2024 Roundtable Topics and Moderators

- **Roundtable 1: Academic and Industry CROs: What are the Differences?**
  - Moderator: Julie Qidwai, Veristat, LLC
  - Description: We often talk about academic and industry CROs as though they are independent universes. What are the main differences between the two? If you've worked in academia, what would it be like to move to industry, or the other way around? What kinds of people thrive in each environment? What does a day in the life look like in one or the other? How can you make the jump to industry from academia? This roundtable is appropriate for all fields within clinical trials, including investigators, data and project managers, statisticians, CRAs, regulatory and study coordinators.
- **Roundtable 2: Active Learning in the Clinical Trials Classroom**
  - Moderator: Mary Putt, University of Pennsylvania
  - Description: Active learning invites students to engage in problem-solving, typically with peers. Research suggests these methods improve critical thinking and retention of information. The design, implementation and analysis phases of a successful clinical trial are characterized by excellent communication and problem-solving by multi-disciplinary teams. Courses in clinical trials thus present a natural opportunity to engage students in active learning. This roundtable invites participants to brainstorm about how to successfully integrate active learning into the classroom. Come with your success (and failure!) stories, or simply your curiosity and willingness to think creatively about ways to teach effectively in the clinical trials space.
- **Roundtable 3: Addressing the Operational Challenges in Conducting Investigator-Initiated Trials (IITs)**
  - Moderator: Shannon Chism, Huron Consulting Group
  - Description: Investigator-initiated trials are essential for an academic institution in addressing real-world critical medical needs and in developing investigators'/physician researchers' understanding of product safety and efficacy. Challenges include grant writing, securing funding, developing a protocol that matches clinical as well as regulatory requirements, preparing FDA submissions, maintaining clinical and regulatory operations throughout the lifecycle of the study, and training research staff as well as new investigators. Developing a robust IIT program within each institution that includes sufficient staffing and a training model for research staff and new investigators is the first step in addressing the above challenges.
- **Roundtable 4: An Introduction to the Society of Clinical Trials (SCT) and Leadership Roles in the Society**
  - Moderator: Dikla Blumberg, The Emmes Company
  - 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 also 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 leadership positions.
- **Roundtable 5: Bayesian Adaptive Design of Phase 1 Dose-Finding Trials**
  - Moderator: Wendy London, Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Harvard Medical School
  - Description: Many phase 1 dose-finding trials use the 3+3 design to identify the maximum tolerated dose (MTD). Bayesian adaptive designs are becoming increasingly more popular: BOIN, CRM, TITE-CRM, EWOC. However, statisticians and clinicians may be hesitant to use Bayesian methods, due to perceived complexity to implement or interpret, or logistical concerns about real-time data and modeling. Others may think that efficiency and flexibility benefits of Bayesian approaches outweigh concerns. Perhaps a balance can be achieved in the right design for a given trial, sometimes Bayesian design and sometimes rule-based design. A roundtable will provide an opportunity to express differing views.
- **Roundtable 6: Budgeting for Multi-Site Clinical Trials: Factors and Considerations**
  - Moderator: Jennifer Hagar, Massachusetts General Hospital
  - Description: This roundtable discussion will focus on the various factors to consider, and components required in clinical trial budgeting, specifically in budgeting for multi-center clinical trials. Clinical trial operations on a multi-center scale are complex and providing sites with a budget that is financially stable and reflective of actual costs to participate in a trial is essential. The goal of optimal budget development is to create a budget that meets site needs while also staying within sponsor thresholds of what is considered fundable. Factors discussed will center around building budgets that are reasonable to sponsors and financially sound for sites.

- **Roundtable 7: Career Advancement for Women and Gender Minorities Working in Clinical Trials**
  - Moderator: Cody Chiuzan, Institute of Health System Science, Northwell Health
  - Description: Female-focused groups are a great place for women to meet, inspire, learn from each other, establish new collaborations, support, and promote women and gender minorities in the field. This roundtable will provide an opportunity for women working in clinical trials to connect and lead conversations around the advancements of clinical trial research. Junior and senior faculty, students and/or other professionals from different institutions (academia, industry, government, etc.) are welcome to join, share their career paths and what it takes to be a successful clinical trialist. Note: This session was offered for the first time last year at maximum capacity.
