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INSIDE THIS ISSUE:

SCT President's Column

Lehana Thabane
Society for Clinical Trials President 2022-2023

Update on the financial health of the SCT and how you can help strengthen our great organization

One of the main responsibilities of the President is to oversee the general management and business affairs of the Society. This includes its financial activities and potential risks. At the start of my tenure this past May, I requested an assessment of the Society's financial situation to better understand how COVID-19 has impacted us.

During my review, it was clear that the Society's financial reserves have been declining over the past few years (due to the pandemic and other reasons outside of our control including higher annual meeting costs and the downturn of the financial markets).

I therefore made it a priority of mine to strengthen the Society and improve our financial stability. As a rule of thumb, an organization like ours should strive to have enough in its financial reserves to operate for at least two years.

What measures have we put in place to address the situation?

Together, with the Executive Committee and the Board of Directors, we have developed a plan to enable the Society to build up its reserves and become even more stable and member-focused. As part of prudent budgeting for this year, we will be implementing the following measures:

- We are no longer going to offer virtual attendance to our annual meeting, as expenses for offering this remote option exceed the revenue it generates.
- We increased membership dues from $180 to $220.
- We increased the registration fee for the annual meeting from $595 to $695 to help us cover the rising costs of putting on a live event.
- We are investigating ways to reduce the high food and beverage costs and may reduce or eliminate one or more of the provided breakfasts.
- We reduced the number of concurrent sessions offered at the Annual Meeting from six to five to save on room rental and audio/visual expenses.
- We formed a Strategic Planning Committee, led by Mithat Gönen, whose responsibilities, among others, include devising a strategy to strengthen the financial health of the Society.
- We have also included a financial risk assessment in the annual work plans of both the Executive Committee and the Board of Directors, to ensure we continuously monitor the situation.

How can you help?

There are a few things you can do to help us including:

- Help us increase our membership by encouraging your colleagues and people in your professional networks (including your mentees and

SCT President's Column

trainees) to join the Society. Please share any additional ideas you might have with the chair of the Membership Committee, Dikla Blumberg (dikla.blumberg@gmail.com).

- Help us increase the number of registrants at our May 21-24, 2023, meeting in Baltimore by registering for the meeting, which is our main source of revenue, and encourage others in your professional networks to do the same. This is going to be a great meeting and we anticipate registration will open in early February.
- Support the Development Committee's efforts to raise funds. We need to attract new exhibitors and sponsors. For more details, please reach out to the committee chair, William Wang (William_wang@merck.com).
- Support the Outreach Committee with its engagement activities. For more details, please reach out to the committee chair, Rick Chappell (chappell@biostat.wisc.edu).
- Donate money to the Society and encouraging others in your professional networks to do the same by going to www.sctweb.org and clicking the 'Donate' button. We'll recognize our donors in an upcoming newsletter and will issue tax receipts for all donations made.
- Share your ideas with the chair of the Strategic Planning Committee, Mithat Gönen (gonenm@mskcc.org). The committee will communicate the results of their work at our upcoming annual meeting in Baltimore.

You can also contact me directly at thabanl@mcmaster.ca, if you have any ideas related to how we can enhance the future stability of the Society so that we can continue to grow and increase the support we provide to our members. In the meantime, please know that I remain confident in the Society and in our ability to become stronger and more vibrant than ever.

Thank you,

Lehana Thabane,

SCT President

Is Your Membership Expiring?

Don't forget to renew your membership for the new year! Your dues help sustain the society in its mission and provides benefits such as webinars and a discounted registration fee for the meeting.

Visit sctweb.org to renew now!

CLINICAL TRIALS

Journal of the Society for Clinical Trials

By Colin Begg, Editor

November, 2022 Issue Highlights

The **November** issue of *Clinical Trials* includes articles on a wide variety of topics relevant to the practice of clinical trials. Authors from the **Cholesterol Treatment Trialists Collaboration** address the challenges of harmonizing data on adverse events in a meta-analysis of 23 statin trials. **Stephanie Morain** and colleagues demonstrate how sharing participant level data from pragmatic trials can present distinct ethical challenges for individual participants. **Ira Longini** and colleagues describe a creative design for testing multiple vaccine candidates against the Marburg virus that uses a mix of individual and cluster randomization. **Tasmin Rookes** and colleagues explain that the concept of fidelity of the distinct intervention components is critical for interpreting the results of trials of self-management interventions. And **Brad Hammill** and colleagues evaluate the use of real world data by comparing them with trial data, finding that real world data may not yet be ready for prime time. As always we welcome submissions of articles from SCT members as well as the wider academic community.

