

VOLUME 37, #1

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SCT PRESIDENT'S COLUMN

Happy New Year! It is hard to believe that we are less than four months away from the in-person Annual Meeting in Phoenix, Arizona. Despite our busy schedules, the new year typically brings time to reflect on accomplishments from the past year and future goals. For SCT, I am always impressed at what is accomplished by our members and various committees. We are excited to be finalizing the Annual Meeting program and look forward to sharing highlights with you during the registration period through our email blasts, website, and LinkedIn page. We will also share links to local attractions in the Phoenix area, which offer beautiful scenery and outdoor activities. Returning to reflections and goals for the year ahead, I think about the importance of clinical research and how I can help promote the practice of clinical trials. Publishing methodology and trial results is one contribution, but what about volunteering to talk about clinical trials within your own institution or community? I have been visiting our local middle and high schools for some time to share my career path, the importance of clinical trials and career opportunities. I tend to get a few 'I didn't even know that was a career path' or 'My aunt was in a clinical trial' which reinforces why I took the time to share a possible new career path for students to consider. Maybe it sparked a conversation at the dinner table that evening or the possibility of an internship opportunity. I also enjoy talking to other departments and colleges in my university and surrounding institutions about clinical trials. Sharing methodology and current research topics with students, basic scientists, bioinformaticians, epidemiologists, physicians and clinical research professionals always brings new perspectives and possibly new collaborations. It also offers the opportunity to promote the importance of a multidisciplinary clinical research workforce. Several of you may also give back in this way. As we enter the new year, I encourage you to reflect on ways to give back and to consider doing at least one activity in your community that promotes the practice of clinical trials.



**VALERIE DURKALSKI-MAULDIN,
MPH, PHD**

Society for Clinical Trials
President 2025-2026

I hope you enjoy this issue of the SCT Newsletter. Check out the activities of our two new SCT Special Interest Groups as well as our new membership spotlight and updates from the SCT Clinical Trials Journal Editor. And remember to make your plans to join us in Phoenix in May 2026. This is the one professional meeting where you will have the opportunity to engage with all disciplines of our profession – clinicians, regulatory specialists, data and project managers, clinical research coordinators, IT specialists, and biostatisticians from academia, regulatory and industry. This is what makes SCT unique and why it has been my professional home since I started my career in clinical research.

My best wishes for a healthy and happy new year. I look forward to seeing you in Phoenix! - Valerie

FEBRUARY 2026 ISSUE HIGHLIGHTS



COLIN BEGG
Editor

The February issue of Clinical Trials covers an unusual variety of topics relevant to the design and conduct of trials. Lisa Eckstein and colleagues have examined Data Monitoring Committee charters, and they find considerable variability with regard to data availability, external communication, post-trial responsibilities and conflict resolution. Carla Godoy and colleagues examined recent FDA approvals that were based on a single pivotal trial, finding that only 20% had referenced confirmatory evidence, though this proportion increased markedly after 2019 FDA guidance. Stephanie Morain and colleagues address the issue of whether participants enrolled in pragmatic clinical trials without consent should be notified. Christine Girges and colleagues observe that mild-to-moderate depressive symptoms, below the threshold for diagnosing a depressive disorder, are associated with negative self-reporting of symptoms in clinical trials. Finally, David Dunn et al show dramatic reductions in sample size can be achieved using the averted events ratio rather than the conventional method based on the rate ratio for non-inferiority active-control prevention trials with a time-to-event outcome. As always, we encourage all SCT members to submit their best research accomplishments to the Society journal, Clinical Trials.

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MEMBERSHIP SPOTLIGHT



MICHELLE LANCET, BS
Senior Clinical Trial Manager
Center for Biostatistics and Qualitative
Methodology (CBQM)
University of Pittsburgh

WHAT IS YOUR CURRENT POSITION?

I am the clinical data coordinator for multiple clinical trials as well as function as the core lead for CBQM's Data Coordination Core.

WHAT ARE YOUR PAST POSITIONS?

I've been involved in research since day one of my professional life. I started as a research assistant for a junior investigator doing everything from data entry, recruitment activities, and participant assessments. I then moved into a clinical research coordinator position for well over 10 years. I decided to pursue some other interests outside of research for a few years but ultimately decided that research is where I belonged for the remainder of my career. The data coordinating side of clinical trials is where I thrive, but my years as a clinical coordinator allows me to dissect operations from many perspectives.

