

VOLUME 36, #4

NEWSLETTER

November 2025

INSIDE THIS ISSUE:

SCT President's Column	1	

Highlight Articles from the 2 Clinical Trials Journal

Membership	Spotlight	2 - 4
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Giving	Day	5

Highlights from SCT's 46th	6
Annual Meeting	

SCT Announcements	7 - 10
New Emerging Leader Av	vard 9

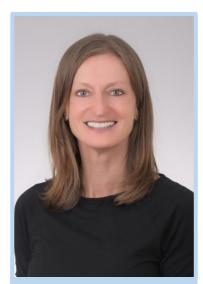
Sponsors	11
----------	----

Information about SCT 12

Future SCT Meetings 13

SCT President's Column

Welcome to the Fall issue of the SCT Newsletter! The SCT Committees have been busy since the May 2025 meeting in Vancouver as we prepare for our next annual meeting in Phoenix, Arizona May 17-20, 2026. I hope everyone can join us in Phoenix to share ideas, connect with colleagues, meet new colleagues and collaborators, and continue to advocate the importance of clinical trials in the advancement of human health. Please see the abstract submission portal on the SCT website to find details on submission types, award applications and submission deadlines. The 2026 meeting theme is centered around the conduct of clinical trials in an era of cutting-edge information capabilities. We continue to explore the utilization and integration of artificial intelligence (AI) in the clinical trial setting but there are also so many other



Valerie Durkalski-Mauldin, MPH, PhD

Society for Clinical Trials

President 2025-2026

technological capabilities and resources that we need to consider as we continue to advance clinical trial design, operations, data analysis and dissemination of results. Wearable devices to capture daily activity, real-time remote monitoring of vitals such as blood pressure or glucose levels, study resupply and shipment algorithms, and utilization of the electronic health records are just a few data aspects that come to mind; but there are also innovations in protocol and consent development, study design, database and statistical programming, recruitment and retention and dissemination of study results. Bring your experiences to the May 2026 meeting and share the successes and challenges you have encountered so together we can continue to move research development forward and improve outcomes for patients.

In addition, please join me on November 13th for the first annual SCT Giving Day. All donations will be applied towards SCT programs that advocate the importance of clinical trials and support the education and development of clinical trial professionals. Check out the SCT LinkedIn page as well as our email blasts for additional information on how to donate.





October 2025 Issue Highlights

A feature of several articles in **October** issue of **Clinical Trials** is concern for methodological issues that can affect the validity of clinical trials in different ways. A team from Peking University led by **Xiayan Chen** describe guidelines for how best to ensure reliable results in dietary RCTs. Another article by **Gayle Lorenzi** and colleagues addressed important errors in results from x-ray absorptiometry hip scans. Study validity is also the focus of articles by **Megan Othus** and colleagues, who examined the role of timing of outcome measurements, **and Joshua Nugent** and colleagues, who focused on the setting in cluster RCTs where outcome dependence occurs in some clusters but not others. Finally, a team of

experts led by **William Cragg** explored how management of consent withdrawal is important for the integrity of clinical trials. As always, we encourage all SCT members to submit their best research accomplishments to the Society journal, **Clinical Trials**.

Follow the "Society for Clinical
Trials" company page on LinkedIn to
keep up to date with the latest from
the journal!
Linked in

Membership Spotlight



Megan E. McCabe, PhD
Assistant Professor
University of Alabama at Birmingham

What is your current position?

I am an Assistant Professor of Biostatistics in the School of Public Health at the University of Alabama at Birmingham (UAB) and the Assistant Director for Clinical Trials Development for our data coordinating center, the DATA coordinating and Collaborative Research Unit (DATA CRU).

What are your past positions?

Prior to UAB, I completed my PhD in biostatistics at the University of Iowa, where I was so fortunate to work as a Graduate Research Assistant in the Clinical Trials and Statistical Data Management Center (CTSDMC) for about 4 years. During my doctoral studies I also completed an ORISE Fellowship with the FDA CDER Office of Biostatistics and a Co-op in Biostatistics and Data Science at Boehringer Ingelheim. Prior to my time at University of Iowa, I obtained my MS in biostatistics at Northwestern University and worked as a statistical analyst in the Department of Preventive Medicine in Feinberg School of Medicine.

What is your training?

All of my graduate education was in biostatistics (MS at Northwestern, PhD at University of Iowa). I consider my graduate training to be a combination of both the educational programs and the past positions I mentioned above. My undergraduate degree was in biochemistry.

