Announcing a Global Standard for Plain Language in Clinical Research: MRCT Center and CDISC

April 5, 2023

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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Pilot Workgroup

Behtash Bahador
Sarah Balay
Stephen Carr
Jessica Chaikof
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Mary Stober Murray
Gloria Stone
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Desiree A.H. Walker
Robert Weker

Current Workgroup

Behtash Bahador, *CISCRP*
Rebecca Baker, CDISC
Lisa Chamberlain James, *Trilogy Writing*
R Bernard Coley, *Advocate*
Deborah Collyar, *PAIR/Advocate*
Scott Finger, *CISCRP*
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Alice Miller, *Syneos*
Erin Muhlbradt, *NCI Enterprise Vocabulary Services*
Marilyn Neault (co-lead), *Advocate*
Robyn Rennick, *GlaxoSmithKline*
Harold Silverman, *argenx*
Gloria Stone, *G Stone Connections*
Jamie Tyrone, *Advocate*
Cornelia Weiss-Haljiti, *Boehringer-Ingelheim*

Special Acknowledgements

Rhonda Facile, CDISC
Amy Palmer, CDISC
Kayleigh To, MRCT Center
Sarah White, MRCT center

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Webinar Speaker Biographies

Barbara E. Bierer, MD, is the Faculty Director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), a Professor of Medicine (Pediatrics), Harvard Medical School and Brigham and Women's Hospital, and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics, and the Law Program of the Harvard Clinical and Translational Sciences Center, and Director of Regulatory Policy, SMART IRB. Previously she served as senior vice president, research at the Brigham and Women's Hospital for 11 years, and was the institutional official for human subjects and animal research, for biosafety, and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH.

In addition to her academic responsibilities, Dr. Bierer serves on the Board of Directors of Vivli, Inc., a non-profit organization founded by the MRCT Center dedicated to global clinical trial sharing; North Star Research Board; Clinithink, Inc.; Generation Patient; and the Edward P Evans Foundation. Previously she has served on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R) and the Association for Accreditation of Human Research Protection Programs (AAHRPP) and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS, among others. She has authored or co-authored over 270 publications and is on the editorial boards of a number of journals including *Ethics and Human Research.* Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Sylvia Baedorf Kassis, MPH, first joined the MRCT Center as a Program Manager in January of 2018. She 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 assumed her role as MRCT Center Program Director in June 2022. Sylvia champions efforts to make 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).

R. Bernard Coley, JD, MBA, is an executive with 50+ years of experience in the high technology Industry. He is also a Principal in Enable Your Vision, a firm that provides supplier diversity consulting to drive economic vitality for diverse businesses, corporations and the communities in which they reside. He is an experienced President & CEO with a demonstrated history of working in the information services, software development and internet industry. He is skilled in Management Consulting, High Tech Management, Nonprofit Organization Leadership, Strategic Planning, Strategy, Public Speaking, Financial Systems, and Fundraising. He is a business development professional with an AB in Applied Mathematics from Harvard University, an MBA from Stanford Business School, and a Doctor of Law (JD) from Stanford University Law School. He is an inventor and patent holder of the Time Sensitive Scheduling Data Delivery Network Patent.

Mr. Coley has been a delegate on numerous international trade missions [China (2), Australia (14), UK (2), South Africa (2) & Canada]. Mr. Coley has received Distinguished Service Awards recognizing management leadership, community leadership and service contributions to his local community, Stanford University, and youth sports. He has served on many boards in senior leadership roles. He has a long career of volunteer work including community development projects, supporting the arts, youth development, business leadership development and facilitating/mentoring entrepreneurial development in underserved and indigenous communities. He is also an experienced facilitator and mediator. Currently, Mr. Coley is aiming his talents and time in support of those interested in improving the lives of individuals and families impacted by Parkinson's Disease and health disparities. He Co-Chairs with his wife Special Interest Group-Black Disapora focusing on closing health disparities in under-engaged communities, educating health resource and research organizations on engaging communities in a culturally sensitive manner, bringing Black patient advocacy perspectives to PD research, and increasing Black Community participation in clinical research studies. Mr. Coley serves on several patient advocacy councils and especially enjoys a project working on a plain English glossary of research terms. He is a member of the Parkinson's Foundation's Research Advocates group and an Advisory Board member of the CA Chapter of the Parkinson's Foundation. And finally, he is joining his wife, Denise in numerous initiatives to increase awareness of Parkinson's Disease and PD resources in underserved communities of color.

David A. Evans, MS, is recognized industry-wide as a leading technology visionary for developing and implementing complex process and system solutions and as an expert in the areas of information standards, regulatory compliance and quality governance. He was the architect and developer of the first electronic drug submission to the FDA in 1985 and has been responsible for more than 100 electronic regulatory submissions and complex clinical data warehouse systems. He brings over 40 years' experience to CDISC, serving in various executive-level positions in software development, clinical research, regulatory and healthcare industries. Most recently, he was the Global Head of Quality Governance and Regulatory Compliance for Accenture Life Sciences. Prior to that, he was CIO of Octagon Research Solutions and co-founder of Premier Research and Research Data Corporation. He has also served on the CDISC Board and has been an active member of many other industry organizations and initiatives. Dave received his MS in Biomedical Engineering from Drexel University and his BS in Biology from Ursinus College.

Erin E. Muhlbradt, PHD, is a contractor for the US National Cancer Institute's Enterprise Vocabulary Services (NCI EVS) and has been working with CDISC for over 15 years. She is the CDISC and NCI EVS project lead for the CDISC Terminology program. Dr. Muhlbradt holds a Bachelor of Science Degree (Honors) in Molecular and Cellular Biology from the University of Glasgow (Glasgow, Scotland) and a Doctoral Degree in Tumor Biology from Georgetown University (Washington DC). Erin is responsible for CDISC Controlled terminology development; overseeing the development activities across CDISC controlled terminology teams, terminology publication, and maintenance in the NCI Thesaurus. Additionally, Dr. Muhlbradt is a co-lead of the CDISC Genomics team, a co-lead of the CDISC Cell Phenotyping team, a terminology representative for various CDISC therapeutic area standards development teams, and a terminology representative for the CDISC Global Governance Group. She is also a CDISC Authorized Instructor for CDISC Controlled Terminology courses.