WHAT ARE YOUR SPECIFIC RESEARCH INTERESTS OR YOUR SPECIFIC INTERESTS WITHIN CLINICAL TRIALS?

As a clinical research coordinator, I was involved in trials that focused on drug and alcohol treatment interventions. Before I started my research career, I thought my path was to be a drug and alcohol counselor. However, research allowed me to still be in that world in a different capacity. As a data coordinator, I don't have just one area of interest. I love that the trials that come through our center range from drug and device trials to behavioral interventions.

WHAT ARE YOUR HOBBIES (OUTSIDE OF WORK)?

During the spring and summer months, I am an avid gardener and have recently taken great interest in focusing on planting species that are native to my home in Western Pennsylvania. I also love to bake and cook, but I always have some kind of needle art project in progress (knitting, Sashiko, embroidery, and quilting). I have a family of avid skiers so occasionally, I will get out on the slopes with them, but you'll find me more often in snowshoes in the winter.

WHAT ROLE(S) DID/DO YOU PLAY IN SCT?

I have been a member since 2020 and was a first-time presenter in a contributed session last year. I hope to be involved with an SCT committee and/or as a conference volunteer in the near future.

WHAT IS YOUR FAVORITE PART ABOUT BEING INVOLVED IN CLINICAL TRIALS?

I feel very lucky to have found a career perfectly suited to my skill set and contributes to the greater good. At a granular level, I love investigating a good "data mystery," but from a team perspective, I appreciate that data coordination involves such a multi-disciplinary approach. I have learned so much by working with our talented programmers and statisticians and seeing trial operations through their lens. As a result, we continually strategize and improve upon our processes for each new trial that comes through our center.

WHAT DO YOU ENJOY MOST ABOUT ATTENDING THE SCT ANNUAL MEETING?

I have been able to incorporate valuable operational methods presented in sessions led by other data coordinating centers or trial managers. I appreciate the exposure to research in all disciplines presented at SCT. I find that in trials we often operate in silos and getting exposure to operations and trials outside of my institution allows me to evaluate my methods in comparison. I also want to emphasize how much I value hearing about things that didn't work in proposed research to help inform our future trials.

WHAT ADVICE WOULD YOU HAVE FOR JUNIOR RESEARCHERS JUST STARTING OUT IN THE FIELD OF CLINICAL TRIALS?

Selfishly, I would advise them to listen to their data coordinating team! I find that the scope of data coordination is often unclear or misunderstood at the beginning so I would encourage junior researchers to involve coordinators, programmers, and statisticians as early as possible in the planning and implementation phases of their trial.

WHAT IS ONE STRATEGY YOU HAVE USED TO MAINTAIN YOUR SANITY DURING THE RECENT MONTHS/YEARS?

This is a continual area of growth, but I try replacing frustration and impatience with empathy and understanding. If there is a situation that contributes greatly to my frustration, I found that the simple act of checking in on the responsible team member(s) goes a long way. I try to put the focus on the person first instead of the work. The root cause comes to light, and the issue is usually an individual or institutional struggle that I didn't even realize. I can then assess if there is a way I can better support or communicate to facilitate forward movement.

**KORTNEY BARRETT, A.A.**

Research Support Coordinator
University of Iowa, College of Public Health

WHAT IS YOUR CURRENT POSITION?

I am currently a Research Support Coordinator in the Clinical Trials Statistical and Data Management Center at the University of Iowa

WHAT ARE YOUR PAST POSITIONS?

Over the last 10 years, I have worked in a variety of healthcare administration positions. From administrative support for the pediatric specialty clinics of Pulmonary Medicine, Cystic Fibrosis, and Allergy and Immunology, insurance prior authorization, central scheduling for inpatient and outpatient hospital procedures, to working the overnight registration shift in an Emergency Department. It has been quite a journey to where I am now, but each position taught me something valuable.

WHAT IS YOUR TRAINING?

Obtaining my degree was a long and hard road for me peppered with degree and major changes. Looking back, I should have known that a healthcare career dealing with research, science, and administration was where I was meant to be. After exploring many options (and one class away from a para educator's certification), I graduated from Kirkwood Community College in Cedar Rapids, Iowa with an associate's degree.

