# Decentralized Clinical Trials (DCT) Collaborative Workshop Speakers

## Session 1: Demystifying Decentralized Clinical Trials

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|  <br>Kenneth Getz, MBA<br>Tufts University<br><br>**Topic**: Implementation of DCT elements & protocol performance using data-driven approach | Ken Getz is the Executive Director and a professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine, where he conducts grant funded research on pharmaceutical R&D management and execution; protocol design optimization; contract service provider and investigative site management; e-clinical technology and data usage; and patient and community engagement. He is also the chairman of CISCRP – a nonprofit internationally-recognized organization that he founded to educate and raise public and patient awareness of the clinical research enterprise – and president of the Otsuka Patient Assistance Foundation. A well-known speaker at conferences, symposia, universities, investor meetings and corporations, Ken has published extensively in peer-review journals, books and in the trade press and writes a bi-monthly column nominated for a Neal Award in Applied Clinical Trials. He holds a number of board appointments in the private and public sectors and serves on the editorial boards of Pharmaceutical Medicine, Life Science Leader and Therapeutic Innovation and Regulatory Science. Ken received an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University. He is the founder of CenterWatch, a leading publisher in the clinical trials industry, and one of several businesses that he has created and sold. |
|  <br>Rohit Aggarwal, MD<br>University of Pittsburgh<br><br>**Topic:** Rare disease (Mint) using DCT approaches | Dr. Aggarwal is a professor of medicine at University of Pittsburgh and medical director of Arthritis and Autoimmunity Center at University of Pittsburgh Medical Center. He is the co-director of UPMC Myositis Center. His research and clinical areas of interest are clinical and translational research in inflammatory muscle diseases (myositis) and associated interstitial lung disease. He is the past-chair of the medical advisory board of The Myositis Association (TMA) as well as past-chair of the scientific committee of IMACS, which are the largest patient and physician groups working in the field of myositis, respectively.<br><br>Dr. Aggarwal is an established independent clinical investigator with significant funding from NIH, foundations and industry and currently leading several collaborations internationally with other key leaders in the world. He has maintained an extremely high publication record and received national and international recognition of his work. He continues to be a leader in disease criteria and outcomes measures in myositis as well as in clinical trials of novel therapeutic agents for myositis. He is currently the principal investigator or member of the steering committee for several international phase 2/3 clinical trials in the area of myositis and associated ILD. Dr. Aggarwal is also mentoring future generation of rheumatologist with great success and attracting younger rheumatologist towards myositis research for the advancement of the field. Dr. Aggarwal lectures at various international conferences and promotes patient education through his YouTube channel. |

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|  <br>Tufia C. Haddad, MD<br>Mayo Clinic<br><br>**Topic:** Multi-site expansion Clinical Trials Beyond Walls program at Mayo | Tufia C. Haddad, M.D., is a Professor of Oncology, Mayo Clinic, Rochester, MN. She is Co-Leader of the Office of Platform and Digital Information, Mayo Clinic Comprehensive Cancer Center, and the enterprise Medical Director of Clinical Trials Beyond Walls™, Mayo Clinic's decentralized clinical trials initiative. Her prior leadership role includes service in the Mayo Clinic Center for Digital Health as Medical Director for Digital Strategy (2021-2024).<br><br>Dr. Haddad's clinical practice is dedicated to breast cancer. As an oncologist and physician scientist, she is an active member of the Cancer Center's Advanced Clinical Trials & Translational Sciences, Research Program. In the field of digital health, Dr. Haddad's interest is in the transformation of clinical practice and research through the development and implementation of innovative health care delivery models supported by novel connected health and artificial intelligence solutions. Dr. Haddad was named to the HIMSS Future50 Class of 2021 as a Clinical Leader. |

## Patient Panel Topic: What did DCT solve and what problems did it create

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|  <br>Theresa Strong, PhD<br>Foundation for Prader-Willi Research | Theresa Strong, PhD, is a co-founder and Director of Research Programs at the Foundation for Prader-Willi Research (FPWR, www.fpwr.org), a nonprofit organization that supports research to advance the understanding and treatment of the rare neurodevelopmental disorder Prader-Willi syndrome (PWS). Prior to joining FPWR full time, she had an academic career in genetics/cancer gene therapy and remains a volunteer Adjunct Professor at the University of Alabama at Birmingham. At FPWR, she directs the grant program, leads the PWS Clinical Trials Consortium and is principal investigator for the Global PWS Registry. She has four children, including a young adult son with PWS. |
|  <br>Lauren Ariniello, MBA<br>Scripps Research Translational Institute | Lauren Ariniello is a Senior Project Manager at the Scripps Research Digital Trials Center, leading decentralized research studies using digital health technologies. This approach involves innovative strategies for remote, site-less participation and leverages state-of-the-art methodologies for data analysis. Lauren is focused on patient-centered design to optimize recruitment and retention in research studies. She excels in collaborating with interdisciplinary teams consisting of patients, physicians, data scientists, web and app developers, and executives from various industries. Lauren received her BS in Biology from UCLA and an MBA from the Rady School of Management at UCSD. |

