

2025 Annual Meeting Roundtable Topics, Moderators, and Descriptions

- **Table #1: A Career as an Academic Statistician Within a Data Coordinating Center**
 - Moderator: Valerie Durkalski-Mauldin, MPH, PhD, Medical University of South Carolina
 - Description: A data coordinating center (DCC) typically provides a comprehensive statistical and data management infrastructure for conducting high quality research that will improve outcomes for patients. Close integration of DCCs with clinical teams allows for the rapid conduct of rigorous clinical trials, and for the development and implementation of novel study designs, including studies aimed at biomarker discovery/validation, mechanistic studies. Statisticians face exciting methodological challenges that have deep implications for shaping the future of medical research. In this roundtable discussion, seasoned statisticians will share stories about their professional growth and personal achievements resulting from involvement in work at their DCC.
- **Table #2: Building a DCC**
 - Moderator: Catherine Dillon, MS, Medical University of South Carolina
 - Description: Academic groups across the country serve as Data Coordinating Centers (DCCs) for multicenter clinical research, playing a vital role in high-quality research through collaborative leadership in data management and statistical support. DCC responsibilities typically encompass three core domains: Trial Operations, Information Systems, and Biostatistics, each with specialized professionals who drive trial design, implementation, analysis, and reporting. In this roundtable discussion, experienced DCC staff—including statisticians, project managers, data managers, and IS developers—will share insights on the development and evolution of their centers, highlighting key strategies for building and sustaining a successful DCC in an academic setting.
- **Table #3: An Introduction to the Society for Clinical Trials (SCT) and How to Become More Involved**
 - Moderator: Dikla Blumberg, PhD, Rho, Inc.
 - Description: This roundtable will provide an overview of the SCT organization, mission, membership and opportunities to participate in committees and initiatives. We will begin with an introduction to the Society, including the organizational structure, and discuss some of the benefits of membership, and the process of becoming a member. We will conclude with a discussion about the different SCT committees, their unique roles in the Society, and the opportunities for members to participate in these committees.
- **Table #4: Bridging the Gap: Improving Communication Between Statisticians and Clinicians in Advanced Bayesian Trial Design Implementation**
 - Moderator: Danila Azzolina, PhD, University of Ferrara
 - Description: Effective communication between statisticians and clinicians could be a relevant challenge in implementing advanced trial designs, particularly Bayesian approaches. This roundtable will explore the challenges of explaining complex statistical ideas, addressing medical professionals' worries about adaptability and interpretability, and improving comprehension through graphical and storytelling approaches. Real-world case studies and interactive discussions will help identify critical barriers and practical solutions. Addressing these challenges is important to build trust, foster collaboration, and ensure informed decision-making, which is essential for successfully designing and implementing complex trials.
- **Table #5: How to Be an Effective Clinical Trial Statistician**
 - Moderator: Jennifer Le-Rademacher, PhD, Mayo Clinic
 - Description: Designing and conducting a clinical trial demands strong collaboration from a multidisciplinary team, with the trial statistician as a key player. Effective trial statisticians need collaborative and communication skills, often gained through experience or guidance from seasoned colleagues. However, not all statisticians have clinical trial experience or access to knowledgeable peers. This roundtable offers a platform for both new and experienced trial statisticians to connect, share insights, and build expertise, fostering a supportive community for professional growth in clinical trials.
- **Table #6: Effective Information Sharing Between Data Monitoring Committees and Regulatory Agencies**
 - Moderator: Emily Woolley, MS, Axio, a Cytel Company
 - Description: Data Monitoring Committees (DMC) review unblinded clinical trial data and issue recommendations. Information from a DMC to regulatory agencies generally goes through the sponsor.

Regulatory agencies are sometimes interested in unblinded materials to which the sponsor does not have access. This roundtable will discuss proceeding with requests, managing communication pathways, and will provide examples of addressing common situations while avoiding inadvertent unblinding. We will discuss how SDACs should prepare for and respond to regulatory requests for: unblinded reports, closed meeting minutes, direct conversations with DMCs, DMC review of additional TLFs, and DMC responses to specific safety or efficacy queries.

