food and Drug Administration (FDA), Center for Medicare and Medicaid Services (CMS), and the European Medicines Agency (EMA). Ms. Okun joined PLM in 2008 as the manager of Health Data Integrity and Patient Safety, where she oversaw the site's medical ontology including the curation of patient-reported health data, the patient voice vocabulary, and the development of an integrated Drug Safety and Pharmacovigilance Platform. Prior to 2008 Ms. Okun, a registered nurse, practiced as a community-based palliative care specialist and held other clinical positions for over three decades.

## Opening Remarks, Day 2

**Celia Witten** is Deputy Center Director at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). Between 1996 and 2005 she served as Director of the Division of General, Restorative, and Neurological Devices in the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). Before FDA, she worked for over 10 years as a practicing physician at the National Rehabilitation Hospital (NRH) in Washington, D.C. Her educational background includes a B.A. earned at Princeton University (Magna Cum Laude), a Ph.D. from Stanford University, and an M.D. from the University of Miami School of Medicine. In addition to her academic achievements, she is Board Certified in Physical Medicine and Rehabilitation.

## Federal Partners Perspectives

**John Beigel** is at the National Institute of Allergy and Infectious Diseases. He attended medical school at the Medical College of Ohio, residency at the University of Cincinnati, a fellowship in Critical Care Medicine at the National Institutes of Health, and a fellowship in Infectious Disease at the Massachusetts General Hospital. He has been at the NIH since 2000 (except for one year venture in the biotechnology industry). His research interests are focused on clinical research in influenza, COVID-19, and other emerging infectious diseases. He has led several of NIAID's programs for



COVID-19 therapeutics, including the Adaptive COVID-19 Treatment Trial (ACTT), the ACTIV-5– Big Effect Trial, and several COVID-19 vaccine trials including the Moderna COVID-19 vaccine phase 1, the mix and match trial, and several variant vaccine trials. His current position is Associate Director for Clinical Research within NIAID’s Division of Microbiology and Infectious Diseases.

**Meg Mooney** is Associate Director for the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI, NIH. Dr. Mooney received her medical degree from the University of Chicago Pritzker School of Medicine in Chicago and her general surgical training from the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. She completed a Surgical Oncology fellowship at Roswell Park Cancer Institute in Buffalo, New York and holds a MS degree in Management from the Massachusetts Institute of Technology in Cambridge, Massachusetts. Dr. Mooney joined the National Cancer Institute in 2002 as Head of Gastrointestinal and Neuroendocrine Cancer Therapeutics in the Clinical Investigations Branch in the Cancer Therapy Evaluation Program (CTEP) and became the Associate Director of CTEP in April 2020. In her capacity as CTEP Associate Director, she has oversight and coordination responsibilities for programmatic, financial, and administrative functions for a broad, multidisciplinary, clinical research effort to coordinate and conduct phase 1 through phase 3 trials testing new therapies and precision-medicine, multi-modality, approaches for cancer treatment in national network programs covering over 1,800 sites and accruing over 20,000 patients annually.

**Salina P. Waddy** is the associate director of clinical affairs for the Clinical and Translational Science Awards (CTSA) Program and chief of the CTSA Program Clinical Affairs Branch within NCATS’ Division of Clinical Innovation. In this capacity, she directs the activities of the Trial Innovation Network, which includes the Trial Innovation Centers and the Recruitment Innovation Center, and she oversees clinical activities across the CTSA Program, including trials of nationally important health conditions. Prior to joining NCATS, Waddy served in significant scientific and administrative roles in clinical trials and health disparities research, increasing trial recruitment and inclusion of minorities and women in clinical research. Her federal work has included studies working with communities and scientists across the United States and in several African nations. Waddy has increased the diversity of the scientific workforce, particularly in neurological disorders, by developing programmatic initiatives that provide mentorship and skill development to early-career-stage mentees while increasing the opportunities of the trainees to work on large-scale scientific projects. Prior to joining NCATS, Waddy served as the director of stroke and inpatient neurological services at the Atlanta Veterans Medical Center and as a program director at several NIH Institutes and Centers.



## **Creating Resilience in Clinical Studies Through Advanced Planning for Disruptive Emergencies**

### **Panel Discussion #1: Emergency Preparedness in Clinical Studies**

**John H. Alexander** did his internal medicine training (1993-1996) at the Brigham and Women's Hospital in Boston. He did his cardiology fellowship training at Duke University (1996-2000). He is now a cardiologist and Professor of Medicine in the Department of Medicine, Division of Cardiology in the Duke University School of Medicine. He is a senior investigator at the Duke Clinical Research Institute where he designs and leads multicenter clinical trials and helps to mentor research fellows and junior faculty. Dr. Alexander's clinical interests are in acute and chronic cardiovascular disease, valvular heart disease, and echocardiography. His research is focused the conduct of clinical trials, specifically on the therapeutics of acute coronary syndromes, chronic coronary artery disease, atrial fibrillation, and cardiac surgery. Dr. Alexander has published extensively and has served as a lead investigator of numerous multicenter clinical trials. He is a member of the American Society of Clinical Investigation and currently serves as the Duke Co-chair of the Clinical Trial Transformation Initiative (CTTI).