- **Roundtable 8: Career Paths in Clinical Trials- Opportunities for Nurses**
  - Moderator: Isatou Mahmoud, Clinical Trials Unit at MRCG at LSHTM
  - Description: The aim of the discussion is to explore various career paths available for nurses in clinical trials. we will examine the various responsibilities and roles nurse can perform in clinical trial, including clinical/field research nursing, patient advocacy, data collection, quality control and trial coordination. Learning Objectives: Identifying career opportunities available for nurses in clinical trials. Identifying skill sets and qualifications needed to advance in these roles. Discuss the impact of nurses on patient care and safety, trial integrity, ethical conduct, and research outcomes. Share insights on career development for nurses in clinical trials.
- **Roundtable 9: Cluster-Randomized Crossover Trials (CRXO): Design and Analysis Features**
  - Moderator: Edward Mascha, Cleveland Clinic
  - Description: Cluster-randomized crossover studies (CRXO) are becoming more common on medical research since they are easier to conduct than a cluster randomized trial or individual randomization. In this session we will discuss how to be design a CRXO study, sample size and power considerations, and methods of analysis. Participants will be encouraged to share examples or experience in sample size calculations, including with binary and continuous endpoints, and how to best estimate the within-cluster within-period and within-cluster between-period correlations that are needed. Different estimands related to intent-to-treat, modified intent-to-treat and per-protocol analyses will be discussed.
- **Roundtable 10: Data Management Career Development and Career Paths in Clinical Trials**
  - Moderator: Amber Boose, American Society of Clinical Oncology
  - Description: This roundtable discussion explores career development and pathways within the field of clinical trials, specifically emphasizing data management roles. Participants will delve into the evolving landscape of data management in clinical research, discussing skill sets, educational prerequisites, and advancement opportunities. By sharing insights and experiences, attendees will gain a deeper understanding of how to navigate and excel in this critical aspect of the clinical trials industry.
- **Roundtable 11: Design and Analysis of Clinical Trials with Real World Data for Decision-Making**
  - Moderator: Li Chen, Amgen, Inc.
  - Description: In this roundtable, we will discuss (1) the use of real world data to support clinical trials with case studies (e.g., external controls including hybrid controls), (2) recent methodology development (e.g., propensity score and dynamic borrowing) and how casual inference can inform the design and analysis of clinical studies with real world data, and (3) challenges implementing the design and analysis of clinical trials with real world data including real world dataset standardization for decision-making.
- **Roundtable 12: Harnessing Real-World Data for Enhanced Drug Development**
  - Moderator: Gregory Ginn, Fortrea
  - Description: "Harnessing Real-World Data for Enhanced Drug Development" In an era marked by rapid technological advances, evolving regulatory landscapes, and growing patient-centricity, the pharmaceutical industry is undergoing a profound transformation. Statisticians play a pivotal role in this evolving landscape by leveraging real-world data (RWD) to inform drug development, assess product safety, and enhance clinical trial efficiency. This presentation will explore the emerging methodologies, challenges, and opportunities in harnessing RWD for a data-driven approach to pharmaceutical decision-making. 1. RWD in Pharmaceutical Context 2. Data Integration and Quality 3. Adaptive Clinical Trials 4. Patient-Centric Approaches 5. Regulatory Considerations 6. Case Studies 7. Future Directions

- **Roundtable 13: How to Use PCORnet® for Your Next Study: A "Quick Start" Guide**
  - Moderators: Schuyler Jones, Duke Clinical Research Institute & Greg Merritt, PCORnet® Patient Engagement Core
  - Description: PCORnet® is a national resource, open to all, that combines high-quality health data, patient partnership, and research expertise to deliver fast, trustworthy answers that advance health outcomes. The moderator and panelists will discuss topics including examples of the wide ranging studies and study designs that PCORnet has supported; unique data capabilities of network, including the PCORnet® Common Data Model; PCORnet® Front Door services, which provide access to investigators interested in using the network; state-of-art infrastructure innovations that enable efficient, multi-site research at scale; and the steps researchers can take to initiate and participate in national-level studies that leverage PCORnet.
- **Roundtable 14: Implementation of Complex Clinical Trials**
  - Moderator: Bareng Aletta S. Nonyane, Johns Hopkins Bloomberg School of Public Health
  - Description: This roundtable will bring together people to discuss and exchange ideas on how to approach challenges in implementing complex clinical trials. We hope discussants will make connections with other researchers and exchange ideas beyond the conference. Complexity in clinical trials can be defined in terms of a)protocol complexity (e.g. multiple interventions within a trial, complexity of the interventions and corresponding endpoints, implementation science approach to the trial, etc) b) operational complexity (e.g. multi-site trials with varying capacities , implementation logistics, etc.) c) unanticipated changes (e.g. external shocks to trial procedures due to public health emergencies, national health guideline changes, etc.).