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

I am interested in the design and conduct of large, multisite observational studies and clinical trials, particularly adaptive or innovative trial designs. My dissertation work focused on platform trials, an adaptive clinical trial design which utilizes a master protocol. I also have interests in pragmatic and decentralized trial designs, as well as practices related to data coordinating centers.

What are your hobbies (outside of work)?

I love to follow women's sports, especially basketball and soccer, so I try to keep up with the WNBA, NCAA basketball, and the NWSL.

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

I have been a member of the Outreach Committee since 2023. During that time, I have also been working on an initiative focused on early career clinical trialists for SCT.

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

I have two favorite parts: (1) the teamwork and collaborative nature of the work and (2) being able to be involved in every stage of a study, from design through conducting the analysis.

Your least favorite?

I don't think I necessarily have a "least favorite" part, but a challenging aspect of clinical trials work is that you cannot always plan for what will happen (and I consider myself a planner generally speaking). You can create robust systems that prepare you for almost every situation, but part of the job is being able to adapt in appropriate ways to address the unexpected. I think this is also part of the appeal for me because I am always learning something new.

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

My favorite part about attending the Annual Meeting is always the people. I love connecting with old friends and mentors, as well as meeting new people over shared interests.

How has being in SCT benefited you?

It would be hard to succinctly describe how SCT has benefitted me, but if I had to choose one way in which it has, I would say that it has provided a community of incredible mentors, peers, and friends who support me and who I learn so much from. SCT was a fantastic organization to be a part of as a graduate student, and it has continued to benefit me in my faculty role.

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

Ask lots of questions! There are so many new things to learn when you are starting out in clinical trials, including a ton of acronyms and new terminology that people can take for granted when they have been working in the field for a while. It is also extremely useful to learn from colleagues who have different roles from you on the study team, so try to learn from others who you are working with. Cross-functional training is particularly helpful in clinical trials work.

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

More than anything else, I think being in community and leaning on friends and family has helped me through challenging times, both recently and throughout my life. It has been nice to see colleagues and friends at conferences or virtual meetups to catch up and share, especially over the past year.



Alexander Lim,
LLM (Health Law), MPH, PMP, CHE(c)
Program Director, Accelerating Clinical Trials Consortium
Population Health Research Institute,
McMaster University, Hamilton, ON, Canada

What is your current position?

I am currently the Program Director for the Accelerating Clinical Trials Consortium based out of the Population Health Research Institute in Hamilton, Ontario, Canada. My role involves managing a team of staff in overseeing the combined efforts of hundreds of trialists, patient-partners, industry, government, and health research professionals across Canada to address barriers and

challenges in the conduct of clinical trials, and to improve the efficiency of clinical trials through large-scale system transformation initiatives in partnership with our 34 research networks, 11 clinical trial units, and 20 community portfolio hospitals spread across the country.

What are your past positions?

Previously, I have worked in strategic leadership, program management, and project implementation roles at the regional, provincial, and pan-Canadian levels for organizations including: the Centre for Effective Practice, Hills of Headwaters Collaborative Ontario Health Team, Cancer Care Ontario (Ontario Health), the Canadian Partnership Against Cancer, Trillium Health Partners, the Canadian Institute for Health Information, and the Ontario Ministry of Health and Long-Term Care.

What is your training?

I have attained an Honours Bachelor of Science degree from the University of Toronto, a Master of Public Health degree from the University of Waterloo, and a Master of Law degree specializing in Health Law from Osgoode Hall Law School, York University. I also have certifications in Project Management (PMP) and Change Management, and recently completed all requirements for the Certified Healthcare Executive (CHE) designation from the Canadian College of Health Leaders.

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

I am particularly interested in health systems transformation, and looking at how we can build cross-sectoral partnerships to improve the clinical trials ecosystem through the application of policy, legal, regulatory, and funding levers, as well as process and quality improvement methodologies.

What are your hobbies (outside of work)?

I enjoy traveling, cooking, trying new foods, biking, hiking, and spending time with my family. I recently picked up pickleball, which has been a lot of fun as well!

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

I was one of the Social Media Ambassadors at the most recent SCT conference.

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

Knowing that I am playing a part in such impactful work that can directly affect the lives of patients has been the most rewarding aspect.

Your least favorite?

The red tape and bureaucracy that is often involved on the operational side.

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

I enjoyed meeting new people whom I might not have normally crossed paths with, and, in my role as an SCT Social Media Ambassador, being able to amplify messaging from the meeting to expand the reach of SCT. Hearing about all the incredible research being done and seeing the poster presentations was another highlight.