WHAT ARE YOUR SPECIFIC RESEARCH INTERESTS OR YOUR SPECIFIC INTERESTS WITHIN CLINICAL TRIALS?

My main areas of clinical trial work that I handle, and am interested in, are organizational aspects, large- and small-scale event management, multi-website development and management, QA/QM, equipment and software purchasing and licensing, and being a liaison between our College and Center. Assisting in various tasks within pre- and post-award and maintaining publications and presentations across multiple studies and my Center. I could continue to list things off that are of my interest within clinical trials, but it could get rather long. I will end this question with this: I may not do statistical analysis, or trial design, or the bright and flashy parts of trials. Most of the work I do, if done right, you would never notice; but when those tasks go wrong, it can become chaotic..

WHAT ARE YOUR HOBBIES (OUTSIDE OF WORK)?

Outside of work, I enjoy reading a lot! I don't have a specific favorite genre; I tend to read whatever sounds interesting at that moment, but I do enjoy challenging myself with reading! I also enjoy crafting, gardening, swimming, and going to concerts. I love supporting live music!

WHAT ROLE(S) DID/DO YOU PLAY IN SCT?

Currently, I am a member of the SCT Membership Committee and an SCT Member. I have been enjoying the experience with the Membership Committee immensely. I am looking forward to being able to continue that participation and contribute towards the effort of diversifying our membership!

WHAT IS YOUR FAVORITE PART ABOUT BEING INVOLVED IN CLINICAL TRIALS?

My favorite part of clinical trials is that they are always different and there is always a new challenge or something new to learn. Whether it is learning about new conditions or results, or learning how to use new software, then using that to help change the lives of people I will never know.

WHAT DO YOU ENJOY MOST ABOUT ATTENDING THE SCT ANNUAL MEETING?

I love meeting people and learning about the various trials that have happened, successes, breakthroughs, and most of all hearing how other institutions and groups have been using tools, processes they have been implementing, or lessons they have learned. Seeing how others think and problem-solve can be very insightful!

HOW HAS BEING IN SCT BENEFITED YOU?

SCT has given me the opportunity to open my network and experience just how expansive the clinical trial world is and how interconnected we all are. It has also given me the opportunity to participate and share my knowledge with others from a wide range of places.

WHAT ADVICE WOULD YOU HAVE FOR JUNIOR RESEARCHERS JUST STARTING OUT IN THE FIELD OF CLINICAL TRIALS?

Get on your research administrator's good side. We are usually the ones with the cookies! All fun aside, don't overlook your team members or support staff. If they are like me, they are doing all they can possibly do so that you have everything you need to do the best you can, and sometimes we can help when you least expect it!

WHAT IS ONE STRATEGY YOU HAVE USED TO MAINTAIN YOUR SANITY DURING THE RECENT MONTHS/YEARS?

Finding out how to give myself grace. I tend to pick at my work or be too close to it that seeing the whole becomes hard. So, over the last couple of years, learning my limits and how to allow myself the grace I do others has really given me the space to appreciate what I do.

SCT'S NEW EARLY CAREER GROUP

Creation and Mission Statement

In September 2024, the SCT Executive Committee approved a proposal for a new group: the Early Career Group (ECG). This initiative was created to explore ways to make SCT more engaging and approachable for early-career clinical trialists and those new to careers in clinical trials. Overall, we want to identify the best ways to support these individuals and foster future leaders in clinical trials and SCT.

Gathering Success: SCT 2025 Vancouver

As an initial endeavor for this group, a gathering was hosted at the 2025 Annual Meeting in Vancouver. The inaugural Early Career Group Gathering took place on Sunday, May 18th from 5:15 - 6:15pm.

To understand interest in the event and the ECG, we added an item on the conference registration to collect whether someone was interested in learning more about the ECG.

- 72 individuals expressed interest in the group
- 31+ attendees participated
- Several experienced SCT members attended to network and mentor early career attendees

Among the 31 participants who completed a brief survey

- 26 were first-time e SCT Annual Meeting attendees
- 10 identified as recent graduates (within 5 years)
- 12 identified as current students

The strong turnout and engagement underscored the enthusiasm and need for a dedicated early career community within SCT.

