



VOLUME 35, #1

NEWSLETTER

MAY 2024

SCT President's Column



Dixie Ecklund
President 2023-2024

Annual Meeting of the Society for Clinical Trials in Boston May 19-22. I hope to see you all there! The theme of the meeting this year is “It Takes a Village: Patient-Centered Partnerships in Clinical Trials”. This is an important reminder in our day-to-day work in clinical trials that our patient partners are at the very center of the “why”. Clinical trials are a very important nexus between science-driven decisions and improving health care outcomes. We are honored to have two very distinguished keynote speakers this year. Penney Cowan, founder of the American Chronic Pain Association (ACPA) and a member of the Board of Directors of the World Patients Alliance, will give the Founders Keynote Lecture on Tuesday, May 21, at 8:30 am on “Perspective of Those with Lived Experience: Involving a Patient in Clinical Trials”. We will be honoring Curtis Meinert, one of the Founders of SCT who passed away this past year, on Wednesday, May 22, at 8:00 am for his extensive contributions to the field of clinical trials and the advancement of clinical trials methodology and rigor. The tribute will be followed at 8:15 by the Curtis Meinert Keynote Lecture presented by Merit Cudkowicz, MD, from Mas-

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Happy Spring!

Greetings to all! Thank you to all of you who have renewed your membership dues for 2024. Membership for 2023 finished strong with 850 members. This was the highest number of members we have seen for the past several years (even pre-pandemic!) We would like to top that number for 2024. If you have not renewed your membership, you are able to do that as part of the registration process for the Annual meeting. Please reach out to the EAI membership coordinator, Kelly Burns at kelly-burns@sctweb.org with any questions. Plans are coming to fruition for the 45th

SCT President's Column

sachusetts General Hospital on “Accelerating Therapy Development in ALS and Other Neurological Disorders”. Dr. Cudkowicz has pioneered advancements in neurological research in ALS from funding received from the Ice Bucket Challenge to the ongoing Healey ALS platform trial.

I am also very much looking forward to seeing the session with the David Sackett Trial of the Year awardee presented on Monday, May 20, at 9:00 am by Adam Devall, PhD, from the University of Birmingham, UK. This incredibly important trial, “Early Detection of Postpartum Hemorrhage and Treatment Using the World Health Organization MOTIVE ‘First Response’ Bundle: A Cluster Randomized Trial” was published in the NEJM in July of 2023 and demonstrates the far reach and importance of the work that each and every one of you do. This international cluster-randomized trial assessed a clinical intervention involving a calibrated blood-collection drape for early detection of postpartum hemorrhage and a bundle of first-response treatments to improve maternal outcomes of bleeding and death.

Another exciting initiative for this year was the ad-

dition of “Targeted Invited Sessions” where we asked the Board of Directors to target current and cutting edge topics in clinical trials and invite presenters to the Annual Meeting. It is my great honor to present Targeted Session 1: Breaking Through – Navigating the New Horizons of Patient-Partnered Clinical Trials Through the Expertise of Clinical Research Nursing; Targeted Session 2: Patient-Centric Clinical Trials based on Benefit-Risk: An Open DOOR; and Targeted Session 3: Catching up with PCORI – New Priorities, Innovations, and an Update on Funding Opportunities to Advance Patient-Centered Comparative Clinical Effectiveness Research.

Thank you to all of you for the work that you do in support of the Society for Clinical Trials. Please visit the SCT website at <https://www.sctweb.org/> for updates and follow up on social media. We are looking forward to a very strong attendance at the Annual Meeting and I look forward to seeing you all in person.

Dixie J. Ecklund, RN, MSN, MBA

President, Society for Clinical Trials

**CLINICAL
TRIALS**
Journal of the Society for Clinical Trials



By Colin Begg, Editor

February, 2024 Issue Highlights

The February issue of *Clinical Trials* is primarily devoted to a series of articles focusing on the methodology of clinical trials in neurofibromatosis and schwannomatosis, rare conditions that lead to multiple nerve sheath tumors. This series was put together by a committee from the REiNS International Collaboration, led by **Vanessa Merker**. Other articles in the issue include a critique of how comparative effectiveness trials in critical care are being conducted by **Verity Ford** and colleagues, methodology for how to infer treatment effi-

cacy versus a placebo when a trial uses an active control by **Yifan Zhu** and colleagues, and a strategy for validating statistical programming used in clinical trials by **Carroll Gamble** and colleagues. As always we encourage you to submit your best work to the journal.

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45th Annual Meeting

It Takes a Village: Patient Centered Partnerships in Clinical Trials

About the Annual Meeting

The Annual Meeting of the Society for Clinical Trials is a multidisciplinary program with broad participation. The Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and centers and clinical research entities.

