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NEWSLETTER

OCTOBER 2022

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SCT President's Column



Lehana Thabane
Society for Clinical Trials President 2022-2023

We need all hands on deck in the leadup to the 44th annual meeting in Baltimore.

Preparations for the 44th Annual Meeting of the Society for Clinical Trials in Baltimore, Maryland, have begun with earnest. The theme for next year's meeting is **"Championing High-quality Evidence to Optimize Human Health"**. I am pleased to note here that our dedicated Program Committee, with support from the Education Committee, the EDI Committee, and the Student Scholarship Committee, continue to plan for an enriching experience for all our members and trainees.

For your consideration, I have highlighted below a list of the 'milestone' events and awards tied to next year's meeting.

- Annual Meeting Submission Portal is Open (Invited and Contributed Presentations, Sylvan Green Travel Award Submissions, Thomas C. Chalmers Student Scholarship Submissions, and Roundtable Topic Submissions)
- 2023 EDI Early Career Award
- 2023 EDI Student Travel Award

More details on these events, awards and more are forthcoming, beginning with the October edition of our newsletter. In the meantime, I kindly ask that you begin to think about how you might be able to assist the Society in promoting next year's meeting across your professional networks.

A call for proposals has gone out, and I encourage all our members to take the time to submit one for an invited session, contributed session, or roundtable discussion. You can also mentor someone through the process of putting together an invited session. Our ability to feature an enriching, educational, and exciting program depends mostly on the diversity of the proposals we receive. The richer and more diverse the pool of proposals, the better the program will be.

I also encourage our members to consider nominating a trainee for a travel award or scholarship. While this might seem like a mundane activity, winning an award or scholarship can transform the trajectory of a trainee's academic, personal, and professional future. Success breeds success: many leaders in trials who developed innovative interventions and discovered cures for diseases started their journeys with small successes, such as winning a travel award to attend a conference.

Thank you, and I very much look forward to your enthusiastic participation in the leadup to and during next year's meeting.

Sincerely,

Lehana Thabane,

SCT President

CLINICAL TRIALS

Journal of the Society for Clinical Trials



By Colin Begg, Editor

October, 2022 Issue Highlights

The **October** issue of *Clinical Trials* is led by a series of articles on how to address the confounding effects of temporal drift in platform trials. **Ben Saville** and colleagues approach this using Bayesian methods, while **Ian Marschner** and **Manjula Schou** propose adaptation of network meta-analysis techniques. A commentary is provided by **Marta Roig**, **Franz Konig**, **Elias Meyer** and **Martin Posch**.

Jessie Pappin and colleagues take a historical deep dive into the clinical trials evidence supporting Health Canada's approval of Oxycontin.

Jack Wolf and colleagues address the thorny question of how to perform analyses to detect heterogeneous treatment effects in clinical trials while controlling false positives.

Julie Hom and colleagues use an example to investigate the capability of natural language

processing methods to derive performance status from free text in a lymphoma clinical trial.

As always we encourage all SCT members to submit their best ideas for publication in the Society journal.

Follow us on twitter [@clintrialsj](https://twitter.com/clintrialsj) to keep up to date with the latest from the journal.



Call for President-Elect and Board of Directors Nominations

Deadline: October 31, 2022

We are soliciting nominees for President-Elect for 2023-2024
and

Two members of the Board of Directors for 2023-2027

Nominees should be a member of the Society in good standing for at least five consecutive years and preferably an active participant in SCT activities and/or committees

SCT is strongly committed to achieving equity, diversity and inclusion (EDI) within leadership. We seek nominees well respected in any area of clinical trial activities, whether it be in information technology, patient care, statistics, project management, regulatory affairs, epidemiology, laboratory sciences, or any of the other disciplines that are important for the planning, conduct, analysis, interpretation and reporting of clinical trials. Additionally, we encourage international nominees in addition to those residing in the US. If you have suggestions for possible nominations, please reach out to Emily Dressler, Chair of the SCT Nominating Committee via [email](mailto:emdressler@clintrialsj.org).

2022-2023 Nominating Committee

Emily Dressler, Chair • Sameer Parpia, Co-Chair

Lehana Thabane • Dixie Eckland • Alexia Iasonos • Masha Kocherginsky • Sharon Love



[Submit a Proposal/
Abstract](#)

**Submission Portal is Now Open for the
44th Annual Meeting of the Society for Clinical Trials!**
The meeting theme is: "Championing High-quality Evidence
to Optimize Human Health."