Looking Ahead: SCT 2026 Phoenix

Building on the success of 2025, the 2026 Early Career & First-Time Attendee Gathering will be held:



Sunday, May 17, 2026, from 5:15-6:15pm

Registration for the 2026 Annual Meeting is now open, and once again, attendees can indicate their interest in the ECG during conference registration.

Please share this opportunity with trainees, students, early career colleagues, and first-time Annual Meeting attendees who will be joining us in Phoenix

Stay Connected

We look forward to continuing to explore opportunities for the ECG to contribute to SCT and supporting early career trialists.

For more information on the ECG or the Early Career & First-Time Attendee Gathering, feel free to contact



Megan McCabe
memccabe@uab.edu

Ideas and suggestions for the ECG are also welcome.

UNICORN NETWORK OVERVIEW

What is UNICORN

Academic Data Coordinating Centers (DCCs) provide collaborative leadership in multi-site clinical research studies. They offer support with study design and are responsible for collecting, verifying, storing, and analyzing data. DCCs are essential to the success of large clinical research studies. However, not every DCC operates the same.

The **UN**iversity data **CO**ordinating ce**N**ters (UNICORN) Network convenes members of academic institutions that lead DCC activities to advance the discipline of data coordination.

The Mission

UNICORN aims to improve the rigor and impact of clinical research using a collaborative approach.

The Network works to:

- Develop and share best practices for establishing and sustaining academic DCCs
- Strengthen standards for conducting DCC activities
- Train and support DCC personnel
- Advocate for best practices in study design, DCC operations, and statistical analysis
- Advocate for a broader discipline for academic data coordination

Areas of Focus

DCC Infrastructure

UNICORN evaluates the national infrastructure for academic DCCs using the results to offer recommendations or identify gaps in this critical component of clinical research.

Good Data Coordination Practices

UNICORN develops, reviews, and disseminates guidelines for best practices to enhance academic DCC activities.

Professional Development

UNICORN creates pathways and professional development programs that encourage careers in clinical research, data coordination, and train current data coordinating center personnel.

Advocacy

UNICORN advocates at the local, state, and national level in support of the science and practice of DCC activities.

UNICORN does not intend to conduct health research or engage in DCC activities for specific studies.

UNICORN Meetings

UNICORN meetings bring together academics and researchers who lead DCC activities.

These meetings provide a platform to:

- Discuss data coordination approaches
- Share DCC management and leadership strategies
- Increase awareness of the critical role DCC's play in clinical research



Meetings are held bi-monthly, on the last Friday of the month, from 2:00 - 3:00 PM ET

To join a meeting or learn more about UNICORN, please visit:



<https://unicorn-dcc.org/>

REGISTRATION FOR SCT'S 2026 ANNUAL MEETING IS NOW OPEN!

Please join us! This year's theme is:

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

May 17 - 20, 2026

Arizona Grand Resort & Spa

Phoenix, Arizona

Our Annual Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and clinical research entities.



[Click here to learn more about SCT's 2026 Annual Meeting and to register.](#)

Highlights include:

- Cutting edge pre-conference workshops by leaders in the field
- Invited sessions, targeted sessions, contributed sessions, and poster presentations
- Curtis Meinert Keynote Lecture delivered by Cyrus Hoseyni, PhD titled "Quantitative Sciences and Artificial Intelligence: Opportunities and Considerations for Strategic and Responsible Application in Clinical Development"
- Founders Lecture delivered by Brandy Fureman, PhD, FAES, titled "How Cutting-Edge Information Capabilities, Population Health Management and Co-production Can Enable a New Era for Clinical Trials"
- Annual Thomas C. Chalmers Student Scholarship competition
- Sylvan Green Award presentation by Nuru Noor titled "PROFILE Trial - Disease Modification With Early Treatment in Newly-Diagnosed Crohn's Disease"
- 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 2026 Fellows
- Presentation of the 2025 David Sackett Trial of the Year Award
- Roundtable small group discussions on a wide range of topics
- Networking with your colleagues

We're looking forward to seeing you this May in Phoenix.

SCT'S 2026 ANNUAL MEETING: CALL FOR SPONSORS/EXHIBITORS



May 17-20, 2026



Phoenix, AZ, US



Interested in sponsoring or exhibiting?

