2026 Roundtable Topics, Moderators, and Descriptions
Monday, May 18 | 11:30 am – 1:00 pm

- **Table #1 – AI, Clinical Trials, and Biostatistics**
  - **Moderator:** Pedro Torres-Saavedra, National Cancer Institute
  - **Description:** Artificial intelligence (AI) is reshaping the way clinical trials are designed, conducted, and analyzed, presenting both exciting opportunities and important challenges for the biostatistics community. This roundtable will bring together members of the Society for Clinical Trials, particularly biostatisticians, to share their experiences in using AI in clinical trial design, monitoring, and data analysis. Participants will discuss current trends in the application of AI across various aspects of clinical trials, as well as practical considerations for integrating AI into their workflows. The discussion will also address issues of transparency, reproducibility, and regulatory alignment, highlighting how biostatisticians can contribute to the responsible and effective implementation of these principles. Through this interactive exchange, attendees will gain insight into emerging applications, learn about AI tools currently being adopted in clinical research, and gather recommendations for incorporating AI in their own daily work. Learning Objectives: - Describe current AI applications, trends, and tools used by biostatisticians in clinical trials. - Discuss challenges, best practices, and practical recommendations for using AI responsibly and effectively in clinical trials.

- **Table #2 – Bridging the Gap: Trial Innovation vs. Regulatory Reality**
  - **Moderator:** Kelley Kidwell, University of Michigan
  - **Description:** Despite growing enthusiasm for innovative clinical trial designs—Bayesian approaches, adaptive decision points, platform protocols, registry-embedded trials, and the use of real-world data—implementation in practice remains limited. U.S. regulatory agencies have issued guidance indicating openness to these methods, yet many sponsors report that when a pivotal trial is on the line, implicit pressure still pushes them back toward traditional designs. This roundtable will explore the persistent “chicken-and-egg” dilemma: regulators want evidence that novel designs work before relying on them, but such evidence cannot accumulate unless the designs are allowed in the first place. We will discuss what it takes to move from theoretical appeal to operational feasibility: What statistical assurances are regulators actually seeking? How do we communicate the validity, transparency, and robustness of Bayesian and adaptive methods? Can real-world data be integrated without compromising rigor? Just as importantly, how do we ensure that innovation aligns with patient needs, ethical considerations, and practical implementation constraints in clinical settings? The goal is to identify concrete paths for making modern trial designs not only acceptable, but expected, in the next generation of clinical research.

- **Table #3 – Data Management Strategies for Unifying High-Velocity, Multi-Source Clinical Data**
  - **Moderator:** Amber Boose, American Society of Clinical Oncology
  - **Description:** In this era of cutting-edge information capabilities, the data manager's role has fundamentally shifted from managing single-source Electronic Data Capture (EDC) to architecting a unified data flow from diverse, high-velocity sources like EHRs, wearables, and RWE registries. This roundtable is a critical forum for data managers to collaboratively tackle these complexities. We will focus on 1. Ingestion and Standardization: Sharing practical, experience-based strategies for data harmonization 2. Real-Time Data Quality: Implementing real-time data validation, anomaly detection, and automated query generation 3. Toolkits and Skills: Evaluating new tools and discussing the evolving data science skills critical to succeed in this technology-focused role.

- **Table #4 – Enhancing Cross-Functional Interactions: The Three Cs for Data Managers**
  - **Moderator:** Saira Anam Qadir, Massachusetts General Hospital (MGH)/Neurological Clinical Research Institute (NCRI)
  - **Description:** Data Managers play a key role in meeting milestones throughout each phase of clinical study. Study start-up requires working closely with project managers, while study conduct and study close-out phases demand effective engagement with sites, vendors, study monitors and biostatisticians. By prioritizing

Communication, Collaboration, and Coordination – the "Three Cs" – Data Managers foster productive cross-functional interactions. This roundtable provides actionable strategies for both new and experienced Data Managers to master the Three Cs, ensuring clarity, operational efficiency, and team alignment to meet study objectives and deadlines with confidence.

