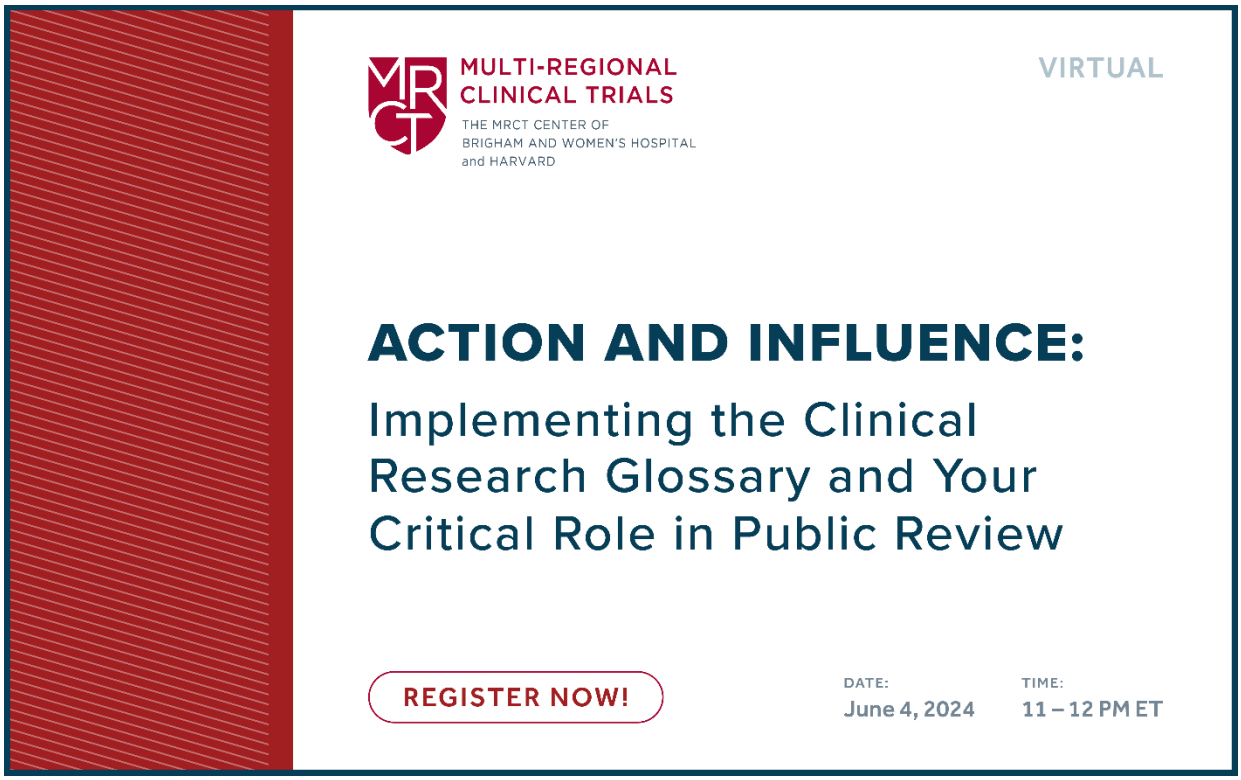
Clinical Research GLOSSARY



June 4, 2024

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Webinar Speaker Biographies

Amy Mirabella PhD, RN, CHPN, is a registered nurse who has provided care to patients, families, and communities for more than 30 years. She is certified as a Hospice and Palliative Care Nurse (CHPN) and is currently the Director, Clinical Research Operations at HonorHealth Research Institute in Arizona. Prior to taking on the role of Director, Amy spent 6 years as an oncology research nurse and educator within the research institute. Amy has also served as Principal Investigator on three supportive care studies and currently co-leads the Health Literacy Committee within HonorHealth Research Institute. Amy has a passion for clear communication and ensuring that patients and families receive healthcare information in a manner that builds understanding and allows them to make informed decisions. Amy believes that there is something to learn from every patient and she takes what she learns from patients and puts knowledge into action, always thinking about how to improve patient outcomes.

Amy's work within health literacy is impacting others daily. Understanding that communication does matter, Amy has educated numerous patients and family members using the universal approach to health literacy. This is important work as we know that when patients are engaged with their healthcare team, they have better outcomes. Additionally, Amy has educated hundreds of nurses and patient facing staff to ensure they understand how to provide education using this same approach; ensuring that this positive impact to patients does not end with Amy.