**Jeffrey Blank** is an adult patient with Cystic Fibrosis (a genetic chronic illness with multisystem impact, especially respiratory and GI). Jeffrey is a participant in numerous clinical trials for multiple treatments, including before/during/after the Covid pandemic. He is also a former government attorney currently focusing on health and raising his two young children.

**Marianne Chase** is currently the Senior Director of Clinical Trial Operations for the Neurological Clinical Research Institute (NCRI) and Healey Center for ALS at MGH. The Healey Center, along with key collaborators, designed and initiated the first Platform Trial for Amyotrophic Lateral Sclerosis, which launched in 2020. The NCRI is the Clinical Coordinating Center for the National Institute of Neurological Diseases and Stroke (NINDS) Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT); the Clinical and Data Coordinating Center for the Northeast Amyotrophic Lateral Sclerosis (NEALS) Network and the Parkinson's Study Group (PSG) Network. Marianne is an active member of the Clinical Trial Transformation Initiative (CTTI) and has over 25 years of experience in both investigator-initiated NIH / foundation-funded and industry-sponsored research including Pre-Clinical Study Design, Clinical Study Coordination, Trial Site Management, Protocol Development, Regulatory Compliance, and Project Management. In addition, serves as an adjunct faculty member for the NINDS-funded Clinical Trials Methodology Course and has developed and presented courses on various topics including Good Clinical Practice, Good Source Documentation and Data Management Practices, Adverse Event Reporting, Standard Operating Procedures (SOPs), Overall Management of Multi-Center Clinical Trials, and Complexity of Clinical Trial Design: Ethical and Practical Challenges.





**Hassan Kadhim** is the Head of Clinical Trial Business Capabilities. In that role, Hassan led a team that governs the business technology capabilities strategy within Global Development Operations, and drives change and innovation towards better outcomes for clinical trial stakeholders. Hassan's group at BMS spans the entire clinical trial journey from Patient Engagement and Awareness, Site Engagement to Data Collection capabilities and Decentralized Clinical Trials. Hassan is passionate about transforming the clinical research arena in the pharma industry using technologies and patient-centric clinical trials and is a firm believer of the need for clinical innovation grounded in strong business practices for sustainability, change management and adherence to compliance and regulatory commitments. Hassan regularly appears and speaks at industry events around improving the clinical trial experience with digital tools and wrote "The Remote Clinical Trials Model" whitepaper in 2016, to formalize a new patient-centric clinical trial research model leading to what we know today as Decentralized Clinical Trials. Beyond BMS, Hassan actively collaborates across industry collaborations such as TransCelerate and others to advance relevant and high-value industry challenges. He has degrees in bioinformatics and pharmaceutical sciences, both from the University of Montreal in Canada.

**Nina Movsesyan** is a dedicated researcher with a background in Biotechnology and clinical research. She earned a Ph.D. in Biotechnology from Yerevan State University, Armenia, in 2001 and subsequently conducted postdoctoral research in translational immunology at the Institute for Molecular Medicine, California. Her work there, alongside collaborators from the University of California, Irvine, focused on developing an Alzheimer's Disease vaccine. She received Ruth L. Kirschstein National Research Service Award from the NIA in 2007. Nina's passion for bridging scientific data with individuals led her to volunteer and gain hands-on experience by assisting Clinical Research Coordinators in various aspects of Clinical Trials. In 2010, Nina joined the Down Syndrome Program at the University of California, Irvine, where she coordinated NICHD-funded study related to Alzheimer's Disease in adults with Down Syndrome. In 2014, Nina undertook the role of coordinating clinical trials which included overseeing the participation of local, out-of-state, and international patients relocated to the US for research purposes, registries, single patient IND applications at the Division of Metabolic Disorders at CHOC. Throughout her career, Nina has co-authored scientific publications & presentations. Currently, Nina is serving as a Manager of Clinical Research Programs with a focus on rare metabolic diseases at CHOC.

**Veronica Suarez** is Executive Director, Global Product Leader in the Vaccines Innovation Unit at CSL. She has over 25 years of experience in Global Clinical Development having overseen clinical trials in every continent. During the COVID-19 pandemic, Veronica headed the Vaccines Clinical Development Operations team, managing a global portfolio of planned and ongoing vaccine clinical trials. Veronica currently leads the CSL vaccines portfolio including Pandemic influenza and other vaccines, leveraging the lessons learned during the COVID pandemic to strengthen preparedness planning for clinical studies and clinical development during public health emergencies.