How has being in SCT benefited you?

It has allowed me to expand my network and develop new relationships with trialists and researchers from across Canada, the US, and internationally.

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

Invest time into relationships and building your own networks. Finding peers as part of a community of practice, as well as one or two solid mentors to guide your professional journey will be crucial in setting you up for success.

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

The external environment and global whirlwind can often times be overwhelming. I try to stay grounded by focusing on what is within my realm of control, and the actions I can take to make an impact or difference in any given context.

SCT Giving Day

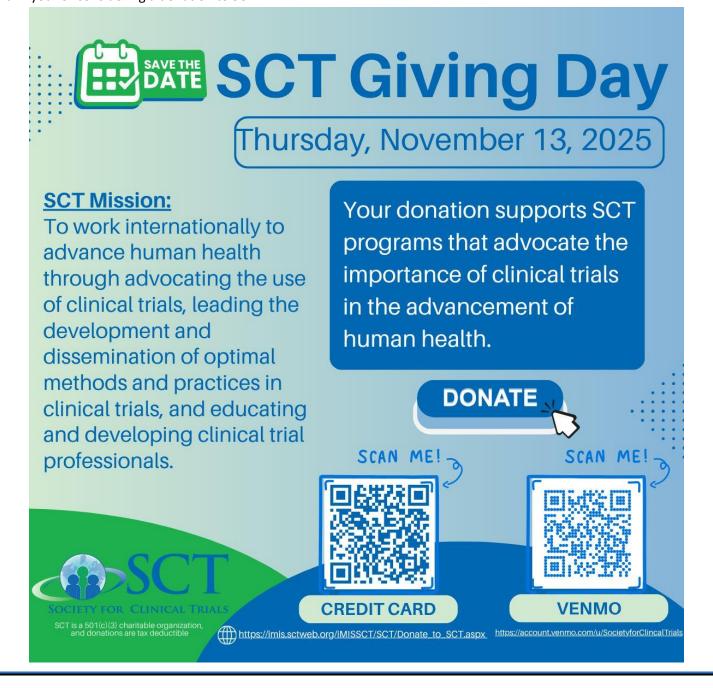
On **November 13**, the Society for Clinical Trials (SCT) invites you to be part of the Giving Day.

Your contribution on the Giving Day will help us make an impact on the clinical trial profession and community, and positively impact the careers of students, researchers and health care providers who want to pursue advanced clinical trial training.

We welcome your gift of any amount that will go towards supporting the mission of SCT. You can donate using <u>Venmo</u> or the <u>SCT</u> website.

Society for Clinical Trials is a 501(c)(3) charitable organization and donations are tax deductible.

Thank you for considering a donation to SCT.



Highlights from SCT's 46th Annual Meeting

The SCT's 2025 Annual Meeting "Shaping the Future: The Right Questions, Robust Answers" was held on May 18-21 in Vancouver. The meeting brought together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and clinical research entities, and it was a huge success.



The Founders Lecture



Scott Evans with the Founders Lecture presenters



Scott Evans with Dr. Arun Sanyal, the Curtis Meinert Keynote speaker



2025 ED&I Early-Career Award recipients which has now become the RISE Emerging Leader Award



Dr. Ryan Berry, the 2025 Sylvan Green Award winner



Mollie Payne, the 2025 Thomas C. Chalmers Student Scholarship Winner



SCT's 2026 Annual Meeting Submission Portal is Open!

"Advancing Public Health: Clinical Trials in an Era of Cutting-Edge Information Capabilities"

May 17-20, 2026 Arizona Grand Resort & Spa Phoenix, Arizona

Roundtable Topic Submissions

Roundtables are informal discussions on a variety of topics such as "Career Paths in Clinical Trials" that will take place during lunch at the Annual Meeting. If you'd like to share your knowledge in an interesting roundtable discussion, we encourage you to submit a topic. Submission Deadline: November 7, 2025, by 11:59 pm ET

Thomas C. Chalmers Student Scholarship Submissions

Are you a graduate student or post-doctoral fellow interested in sharing your knowledge on clinical trials? If so, we invite you to submit an application for the Thomas C. Chalmers Student Scholarship. The top three selected finalists will each give an oral presentation at the Annual Meeting. Submission Deadline: November 7, 2025, by 11:59 pm ET

Sylvan Green Award Submissions

Are you physician, dentist, or other clinician interested in sharing your work on clinical trials? If so, we encourage you to submit an application for the Sylvan Green Award. The selected recipient will give an oral presentation at the Annual Meeting. Submission Deadline: November 7, 2025, by 11:59 pm ET

