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NEWSLETTER

JUNE 2022

Welcome From SCT President Lehana Thabane



Lehana Thabane

Society for Clinical Trials President 2022-2023

I am sharing here the same message that I communicated to those who attended our business meeting in San Diego.

“As a start of my tenure as President for the Society, I first want to start by thanking you for electing me; for the trust and honor to serve. I pledge to do all I can to make you proud to be a member of this Society.

I challenge everyone to commit to walking with me through a year of transformation and renewal for the Society. We have been through a lot together during the last two years as battled the pandemic by using trials to generate the evidence to guide treatment, prevention, and management of COVID-19. We relied on each other for collaboration as the world came together through an incredible spirit of solidarity. I call on everyone of you to use the same spirit of humanity and solidarity to do two things for the Society:

To commit yourself to mentoring someone within or outside the SCT. I urge everyone

of you to make decision to take a junior colleague under your wing. It can be someone at your local institution, your international collaborations, your peers, your students, your colleagues, and bring them along to mentor them in clinical trials. There are several things you can do for them. They include, but not limited to providing learning opportunities for: i) Supporting them in proposing an invited session for next year’s SCT annual meeting; ii) Reviewing manuscripts for journals; iii) Reviewing grants for granting agencies; iv) Reviewing IRB (institutional review board) submissions; v) Reviewing drafts of manuscripts, grants, etc. vi) Observing your interactions with collaborations during research meetings, Data Safety Monitoring Board meetings, IRB meetings, or any meeting that you think would benefit the trainee to observe; vii) Discuss career goals and options; viii) Discuss strategies for success in health collaborations—what works for you and what doesn’t work; any lessons you can share from your experiences; and ix) Networking opportunities for the mentee. If your mentee is not a member of the Society, consider encouraging them to join the Society. For more details on how to become a member of the SCT, they can visit our [membership page](#).

To cultivate the spirit of Ubuntu in the Society. Ubuntu means ‘I am because you are,’ ‘I am because we are’. We cannot live this, embody this, cultivate this, unless we are willing to get to know each other, walk a

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SCT President's Welcome (continued)

mile in each other's shoes, spend some time to learn about each other. So, I ask you to make sure that you reach out to at least one person you have not met before—to introduce yourself so as to build connections. They can be a member of the Society or someone whose work in clinical trials you have admired but have never had a chance to connect with them.

If there is anything that this pandemic reminded us of is that we are connected to each other, our survival is interlinked, our humanity is interlinked, that 'we are because they are', we need others to support us and others need us for support. Mentorship without borders and Ubuntu are the two easy low hanging fruits that will mutually benefit both the giver and the receiver. Our Society will be the greatest beneficiary because we will double the membership by showing kindness, by attraction rather than promotion, by our friendliness, by our caring. These are the values that we stand on, values that have sustained the Society over the years.

I look forward to our journey over these 12 months with enthusiasm and excitement, with hope and anticipation, with a renewed spirit of solidarity that got us through the pandemic. To be a role model of how scientists can build a more caring inclusive equitable Society in pursuit of the best evidence to guide public and health policy.

Lastly, I wish to remind you to hold the dates for next year's annual meeting which be held in Baltimore, Maryland on May 21-24, 2023, at the Marriott Hotel. I look forward to welcoming every one of you, and your mentees at our next year's meeting!"

Lehana Thabane

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

June, 2022 Issue Highlights

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



By Colin Begg, Editor

The **June** issue of *Clinical Trials* features several contributions addressing the use of patient-reported outcomes (PROs). **Paul Novotny** and colleagues address the issue of the ordering of questions/domains in a PRO, providing evidence that the ordering does not affect the results.

Bellinda King-Kallimanis and colleagues examined how frequently PROs should be reported in cancer trials to avoid under-reporting of symptoms, finding that weekly reports are necessary.

In a commentary **Ethan Basch** and

colleagues provide a list of methodological standards for the use of PROs in cancer clinical trials.