## **Creating Resilience in Clinical Studies Through Advanced Planning for Disruptive Emergencies**

### **Panel Discussion #2: Digital Health Technologies (DHT) and Study Monitoring during Disruptive Emergencies**

**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.

**Catherine Gregor** is a transformational leader and business advisor with close to two decades of experience in clinical research. She currently serves as the Chief Clinical Trial Officer for Florence Healthcare, a software company focused on connecting sponsors and sites worldwide. Catherine is a subject matter expert and key opinion leader on patient-centric, decentralized and hybrid trial design. She has worked in multiple therapeutic areas in both academic and community hospitals, with her most recent appointment being Director of Clinical Research Administration for the Vanderbilt-Ingram Cancer Center. Catherine has an MBA in Healthcare Administration from Belmont University and a Master's in Modern European History from Loyola University Chicago. She is a Certified Clinical Research Professional (CCRP) and a Certified Clinical Research Coordinator (CCRC). She is passionate about changing the clinical trials industry and empowering women as leaders.

**Patrick Nadolny** is the Global Head of Clinical Data Management at SANOFI, Chair of the SCDM Content Alignment Committee since 2023, and Vice Chair of the SCDM Board. Mr. Nadolny has over 30 years of industry experience across pharmaceutical, device and biologics as well as technology solution development. Mr. Nadolny is a pragmatic leader focusing on technology, innovation, strategic planning, change management, and the setup of new capabilities. Mr. Nadolny is the Global head of Clinical Data Management at Sanofi. In addition to being the Vice Chair of the SCDM board, he led the SCDM innovation committee from 2018 to 2022 which released many papers on the evolution of Clinical Data Management toward Clinical Data Science.



**Pamela Tenaerts** is Chief Scientific Officer at Medable, Inc. Dr. Tenaerts leads efforts at Medable to drive responsible advancement of decentralized research methodologies with evidence-based metrics and best practices. Dr. Tenaerts joins Medable from Duke University, where she led the Clinical Trials Transformation Initiative's (Public Private Partnership co-founded by Duke University and the Food and Drug Administration) efforts to develop and drive adoption of practices that increase the quality and efficiency of clinical trials. She is a member of the Drug Forum at the National Academies of Science and a Board Member of the MedStar Research Institute and is a Dime Founding Members Council member. Tenaerts is one of the leading advocates for innovation in clinical trials, with an emphasis on patient engagement, responsible evidence generation and clinical trial methodology improvements. With more than 30 years' experience in the conduct of clinical trials across several stakeholders, she practiced medicine in both the emergency department and as a family practitioner in the private practice setting before embarking on a career in research. She received her MD from Catholic University of Leuven, Belgium, and MBA from the University of South Florida.

**Ramya Thota** is a GI medical oncologist at Intermountain Health, Utah. She finished her Hematology and Medical Oncology fellowship training from Vanderbilt University, Nashville, Tennessee. She is an active member of American Society of Clinical Oncology (ASCO) and Southwest Oncology Group (SWOG). She receives research funding from American Cancer Society Clinician Scientist Development Grant to improve outcomes of patients with small bowel cancers. She is the past co-chair for ASCO Research Committee and current co-chair of ASCO Form 1572 task force. Dr. Thota is passionate about improving access and participation of patients to clinical trials and transforming the way we do clinical trials.

**Marion Wolfs** is the Head of Risk Management and Central Monitoring Oncology at Johnson & Johnson Innovative Medicine. Wolfs is an established senior leader and risk practitioner with Risk Management, Clinical Operations and Data Analytics expertise in pharma and medtech R&D. She provides leadership and global strategic direction for Data Management and Central Monitoring activities, ensuring Quality & Compliance and facilitating agility and data driven decision making. Wolfs is a strong business development professional with a MSc focused on Biomedical Sciences from the Maastricht University and holds an international certificate in Enterprise Risk Management from the Institute of Risk Management in London.

### **Concluding Remarks, Day 2**

**M. Khair ElZarrad** is the Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER). He has served as the Deputy Director of OMP since 2017. As Director of OMP, Dr. ElZarrad leads the development, coordination, and implementation of medical policy programs and strategic initiatives. He works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory



review processes. OMP is comprised of the Office of Prescription Drug Promotion (OPDP) and the Office of Medical Policy Initiatives (OMPI). OPDP oversees the regulation of prescription drug promotion and advertising. OMP provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas. Before joining FDA, he served as senior science policy analyst and Director of the Clinical and Healthcare Research Policy Division at the Office of the Director of the National Institutes of Health (NIH). He also served as a fellow on both the FDA's Interagency Oncology Taskforce, as well as the National Cancer Institute's Cancer Prevention Fellowship Program within the Division of Cancer Control and Population Sciences. Dr. ElZarrad earned his doctoral degree in medical sciences with a focus on understanding cancer metastases from the University of South Alabama College of Medicine, his Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health, and his bachelor's degree in biochemistry from Samford University.