Optimizing Data Capture for Clinical Trials
An OSTP/ONC Listening Session

Event URL: https://www.healthit.gov/news/events/optimizing-data-capture-clinical-trials-ostponc-listening-session

Date: Wednesday, 1/11/2023

Time: 11:30am – 1pm EST

Facilitator / Moderator Biographies

Grail Sipes

Assistant Director for Biomedical Regulatory Policy,

White House Office of Science and Technology Policy (OSTP)

Grail Sipes, J.D. serves as Assistant Director for Biomedical Regulatory Policy at the White House Office of Science and Technology Policy (OSTP), where her portfolio includes clinical trial infrastructure, related preparedness issues, and other matters related to the development and marketing of medical products. For ten years prior to her work at OSTP, Grail worked in a variety of roles at the FDA, most recently serving as Deputy Director for Regulatory Policy in FDA's Center for Drug Evaluation and Research (CDER). Prior to that, she was a lawyer in private practice and a partner at Covington & Burling LLP. At FDA, Grail worked on a wide range of matters involving drugs and other FDA-regulated products, including reproductive health, drug pricing and access, drug shortages, digital health, and First Amendment challenges to regulation. At FDA and at OSTP, Grail's role has been to develop effective public health strategies and policies in light of evolving science, differing stakeholder viewpoints, and various regulatory challenges.

Jennifer Roberts

Assistant Director for Health Technologies

White House Office of Science and Technology Policy (OSTP)

Jennifer Roberts currently serves as the Assistant Director for Health Technologies at the White House Office of Science Policy. Her portfolio includes healthcare data interoperability, digital health transformations, and ARPA-H. Prior to joining OSTP, Dr. Roberts served as the Deputy Director of the Information Innovation Office at DARPA, where she oversaw research programs that spanned artificial intelligence, cyber, and data analysis; and she received the DARPA Superior Public Service Medal for her contributions. She earned a Ph.D. in Computer Science from MIT, where she was a Hertz and NSF Fellow.

Stephen Konya

Senior Advisor to the Deputy National Coordinator for Health IT and Innovation Portfolio Lead

Office of the National Coordinator for Health IT (ONC), U.S. Department of Health and Human Services

Stephen Konya serves as the Senior Advisor to the Deputy National Coordinator, and Innovation Portfolio Lead for the Office of the National Coordinator for Health IT (ONC), U.S. Department of Health and Human Services (HHS). In addition to shaping the Agency's long-term strategy, he also serves as the Agency's primary liaison to the White House Office of Science and Technology Policy (OSTP) and the external healthcare startup and investor community.

Mr. Konya has led several key ONC projects, including the HHS PandemicX Innovation Accelerator, the FHIR at Scale Taskforce (FAST) Initiative, the ONC Patient Engagement Playbook for Providers, the SMART App Gallery, and is a founding Co-Chair of the Together.Health Collaborative.

Panelist Biographies

Derk Arts

CEO and Founder, Castor

Derk Arts MD, PhD has 15+ years of experience in medicine, research, and technology. He founded Castor to solve the biggest issues in clinical research: a lack of inclusivity, patient focus, and impact of data. Castor enables sponsors worldwide to run patient-centric trials on a unified platform that helps them maximize the impact of research data on patient lives. Dr. Arts believes the key to achieving lasting change in the industry is through scalability and standardization.

Scott Chetham

CEO and Co-Founder, Faro Health

Scott Chetham Ph.D. is an experienced healthcare entrepreneur who is currently the CEO and co-founder of Faro Health. Scott leads the strategy for the Faro Health platform, which is designed to power clinical development by connecting data to decision making in a fundamentally new way. Previously, he was the Head of Clinical Research Operations and Data Management at Verily Life Sciences, formerly known as Google Life Sciences. This multi-faceted strategic and operational role involved leading the clinical strategy, clinical teams, process development and operations for all clinical projects of the company, including Google and Google[x]. Scott has also served as a Venture Partner at Versant Ventures, CTO and Co-founder of Intersection Medical (sold to ImpediMed), and VP Clinical Affairs (ImpediMed). In these latter two roles he was responsible for clinical research strategy and operations.