In other papers related to clinical trials policy, **Minghee Kang** and colleagues address ICH guidelines on estimands, providing a template to align these with the planned analyses of clinical trials, and **Maia Slaholz-Hillel** studied the linkage of trial registration numbers with published trials in Germany, finding that the system falls short.

As always, Society members are encouraged to submit their work to *Clinical Trials*.

New Officers of the Society for Clinical Trials

In the May, 2020 newsletter, we announced that **Dixie J. Ecklund, BSN, RN, MSN, MBA, CCRC** was voted in as President-elect of the Society (congratulations again Dixie!). Because Dixie was completing her first year on the Board of Directors, that created a vacancy on the Board. The by-laws of the Society indicate that the President can nominate people to fill board vacancies. We are pleased to announce that Lehana Thabane nominated Theodore (Ted) Lystig and the Board approved the nomination. Ted will complete the 3 years remaining in Dixie's term.

In addition, SCT Secretary Domenic Reda decided to step down in May after completion of his second term (4 years total) as Secretary.

The SCT President nominated Michael Grayling to fill the position of Secretary. This nomination was confirmed by the Board.

Congratulations to Ted Lystig and Michael Grayling in their new SCT leadership positions.



Michael Grayling, PhD Biostatistics; MSci Systems Biology; BA Mathematics

Principal Statistician, Statistical Modelling and Methodology, Janssen



Theodore (Ted) Lystig, PhD Biostatistics

SVP, Chief Analytics Officer at BridgeBio; Adjunct Assistant Professor, Div. of Biostatistics, University of Minnesota

Society for Clinical Trials 2022 Annual Meeting Wrap-up

Thank you to all who attended the 43rd Annual Meeting of the Society May 15-18, 2022 in San Diego, CA. This year, we decided to offer both a virtual attendance option as well as an in-person attendance option due to the unpredictable changes in the pandemic. After two years of virtual meetings, it was great to see many of you attend in person. Here's a summary of our attendance numbers:







	In-Person	Virtual	Total
Full Registration	332	81	413
Student	44	11	55
Developing Country	2	1	3
Student Developing Country	1	0	1
<u>Total Registration</u>	<u>379</u>	<u>93</u>	<u>472</u>
Pre-Conference Workshops	64		
In-Conference Workshops	51		
RoundTables	75		

SCT 2022 Thomas C. Chalmers Student Scholarship Finalists and Winner

This Scholarship was named in honor of Dr. Thomas C. Chalmers, who was a founding member of SCT, served on the Board and was President in 1984.

Dr. Chalmers was a dedicated early advocate of randomized trials, evidence-based medicine, pioneered methods of practices that have become standards today. Students enrolled in a degree program of an accredited college or university, or post-doctoral fellows are eligible to apply for the scholarship.

Appropriate Topics for Submission: All clinical trial-related issues including (but not restricted to) study design and data analysis methods; meta-analysis; medical, ethical or legal issues in clinical trials; diversity and inclusion in clinical trials; data entry, management, monitoring, sharing, informatics, software development, and computing as it relates to clinical trials; review of the results or methods of a class of trials; or scholarship in the history of clinical trials. Important papers illustrating applications of novel methodology in clinical trials are particularly encouraged.

<p> Winner</p> <p>Peter Godolphin University College London</p>  <p>Title: Estimating Interactions and Subgroup-Specific Treatment Effects in Meta-Analysis Without Aggregation Bias: A Within-Trial Framework (See Recipient Archive tab for full abstract)</p>	<p> Finalist</p> <p>Jiyang Wen Johns Hopkins Bloomberg School of Public Health</p>  <p>Title: Simultaneous Hypothesis Testing for Multiple Competing Risks in Comparative Clinical Trials (See Recipient Archive tab for full abstract)</p>	<p> Finalist</p> <p>Jack Wolf University of Minnesota School of Public Health</p>  <p>Title: A Permutation Procedure to Detect Heterogeneous Treatments Effects in Randomized Clinical Trials While Controlling the Type-I Error Rate (See Recipient Archive tab for full abstract)</p>
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SCT 2022 Best Poster Presentation Awards

Congratulations to the 2022 Best Poster Presentation Winners!