- **Table #7: Ethical Challenges and Considerations in Decentralized Clinical Trials**
 - Moderator: Matt Hammond, MSc, BSc, Norwich Clinical Trials Unit, UK
 - Description: Whilst elements of decentralization, such as remotely collected consent and patient outcome reported measures have been present in clinical trials for decades, the need to undertake more research in the home rather than the clinic during the COVID-19 pandemic accelerated the adoption of decentralized practices. This session aims to explore the ethical and logistical challenges in conducting decentralized clinical trials (DCTs) including but not limited to the use of informed consent, decentralized safety reporting, guaranteeing participant privacy and confidentiality, ensuring digital access and proficiency and maintaining appropriate oversight of decentralized trial activities.
- **Table #8: Executing Startup of a Multi-Site Intermediate-Sized Expanded Access Protocol**
 - Moderator: Jennifer Kulesa-Kelley, RN, DNP, Massachusetts General Hospital Neurological Clinical Research Institute
 - Description: The study startup period, from funding notification to the first participant enrolled, of a multi-site intermediate-sized expanded access (EA) protocol is a collaborative process. The aim of this roundtable topic is to identify the complexities involved in startup and discuss essential factors in successfully executing startup of a multi-site intermediate-sized EA protocol including the collaborative approach of a comprehensive Academic Research Organization (ARO) infrastructure with specialized functional teams and preferred vendors.
- **Table #9: Expanding Global Partnerships: Advancing Clinical Trial Collaborations in Japan and Beyond**
 - Moderator: Susan Halabi, PhD, Duke University
 - Description: Our objective is to foster international collaboration among statisticians and clinicians in clinical trials through the SCT Outreach Committee, building impactful global partnerships and expanding member diversity. These collaborations will promote the exchange of advanced statistical methodologies to support both research and education. We aim to identify and prioritize key collaboration areas—such as the use of external controls in rare diseases with recruitment challenges—where shared expertise can drive progress. Formal and informal partnerships will accelerate the development of innovative statistical methods, strengthen recruitment efforts, and enhance the SCT ability to address critical challenges in patient care globally.
- **Table #10: HIV Treatment and Prevention Trials: What's Happening?**
 - Moderator: Mary Putt, ScD, University of Pennsylvania
 - Description: Many SCT members are involved in HIV-related research, either through affiliation with a Center for AIDS research or another entity. This roundtable invites you to get together with colleagues to discuss work designing, implementing and analyzing trials involving HIV prevention and treatment. Please join us if you are actively involved in this area or simply interested in hearing more.
- **Table #11: Implementing Model-Assisted Designs to Enhance the Success of Clinical Trials**
 - Moderator: J. Jack Lee, PhD, DDS, University of Texas MD Anderson Cancer Center
 - Description: Clinical trial designs can be classified into three categories: rule-based, model-based, and model-assisted. Rule-based designs are simple but not rigorous. Model-based designs are rigorous but complicated. Model-assisted designs are simple, rigorous, and easy to implement, thus, ideal for clinical trials. Thanks to the user-friendly free software at <https://trialsdesign.org>, model-assisted designs have been used increasingly, particularly, in early phase clinical trials for dose finding and dose optimization. In the roundtable, we will share the experiences, challenges, benefits, and lesson learned in applying model-assisted designs. We will discuss the practical considerations for successful implementation of these designs.