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

Nominations Still 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.

Fellow of the Society for Clinical Trials Nominations

Deadline: January 30, 2023 by 11:59 pm ET

David Sackett Trial of the Year Nominations

Deadline: January 16, 2023 by 11:59 pm ET

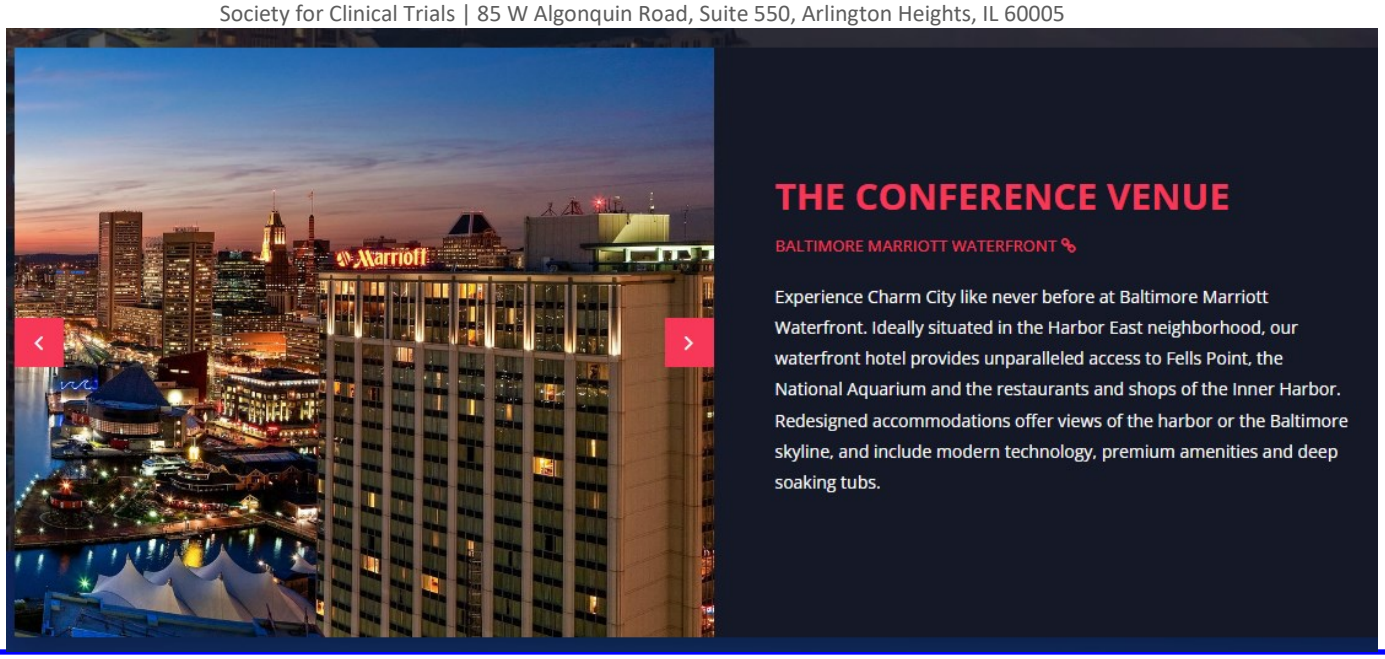
ED&I Early-Career Award Nominations

Deadline: January 6, 2023 by 11:59 pm ET

Visit the SCT website for more information.

Contact SCT **Join SCT**

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



Member Spotlight

Corinne McGill, MPH

What is your current position?

I am a doctoral student in biostatistics and graduate research assistant at the Medical University of South Carolina (MUSC).

What are your past positions?

I worked as a chemist and neuroimaging analyst before enrolling in the MPH program at MUSC. Between the completion of my MPH and enrollment in the PhD program, I worked as a master's level statistician for the Data Coordination Unit (DCU) in the Department of Public Health Sciences at MUSC.

What is your training?

I earned a BS in chemistry before pursuing an MPH in biostatistics. During my time in the PhD program, I have had the privilege to work with and learn from the clinical trialists in the DCU.

What are your specific research interests?

My research focuses on the effect of subject accrual on futility analyses in time-to-event studies with variable follow-up.

What are your hobbies (outside of work)?

I love maintaining an active lifestyle which includes walking my dog, hiking, cycling, lifting weights, and yoga. I also enjoy experiencing new parts of the world, listening to music, and keeping up with the latest fashion/beauty trends.