- **Table #5 – Federated Learning Methodologies in Modern International Randomized Clinical Trials**
  - **Moderator:** Tolulope Sajobi, University of Calgary
  - **Description:** Modern international randomized controlled trials (RCTs) increasingly operate across multiple jurisdictions and nations, each governed by distinct data privacy regulations and ethical frameworks. This global complexity poses a persistent challenge: how can trialists conduct robust, collaborative analyses without compromising patient confidentiality or violating regional and national data governance laws? Federated learning (FL) and other distributed analysis methodologies offer a promising approach to this problem, by enabling machine learning algorithms to train on decentralized datasets without requiring data centralization. FL preserves privacy while unlocking valuable insights and inferences from diverse, distributed data sources. These approaches hold promise for applications such as pharmacovigilance, data quality assurance, interim analyses, and post-market surveillance. This roundtable aims to illuminate the technical and regulatory landscape of federated learning in clinical research. It will foster dialogue among methodologists, data scientists, statisticians, research coordinators, and regulators, and identify future directions and collaborative opportunities for FL in clinical trials. Together with participants, we will explore: • The current adoption of FL in international RCTs and observational studies • Regulatory perspectives and compliance strategies across jurisdictions • Methodological advances in privacy-preserving machine learning • Practical applications and case studies demonstrating FL's impact in real-world settings Target Audience: • Clinical trial methodologists • Data scientists and statisticians • Research coordinators and site managers • Regulatory and ethics experts • Health informatics professionals

- **Table #6 – From Hallway Hellos to Lasting Collaborations: Networking That Works at Clinical Trials Conferences**
  - **Moderator:** Gayle Flynn, Cognizant
  - **Description:** Networking can feel awkward. This lunch-time roundtable is a practical, conversational exchange on small, repeatable habits that turn brief conference encounters into durable collaborations. We will discuss what actually works, swap scripts, and co-create a simple "first 24 hours / first 7 days" follow-up plan. Proposed talking points: 1. Micro-behaviors that lower the barriers to engagement 2. A 30-second "value sentence" 3. Fast, inclusive intros: the 5-word "what I'm looking for" round 4. Equity and inclusion: making space for everyone.

- **Table #7 – How to Implement Response Adaptive Randomization**
  - **Moderator:** Wenle Zhao, Medical University of South Carolina
  - **Description:** Response adaptive randomization (RAR) has been used more frequently in recent years. There are two major challenges for implementing RAR in trial practice. First, target allocations could be multi-arm unequal with the greatest common divider too larger for blocking randomization, for example 100:123:159. Second, the number of assignments within a RAR allocation could be unknown if the RAR is updated by pre-specified time point, such as every 3 months. As a consequence, many investigators choose to use simple randomization to implement RAR, giving up the control on treatment imbalance and baseline covariate imbalances. It is hard to justify the use of simple randomization in RAR while restricted randomization has been widely used in trials with fixed target allocations. It is possible that the reason of using simple randomization for RAR is because investigators do not know other randomization designs that are able to accurately target allocations like 100:123:159. In the StrokeNet and SIREN clinical trial network, both funded by NIH, the mass-weighted urn design and the minimal sufficient balance method have been implemented in several large multicenter adaptive trials. This roundtable discussing aims to provider an opportunity for researchers working on adaptive trials to share their experiences and lessons in the implementation of RAR in trial practice.

- **Table #8 – Maintaining the Blind in Statistical Teams**
  - **Moderator:** Haley Hedlin, Stanford University
  - **Description:** Clinical trials vary widely in the size and structure of the statistical team(s) involved, ranging from a single statistician to separate blinded and unblinded statistical teams. This roundtable will discuss the challenges faced by statisticians in maintaining the blind in randomized controlled trials, particularly when all statisticians are unblinded or the blinded and unblinded statisticians are in the same institution. Examples of challenges include how to interact with blinded members of the study team in the former situation and how to maintain a firewall in the latter. Participants will leave the roundtable with examples of how other statisticians have successfully approached common challenges and with concrete recommendations on how to approach blinding.