- **Roundtable 15: Implementing Patient-Centered Research in Industry Sponsored Trials: Facilitators, Barriers, and Lessons Learned**
  - Moderator: Sarah Daugherty, Carelon Research
  - Description: Life science companies are growing in their capabilities and interest to incorporate patient-centered strategies into the research they fund. Regulatory pressure by the FDA through their Patient-Focused Drug Development (PFDD) program has encouraged this growth, and yet, only a small minority of published clinical trials sponsored by life science companies currently integrate patient-centered approaches. This roundtable discussion will focus on identifying facilitators and barriers to implementing patient-centered research as an integral part of life science product development. A specific emphasis will be on shared lessons learned developing community-based and other key partnerships to facilitate a stronger emphasis on patient-centered strategies.
- **Roundtable 16: Introducing Undergraduates to Clinical Trials**
  - Moderator: Maria Houghton, Massachusetts General Hospital
  - Description: Since 2022, the NeuroNEXT Clinical Coordinating Center at Massachusetts General Hospital has hosted cohorts of pre-medical undergraduate students as part of an "Introduction to NeuroNEXT" internship. This is an ongoing partnership between NeuroNEXT and Georgetown University to foster a diverse pipeline of clinical researchers. Students meet with Principal Investigators, sIRB Liaisons, Project Managers, Grant Administrators, NIH Program Officials, and members of the Data Coordinating Center (DCC) and central pharmacy teams; contribute to weekly cohort discussions; and prepare a final presentation. The session objectives are to discuss what other institutions are doing and how to develop a program at your institution.
- **Roundtable 17: Job-Hunting Lessons Learned During the Biotech Market Correction**
  - Moderator: Ken Kobayashi, Small Woods Biopharma Consulting, LLC
  - Description: The recent market correction has had a brutal impact on the pharma sector in general, and the biotech sector in particular. Some of the impact will disappear, but a lot of it will linger. Jobhunting during this time has taught me a lot of lessons that may be of use to those looking for jobs now or in the near future. Will host roundtable and open discussion.
- **Roundtable 18: Opportunities for Students in Clinical Trials (Student-Led)**
  - Moderator: Megan McCabe, University of Iowa
  - Description: As a student in biostatistics or statistics, there are a wide variety of research directions one could pursue, and clinical trials is an area in which there is so much potential for students. This roundtable will be a discussion amongst students about research areas, internship opportunities, and career trajectories for statisticians in clinical trials. Depending on interest, we could discuss logistics for obtaining an internship, as the moderator has completed internships at FDA and in the pharmaceutical industry. Also, it will provide a space for students, and potential future leaders of the Society, to meet and network!

- **Roundtable 19: Recent Developments and Challenges in Early Phase Trial Design in Oncology**
  - Moderator: Alexia Iasonos, Memorial Sloan Kettering Cancer Center
  - Description: Regulatory requirements for novel therapies in oncology, such as immunotherapy, molecularly targeted therapy, and CAR T cell therapy, have placed increased emphasis on identifying less toxic dosing of the agents that may provide the same level of clinical activity. This has been highlighted by Project Optimus at the Food and Drug Administration. This discussion will aim to address these new challenges as follows: 1)randomization aimed to compare multiple dose levels 2) dose allocation strategies using backfill and expansion cohorts, 3) optimal simulation strategies to compare existing dose-finding approaches; 4) timely concepts on the review, approval, and monitoring of early phase trials.
- **Roundtable 20: Risk-Based Monitoring**
  - Moderator: Michele Costigan, University of Iowa
  - Description: Roundtable discussion on risk-based monitoring and approaches used to meet monitoring goals. Share tips, techniques, reports, etc. used in risk-based monitoring. What's working well? What are the challenges?
- **Roundtable 21: Source and Central Data Monitoring in a Data Coordinating Center**
  - Moderator: John VanBuren, University of Utah
  - Description: The goal of this round table is to discuss how source data monitoring and central data monitoring complement each other. We will discuss high-level techniques and round-table participant's experiences with the topic. The discussion will be focused on a clinical and data coordination center perspective.
- **Roundtable 22: Undertaking Impactful Patient and Public Involvement (PPI) for Statistical Trial Methodology Research**
  - Moderator: Laura Gray, 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.