- **Table #12: Integration of Software Systems for Clinical Trials**
 - Moderator: Wenle Zhao, PhD, Medical University of South Carolina
 - Description: Clinical trial operation management and data management are heavily depending on information technologies, such as Electronic Data Capture (EDC) system, Interactive Response Technology (IRT) system, and other Clinical Trial Management System (CTMS). Multiple silo-type systems used in a clinical trial result in redundant data entry and data discrepancies among them. We are looking for clinical researchers and software developers to share their expectations and experiences for system integration and integrated system development.
- **Table #13: Sharing Experiences from Academic and Industry CROs: Where Do You Fit?**
 - Moderator: Julie Qidwai, MS, CCRC, WEP Clinical
 - Description: This roundtable welcomes participants of all experience levels and from all clinical trials specialties. We will share characteristics of our careers in industry and academic CROs. We'll talk about the working experience in both sectors and what you can expect if you're considering a career change or starting out in your first clinical trials position. Come prepared with your questions; this will be an open discussion of the pros and cons of industry and academic work, from salary and benefits to quality of life, intellectual property to opportunities for advancement.
- **Table #14: Should We Throw Sample Size Calculations in the Trash?**
 - Moderator: Kelley Kidwell, PhD, University of Michigan, Biostatistics
 - Description: Every clinical trial protocol is expected to include a justification of sample size. Sample size allows us to have enough power to find a meaningful effect, yet not waste resources or put too many people at risk. Yet every sample size justification requires many assumptions. Are we ever right? A recent JAMA article explains <50% of surgery trials met their enrollment target where similar rates exist across other settings. Are these calculations necessary? If we discard them, how do we budget trials and shift the paradigm? This roundtable will explore the necessity and alternatives to clinical trial sample size calculations.
- **Table #15: Training Clinical Trialists: Opportunities for Trainees and Enhancing Our Approaches to Training**
 - Moderator: Megan McCabe, PhD, University of Alabama at Birmingham
 - Description: Clinical trials research is dynamic and requires skills and knowledge which may not have been learned prior to one's involvement in trials. Additionally, the clinical trials workforce is extremely diverse in terms of educational background and prior experience. This can lead to barriers in learning aspects of clinical trial design, conduct, and analysis. A key question for those of us already involved in clinical trials is how to design and implement opportunities to best prepare trainees. In this roundtable, participants can discuss unique training opportunities they are aware of and ways we can improve our approaches to training going forward.
- **Table #16: Undertaking Impactful Patient and Public Involvement (PPI) for Statistical Trial Methodology Research**
 - Moderator: Laura Gray, PhD, University of Leicester, UK
 - Description: We have surveyed statistical methodologists about their attitudes and practices regarding PPI for statistical methodology research. We found that the majority of respondents did not feel confident in conducting PPI activities and required more training, guidance and case studies to be available. We have developed resources for undertaking PPI in this field of research. We will discuss barriers faced by those attending in undertaking PPI, we will ask those who have examples of impactful PPI to share their experiences. We have gathered a number of case studies of statistical methodology research related to trials which we can share with participants.
- **Table #17: Working with Peer-Reviewed Journals to Promote High-Quality Evaluation of and Critical Commentary on Clinical Trials**
 - Moderator: Alison Huang, MD, MAS, Mphil, University of California San Francisco, JAMA Network Clinical Trials Platform
 - Description: This roundtable will engage SCT attendees interested in promoting critical evaluation and discussion of clinical trial designs and methods in the wider clinical research community, by serving as reviewers, editors, or commentators for peer-reviewed journals and journal-affiliated platforms. Discussion, moderated by SCT members with experience as journal editors or reviewers, will focus on how SCT members can influence journal decisions about clinical trial submissions and enhance their careers by working with

journals, as well as future opportunities to provide critical commentary about newly completed clinical trials on journal platforms.

- Table #18: Historical Data and Synthetic Controls for Clinical Trials Related to Rare Diseases
 - Moderator: Wei Wei, PhD, Yale University
 - Description: Leveraging external data holds significant potential to enhance the efficiency and accuracy of rare disease research. However, concerns about hidden bias have hindered its broader application in the design and analysis of rare disease trials. Have you successfully incorporated external data into a rare disease trial? What strategies would you recommend to demonstrate the validity of your study to regulatory authorities and funding agencies when using external data?
- Table #19: Challenges in Using Electronic Health Record Data in Multisite Clinical Trials
 - Moderator: Denise Esserman, PhD, Yale School of Public Health
 - Description: Although there are benefits to using electronic health record data, the fact that data were not collected for research purposes and may be of variable data quality poses challenges. How did you use the data in your trial, what challenges did you face and how did you overcome those challenges?
- Table #20: Crystal Clear: The Central Role of DMs in Effective Communication
 - Moderator: Christina Scheele, MA, Emmes
 - Description: Effective communication is pivotal to the success of a clinical trial yet challenging when there are several contracted groups in various role. Data managers play a key role in communicating to the sites, sponsors, vendors and other key stakeholders throughout the duration of the trial to ensure data are captured cleanly and in accordance with the protocol. Understanding how to stay connected is a delicate dance that DMs must learn to master. This presentation will delve into effective communication techniques that facilitate positive working relationships with all key stakeholders and how to avoid key pitfalls in various sponsor/CRO/vendor relationships.
- Table #21: Overcoming Implementation Challenges in Platform Trials
 - Moderator: Shelby Roberts, BA, Almac Clinical Technologies
 - Description: Implementing platform trials in the real world presents unique challenges. While these trials are elegantly designed to rapidly onboard new treatment arms, study operations teams often face hurdles when transitioning from theory to practice. These hurdles may be in technology, randomization, drug supply, vendor management, team dynamics and more. Join us for an engaging discussion where we can learn from each other and explore practical solutions to common challenges in platform trials.
- Table #22: How to Power Your Comparative Effectiveness Research with PCORnet®
 - Moderator: Lauren Cohen, Duke University
 - Description: Real world implementation of platform trials is not easy. Elegantly designed to achieve the mission of rapid onboarding of new treatment arms, study operations teams will nonetheless face challenges as they attempt to move from theory to practice. Concerns that may emerge include, whether technology vendor(s) can handle the complex randomization methodology, drug supply sourcing and logistics to support new treatment adaptations, and ensuring teams understand their roles and responsibilities in the face of staff turnover and protocol changes. The facilitator will offer some examples of these challenges and how they were overcome and welcomes you to share yours.
- Table #23: Does Optimization for Early Oncology Trials in Heterogeneous/Diverse Patient Populations
 - Moderator: Yutao Liu, PhD, AstraZeneca
 - Early oncology trials often include diverse patient populations, allowing opportunities to pursuing therapies that may fit for multiple different indications. And even within the same indications such as Myelodysplastic syndrome (MDS), patients are heterogeneous in terms of clinical presentation, disease progression, and response criteria. Therefore, it's relevant to consider that the optimal dose may be different for different patient subgroups. One approach to dose optimization (DO) across indications may be to assume the same optimal dose for each, heavily relying on homogeneity assumption. Therefore, it's worth discussing alternative approaches to dose optimization, the challenges and practical considerations.