- **Table #9 – Nonadherence in Clinical Trials**
  - **Moderator:** Sherry Livingston, Medical University of South Carolina
  - **Description:** Nonadherence to clinical trial protocols can compromise study integrity and obscure true treatment effects. This roundtable will explore challenges and share practical strategies to improve adherence, including participant engagement and protocol design. We'll consider differences in adherence between intervention types, such as oral medications versus medical devices. Methods for measuring adherence—self-reports, electronic monitoring, and biomarkers—will be discussed, along with their limitations. Statistical approaches to account for nonadherence, including per-protocol and instrumental variable analyses, will be reviewed. Attendees are invited to share experiences, challenges, and innovations to foster best practices and improve trial reliability.

- **Table #10 – Optimizing Clinical Operations for Complex Innovative Trial Designs: Strategies and Lessons Learned**
  - **Moderator:** Bambi Smith, Almac Group
  - **Description:** The clinical trial landscape is advancing with the adoption of complex adaptive designs, including dose optimization aligned with FDA's Project Optimus, Master Protocols, and other Complex Innovative Designs (CID). These trials require Clinical Operations teams to adjust planning, execution, and cross-functional coordination to manage adaptive elements such as new doses, treatment arms, and patient populations. This roundtable will discuss the operational challenges encountered on these types of trials where participants are encouraged to share experiences in effective planning, implementation, and management. Moderator will provide an example of a successful CID Project Management program that provides ongoing education and support throughout the eClinical System life cycle. The session will highlight lessons learned, current challenges, and practical approaches to improve readiness and execution.

- **Table #11 – Project Optimus and e-Clinical Operational Agility Strategies**
  - **Moderator:** Shelby Roberts, Almac Clinical Technologies
  - **Description:** FDA's Project Optimus brings several benefits such as identifying more effective doses with less toxicity, as well as patient centricity. However, meeting the recommendations of Project Optimus can be operationally challenging due to the complexity involved such as randomized dose cohorts, adaptive trial designs, backfill cohorts and identification / introduction of new variables mid-trial (e.g., new stratification, patient populations / indications, dose levels / formulations / strategies). For successful implementation, designing modular eClinical systems for flexibility is key. This roundtable will encourage dialogue about how e-Clinical systems must evolve to support the operational demands of Project Optimus. Discussions will include participants' experienced challenges and exploration of strategies to overcome these challenges (i.e., how to build scalable, responsive infrastructure to meet the agility required for modern oncology trials under the Project Optimus paradigm).

- **Table #12 – Streamlining DMC Data Summaries for Modern Trial Designs**
  - **Moderator:** Emily Woolley, Axio, a Cytel company

- **Description:** Data Monitoring Committees (DMC) review unblinded clinical trial data and issue recommendations based on risk-benefit to designated sponsor liaisons to safeguard trial participants and ensure the scientific integrity of a clinical trial. Increasing trial complexity, expanding volume and types of data produced by a clinical trial, and concurrent cost sensitivity demand a renewed focus on how to efficiently summarize data for DMCs. This discussion will explore how to efficiently summarize data for DMCs overseeing increasingly complex trial designs. Key points include: • How should data from a platform trial be presented such that each trial is interpretable against the common control group and can be evaluated as a whole? • How should data from a randomized trial be presented alongside that from a long-term extension where all participants are on active therapy? • What additional summaries are necessary to parse emerging safety concerns in basket trials? • Are combined population summaries useful for DMC review if sub-populations are analyzed separately in the primary analysis?

- **Table #13 – Strengthening Global Capacity for Investigator-Initiated Trials (IITs): Opportunities for International Collaboration and Industry Engagement**
  - **Moderator:** Chen Hu, Johns Hopkins University
  - **Description:** Investigator-Initiated Trials (IITs) are increasingly recognized as a critical driver of evidence generation, innovation, and clinical practice, especially in oncology, rare diseases, and emerging therapeutic areas. Across Asia-Pacific, Europe and other regions, there is strong and growing interest in designing and conducting high-quality IITs that meet international methodological and regulatory standards. This roundtable will bring together SCT members and guests from academia, regulatory bodies, and the pharmaceutical industry to discuss opportunities and challenges for global collaboration around IITs. Key themes will include: - Knowledge sharing and training in protocol development, statistical design, and operational execution; - Models for international collaboration and regional capacity-building; - The role of pharma and regulatory stakeholders in supporting IITs through infrastructure, technical support, or co-development; - How SCT can serve as a bridge—facilitating mentorship, methods exchange, and shared educational resources across regions. Participants will be invited to share experiences, highlight local barriers or success stories, and brainstorm collaborative strategies. This session is sponsored by the SCT Outreach Committee and intended to guide future society-wide engagement efforts in global trial development.