Katie Mellor

University of Oxford

“Inclusion of Progression Criteria in External Randomised Pilot Trial Funding Applications Submitted to UK NHR Research for Patient Benefit”

Emily Roberts

University of Michigan

“Evaluating Intermediate Clinical Endpoints for Futility Analysis in Clinical Trials”

Chris Cook

SWOG Statistic and Data Management Center

“A More Efficient Approach to Clinical Trial Data Collection: The SWOG-nCartes Pilot Collaboration



Biostatistics/Informatics Junior Faculty Award - National Multiple Sclerosis Society

To attract and train promising young investigators and doctors and help more established investigators learn new techniques, we offer a full spectrum of research and clinical training programs and early career support. We have funded many of the MS researchers and clinicians making breakthroughs today. www.nationalmssociety.org

The application can be found at: <https://www.nationalmssociety.org/For-Professionals/Researchers/Society-Funding/Training-Grants-and-Fellowships/Biostatistics-Informatics-Junior-Faculty-Award>

As part of our commitment to building a workforce of research leaders to drive pathways to MS cures, the National MS Society established a junior faculty award in **biostatistics/ informatics/computational biology**, with funding from the Marilyn Hilton MS Research Fund. The goal is to create protected time for a junior faculty member to collaborate with an established MS research group to develop expertise in MS clinical trials, real-world evidence, epidemiology, data mining, and/or other related bioinformatics research, and to inspire them to pursue critical questions in MS research throughout their career.

Deadlines 2022: Open for applications: May 18, 2022

Pre-application deadline: **August 10, 2022**, 5p.m. Eastern

Full application deadline: **August 17, 2022**, 5p.m. Eastern

Diversity & Inclusion in Clinical Trials

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) issued a [new policy](https://lnkd.in/eKPbQ_3A) on 'Diversity & Inclusion in Clinical Trials: Bioethical Perspective and Principles': https://lnkd.in/eKPbQ_3A.



International Federation
of Pharmaceutical
Manufacturers & Associations

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Diversity and Inclusion in Clinical Trials: Bioethical Perspective and Principles

Published on: 20 May 2022

As IFPMA members, we believe that the knowledge gained from clinical trials should be used to support the development and use of innovative medicines, vaccines and other therapies, in order to develop the right treatment for the right patient. We believe that patient populations in clinical trials should be reflective of the epidemiology and demographics of those who would benefit from the therapeutic agent. To this end, we believe that diversity and inclusion in clinical trials is a matter of both equity and scientific rigor and, as such, that all individuals should have equal opportunity to participate in relevant clinical trials. The biopharmaceutical industry is committed to take affirmative steps to increase clinical trial diversity.

FDA Takes Important Steps to Increase Diversity in Clinical Trials

The FDA has a new [draft guidance](#) for industry on how to develop a Race and Ethnicity Diversity Plan to enroll more participants from underrepresented racial and ethnic populations in the U.S. into clinical trials. This new resource expands on the agency's [previous industry guidances](#) centered around improving diversity in clinical research. [Learn more](#) about CTTI's contribution to helping stakeholders adopt organization-level practices that increase clinical trial diversity.



Clinical Trials News & Announcements from the Clinical Trials Transformation Initiative

Recording Now Available: Digital Health Trials Hubs Webinar

In April, CTTI conducted a [public webinar](#) introducing our new online Digital Health Trials Hub, featuring enhanced recommendations and additional resources. The refreshed recommendations are the culmination of CTTI's 2021 [Digital Health Trials work](#), which highlighted the importance of early stakeholder engagement, flexibility and tailored approaches to trial design and conduct, and flexible support of sites.

