

VOLUME 34,#6

NEWSLETTER

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SCT President's Column



Dixie Ecklund
President 2023-2024

Greetings!

As summer slips away and fall quickly takes it's place, my thoughts turn to amazement at all of the incredible work that goes into supporting Society for Clinical Trials and planning for the 45th Annual Meeting in Boston in May of 2024. Our partners at Executive Administration, Inc. (EAI) provide a steady hand to guide the mission of SCT. An extra big shout out to Lisa Aguado, SCT Program and Governance Manager, who takes organizational skills to a whole new level! New work plans and initiatives are being developed and implemented. New partnerships are being explored with groups such as the

International Association of Clinical Research Nurses (IACRN) and the Association for Clinical and Translational Science (ACTS).

Eleven Standing Committees have been convened, chartered, and are actively meeting. The Program Committee, chaired by Charity Patterson and Cory Goldstein, have hit the ground running and report that the submissions for Invited Sessions are plenty and robust – it will be hard to choose! Submissions for Contributed (oral/poster) presentations remain open until December 1st so please continue to consider and submit ideas on any topics relevant to clinical trials. The Education Committee, chaired by Gustavo Jiminez-Maggiora and Sarah Gaussoin, are presently reviewing pre-conference workshop submissions and report that the proposals are strong. They are also working on setting up a pre-conference workshop on the Essentials of Clinical Trials that will be provided at no charge to new members and first-time attendees on a first come/ first serve basis. The Education Committee also wants to remind everyone that roundtable topics are open until November 13th. We are planning to host roundtable topics for all members at lunch

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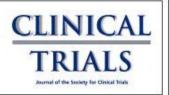
SCT President's Column

on Monday, May 17th so please take a moment to consider submitting a topic and serving as a moderator. Ask your colleagues to help out as well!

Submissions for the Thomas C. Chalmers Student Scholarship and the Sylvan Green Travel Award remain open until November 17th and the EDI Early-Career Award, Fellows of the Society for Clinical Trials, and David Sacket Trial of the Year award remain open through December and into January. This is an excellent opportunity to highlight the work of students or early career investigators and foster growth in Society for Clinical Trials and gain recognition for all of the considerable contributions that our clinical trials community makes in forming patient-centered partnerships to advance health care outcomes globally.

Thank you all for all the work that you do to support the Society for Clinical Trials. Please continue to visit the SCT website at https://www.sctweb.org/ for the latest updates and follow up on social media.

Dixie J. Ecklund, RN, MSN, MBA





By Colin Begg, Editor

August, 2023 Issue Highlights

The October issue of Clinical Trials includes several articles that address clinical trials. Poorna Kushalnagar and colleagues explore the challenges of recruiting people who are deaf and offer some suggestions. Christopher Mehus and colleagues provide guidance on what to do when conducting a clinical trial in which a participants report a risk of selfharm on an outcome questionnaire. Elizabeth Reid and colleagues quan-

tify the successful blinding of a procedural

intervention in a randomized trial of preterm infants with respiratory distress synchallenging practicalities in the conduct of drome. Finally, Jaime Speiser et al advises us on what to do to analyze a trial with composite endpoints where the censoring mechanism is different for the different endpoints. As always we encourage you to submit your best work to the journal.

> Follow us on twitter @clintrialsj to keep up to date with the latest from the journal.

Interested in Presenting an SCT Webinar?

We encourage all SCT members interested in sharing their knowledge and expertise on a particular topic to submit a Webinar Proposal Form for the SCT Education Committee's review and consideration. To access the SCT Sponsored Webinar Proposal Form, go to https://www.sctweb.org, click on the Member Sign-In button and login. On the Members-Only Area Home page, click on "Propose a SCT Webinar!" in the menu on the righthand side of the screen. Complete and return the Webinar Proposal Form to contact@sctweb.org. We look forward to receiving your proposal!

Submit your abstract for the

45th Annual Meeting of the Society for Clinical Trials

"It Takes a Village: Patient Centered Partnerships in Clinical Trials."

May 19-22, 2024

Boston Marriott Copley Place

Boston, MA

All submissions must be made via the SCT website.

Educational Workshop Submissions

Deadline: PASSED

Invited Session Proposals

Deadline: PASSED

Roundtable Topic Submissions

Deadline: November 13, 2023

Thomas C. Chalmers Student Scholarship Submissions

Deadline: November 17, 2023

Sylvan Green Travel Award Submissions

Deadline: November 17, 2023

Contributed Presentations (Oral/Poster)

Deadline: December 1, 2023

SCT Fellow Nominations

Deadline: December 15, 2023

David Sackett Trial of the Year Award

Deadline: January 5, 2024

Public Workshop to Enhance Clinical Study Diversity

November 29 - 30, 2023 / 10 a.m. - 2:00 p.m. EST







The U.S. Food and Drug Administration (FDA), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is convening a virtual public workshop to solicit input on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups.

The free two-day virtual public workshop will be held on November 29 and 30, 2023, from 10 a.m. – 2 p.m. EST on both days. Registration for the workshop is <u>now open</u> and an agenda for the workshop can be viewed <u>here</u>.

We are inviting those who register to submit questions for our speakers and panelists in advance of the meeting. Please <u>click here</u> to submit your questions.

Member Spotlight



Ashley Magnavita, MPH, PMP

What is your current position?

Director of Clinical Research Project Management at Carelon Research

What are your past positions?

I have been with Carelon Research for over 8 years now. I started as an Associate Clinical Research Project Manager and have now been Director for over 2 years.

What is your training?

I received my MPH from Drexel University and my BS in Biology from Northeastern University. I have been PMP certified since 2015.

What are your specific research interests or your specific interests within clinical trials?