May 21-24, 2023

Baltimore Marriott Waterfront

Baltimore, MD

All submissions must be made via the [SCT website](#).

Thomas C. Chalmers Student Scholarship Submissions

Deadline: October 28, 2022 by 11:59 pm ET

Sylvan Green Travel Award Submissions

Deadline: October 28, 2022 by 11:59 pm ET

Roundtable Topic Submissions

Deadline: October 28, 2022 by 11:59 pm ET

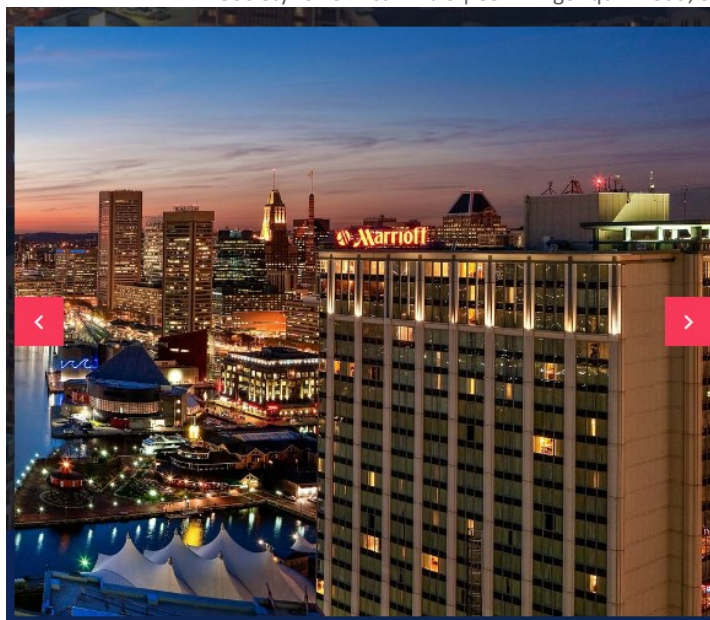
Contributed Presentations (Oral/Poster)

Deadline: November 14, 2022 by 11:59 pm ET

[Contact SCT](#)

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Society for Clinical Trials | 85 W Algonquin Road, Suite 550, Arlington Heights, IL 60005



THE CONFERENCE VENUE

BALTIMORE MARRIOTT WATERFRONT

Experience Charm City like never before at Baltimore Marriott Waterfront. Ideally situated in the Harbor East neighborhood, our waterfront hotel provides unparalleled access to Fells Point, the National Aquarium and the restaurants and shops of the Inner Harbor. Redesigned accommodations offer views of the harbor or the Baltimore skyline, and include modern technology, premium amenities and deep soaking tubs.

Member Spotlight



Cristina Murray-Krezan, PhD

What is your current position?

Biostatistician and Associate Professor of Medicine at the University of Pittsburgh. I am also the Associate Director for Clinical Trials in Pitt's Center for Research on Health Care, and the Co-Director of the Center for Clinical Trials and Data Coordination.

What are your past positions?

Before coming to Pitt in 2021, I was at the University of New Mexico for 11 years where I was the co-founding Director of the UNM Statistics and Data Coordinating Center. I also worked with UNM's Clinical and Translational Science Center and Comprehensive Cancer Center.

What is your training?

I have a BS in Astrophysics, and MS and PhD in Statistics.

What are your specific research interests?

I enjoy working on clinical trials and observational studies that aim to improve the lives of underrepresented and marginalized populations in areas including substance use disorder, pain, and social isolation. I also have an interest in methods to identify and adjust for the presence of informative censoring in survival analysis.

What are your hobbies (outside of work)?

Currently I am taking a rowing class and enjoying the Allegheny River. After watching my son earn a black belt in taekwondo, my husband and I started taking taekwondo classes this last year. I adore hiking and in my past life ran two marathons. I also play the flute and piano and love gardening.