## Session 2: Building Successful DCTs

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|  <br>Courtney Granville, PhD, MSPH<br>$GO_2$ for Lung Cancer<br><br>**Topic:** Key components for DCT based on work in decentralized specimen collection trials | Courtney Granville heads the Science and Research Team at GO2 for Lung Cancer. In this role, she oversees GO2's community engaged research, clinical research, Lung Cancer Registry, and LungMATCH programs. She identifies areas of unmet clinical research need and develops innovative research strategies to address the needs of people at risk or living with lung cancer and their loved ones.<br>These studies are implemented through community and research partnerships, GO2 programs, and the Addario Lung Cancer Medical Institute (ALCMI), GO2's medical research consortium.<br>Courtney was inspired to join GO2 in a role that brings together her passion for ending cancer, lifelong support of those living with a diagnosis, and her research interests. For over two decades, her research career focused on understanding the molecular and environmental drivers of lung and other cancers by leveraging multidisciplinary teams in government, academic, commercial, and nonprofit settings.<br>Courtney holds degrees in biology (B.S., Yale), public health (M.S.P.H., UNC Chapel Hill), and biochemistry and molecular genetics (Ph.D., George Washington). She resides in Bethesda, MD, with her husband, their three children, and two dogs. She enjoys spending as much time as possible outside, running, playing tennis and pickleball, and watching her children play sports. https://go2.org/about-us/our-staff/ |
|  <br>J. Kaitlyn Morrison, PhD<br>Univ North Carolina Chapel Hill<br><br>**Topic:** Key components for DCT based on work in establishing oncology DCTs across the state of North Carolina | J. Kaitlin Morrison, PhD is the Executive Director, LCCC Clinical Research for Lineberger Comprehensive Cancer Center (LCCC) at the University of North Carolina Chapel Hill (UNC) and an Assistant Professor of Medicine in the Division Hematology at UNC. Kaitlin is responsible for the leadership and oversight of the LCCC clinical research infrastructure, and co-leads strategic planning driving clinical research infrastructure optimization, process improvements, recruitment/retention of employees and alignment of LCCC and UNC Healthcare system goals. Kaitlin is also responsible for the oversight of LCCC's clinical development program that includes investigator-initiated trials using UNC developed investigational drugs/biologics provided (e.g., CAR-T cells, vaccine & radiopharmaceuticals). As part of this work, she has become a leader in operationalizing hybrid decentralized clinical trials to enhance patient access to innovative therapies.<br><br>https://unclineberger.org/directory/j-kaitlin-morrison/#:~:text=Kaitlin%20Morrison,%20PhD,%20is%20a%20UNC<br><br>https://www.med.unc.edu/medicine/hematology/people/j-kaitlin-morrison-phd/#:~:text=Kaitlin%20Morrison,%20PhD.%20Assistant%20Professor%20o |
|  <br>Kate Lyden, PhD<br>VivoSense<br>**Topic:** Standardization of mobile health data | Kate Lyden, PhD, is the Chief Science Officer at VivoSense, a wearable sensor CRO specializing in developing and validating digital clinical measures for regulated clinical trials. She leads a team in creating novel digital measures and managing their implementation across all phases of drug development for industry sponsors. With extensive experience in wearable sensor methodologies in clinical, academic, and industry settings, her research focuses on integrating real-world physical behavior data with physiological signals and patient-reported outcomes to create contextually rich datasets that support patient-centered drug development and clinical care. |

## Session 3: Navigating the Evolving Landscape

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|  <br>M. Kahir ElZarrad, PhD, MPH<br>Office of Medical Policy<br>FDA's Center for Drug Evaluation and Research<br><br>**Topic:** Modernization of clinical trial design and conduct, regulatory challenges, ethical considerations, patient engagement and inclusion, real-world evidence, and future regulatory directions | M. Khair ElZarrad, Ph.D., M.P.H., 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.<br><br>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.<br><br>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. OMPI provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas.<br><br>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.<br><br>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. |
|  <br>Rachele Hendricks-Sturrup, DHSc, MSc, MA<br>Duke University<br><br>**Topic:** Ethics and health disparities for DCT | Dr. Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Institute for Health Policy in Washington, DC, strategically leading and managing the Institute's RWE Collaborative and RWE policy research portfolio and education. As an engagement expert, biomedical researcher, bioethicist, and policy practitioner with over 18 years of experience, her work centers on addressing implementation, regulatory, and ethical, legal, and social implications (ELSI) at the intersection of health policy and innovation. She presently partners with Duke University faculty, scholars, students, and external practicing experts to advance the Institute's biomedical innovation work. |
|  <br>Mylynda Massart, MD, PhD<br>University of Pittsburgh<br><br>**Topic:** Lessons learned with DCT in an academic setting with a self-service model | Mylynda B. Massart, M.D., Ph.D., is a board-certified Family Medicine physician at UPMC, and associate professor at the University of Pittsburgh. She currently serves as the founder and Medical Director of the UPMC Primary Care Precision Medicine clinic, and as the Associate Director of Clinical Services for the Institute for Precision Medicine. Dr. Massart is co-director for the HUB Core over Research Inclusivity and Community Partners Core at the Clinical and Translational Science Institute (CSTI). Dr. Massart serves as one of the co-Investigators for the All of US Pennsylvania research project working on community education and engagement and as MPI of The Community Engagement Alliance Consultative Resource (CEACR) created in 2021 by the National Institutes of Health (NIH) with the aim of leveraging the CEAL community-engagement expertise to promote and facilitate diversity and inclusion of racial/ethnic minority populations and rural underserved populations in clinical research. |