The Clinical Research team at Carelon Research does a lot of work in pediatric cardiology research as part of the Pediatric Heart Network as well as outside the network. I lead a pediatric cardiology feasibility trial as the Principal Investigator. I started on that project as a Project Manager so this one in particular is near and dear to me.

What are your hobbies (outside of work)?

We love to visit the local farmer's market each Saturday with our three kids. I've recently started boxing and it has been a really fun experience and great workout.

What role(s) did/do you play in SCT?

I was observing this year and hope to have several abstracts submitted for next year's meeting in Boston.

What is your favorite part about being involved in clinical trials?

My favorite part is knowing that we are making an impact on people's lives. Hearing feedback and stories from the participants, and the families of these participants, in these clinical trials makes the long clinical trial process more than worth it.

Your least favorite?

The contracting process with sites

What do you enjoy most about attending the SCT Annual Meeting? And/or:

With this being my first SCT meeting, I joined the round table for the introduction to the Society of Clinical Trials. I really enjoyed getting to know the people that also joined this round table. The leader of the round table gave us valuable information on how to become more involved and was genuinely interested in the groups ideas of ways to grow SCT in the future.

What advice would you have for junior researchers just starting out in the field of clinical trials?

Don't let the day-to-day struggles get you down. Keep you eye on the big picture and what you are trying to accomplish as a team. Working as a team is critical and communication is key. We all come with diverse backgrounds and knowledge of clinical trials so the more we collaborate, listen and focus on the end goal together, the more successful we will be.

What is one strategy you have used to maintain your sanity during the recent months/years?

Taking a walk with our pup. A little fresh air and vitamin D always improves my mood.

ICTMC 2024 Conference

ICTMC 2024

The MRC-NIHR Trials Methodology Research Partnership is delighted to welcome you to the 7th International Clinical Trials Methodology Conference 2024.

ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology. The meeting also offers valuable networking and training opportunities, with 900 delegates from 16 countries attending in 2022.

The 2024 conference will take place in the capital city of Scotland, Edinburgh, which is known worldwide for the amazing events taking place throughout the year. The city boasts an abundance of historic sites and magnificent architecture in the city centre. We hope you take this opportunity to extend your visit to explore the Old and New Town, discover vibrant dining spots and immerse yourself in the city's atmosphere. Visit the website for more information: https://ictmc.org/

7th TMRP Webinar Series



HOW CAN TRIAL TEAMS BUILD PUBLIC TRUST FOR THE USE OF ROUTINE DATA IN TRIALS?

24 OCTOBER 2023, 11AM - 12PM Speakers from the PRIMORANT study team

GREENER TRIALS

13 November 2023, 11am - 12pm Paula Williamson, Lisa Fox, Jess Griffiths

RANDOMISATION - CURRENT PRACTICE FOR METHOD SELECTION

12 December 2023, 11am - 12pm *Cydney Bruce*

PROMOTING INCLUSIVITY THROUGH IM-PROVING THE PRACTICE AND UTILITY OF ETHNICITY DATA COLLECTION IN TRIALS (THE INCLUDED PROJECT)

16 January 2024, 11am - 12pm Sandra Eldridge

ENGAGING NON-RESEARCHERS WITH CLINICAL TRIALS TO ENSURE RESEARCH QUESTIONS, METHODS AND OUTCOMES ARE RELEVANT

14 February 2024, 11am - 12pm Speakers from The Global Health Network Mesh Community of Practice

Association for Clinical and Translational Science



As the Association for Clinical and Translational Science (ACTS) prepares for the Translational Science 2024 (TS24) annual meeting, we look to our networks, communities and partners to encourage participation and submissions of your science. I am thinking of how people, like all of you, enjoy sharing study findings, and discussing studies and methods that have been impactful. I think of how you have inspired so many people with your projects and how important it is to share these findings and methods with all of us.

Join us April 3 to 5 in Las Vegas at the Paris Hotel with Pre-meeting Activities April 2. This year is going to be the very best conference we ever had because of researchers and community members like you!

Linda B. Cottler, PhD, MPH, FACE ACTS President

From the NIH: Revised Grant Review Process

The National Institutes of Health is taking steps to simplify its process to assess the scientific merit of research grant applications and mitigate elements that have the potential to introduce bias into review. The changes will help reviewers focus on the potential for proposed research to advance scientific knowledge and improve human health. Previously, five criteria were individually scored using a common scale; the simplified review framework reorganizes these criteria into three factors. Two of these factors – importance of research and rigor and feasibility – are scored using a common scale. A third factor, expertise and resources, is evaluated for sufficiency only and not given a numeric score. The simplified review framework will be implemented for grant applications received on or after Jan. 25, 2025.

"Studies have shown that consideration of reputation of the institution or investigator in the grant review process could affect assessment of scientific merit, potentially giving reputation greater weight than other factors," said Lawrence A. Tabak, D.D.S., Ph.D., Acting Director, NIH. "Ultimately, the potential impact of ideas on advancing science should outweigh the reputation of who is applying and where they work."

Read more on the NIH website.

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The Data Coordinating Center (DCC) is a component of the Clinical Trials Program in the Department of Biostatistics and Medical Informatics at the UW School of Medicine and Public Health. The DCC supports investigator-initiated NIH or industry-sponsored RCTs. We provide expertise in planning, conduct, monitoring, and analysis of clinical trials.

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Save the Dates - Upcoming SCT Annual Meetings



45th Annual Meeting May 19-22, 2024 Boston, MA



46th Annual Meeting May 18-21, 2025 Vancouver, BC, Canada



47th Annual Meeting May 17-20, 2026 Phoenix, AZ, USA

Information About SCT

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