Claudine Moore, is the sitting Chief Editor for the Journal of the Society of the Society of Clinical Data Management (JSCDM). Ms. Moore is also a Clinical Data and Strategy Operations Program Lead in Oncology at AbbVie.

Ms. Moore began working in Clinical Data Management in 2003 and has experience working on pre-clinical through Phase III clinical trials in a comprehensive array of therapeutic areas including gastroenterology, virology, immunology, neurology, and viral immuno-oncology, oncology. Ms. Moore maintains strong data management technical expertise in performing and overseeing clinical data management activities from study start-up through database lock, including protocol review; database design, testing, and documentation; and vendor management. Additionally, she has extensive experience leading global clinical data management and programming teams. Having held positions in data management with both therapeutic development companies and contract research organizations, she provides a practical understanding of clinical data management contract research organizations' structure and functional roles that assist in developing effective vendor oversight as the sponsor company's representative.

Ms. Moore joined the SCDM Publications Committee in November 2016 and served as the Committee Chair providing leadership through the transition of SDCM's Data Basics publication to the open-access Journal of the Society for Clinical Data Management (JSCDM) through January 2021. From 2021 through 2023, Ms. Moore served on the Good Clinical Data Management Practices (GCDMP) Executive Committee, focused on the Glossary project.
Claudine Moore holds a Bachelor of Arts with emphases in Music Performance, Italian and Chemistry from Louisiana State University and a Master of Music in Musicology and Music Theory from Louisiana State University. She obtained her Certified Clinical Data Manager (CCDM™) certification from the Society of Clinical Data Management in 2008.

Holly Parker is a Program Manager at the Massachusetts General Hospital Laboratory of Computer Science, where she has worked for 15 years on software applications aimed at improving healthcare experiences. With a focus on product management, user experience, community building, and communications, her work shapes the development of innovative patient-facing tools. Her primary project is Rally with Mass General Brigham, a platform aimed at increasing transparency and patient engagement in research studies.

Ms. Parker has also lent her expertise to other patient-centric projects at MGH, including the iHealthSpace patient portal, DSC2U, and the MGH Down Syndrome Program intake application. Throughout her tenure, she has demonstrated a passion for leveraging technology to enhance patient interactions and outcomes. Parker draws upon her technical knowledge combined with excellent communication skills to design user-friendly solutions that empower patients.

A graduate of Emerson College with a Bachelor's degree in Writing, Literature, and Publishing, Parker's efforts play a key role in delivering accessible, compassionate patient care and resources.

Sophia Zilber has over 20 years of experience with drug development, including clinical data analysis, and managing statistical programming teams to ensure successful delivery of clinical study analysis requirements. Sophia is deeply involved with and volunteers a lot of her time to help rare disease patient community. Sophia has been involved in multiple efforts with the goal of raising awareness in the mitochondrial disease community and general rare disease community regarding patient registries and what is involved with collecting high quality data that can be used for research. Sophia is proud to be a board member and a patient registry director for Cure Mito Foundation, where she is leading a global Leigh syndrome patient registry

Moderator: Sylvia Baedorf Kassis, MPH, is a Program Director at the MRCT Center. Sylvia joined the MRCT Center in January 2018 and previously held the Program Manager position at the Center. Sylvia brought with her more than 20 years of clinical research-related experience in Canada and the United States of America. Her expertise includes ethical/regulatory review of research, clinical trial workforce training and capacity building, and study coordination, management, and oversight. Sylvia champions making clinical research more understandable and accessible to patients, participants, and caregivers through her work on Health Literacy in Clinical Research and the first-of-its-kind, plain-language Clinical Research Glossary. In addition, she supports other MRCT Center initiatives in applying health literacy principles to their outputs. Sylvia is passionate about patient/participant engagement and, as such, strives for inclusivity in the programs she leads so that patient/participant voices are prioritized.

Sylvia's clinical research interests include understanding study participants' experiences in research and incorporating their insights into study processes, supporting research coordinators through networks and training, and ensuring all research stakeholders have the resources they need to conduct ethical and compliant studies involving study participants and their data/samples. Sylvia earned a Master of Public Health degree in Global Health from Boston University School of Public Health (2008) and a Bachelor of Science from the University of Toronto (2001).