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

I love having the opportunity to collaborate with and learn from experts in various biomedical fields, and I am very motivated by the idea my everyday contribution could lead to a breakthrough in the treatment of a debilitating illness.

Your least favorite?

Experimenting on human subjects carries a great amount of responsibility and can cause me to second-guess even the smallest decisions.

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

In May 2022, I attended the SCT Annual Meeting for the first time where I moderated a session and presented my research. It was a very educational and empowering experience, and I hope to become a more active SCT member in the future.

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

I most enjoyed the opportunity to connect with and learn from other clinical trialists.

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

I am still a junior researcher myself, but I would encourage my peers to seek out meaningful research and collaborators with whom you work well.

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

No matter how busy my work schedule is, I make time to exercise every day and have at least one social outing per week. Something as simple as a quick lunch with a friend can really boost my productivity.

SCT Webinar Highlights

The Estimand Framework from the ICH E9(R1) Statistical Principles for Clinical Trials Addendum: Current Implementation Status and Looking Forward

June 6, 2022, 12:00 – 1:30 pm Eastern Time (11:00 am – 12:30 pm Central Time)
Organizer and Presenter: **Xiangrong Kong**, PhD, Associate Professor, Johns Hopkins University
Presenter: **Godwin Yung**, PhD, Principal Statistical Methodologist, Genentech
Presenter: **Rachael Lawrance**, CStat, Director & Functional Lead Statistics, Adelphi Values
Presenter: **Yixin Fang**, PhD, Director, Global Medical Affairs Statistics, Abbvie
Discussant: **Catherine Njue**, PhD, Manager, Office of Biostatistics, Health Products and Food Branch (HPFB) of Health Canada

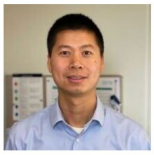
This webinar focused on educating attendees on the Estimand Framework proposed in the ICH (International Council for Harmonization) E9(R1) Statistical Principles for Clinical Trials Addendum released in November of 2019. Highlights from the presentation included:

1. Coverage of the Statistical Principles for Clinical Trials ICH E9(R1) Addendum
2. Explanation of the Estimand Framework (EF) and what constitute the framework
3. Applications of EF in designing clinical trials
4. Preparation for adopting the EF in conceptualizing and designing research studies and clinical trials

Xiangrong Kong, PhD
Johns Hopkins University

Godwin Yung, PhD
Genetech

Rachael Lawrance, CStat
Adelphi Values



Yixin Fang, PhD
abbvie

Catherine Njue, PhD
Health Products and Food Branch (HPFB) of Health Canada

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 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 info@sctweb.org. We look forward to receiving your proposal!

SCT Webinar Highlights

The PROTEUS Consortium: An Interdisciplinary Collaboration Promoting Quality Patient Reported Outcomes in Clinical Trials

February 15, 2022, 11:00 am – 12:30 pm EST
Moderator and Presenter: **Michael Brundage**, MD MSc, Professor Queen's University.
Introduction: **Mithat Gönen**, PhD, Professor, Memorial Sloan-Kettering Cancer Center, SCT President
Presenter: **Claire Snyder**, PhD, Professor, Johns Hopkins University and Bloomberg School of Public Health
Presenter: **Albert Wu**, MD, MPH, Johns Hopkins Bloomberg School of Public Health

The purpose of this webinar was to inform attendees on the Patient Reported Outcomes – Engaging Users and Stakeholders (PROTEUS) Consortium which ensures that patients, clinicians, and other decision-makers have quality Patient Reported Outcomes (PRO) data from clinical trials to make the best decisions they can about treatment options. Highlights from the webinar included:

1. Review of the potential for PROs from clinical Trials to inform clinical care
2. Review of the evidence for existing barriers to reaching this potential
3. Introduction of the PROTEUS consortium as an interdisciplinary project to address these barriers by promoting and disseminating tools designed to improve the quality of PRO components of RCTs
4. Review of the PROTEUS tools that provide guidance for quality of PROs in clinical trials all of which are freely available on the PROTEUS website (www.theproteusconsortium.org).

Ethics of Trust and Trustworthiness in Health Research: How far have we come? Where should we be going?