Thank you to the following speakers for their participation:

- Megan Doyle, Amgen
- Jörg Goldhahn, ETH Zurich
- Phil Green, CTTI patient caregiver representative
- Elizabeth Kunkoski, FDA
- Jeremy Wyatt, ActiGraph
- Reem Yunis, Medable

Recording Now Available: May's Expert Meeting

Last month, CTTI hosted an [expert meeting on Embedding Trials in Health Care Settings](#). The recording and meeting materials are now available. Insights gathered from the meeting will be used to refine and develop recommendations & resources for release later this year.

Thank you to the following speakers for their participation:

- Amy Corneli, Duke University
- Laura Esserman, UC San Francisco
- Ryan Ferguson, Department of Veteran's Affairs
- Kraig Kinchen, Eli Lilly
- Martin Landray, Oxford University
- Mark Steward, Friends of Cancer Research

Politico's Article: The Push for Clinical Trials 2.0

Last week, [Politico](#) published [an article](#) about how to modernize clinical trials. CTTI Executive Director Sally Okun was quoted, saying "we have the beginnings of a regulatory environment that's welcoming modernization and also fostering it."

Case Study Exchange Spotlight: Curebase

Curebase started as a company highly focused on building software to optimize decentralized clinical trials, and it has since expanded into providing services for the operationalization and conduct of these trials. Using CTTI's [Decentralized Clinical Trials recommendations](#), Curebase was able to navigate the legal and regulatory challenges presented by DCTs in order to improve their specialized DCT software platform. As a result, when the COVID-19 pandemic hit, Curebase was ahead of the curve and ready to offer the digital solutions that the clinical trials industry urgently needed.

Learn more about Curebase's approach to operationalizing and conducting DCTs using CTTI's recommendations [here](#).

ICTMC 2022

**Event Date**

3rd - 6th October 2022

**Event Location**

Harrogate Convention Centre, UK

**Email Us**

ictmc@in-conference.org.uk

The MRC-NIHR Trials Methodology Research Partnership is delighted to welcome you to the 6th International Clinical Trials Methodology Conference 2022.

ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology research. The meeting also offers valuable networking and training opportunities, with over 750 delegates from 22 countries attending in 2019.

The 2021 conference will take place in the beautiful and vibrant spa town of Harrogate, located in the heart of Yorkshire and on the edge of the Yorkshire Dales National Park, a designated Area of Outstanding Natural Beauty. Nearby is the historic city of York, as well as a number of attractive market towns, which altogether make an extended visit to the region appealing.



The meeting venue is Harrogate Convention Centre, which is both spacious and modern. A variety of accommodation options are available within a short walking distance to suit any budget. We also hope many of you will join us for the Conference Dinner which promises to be an unforgettable event at the Edwardian Royal Hall Theatre.

A diverse programme will be prepared by the Scientific Committee and Education Committee, which promises to make this a highly rewarding and enjoyable meeting for all.

We look forward to welcoming you to ICTMC 2022!

Prof Paula Williamson

ICTMC 2022 Local Organising Committee Chair

Early bird registration is available until 22 August, 2022

[Register Now](#)

Conference Registration Fee for all delegates includes:

- Attendance at all scientific sessions and entry to the exhibition hall (Tuesday 4th October to Thursday 6th October)
- Delegate bag and conference material
- Morning and afternoon tea/coffee breaks and lunch (Tuesday 4th October to Thursday 6th October – *lunch is not included on the last day of the conference*).

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Amgen strives to serve patients by transforming the promise of science and biotechnology into therapies that have the power to restore health or save lives. In everything we do, we aim to fulfill our mission to serve patients. And every step of the way, we are guided by the values that define us.

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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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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.

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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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 Dixie Ecklund (President-Elect)
 Mithat Gönen (Past-President)
 Li Chen (Treasurer)
 Michael Grayling (Secretary)

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 Alexia Iasonos (2019-2023)
 Masha Kocherginsky (2022-2026)
 Robert Lindblad (2019-2023)
 Theodore Lystig (2022-2025)
 Letitia Perdue (2020-2024)
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