Tony Clapsis

Senior Vice President, General Manager

CVS Health Clinical Trial Services

Tony is the General Manager and Senior Vice President of the CVS Health Clinical Trial Services (CTS) business unit. CTS' mission is to expand access to clinical trials with a relentless focus on health equity, while improving research effectiveness and patient outcomes through a unique patient-centric delivery model.

Prior to CTS, Tony built and led the CVS Health Enterprise Strategy Team that develops the long-term strategy for the overall business, CVS Pharmacy, CVS Caremark, and Enterprise Transformation. He has played a leading role in new growth opportunities, including the creation of CVS Kidney Care, acquisition of Aetna, and creation of the nationwide COVID-19 testing platform.

Before joining CVS Health in 2015, Tony served as Chief of Staff to the CEO of Caesars Entertainment. As part of this role, Tony chaired the Business Roundtable (BRT) Health Care Committee, where he worked with Fortune 500 CHROs on national employer policy priorities.

Tony's additional experience includes serving as as Professional Staff on the Senate Finance Committee where he helped draft the Affordable Care Act (ACA), as part of a portfolio managing value-based care models, provider payments, and insurance markets. Tony also spent five years as a senior healthcare equity analyst at Lehman Brothers and Barclays Capital, after starting his career in the Massachusetts State Senate.

Tony graduated Phi Beta Kappa from Boston University. He is currently an Aspen Institute Health Innovation Fellow, sits on the Board of Directors of Parsley Health, and serves on the Rhode Island Health Care Cost Trends Steering Committee and the Health in Rhode Island Committee.

Michael Cohen-Wolkowiez, MD PhD

Head, Pediatrics, Duke Clinical Research Institute

Kiser-Arena Distinguished Professor of Pediatrics, Duke University

Michael (Micky) Cohen-Wolkowiez, MD, PhD, was born and raised in Venezuela and is currently the Kiser-Arena Distinguished Professor of Pediatrics at Duke University and the Director of the Innovation Center at the Duke Clinical Research Institute. His research focuses on computational and patient-centric methods to advance and accelerate clinical trials. Micky is trained in pediatric infectious diseases, is a clinical pharmacologist, and worked for two years at the FDA as a scientific advisor. He is also serving as the Chief Medical Advisor at Lightship, a company providing clinical trial services specializing in hybrid and decentralized studies.

Amy Cramer

Janssen Clinical Innovation Focus Area Leader, and Co-Chair Vulcan FHIR Accelerator

Amy Cramer draws on her experience as a critical care nurse, clinical research coordinator, healthcare quality professional, informaticist and intrapreneur. She is a Director at Janssen Pharmaceuticals and leads the “Capitalizing on Data Assets” Focus Area for Janssen Clinical Innovation (JCI). JCI is a function within J&J R&D Global Development with a mission to accelerate the discovery, development, and deployment of innovative capabilities in the business. Her team is pursuing innovative opportunities in utilizing clinical care and patient mediated data for research, streamlining processes through intelligent automation, applying novel analytical methods to diverse/emerging data sources, and expanding capabilities in emerging markets.

Amy is a founding member and Co-Chair of Vulcan, the HL7 Fast Healthcare Interoperability Resource (FHIR®) Accelerator dedicated to connecting translational and clinical research with clinical care. Vulcan is comprised of members spanning across the research community collaborating to improve data utilization for research. Amy's expertise for innovation and interoperability is demonstrated in her publications. She is a member of TransCelerate Biopharma, Inc. , Vice-Chair of the Society for Clinical Data Management (SCDM) eSource Implementation Consortium and former Co-Chair of HL7 Clinical Interoperability Council.