Fellows of the Society for Clinical Trials Nominations

Do you know someone who has made significant contributions to the advancement of clinical trials and to the Society who is currently an SCT member and has been for at least five consecutive years at any time or a total of at least 10 years? If so, we encourage you to contact the SCT office to confirm their eligibility by November 7, 2025, and then submit a nomination form and packet. Submission Deadline: November 21, 2025, by 11:59 pm ET

Representation, Inclusion, Support & Engagement (RISE) Emerging Leader Award Applications

Are you early in your career with an interest in pursuing a career in clinical trials and involved in any aspect of clinical trials methodology, development, conduct or dissemination? If so, we encourage you to submit an application for the Representation, Inclus8ion, Support & Engagement (RISE) Emerging Leader Award. Submission Deadline: December 1, 2025, by 11:59 pm ET

Contributed (Oral/Poster) Proposals

If you're interested in sharing novel research on the design, organization, operations, analysis, ethics, or reporting of clinical trials, we invite you to submit a proposal for consideration as an oral/poster presentation. Submission Deadline: December 1, 2025, by 11:59 pm ET

David Sackett Trial of the Year Award Nominations

Do you know of a clinical trial that has been peer reviewed within the 2025 calendar year and improves the lot of humankind, provides a basis for substantial, beneficial change in health care, and overcame obstacles in implementation? If so, we encourage you to submit a nomination. Submission Deadline: January 6, 2026, by 11:59 pm ET

All content entered in the submission portal by the designated deadlines will be considered final. No extensions will be given.

Visit the SCT website for more information.

Save the Date!

Society for Clinical Trials' 2026 Annual Meeting "Advancing Public Health: Clinical Trials in an Era of Cutting-Edge Information Capabilities"

May 17-20, 2026 Arizona Grand Resort & Spa

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.

Visit the **SCT website** for more information. We look forward to seeing you in Phoenix!

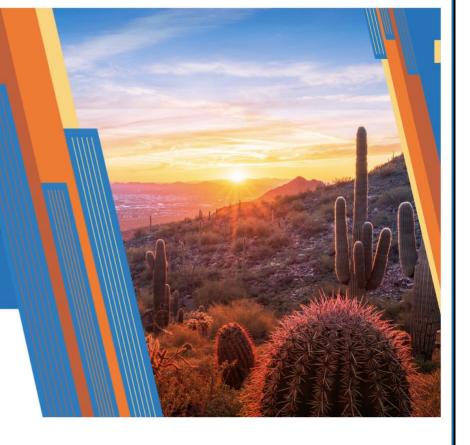
Save the Date!

47_{TH}
Annual Meeting

PHOENIX

May 17-20, 2026





Representation, Inclusion, Support & Engagement (RISE) New Emerging Leader Award

The Society for Clinical Trials (SCT) is pleased to announce the launch of the **Representation, Inclusion, Support & Engagement (RISE) New Emerging Leader Award**. This award recognizes early-career professionals who demonstrate exceptional potential in the methodology, development, conduct, or dissemination of clinical trials and who show a strong commitment to advancing engagement and representation in the field.

The award will be presented across two professional tracks:

- Public Health and Clinical Research Track
- Study Coordination and Operations Track

Each awardee will receive:

- Complimentary registration for the SCT Annual Meeting
- One-year SCT membership
- \$1,600 for travel/hotel expenses

Application Deadline: December 1, 2025.

Information and submission details can be accessed at: https://www.sctweb.org/rise.cfm

Call For The David Sackett Trial Of The Year Nominations

We Are Accepting Nominations For The Trial Of The Year 2025!

Each year The Society for Clinical Trials presents an award to the randomized clinical trial published (either electronically or in print) in the previous year (2025 in this case) that best fulfills the following standards:

- It improves the lot of humankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcame obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Nominations Due By: January 6, 2026

The award will be presented at the 47th SCT Annual Meeting, May 17-20, 2026, in Phoenix.

To nominate the trial that you think best meets these standards, please submit it on the SCT website.

The SCT 2024 Trial of the Year was "Blinatumomab in Childhood Standard-Risk B-Cell Acute Lymphoblastic Leukemia."

Click here to read more about the past Trial of the Year recipients. https://www.sctweb.org/toty.cfm

Call For 2026 Fellow Nominations!