- **Table #14 – The Crucial Role of Regulatory Specialists in Clinical Research: Safeguarding Compliance and Advancing Innovation**
  - **Moderator:** Ramya Krishna Chunduru, Baylor Scott and White Research Institute
  - **Description:** This roundtable expands upon the recently published article “The Crucial Role of Regulatory Specialists in Clinical Research: Safeguarding Compliance and Advancing Innovation” to highlight the indispensable yet often overlooked contributions of regulatory professionals in clinical research. While much of the spotlight in clinical trials focuses on investigators and coordinators, regulatory specialists serve as the critical link ensuring compliance, ethical integrity, and operational efficiency. Their work drives timely study activation, accurate documentation, and audit readiness—elements fundamental to advancing high-quality, patient-centric research. Key discussion points will include: How regulatory operations influence study timelines and data quality. Strategies to enhance collaboration between regulatory teams, investigators, and sponsors. The role of technology and AI in optimizing regulatory workflows. Career growth, training, and recognition for regulatory professionals—an unexplored or forgotten career path within the clinical trials ecosystem. This informal discussion aims to elevate the visibility of regulatory professionals and inspire attendees to consider regulatory operations as a meaningful and rewarding career direction. Target Audience: Clinical research professionals at all career stages, including coordinators, investigators, project managers, regulatory staff, and students interested in learning about diverse career pathways in clinical trials.

- **Table #15 – The Role of Trial Operations at a Data Coordinating Center**
  - **Moderator:** Jessica Griffin, The Data Coordination Unit (DCU), Medical University of South Carolina
  - **Description:** The role of trial operations differs across Data Coordinating Centers (DCCs). Where some DCCs may only have Data Managers as part of their trial operations group, others may also have Project Managers,

Regulatory Specialists, Trial Operations Managers, and/or other roles that help to make their group function effectively. This roundtable will discuss the common trial operations roles at DCCs and the typical responsibilities of each of those roles. The discussion will include asking those in attendance to share how their trial operation groups are organized and managed. Ideally those attending this roundtable will learn how other DCCs organize their trial operations groups to successfully manage clinical trials. Target Audience: Trial Operations Personnel at Data Coordinating Centers (Data Managers, Project Managers, Regulatory Specialists, Trial Operations Managers)

- **Table #16 – Using Artificial Intelligence with Public Partners in Clinical Trial Research – Can AI be a Collaborative Tool?**
  - **Moderator:** Liam Bishop, University of Leeds
  - **Description:** Artificial Intelligence (AI) is being used across clinical trial research to enhance trial delivery, optimise intervention development, and has many other potential uses. There is limited understanding about AI's use at research ideation stages, and in whether it can be a collaborative tool with public partners in that process. There is a need to incorporate patient public involvement and engagement (PPIE), as well as PPIE that is inclusive, at this specific stage of research design. Can AI help in this space? While there there is suspicion over the use and role of AI from public partners, lack of knowledge on how to use AI, there is evidence of support and interest in its use by public partners (e.g., Sonawane, et al., 2023 ; Teodorowski, et al., 2023). Some AI tools include Google Gemini, Notebook LM, Microsoft Co-Pilot and paid versions of online AI tools (e.g. Claude). These tools can help with writing in plain English, or supporting literature searches of underserved groups. However, there is little amount of published literature on the utilisation of AI tools with public partners in this space, and we need to start these discussions about how to do so. This roundtable is a setting for an engaging discussion on the potential collaborative power of AI and how we can use its tools to facilitate involvement from public partners. We will discuss whether it can lead to efficiencies in research development and engagement with public partners, as well as strengths and weaknesses.