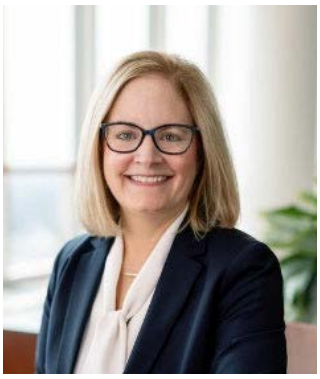
Manny Fombu

Vice President, Digital Health Solutions

Alira Health

Dr. Fombu is an entrepreneur and innovative healthcare executive with vast experience in medical and clinical affairs in pharmaceutical, device, imaging and laboratory diagnostic industries as well as quality experience in healthcare delivery. He is an advocate for value-based healthcare and a leader in designing clinical trials using innovative study designs to evaluate complementary health approaches and their integration into real world health care. He is also passionate about ehealth, nanotechnology, big data, artificial intelligence, machine learning, digital medicine and is an external advisory board member at the Massachusetts Institute of Technology's MIT.nano project.

Dr. Fombu did his clinical training at Emory-Crawford Long Hospital and holds an MBA from Cornell SC Johnson College of Business. He lives in New York City.



Karen Hartman, M.S.

Vice Chair, Research Administration, Mayo Clinic

Karen Hartman is the Vice Chair, Research Administration for Mayo Clinic and Assistant Professor of Health Care Administration. She is responsible for oversight and advancement of strategic priorities for clinical trials and leadership of research administration business units including Research Subjects Protection Programs (IRB), Institutional Animal Care and Use Committee (IACUC), Office of Sponsored Projects Administration, Research Compliance, Research Regulatory Support, Legal Contracts Administration, Office of Clinical Trials, Research Education & Quality, and Research Service Center.

She joined Mayo Clinic in 1997. Previously, she served as the Research Compliance Officer at Mayo Clinic for six years and as operations manager for the Office of Research Regulatory Support for five years. Earlier in her career, she served as a nurse and officer in the U.S. Navy, last stationed at Portsmouth Naval Hospital.

Karen earned her bachelor's degree in Nursing from Winona State University and a master's degree in Clinical Research Management from Duke University. She is involved in many professional organizations including Council on Governmental Relations, National Council of University Research Administrators and Women's Health Leadership TRUST.

Karen and her husband live in Rochester, Minnesota where they raised two children Michael and Morgan. She is currently the President of the Board of Directors for Samaritan Bethany and volunteers for other community organizations. Karen is an avid sports enthusiast, enjoys hiking, book clubs, and traveling with her family.

Melanie Ivarsson OBE, PhD, MBA

Chief Development Officer, Moderna

Dr. Melanie Ivarsson has more than 20 years of experience in the life sciences sector at pharmaceutical companies including Eli Lilly, Pfizer, Shire and Takeda, working across all phases of clinical drug development. She is currently Chief Development Officer at Moderna, where she oversees the delivery of all clinical development programs across the company's portfolio and led clinical trials to develop one of the world's first Covid-19 vaccines.

Melanie has a PhD in Neurophysiology from the University of Bristol in the UK and an Executive MBA from Sloan School of Management, MIT in the USA. Dr. Ivarsson was awarded an OBE by Her Majesty The Queen in the 2022 New Year's Honours List for Services to Public Health, and was appointed a Non-Executive Director of UK biotech company LoQus23 in Jan 2022.

Craig H Lipset

Co-Chair, Decentralized Trials & Research Alliance

Adjunct Assistant Professor, Rutgers University

Vice President, Foundation for Sarcoidosis Research

Managing Partner, Clinical Innovation Partners

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Craig is Co-Chair for the Decentralized Trials & Research Alliance and Vice President of the Foundation for Sarcoidosis. He is Adjunct Assistant

Professor in Health Informatics at Rutgers University and serves on the Advisory Council for HL7 Project Vulcan and External Stakeholder Board for IMI Trials at Home.

Craig was previously the Head of Clinical Innovation and Venture Partner at Pfizer, and on the founding management teams for two successful startup ventures.

Michelle Longmire

CEO & Co-founder, Medable

As the co-founder and Chief Executive Officer of Medable, Dr. Michelle Longmire is mission-driven to accelerate the development of new therapies for disease. A Stanford-trained physician-scientist, Dr. Longmire witnessed firsthand the critical barriers to drug development – including the time and costs associated with clinical trial participation. She founded Medable to pioneer a new category of clinical trial technologies that remove traditional roadblocks to participation and radically accelerate the research process. Medable is now the industry leader in decentralized and direct-to-patient research, with the ability to serve patients in over 120 languages, 60 countries, and across all therapeutic areas. In addition to having raised over $500M in venture capital and driving Medable to an industry-leading position, Dr. Longmire has received recognition as a leading innovator and businesswoman, including being named as one of the 100 most creative people in business by Fast Company.