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

I think I love almost everything about clinical trials. I enjoy the challenge of the proposal stage and helping clinical investigators to refine their outcome measures. I enjoy contributing to protocol development and writing the statistical analysis plans. Being actively involved in developing the databases and overseeing the data collection efforts is rewarding and nothing beats seeing the first enrollment reports! Analyzing the data and writing manuscripts also great. The best part, though, are the wonderful collaborations built with research teams, from PIs and clinicians to data analyst staff and data collectors.

Your least favorite?

Honestly? Sample size calculations.

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

I have been a member of SCT since 2012. I'm enjoying my second year on the Membership Committee and first year on the Program Committee. I also was a member of the Nominating Committee last year.

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

It is wonderful meeting others, regardless of discipline, who enjoy clinical trials as much as I do. The conference is pretty laid back but the sessions are engaging, interesting, and useful. I can definitely say I've made new friends at the Annual Meetings.

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

Identifying productive and supportive teams to work with is a bit of trial and error at first. Find a supportive mentor who is either involved in clinical trials or who can help connect you to others in clinical trials. Go with your gut on who might make a good collaborator and don't be afraid to ask lots of questions to help you make this determination.

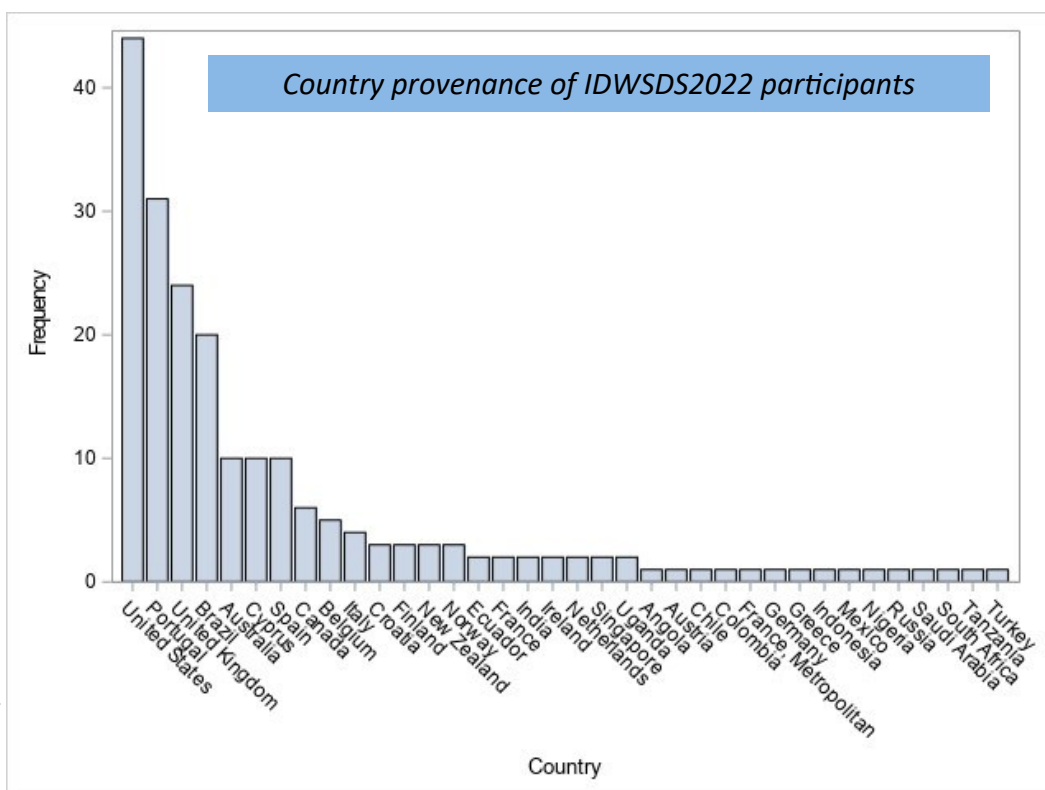
Where and when was your favorite SCT meeting (so far)?

It has to be the Liverpool meeting where I attended some great short courses and talks. I also took an extra day to explore Wales!