April 27, 2022, 1-2 pm ET
Presenter: **Stephen Olufemi Sodeke**, PhD, MA (Bioethics and Health Policy), Resident Bioethicist, Center for Biomedical Research, Professor of Bioethics and Allied Health Sciences, College of Arts & Sciences, Tuskegee University

This seminar informed attendees about the importance of promoting and maintaining a culture of trust and trustworthiness when collaborating with research partners, institutions, and networks engaged in biomedical and health research is crucial for an ethical research. The seminar sensitized stakeholders to the need for increased awareness of, and intentional reflections on the tensions, concerns, and other pertinent issues moving forward.
Highlights from the webinar included:

1. Review of the concepts of trust and trustworthiness
2. Discussion of the need for reflection on issues of trust and trustworthiness in biomedical and health research
3. Discussion regarding the implications of a "culture of trust and trustworthiness" in collaborating with research partners and institutions
4. Delineation of the practical steps for promoting trust and trustworthiness among collaborating researcher, institutions, and those volunteering for research

SCT Webinar Highlights

Considerations when Collecting Real World Data (RWD) and Evaluating Real World Evidence (RWE) from Expanded Access Programs

June 2, 2022, 1:00 – 2:30 pm Eastern Time
Presenter: **Alison Bateman-House**, PhD, MPH, MA, Assistant Professor of Medical Ethics, Department of Population Health, New York University Grossman School of Medicine
Presenter: **Hayley Belli**, PhD, MS, Assistant Professor of Biostatistics, Department of Population Health, New York University Grossman School of Medicine

This seminar informed participants about collecting and evaluating real-world data (RWD) and real-world evidence (RWE) from Expanded Access programs. RWD are defined as any data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD may, in some situations, generate real world evidence (RWE), i.e., insights allowing for decision making regarding the usage and potential benefits or risks of a medical product. Expanded Access is a regulatory pathway that allows patients to use investigational products outside of clinical trials when specific conditions are met. RWD collection from this non-trial use offers an opportunity to learn about the unapproved products' safety and efficacy in situations where there is no ongoing clinical trial or in patients who are outside the parameters of trials of the product.
Highlights from the webinar included:

1. Review of RWD, including how it is used in research, and RWE
2. Review of Expanded Access, and understand how Expanded Access programs differ from RCTs or observational studies
3. Description of opportunities and limitations for collecting RWD from Expanded Access programs (EAPs)
4. Discussion of potential benefits and harms of collecting RWD from sponsor, payer, and patient advocacy perspectives
5. Review of the ethical and research regulatory questions surrounding the collections and use of RWD from EAPs
6. Review of statistical considerations for RWD collected from EAPs that yield high-quality and impactful research

Alison Bateman-House, PhD, MPH, MA
New York University Grossman School of Medicine

Hayley Belli, PhD, MS
New York University Grossman School of Medicine

Highlights From the Web

NCI Interview with Dr. Naoko Takebe on the Perception of Early Phase Trials

Naoko Takebe, M.D., Ph.D.

NCI Cancer Therapy Evaluation Program

Credit: National Cancer Institute

Do you feel like there are misconceptions about phase 1 clinical trials?

Yes, the perception of the potential benefit to patients hasn't caught up with modern drug development. In the past, participants in phase 1 trials generally have had low tumor response rates, about 4%–5%. In addition, the primary purpose of phase 1 trials is to assess safety. So, some doctors have not been enthusiastic about referring patients to phase 1 trials.

People also have to go through the standard treatment options first, and usually only those patients who run out of those options, or are not able to receive those standard options for some reason, are eligible to participate in a phase 1 trial. So there have been concerns about including people with advanced cancer, who may be very ill, in early clinical trials.

But we and others have now shown that things have changed. Participating in phase 1 trials has more potential for clinical benefit than is commonly believed, largely due to the development of modern cancer drugs, like targeted therapies, immunotherapies, and new combination therapies.

So I hope this analysis will have a positive impact on the enrollment of patients into phase 1 trials by doctors, who may feel more comfortable referring patients.

You found a few groups of people who had a slightly higher risk of treatment-related death in phase 1 trials compared with participants overall, including those who were older and sicker, and who had liver problems. Should these people not participate in clinical research?

No, they can definitely still participate, as long as they meet all the criteria for participation in a trial, and their doctor agrees it's safe. And we have to overcome the misperception that they can't.

In addition to the newer types of drugs being developed, we've also had advancements in supportive care. In all clinical trials, we're now much more proactive in supporting patients, including providing pain control and palliative care services, and watching for and appropriately managing side effects.

So factors like age should not necessarily stop patients from participating in a phase 1 clinical trial. But they should serve as an alert for the clinical trial team to be aware, to make sure patients understand the risks, and to monitor older, sicker patients more closely.

Read the full interview on the NCI website

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Frontier Science Foundation is a not-for-profit research organization dedicated to the improvement of data management and statistical quality in clinical trials and medical research.

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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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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

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Li Chen (Treasurer)
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