Highlights include:

- Cutting edge pre-conference workshops by leaders in the field (Pre-Conference Workshop 8: Essentials of Clinical Trials is only available to first-time attendees, students, and post-graduates. First-time attendees, students, and post-graduates interested in registering for this complimentary workshop must be registered for the general meeting. If you are a first-time attendee, have registered for the general meeting and would like to register for Pre-Conference Workshop 8: Essentials of Clinical Trials, we ask that you please email registration@sctweb.org to register for this workshop.)
- Invited sessions, targeted sessions, contributed sessions, and poster presentations
- Founders and Curtis Meinert Keynote Lectures
- Annual Thomas C. Chalmers Student Scholarship competition
- Presentation by the Sylvan Green Award winner
- Exhibitors showcasing publications, technology innovators and other resources for clinical trials
- Discussions of timely issues and research experiences among colleagues in the field
- Presentation of the SCT Class of 2024 Fellows
- Presentation of the 2023 David Sackett Trial of the Year Award
- Roundtable small group discussions on a wide range of topics
- Networking with your colleagues

This year's meeting will be Boston, MA, USA.



Member Spotlight



Kenichi Nakamura, MD PhD MBA

What is your current position?

I am currently the Director of the Department of International Clinical Development at the National Cancer Center Hospital (NCCH) in Japan. I also serve as the Project Leader of the Asian Clinical Trial Network for Cancers (ATLAS) project. I am engaged in the ICH-GCP renovation as an academic representative from Japan.

What are your past positions?

For over 15 years, I served as the Director of the Operations Office of the Japan Clinical Oncology Group (JCOG), which is the largest cancer cooperative group in Japan. In that role, I engaged in the management of nationwide large-scale clinical trials across Japan. I also managed several investigator-initiated registration-directed trials, some of which contributed to obtaining drug approval in Japan.

What is your training?

I had training as a general surgeon and earned a PhD in surgical oncology at Kyoto University. I learned clinical trial methodology in the JCOG Operations Office through actual multi-center clinical trials. I also earned an MBA at the Globos University to incorporate technovate thinking into clinical trials.

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

My current interests include promoting decentralized clinical trials, building international clinical trial networks, and considering future clinical trials from regulatory and operational perspectives.

What are your hobbies (outside of work)?

I love mountain climbing and trail running. There are a lot of beautiful mountains in Japan. I also love to play with Aibo, which is an AI robot dog developed by Sony.

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

In 2023, I attended my first SCT annual meeting in Baltimore and found only 4 participants joined from Japan. I am one of the board members of the Japan Society of Clinical Trials and Research (JSCTR), which is a counterpart of SCT in Japan. Since I have become a member of the Outreach Committee of SCT, I would like to plan several joint initiatives between SCT and JSCTR.

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

My favorite part is that the results of a clinical trial in which I was involved can change a patient's life for the better. Unlike a surgeon, my current position can have a positive impact on a much broader range of patients in the future.

What do you enjoy most about attending the SCT Annual Meeting?

Trial of the Year is a great session, where I can learn about the latest clinical trial trends and methodologies. Since I am not a statistician, there would be more non-statistical sessions. I would like to talk with more SCT members from now on.

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

No path lies before me. As I press on, behind me a path appears. (Japanese proverb).

IBTN 2024 Conference



If you're doing behavioural medicine, this is the place to be this May! Join us in Montreal May 16 to 18 for the IBTN 2024 Conference - Behavioural Interventions: Past, Present, and Future - a leading international conference on trials and interventions in the field of behavioural medicine.

FEATURING

- 34 experts
- From 9 countries
- And 5 continents
- Under 1 roof
- 3 keynote presentations
- 7 interactive workshops
- 12 phenomenal talks
- Over 2.5 amazing days
- 1 full plenary day
- 1 full workshop day
- 2 award ceremonies
- 1 anniversary bash

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 log in. 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!

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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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Amgen harnesses the best of biology and technology to fight the world's toughest diseases, and make people's lives easier, fuller and longer. We helped establish the biotechnology industry, and we remain on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today.

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Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious diseases. The company has approved medicines that treat the underlying causes of multiple chronic, life-shortening genetic diseases — cystic fibrosis, sickle cell disease and transfusion-dependent beta thalassemia — and continues to advance clinical and research programs in these diseases. Vertex also has a robust clinical pipeline of investigational therapies across a range of modalities in other serious diseases where it has deep insight into causal human biology, including acute and neuropathic pain, APOL1-mediated kidney disease, autosomal dominant polycystic kidney disease, type 1 diabetes, myotonic dystrophy type 1 and alpha-1 antitrypsin deficiency.

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



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



48th Annual Meeting
May 16-19, 2027
Chicago, IL

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