Jane Myles

Vice President of Clinical Trial Innovation, Curebase

Jane is dedicated to driving the global implementation of decentralized trials. She is the Founder of JemTech consulting and the former Head, Operational Intelligence and Innovation for Roche, working at Genentech. Her passion is driving innovation into the way we design and execute trials to get medicines to patients faster. She worked at Genentech for 17 years in many roles, including line manager and an operational program manager. In prior lives she held various roles in global trial management at Sanofi, QLT, Lilly and Labcorp.

Jane switched from molecule focus to portfolio focus about 12 years ago, first focused on patient recruitment, then patient voice and input, then patient facing technology and its adoption. She's able to merge them all together in her current role as VP Innovation at Curebase, building DCT technology and services to drive access and inclusion to trials. She's also an initiative co-lead and a member of the DTRA leadership committee.

Jane has focused on improving clinical trials and patient experience for more than 25 years. Her passion is driving innovation into the trial design and execution to get medicines to patients faster. Jane switched from molecule focus to portfolio focus about 13 years ago, first focused on patient recruitment, then patient voice and input, then patient facing technology and its adoption. She's able to merge them all together in her current role as VP Innovation at Curebase, building DCT technology and services to drive access and inclusion to trials.

She's also an initiative co-lead and a member of the DTRA leadership committee. She worked at Roche / Genentech for 17 years in many roles, including operational program manager for hematology ultimately working on driving patient-facing technology into global trials. In prior lives, she held various roles in DCT optimization at LabCorp and ran global trials at Lilly and Sanofi. She's a Canuck who loves San Francisco and the ocean.

Ramita Tandon

Chief Clinical Trials Officer, Walgreens Health

As the Chief Clinical Trials Officer at Walgreens, Ramita Tandon is responsible for leading and driving growth for the Company's new clinical trials business. In her role, Ramita works across the healthcare and life sciences industries to enable next-generation clinical trials so that breakthrough treatments reach patients faster. Her team is focused on unlocking value and improving access, awareness and trust by efficiently matching diverse patient populations to sponsor-led trials, reducing trial operational complexities and patient burdens, as well as capitalizing on Walgreens deep patient insights and leveraging real-world data from owned and partner assets.

Ramita brings more than 25 years of leadership and operational experience across a portfolio of industry-leading businesses and services in real-world evidence and patient-centered health outcomes. Prior to joining Walgreens, she served as the Chief Operating Officer at Trio Health, and prior to that she was the Executive Vice President, Commercialization and Outcomes at ICON.

As a transformational leader, Ramita is passionate in her belief that a best-in-class operating model employing insights and innovation can deliver gains in operations and forge stronger connections with all stakeholders, including biopharmaceutical companies, healthcare systems and payers. Ramita has recently been named to Drug Store News' Top Women in Health, Wellness & Beauty class of 2022 for Business Excellence, Fierce Healthcare's 2022 Women of Influence and listed in the 2018 PharmaVOICE 100.

Ramita is an internationally recognized speaker and author whose focus is on how to bridge the gap between commercial and clinical development. She is a graduate of the University of Michigan and the Boston University School of Public Health.

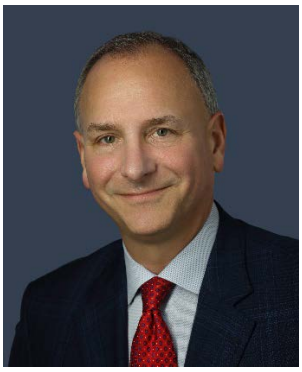
Elena Viboch,

Partner, Life Sciences, General Catalyst

Elena Viboch is a Partner at General Catalyst, where she focuses on investing in life sciences. Her investments include Dewpoint Therapeutics, Eikon Therapeutics, Maze Therapeutics, Odyssey Therapeutics, Variant Bio, and Vial, and she serves on the board of Paradigm.