Exhibitors receive a 15% discount on sponsorship rates, making this an even greater opportunity to maximize visibility and impact

SCT MEETING 2026

The Society for Clinical Trials (SCT) Annual Meeting brings together individuals from throughout the clinical trials community to share insights, advance innovation, and shape the future of clinical research –and sponsorship and exhibitor opportunities are now available.

Contact the SCT team at info@sctweb.org for full details, availability, and deadlines. Or reach out to:

- Margaret Gamalo (meg.gamalo@yahoo.com)
- Xiaotian Chen (xiaotian.chen@abbvie.com), or
- Valerie L. Durkalski-Mauldin (durkalsv@muscedu)



Whether you're exhibiting or not, SCT offers a range of high-visibility options to help your organization connect with attendees, including:

- Branded meeting bags, lanyards, and notebooks
- Refreshment breaks and welcome reception sponsorships
- Onsite Final Program advertising distributed to every attendee

Let's continue advancing excellence and innovation in clinical trials—together

SCT'S 2026 FOUNDERS LECTURE KEYNOTE ANNOUNCEMENT



SCT is pleased to announce the 2026 Founders Lecture Keynote titled **"How Cutting-Edge Information Capabilities, Population Health Management and Co-production Can Enable a New Era for Clinical Trials"**

will be presented on Tuesday, May 19 at SCT's 2026 Annual Meeting by

Brandy Fureman, PhD, FAES

Chief Outcomes Officer, Epilepsy Foundation of America; Independent Consultant, Neuroscience Navigators Consulting

Presentation Summary: This special keynote address will share why current clinical trial systems are 'perfectly designed' to create challenges of slow recruitment, limited diversity and expensive evidence generation that often struggles to meet public health needs. The solution requires systemic redesign leveraging cutting-edge information capabilities (AI, interoperability, real-world data) alongside essential partnerships with patient advocacy organizations. These groups help identify meaningful outcomes, reduce participant burden, and shape inclusive protocols. Key actions include joining pre-competitive partnerships, supporting population health infrastructure at clinical sites, and embedding patient advocacy engagement early in research and development planning to transform how trials work.

The SCT Annual Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and clinical research entities for the purpose of sharing knowledge and networking. The meeting dates and location are as follows:

May 17 - 20, 2026

Arizona Grand Resort & Spa

Phoenix, Arizona



[Click here to learn more about SCT's 2026 Annual Meeting.](#)

SCT'S 2026 CURTIS MEINERT KEYNOTE LECTURE ANNOUNCEMENT



SCT is pleased to announce the 2026 Curtis Meinert Keynote Lecture titled "**Quantitative Sciences and Artificial Intelligence: Opportunities and Considerations for Strategic and Responsible Application in Clinical Development**"

will be presented on Monday, May 18 at SCT's 2026 Annual Meeting by

Cyrus Hoseyni, PhD

Global Head of Quantitative Sciences & Clinical Pharmacology (QSCP), Johnson & Johnson Innovative Medicine, Research & Development

Presentation Summary: This presentation will explore how Quantitative Sciences and Artificial Intelligence can be strategically and responsibly used in clinical development and evidence-based decision making. It will highlight advances in the scientific processes for study design, including simulation guided approaches and AI-supported pharmaco-statistical modeling. Operational applications such as patient recruitment modeling, integrated clinical supply planning, and enhanced data monitoring will also be discussed. The session will further examine organizational considerations, highlighting the importance of a collaborative leadership approach as disciplinary boundaries evolve. It will conclude with perspectives on developing the next generation of experts prepared to integrate quantitative, computational, and clinical insights.

The SCT Annual Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups and clinical research entities for the purpose of sharing knowledge and networking. The meeting dates and location are as follows:

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



[Click here to learn more about SCT's 2026 Annual Meeting.](#)

THANK YOU TO OUR CORPORATE SPONSORS FROM LAST YEAR!

Gold Sponsor

PFIZER

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines.

Silver Sponsor

MERCK & CO., INC.

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.

Silver Sponsor

BERRY CONSULTANTS

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.

Silver Sponsor

SANOFI

Bronze Sponsor

UNIVERSITY OF IOWA DEPARTMENT OF BIOSTATISTICS

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.

Bronze Sponsor

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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.

Silver Sponsor

AMGEN

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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Bristol Myers Squibb is a leading global biopharma company focused on discovering, developing and delivering innovative medicines for patients with serious

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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

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