- **Table #17 – Beyond the Statistician: Diversifying SCT Membership**
  - **Moderators:** Kortney Barrett, University of Iowa & Audrey Mauguen, Memorial Sloan Kettering Cancer Center
  - **Description:** We propose a roundtable session led by members of the SCT Membership Committee to engage our most valuable resource—our members—in a collaborative discussion on expanding SCT's membership beyond statisticians. This session will focus on gathering insights and ideas from professionals across the clinical trials landscape, particularly those in non-statistical roles. The discussion will explore how SCT can broaden its appeal by identifying potential barriers to membership for individuals in non-statistical roles, content that would attract these professionals, and ways to ensure that both newcomers and those in non-statistical roles feel welcomed, engaged, and invested in SCT's growth and long-term success. By fostering this dialogue, we aim to identify initiatives that enhance the diversity of our membership, strengthen our service to the clinical trials community, and ultimately grow a more inclusive and multidisciplinary network. This roundtable will also provide members with a meaningful opportunity to connect with the SCT Membership Committee, contribute their thoughts, and help shape new pathways for engagement. The target audience for this roundtable includes members at any career stage and in any professional role—particularly those who have attended at least one previous SCT meeting or event. This will allow participants to effectively contribute ideas and thoughts from their experiences with SCT. Moderators will be Kortney Barrett, AA, Department of Biostatistics, University of Iowa, and Dr. Audrey Mauguen, PhD, Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center.

- **Table #18 – Career Opportunities in Academic Data Coordinating Centers**
  - **Moderators:** Barbara Braffett, George Washington University & Letitia Perdue, Wake Forest School of Medicine
  - **Description:** We propose hosting a roundtable discussion focused on exploring career opportunities within academic Data Coordinating Centers (DCCs), which play a critical role in supporting multi-site research. Despite their pivotal role in advancing research by providing operational oversight, logistical support, and scientific expertise, many trainees and professionals are unfamiliar with how DCCs operate or the diverse

career opportunities they offer. This interactive roundtable session will convene a diverse group of professionals in biostatistics, epidemiology, trial operations, data management, project management, systems/technology, and regulatory affairs to explore the role of DCCs, highlight how multidisciplinary teams collaborate, and share insights on building fulfilling careers in this environment. Attendees will explore day-to-day academic and operational responsibilities, key skills and competencies required for various roles, as well as avenues for training, mentorship, and advancement. This roundtable will be structured around a set of facilitated conversations that will allow participants to share their own experiences, identify common challenges, and discuss ways they overcome them. The target audience for this roundtable includes students/trainees and early- and mid-career professionals who are looking to explore career options or advance within DCCs, as well as academic administrators or mentors who advise trainees and manage research infrastructure. Moderators will be Dr. Barbara H. Braffett, PhD, Department of Epidemiology, The Biostatistics Center, George Washington University, and Letitia Perdue, MS, Wake Forest School of Medicine.

- **Table #19 – Designing Informed Consent Processes for Trials with Usual Care Groups: What Practical Guidance is Needed?**
  - **Moderators:** Clare Relton, Queen Mary University of London - Wolfson Institute of Population Health, Centre for Evaluation and Methods, Methodology Research Unit & James Flory, Weill Cornell Medical College - Population Health Sciences
  - **Description:** The traditional informed consent pathway provides 'full' information to everyone before randomisation. This 'everything to everyone up front' approach is required for many trial designs, especially those with placebo controls, However, in trials with usual care groups, the health care experience of one group (or sometimes both) is unaltered by their participation in the trial. For trials with usual care groups, the traditional informed consent pathway can create significant obstacles for researchers, impose burdens on patients and clinicians, and undermine trials' central pragmatic aim. These obstacles contribute to slower, more expensive trials that fail to recruit their target population, fewer trials being done, and expose patients to information that is not relevant to the decisions they need to focus on. Existing informed consent guidance provides generic information on the principles of consent and recommendations regarding the preparation of participant information sheets. However, there is no specific guidance for designing informed consent pathways for trials with usual care groups and scant guidance for different types of trial infrastructures (standalone, platform/cohort, and clinically integrated). This roundtable will enable attendees to discuss what additional practical guidance is required to design trials which reduce patient and clinicians' burden and enable pragmatic trials to recruit their target population efficiently. Learning objectives ? to share knowledge and experience of different approaches to informed consent design choices for trials with usual care groups. ? to discuss what practical guidance is needed to support those designing and reviewing informed consent pathways for trials with usual care groups.