The Society for Clinical Trials established the title of "Fellow of the Society for Clinical Trials (FSCT)" in 2005 to honor Society members who have made significant contributions to the advancement of clinical trials and to the Society. This title is granted to a number of Society members each year at the Annual Meeting.

Nominations for the Class of 2026 are currently being accepted. Any member of the Society may nominate a candidate, and Fellows are encouraged to nominate candidates.

Who May be Nominated

The Society actively encourages the submission of nominations representing both the full diversity of persons deserving of recognition and representing all areas of contribution supporting excellence in the conduct of clinical trials.

Candidates must have been an SCT member for at least five consecutive years at any time or a total of at least 10 years. Each nominee will be evaluated by the SCT Fellows Committee on the basis of service to the Society and contributions to the advancement of clinical trials in one or more of the following areas:

- Important contributions to clinical trials in the areas of information technology, data management, data quality, and/or data sharing.
- Important contributions to clinical trials in the areas of site management, training, IP and supply management.
- Leadership, coordination and/or oversight of clinical trials.
- Design, analysis and/or reporting of clinical trials.
- Education and promotion of a better understanding by the general public of the importance and interpretation of clinical trials.
- Ethical considerations and human subjects' protections in the conduct of clinical trials.

How to Submit a Nomination

Please visit the SCT website for complete nomination submission details.

If you know someone who meets these qualifications and is deserving of this particular Society honor, please follow this three-part process:

- Contact the SCT office via email to contact@sctweb.org to confirm the eligibility of your intended nominee by November 7, 2025.
- Preferred format for uploaded materials is PDF only, not PDF Portfolio.
- Prepare a Nomination Packet by the November 21, 2025, deadline.

Submit your candidate's Nomination Packet by clicking here.

The nomination package should include:

- Current curriculum vitae (CV), biosketch, or resume.
- Three or more letters of support from individuals qualified to describe the candidate's contributions:
 - 1. May include a letter of support from the nominator.
 - 2. At least two of the letters should be from individuals at an institution, agency, or organization other than that of the candidate.
- Cover letter to document meeting the criteria. If the nominator writes a letter of support, documentation of meeting criteria may be incorporated into the letter of support instead.
- Preferred format for uploaded materials is PDF only, not PDF Portfolio.

Nomination packets will be reviewed by the SCT Fellows Committee and selected Fellows will be notified in early 2026.

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Berry Consultants ("Berry") is a scientific consulting company specializing in innovative clinical trial design, Bayesian analysis, adaptive trial implementation, and software solutions for the pharmaceutical and medical device industry. Berry's primary services include designing adaptive clinical trials, conducting comparative effectiveness research such as decision analysis and meta-analysis, providing strategic operational excellence and knowledge of advanced trial implementation, supporting interim analysis and trial updates during the implementation of adaptive trials, participating on Data Monitoring Committees, and the development and licensing of software solutions. These commercially available software solutions include QUOTES (Quantification and Optimization of Trial Expectations Simulator), ADDPLAN (Adaptive Design Planner), and FACTS (Fixed and Adaptive Clinical Trial Simulator) which is the most powerful, flexible, and fastest simulation tool on the market for advanced clinical trial design.

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Silver Sponsor

UNIVERSITY OF WISCONSIN

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.

Bronze Sponsor

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The University of Iowa Department of Biostatistics serves as home for the Clinical Trials Statistical and Data Management Center, the Holden Comprehensive Cancer Center Biostatistics Core, the Biostatistics Consulting Center, and provides leadership to the Statistics & Analytics Core of the Institute for Public Health Practice, Research and Policy.

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At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than a century, we've been at the forefront of research, bringing forward medicines, vaccines and innovative health solutions for the world's most challenging diseases.

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Stata statistical software provides everything for your data science needs—data manipulation, visualization, statistics, and automated reporting. Whether you prefer a GUI, a command line, or scripts, Stata puts the statistics you want at your fingertips. Stata is easy to use and has your back with world-class support.

Bronze Sponsor

VERTEX

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.

Bronze Sponsor

POPULATION HEALTH RESEARCH INSTITUTE

The Population Health Research Institute (PHRI) is a world leader in large clinical trials and population health observational studies, involving over 1.3 million participants across 105 countries. PHRI's research has led to breakthroughs in treatments, disease prevention, and understanding risk factors, thus improving health outcomes and informing global healthcare guidelines.

Information about SCT



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Future SCT Meetings

Save the Dates - Upcoming SCT Annual Meetings



47th Annual Meeting **Phoenix, AZ, USA**



48th Annual Meeting Chicago, IL, USA