Prior to joining General Catalyst, Elena served as an Investment Director at SoftBank, where she helped build SoftBank Vision Fund's healthcare portfolio, driving investments in companies such as Devoted Health and Vividion Therapeutics and serving on the boards of Deep Genomics, Karius, and Pear Therapeutics. Earlier in her career, Elena worked in investing at Kearny Venture Partners and held operating roles at Carmot Therapeutics and NanoString. She's passionate about working closely with rising entrepreneurs to help them bring their work from idea to execution to impact.

Elena holds a BA from Swarthmore College, an MS from Johns Hopkins University, and an MBA from Harvard Business School where she graduated with highest honors as a Baker Scholar. Elena lives in San Francisco and she enjoys hiking throughout the Bay Area.



Neil J. Weissman, MD

Chief Scientific Officer, MedStar Health

President, MedStar Health Research Institute

Professor of Medicine, Georgetown University

Neil J. Weissman, MD, FACC, FASE, is the Chief Scientific Officer for MedStar Health and President of MedStar Health Research Institute. Dr. Weissman is a professor of medicine at Georgetown University School of Medicine and an internationally recognized cardiologist with expertise in cardiovascular ultrasound and clinical trials.

As chief scientific officer, he provides leadership for the development and implementation of specific scientific priorities, with a commitment to further advancing MedStar Health as a nationally acclaimed academic health system. As president of the Research Institute, he is responsible for the overall strategic and operational direction of the research arm of MedStar Health.

Dr. Weissman's research interests include the use of cardiovascular ultrasound imaging in clinical trials and the development of artificial intelligent applications for imaging. He has served as principal investigator for hundreds of national and international multi-center trials, served in leadership positions on several national organizations and editorial boards and written hundreds of original reports published in high profile peer-reviewed journals. He is frequently invited to serve as an expert on U.S. Food and Drug Administration advisory panels and National Institutes of Health commissions and held many national leadership positions including past president of the American Society of Echocardiography and past chair of the American College of Cardiology's Imaging Council.

Dr. Weissman received his medical degree from Cornell University Medical College in New York. He completed his internship, residency and chief residency in Internal Medicine at New York Hospital. He followed his residency training with a clinical and research fellowship in Cardiology and a fellowship in Cardiac Ultrasound at Massachusetts General Hospital in Boston.

Brendan O'Leary

Acting Director, Digital Health Center of Excellence (DHCoE)

Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration (HHS/FDA)

Brendan O'Leary is Acting Director of the Digital Health Center of Excellence (DHCoE) at the FDA's Center for Devices and Radiological Health (CDRH). The DHCoE works to ensure that patients in the US have access to safe and effective medical devices that include the state-of-the-art technologies to improve their lives and health. Before joining the Digital Health group as its Deputy Director in 2019, Mr. O'Leary held leadership and engineering roles in FDA's Office of In Vitro Diagnostics and Radiological Health, where he drove Digital Health and diagnostic device policy efforts. He received his bachelor's degree in Mechanical Engineering from the University of Maryland, College Park, and he worked in the aerospace industry before joining FDA in 2009.

John Rancourt

Director, Interoperability Division

Office of Policy, Office of the National Coordinator for Health IT (ONC)

U.S. Department of Health and Human Services (HHS)

John Rancourt serves as the Director, Interoperability Division, Office of Policy, Office of the National Coordinator for Health Information Technology (ONC), U.S. Department of Health and Human Services. The Interoperability Division advances health IT policy implementation through such activities as:

- The Trusted Exchange Framework and Common Agreement (TEFCA).
- Public health interoperability, including the COVID-19 and opioid emergencies.
- State and Medicaid interoperability efforts.
- Strengthening the Technical Advancement and Readiness of Public Health via Health Information Exchange Program (STAR HIE Program).
- Value-based transformation enabled by health IT.
- Consumer engagement and data access.
- Engagement with behavioral health, EMS, and long-term and post-acute care providers.

John joined ONC in 2011 as a Presidential Management Fellow. During his career in health policy, John has worked on Capitol Hill, for pharmaceutical companies, for the Government Accountability Office, for the National Academy of Medicine, as a patient advocate, and as a journalist.