- **Table #20 – How to Make the Most of the SCT Meeting for First-Time Attendees**
  - **Moderators:** Emine Bayman, University of Iowa & Cristina Murray-Krezan, University of Pittsburgh
  - **Description:** Attending the Society for Clinical Trials (SCT) Annual Meeting for the first time can be both exciting and overwhelming. This roundtable, organized by the SCT Membership Committee, is designed to help first-time attendees navigate the meeting with confidence and purpose. The session will provide a guided overview of key activities tailored to new participants, including identifying high-impact scientific sessions, attending networking receptions, learning about different committees, and engaging in mentoring opportunities such as the Early Career Group Gathering and the Networking Welcome Reception. Experienced SCT members will share practical tips on how to plan their schedules, initiate conversations with peers and senior researchers, and make the most of informal networking opportunities throughout the conference. Attendees will also have the chance to ask questions, share their goals for the meeting, and connect with other first-time participants in a welcoming, interactive setting. Whether you're a student, early-career professional, or transitioning into the field of clinical research, this roundtable will help you build connections and maximize your SCT experience from day one. The target audience for this roundtable includes students/trainees and early-career professionals who are attending the SCT for the very first time, as well as

academic administrators or mentors who advise trainees. Moderators will be Dr. Emine Bayman, PhD, Department of Biostatistics, University of Iowa, and Dr. Cristina Murray-Krezan, PhD, Department of Medicine, University of Pittsburgh.

- **Table #21 – SCT Committees and Pathways to Leadership: How to Get Involved**
  - **Moderators:** Dikla (Dee) Blumberg, Rho, Inc. & Sarah Gaussoin, Advocate Health
  - **Description:** This roundtable will provide an overview of SCT's committee ecosystem and practical ways to participate. After a concise overview of the Society and its governance, we will share information about the different SCT committees, their unique roles in the Society, and the opportunities for members to participate in these committees and other initiatives.

- **Table #22 – Early-Career Challenges for a First Role as a Collaborative Trial Statistician**
  - **Moderator:** Alexia Iasonos, Memorial Sloan Kettering Cancer Center
  - **Description:** Trainees and others entering into their first roles as responsible clinical trial statisticians generally have excellent methodological training in the statistical design and analysis of clinical trials. However, trial statisticians are also responsible for other important trial considerations such as assessing the feasibility of accrual or reviewing study databases, and those entering their first role frequently have more limited exposure to such considerations. Even if they have some exposure, important details can differ between trial organizations, and together, these can lead to challenges for new responsible statisticians. The goal of this roundtable is to discuss challenges that new responsible statisticians face in their new role. A key consideration will be the non-methodological aspects of the role, but the discussion may also include methodologies that may be less familiar to new trial statisticians. For these reasons, a key target audience for this roundtable will be students and other trainees from statistics, but the organizer is eager for non-statisticians to join to share their experiences and support these new or upcoming trial statisticians. The organizer is an early-career trial statistician and is joined by an experienced trial statistician as moderator, and we hope for other seasoned statisticians to join and support the discussion as well.

- **Table #23 – Enhancing Efficiency and Quality of NIH Clinical Trial Data and Safety Monitoring: Perspectives from the Research Community**
  - **Moderator:** Michelle Culp, National Institutes of Health
  - **Description:** Research community perspectives on modernizing clinical trial data and safety monitoring for NIH-supported research. Explore flexible, efficient approaches that protect participants, generate high-quality data, reduce burden, and ensure trustworthy results.