- **Table #24: Futility Monitoring in Clinical Trials: When, Why, and How?**
 - Moderator: Corinne McGill Gant, MPH, Medical University of South Carolina
 - Description: Modern clinical trials often include interim analyses of accruing data that seek to declare futility when the demonstration of a meaningful treatment effect is unlikely, even if they continue to their planned conclusion. An appropriate futility determination and decision to halt the study early can avoid unnecessary expenditure of resources and exposures to ineffective therapies. Led by a doctoral student in biostatistics, this roundtable will foster discussion on the following topics while providing information from the current clinical trials literature: • Futility vs safety and efficacy • When and when not to incorporate futility assessment(s) • Should futility looks always be paired with efficacy analyses? • Popular tool(s) to evaluate futility • When and how many analyses to plan? • How to estimate total information?
- **Table #25: Design Cluster Randomized Trials with Hierarchical Composite Outcomes**
 - Moderator: Hrishikesh Chakraborty, DrPH, Duke University
 - Description: Hierarchical composite outcomes (HCO) combine multiple endpoints into a single measure, and they are often used in clinical trials. Various methods exist to create HCO variations, but their use in CRTs is limited, and their power implications are unclear. This discussion will cover different HCO estimation methods and conduct a simulation-based power comparison for these methodologies in a CRT setting, offering possible recommendations.
- **Table #26: The Road Not Taken: Does More Diverse Research Mean More Diverse Career Paths?**
 - Co-Moderators: Liam Bishop, MSc, University of Leeds & Carol Geary, PhD, MBA, RN, University of Nebraska Medical Centre
 - Description: The requirement for clinical trials research to be more inclusive of under-served populations requires us to think of new and innovative ways to design research. It also places an emphasis on community outreach approaches; these are skills and capacities not traditionally seen within clinical trials. Does this mean there is the possibility of new roles and careers within clinical trials research? How do these roles sit alongside more traditional clinical trials roles? And how do we develop skills and expertise in these roles to support the increasing demand for more inclusivity in research? This roundtable will discuss these questions.
- **Table #27: Global Perspectives in Clinical Trials: Addressing Emerging Challenges and Innovations**
 - Moderator: Wendy London, PhD, Boston Children's Hospital/Dana-Farber Cancer Institute
 - Description: This roundtable invites international attendees to discuss unique regional challenges, innovations, and advancements in clinical trials, fostering a cross-border knowledge exchange among trialists. Participants will share insights into navigating diverse regulatory landscapes, resource disparities, and distinct patient populations while highlighting innovative approaches and successful trial designs. By bringing together trialists from various regions, we aim to build a collaborative platform for discussing shared goals and challenges, thereby enhancing the Society's commitment to a global clinical trials focus. This session will deepen understanding and support collaborative solutions, showcasing the Society's role in driving inclusive, global clinical research excellence.
- **Table #28: Strengthening Academic and Pharma Collaborations to Advance Statistical Methodologies in Clinical Trials**
 - Moderator: Chen Hu, PhD, Johns Hopkins University
 - Description: The goal of this roundtable is to facilitate an open dialogue on fostering collaboration between academic researchers and pharmaceutical companies in the design, implementation, and statistical analysis of clinical trials. Key discussion points will include but are not limited to 1) identifying challenges and strategies to enhance collaboration, 2) exploring data-sharing models that benefit both academic research and drug development, 3) establishing a network of professionals committed to advancing clinical trials methodologies, 4) highlighting case studies of successful partnerships.