- **Roundtable 23: Utilizing Interinstitutional Partnerships to Improve Veteran Access to Clinical Research and Foster Research Collaboration Across Aligned Healthcare Systems**
  - Moderator: Dixie Thompson, University of Utah | CTSI Clinical Utah Center for Clinical & Translational Science and Trial Innovation Network Administrative Core at VUMC
  - Description: Academic medical centers (AMCs) and the Veterans Administration (VA) pursue opportunities to maximize operational capabilities across their respective research programs. Practical barriers exist: minimal cross-institutional study enrollment, siloed workflows, limited investigator exposure, inadequate patient education, and funding restrictions between partnered institutions. We will describe progress to establish an AMC/VA shared staffing model, a streamlined funds flow model, and minimize barriers to Veteran enrollment into AMC-conducted studies. We encourage other interested AMC/VA partners to compare institutional models, share lessons learned, and consider joining an extant consortium representing VA/Clinical Translational Science Award (CTSA) site dyads to disseminate research collaboration strategies.
- **Roundtable 24: The Hidden Challenges of 3rd Party Tools in Clinical Trials**
  - Moderator: Scott Rushing, Wake Forest
  - Description: There are numerous challenges faced by those involved in the design and execution of clinical trials in today's environment. Utilizing pre-existing solutions from recognized technology partners can save valuable resources. It's crucial understand the readiness of such external systems for use in clinical research. What appears as a straightforward win-win situation at a high level can turn into a major source of frustration when teams encounter unexpected issues. This discussion will delve into the lessons learned from our external collaborations with technology partners.

- **Roundtable 25: An Overview of Programming of Adjudication Systems**
  - Moderator: Darrin Harris, Wake Forest University School of Medicine
  - Description: For many trials, ascertaining study primary and secondary outcomes are done via adjudication panels. Many types and sources of data are needed by the panel as well as easy to use systems to capture their final decision. This round table will discuss multiple systems used, currently and formerly, and will solicit feedback from the attendees on types of systems and processes they have experienced as well as discussing any potential gaps.
- **Roundtable 26: Transitioning From a Clinical Trial to an Observational Study**
  - Moderator: Letitia Perdue, Wake Forest University School of Medicine
  - Description: Whether due to an early termination of a trial or coming to its natural end, clinical trials are often transitioned into an observational study. We will discuss both types of transitions and discuss the variety of steps including participant communication, revisions to the study protocol, revisions to data collection forms and/or methods, and regulatory aspects. This round table will solicit feedback from the attendees on their experiences on these types of transitions including lessons learned.
- **Roundtable 27: A Discussion on Programming of EDC Websites and Related Systems**
  - Moderator: Mark King, Wake Forest University School of Medicine
  - Description: For many data coordinating centers, the utilization of "home-grown" electronic data capture systems and websites are used instead of systems such as REDCap, Mahoalo Health or Castor EDC. This round table will discuss the behind the scenes programming that goes behind creating an EDC system, including not only data collection forms but tracking systems such as safety monitoring, drug distribution and general website infrastructure. Pros and cons of the systems as well as lessons learned will be discussed.
- **Roundtable 28: From Conception to Citation: Managing Presentations and Publications in Research**
  - Moderator: Julissa Almonte Santana, Wake Forest University School of Medicine
  - Description: In the fast-paced world of clinical research and study dissemination, efficient project management and collaborative systems are essential for facilitating the timely and organized review and approval of proposals for papers and presentations. We will discuss one system currently being utilized and seek feedback from attendees on P&P systems they have encountered including any areas of improvement or additional needs.
- **Roundtable 29: Utilizing the Electronic Health Record and REDCap for Participant Recruitment and Screening**
  - Moderator: Emily Rives, Wake Forest University School of Medicine
  - Description: To minimize coordinator time spent on recruitment, trials can identify potentially eligible patients through the individual electronic health record (EHR). Identifying information for each potentially eligible patient can be loaded into each site's local REDCap application. Messages can be sent through the site's patient portal to invite participants to learn more about the study and include a link to complete a custom-built eligibility screener in REDCap. Per local site regulations, the invitation can be sent via email or text message. We will discuss lessons learned from studies that have utilized a combination of EHR and REDCap messaging to participants.
- **Roundtable 30: An Overview of WakeSHARE Platform**
  - Moderator: John Hepler, Wake Forest University School of Medicine
  - Description: Existing research data and resources are an invaluable catalyst to help investigators foster novel ideas and new directions. This is particularly true in the fields of Alzheimer's Disease, Geriatrics and Gerontology. WakeSHARE was developed to streamline discovery of both aging and Alzheimer's data and resources, as well as provide a consistent and trackable method of requesting resources. This round table will provide an overview of the WakeSHARE platform to spark collaborative discussion and ideas.

Please check the SCT website for updates as the program is subject to change.