Hundreds worldwide celebrated the 1st *International Day of Women in Statistics and Data Science*

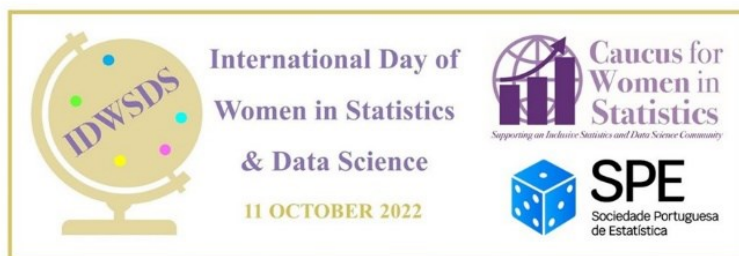
The Inaugural *International Day of Women in Statistics and Data Science* celebrated on October the 11th with support from SCT and 35 other statistical and data science organizations around the world. It was a great success gathering 205 statisticians and data scientists from 36 countries (most participants coming from US, Portugal and UK; see bar chart) of which 55% were academics, 17% students, 10% worked in non-profit organizations or other, 9% were business or industry workers, and a final 9% worked in government. The fascinating selection of sessions included topics as varied as work-life balance, gender issues in statistics and covid-19 studies (see word cloud for a summary). The subsequent lively discussions raised common worries and challenges faced by women in

the field. The SCT sponsored a session on Biostatistics Leadership in Oncology Clinical Trials, highlighting leadership and contributions made by three women biostatisticians in cancer clinical trials, representing three major cooperative groups funded by the National Cancer Institute in the United States: Alliance, SWOG, and the Pediatric Brain Tumor Consortium (PBTC). Sumithra Mandrekar from *Mayo Clinic* covered the all-important topics of precision medicine and patient retention, Megan Othus from *Fred Hutchinson Cancer Research Center* shared important lessons learned



Hundreds worldwide celebrated the 1st *International Day of Women in Statistics and Data Science*

from implementing a novel endpoint is a randomized Phase 2 trial for high-risk resectable melanoma (SWOG Cancer Research Network Trial S1801at), and Arzu Onar-Thomas from St. Jude Children's Research Hospital discussed approaches to clinical trial designs in pediatric brain tumors. The recordings from their talks will be made available on the event's website idwsds.org. The organizing committee



Biostatistics Leadership in Oncology Clinical Trials



Sumithra Mandrekar
Mayo Clinic



Megan Othus
Fred Hutchinson
Cancer Research Center



Arzu Onar-Thomas
St. Jude Children's
Research Hospital




11 October 2022



3:45pm – 5:00pm (UTC)
11:45am – 1:00pm (ET)



Sponsored by  **SCT**
SOCIETY FOR CLINICAL TRIALS

and main sponsors, the *Caucus for Women in Statistics* and the *Portuguese Statistical Society*, thank all contributors and supporting organizations, and would like to invite future volunteers to join the 2023 organizing committee by emailing idwsds1@gmail.com.

Upcoming Webinar: Design and Analysis Considerations in Immuno-Oncology Trials under Delayed Treatment Effect—November 30

The novel mechanism of action of immuno-oncology (IO) agents, in treatment of various types of cancer, poses unique challenges during the design and analysis of clinical trials. This includes observation of a delayed separation (or sometimes crossing) of Kaplan-Meier curves, likely due to heterogeneous treatment effect over time. Although the Logrank test is considered the gold standard for comparing 2 survival curves in pivotal registrational trials, novel IO therapies often violate the proportional hazards (PH) assumptions over time resulting in loss in power. Interpretation of treatment effect can also be challenging, as traditional summary measures such as Hazard Ratios (HR) and median survival can be less intuitive. In this webinar, we discuss these issues surrounding IO drug development using real life case studies of anti-PD1/PDL1 agents and propose ways of addressing these concerns.

Interested in Presenting a future 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 info@sctweb.org. We look forward to receiving your proposal!

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Silver Sponsor
UNIVERSITY OF WISCONSIN DCC

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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Berry Consultants is a statistical consulting company specializing in innovative clinical trial design, Bayesian analysis, adaptive clinical trial execution, and simulation software solutions for the pharmaceutical and medical device industry.

Silver 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 multiple approved medicines that treat the underlying cause of cystic fibrosis (CF) - a rare, life-threatening genetic disease - and has several ongoing clinical and research programs in CF.

Save the Dates - Upcoming SCT Annual Meetings



44th Annual Meeting
May 21-24, 2023
Baltimore, MD



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



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

Information About SCT

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 Lee McDaniel

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