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**NEWSLETTER** 

AUGUST 2022

# SCT President's Column

cized platform COVID-19 trials include the <u>World</u> <u>Health Organization COVID-19 Solidarity Thera-</u> <u>peutics Trial</u>, and the <u>RECOVERY trial</u>, which was recently awarded the David Sackett Clinical Trial of Year Award from the Society for Clinical Trials (SCT). These are just two of many examples that have opened up the possibility for using platform trials in many other disease conditions.

As the COVID-19 pandemic spread quickly around the world, the speed at which clinical trials were conducted to evaluate the effectiveness of potential new treatments and therapies intensified, too. This required that our approaches to synthesizing the continuous emerging evidence be adapted to the situation. Living systematic reviews (LSRs) – a type of review that is continually updated and incorporates relevant new evidence as it becomes available – became the method of choice to synthesize the clinical trial evidence to guide clinical guidelines and decisions. Today, we are seeing LSRs become the standard for evidence synthesis for trial evidence in any disease condition.

## "If you want to fast, go alone. If you want to go further, go together"

African Proverb

One of the main reasons why the world was successful in finding useful treatments and vaccines for COVID-19 was the solidarity underpinning the many collaborations between stakeholders - governments, academia, industry, regulators and the public. As a result, building research consortia to advance research capacity-building for pandemic

SCT President's Col-
umn
Clinical Trials Journal Highlights
44th Annual Meeting Invitation to Submit Proposals for Talks and Workshops
43rd Annual Meeting

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Society for Clinical Trials President 2022-2023 Some key lessons from the COVID-19 pandemic and their implications in shaping our

Lehana Thabane

demic and their implications in shaping our research agenda While the COVID-19 pandemic has had signifi-

cant and devastating negative impacts on almost every aspect of life - health, social, economic, academic and financial - it has also presented a great opportunity to highlight the value of science in society. In particular, the clinical trials community responded with solidarity and speed to investigate different therapies to treat the disease, and to develop and test different vaccines to prevent infections and associated serious outcomes.

#### Clinical trials in a time of uncertainty

The adoption of innovative clinical trial designs accelerated investigation into the effects of medications repurposed for treatment of COVID-19. The success of many teams that used platform trials to test different drugs for their potential to treat the disease led to the wide adoption of adaptive platform trial designs. Examples of well publi-

# **SCT President's Welcome (continued)**

preparedness is now widely advocated by everyone, including clinical trialists. We now have an opportunity to create new alliances and collaborations with other clinical trialists from around the world, and forge new and lasting partnerships across diseases and geographical locations in pursuit of a common goal.

#### **COVID-19 exposed our inequities**

COVID-19 laid bare the social inequities and lack of inclusion in research and knowledge translation. Enhancing equity, diversity and inclusion (ED&I) in research has become a research priority for all stakeholders, including professional societies like ours. In fact, in the summer of 2020, in direct response to the civil rights movements across the U.S., the SCT established its very own EDI Committee. At the time of its formation, we, as a community, promised to pay more attention to the evidence of underrepresented groups in clinical trials, and we remain as committed as ever to ensuring that trials are designed to optimize representation of all segments of the target population.

#### Moving forward

Consequences of COVID-19 and long COVID-19 continue to impact health systems and patient outcomes across a spectrum of population health conditions, including mental health. For the SCT, this presents an opportunity to design clinical trials to investigate interventions that can mitigate or reduce the impact of COVID-19.

These are not the only lessons one can take from the pandemic. My hope is that, as a community, we can continue to play our part to not only advance science, but to help reduce human suffering created by the COVID-19.

Lehana Thabane.

SCT President





By Colin Begg, Editor

Follow us on twitter <u>@clintri-</u> <u>alsj</u> to keep up to date with the latest from the journal.



# August, 2022 Issue Highlights

The **August** issue of *Clinical Trials* is primarily devoted to the 13<sup>th</sup> Annual Conference on Clinical Trials, sponsored by the University of Pennsylvania and organized by **Susan** and **Jonas Ellenberg**. This year's conference was focused on methodological issues related to cluster and steppedwedge clinical trials.

Among the articles published in the issue **Victor DeGruttola** and colleagues explain how network methods can be adapted to facilitate the design of vaccine trials.

Luke Keele and Hyunseung Kang address the impact of "spillover", whereby members of a cluster do not comply with the assigned treatment. **Larry Moulton** examines the challenges of using baseline covariate in randomization strategies for cluster randomized trials.

**David Murray** catalogues the most influential methodological articles that have helped develop this field of investigation. In other articles in the issue,

**Krista Chen** and colleagues examine the completeness of reporting of serious adverse events to ClinicalTrials.gov.

**Narelle McPhee** and colleagues examine willingness of rural patients to participate in cancer clinical trials.

As always we encourage SCT members to submit their research findings to the Society journal.



Submit a Proposal/ <u>Abstract</u>

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.

**Invited Session Proposals** 

Submission Deadline: September 30, 2022 by 11:59 pm ET

**Educational Submissions** 

Submission Deadline: September 30, 2022 by 11:59 pm ET

**Contributed Presentations (Oral/Poster)** 

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

SCT Thomas C. Chalmers Student Scholarship Submissions, SCT Sylvan Green Award Submissions, and Roundtable Topic Submissions Opening Soon!

Visit the <u>SCT website</u> for more information.

Contact SCT

Join SCT

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.



# **Highlights from SCT's 43rd Annual Meeting**

San Diego provided the perfect location for the return of SCT's live, in-person Annual Meeting, held May 15-18, 2022 at the Hilton San Diego Bayfront Hotel. With nearly 400 in-person attendees and 100 virtual participants, 9 exhibiting companies, and more than 200 presenters, "Informing Public Health Policy With Compelling Evidence" was a huge success.

On the social side, all attendees had the opportunity to become reacquainted at SCT's poster sessions, networking breaks, and Welcome Reception



It was a great start to the meeting with Dr. Worta McCaskill-Stevens, who presented the Curtis Meinert Keynote.







Dr. Mithat Gönen, SCT Past President, passed the gavel to Dr. Lehana Thabane, SCT President, during the Business Session Lunch on Tuesday, May 17th.

Attendees enjoyed the intriguing panel discussions during various sessions.

The Networking Welcome Reception on Monday, May 16th was a hit!



Debra Hill presented Drs. Ed Mills and Gilmar Reis with the prestigious 2021 David Sackett Trial of the Year Award.



Attendees interacted with presenters during the poster sessions.

The main session room was filled to listen to Dr. Robert Califf, who presented the Founders Lecture.



Experts in the field facilitated engaging roundtable discussions focused on a variety of topics.

We look forward to seeing you at the 44th Annual Meeting, May 21-24, 2023, in Baltimore, MD.

# Welcome SCT 2022-2023 New Committee Chairs and Co-Chairs

### **Program Committee:**

#### Karla Hemming (Chair)



Karla is a Professor of Biostatistics at the Institute of Applied Health Research, University of Birmingham, UK. Karla's research interests include how to design cluster and stepped-wedge trials so as to maximise their statistical efficiency and minimise their risk of bias; how to model time and treatment effect heterogeneity in longitudinal cluster trials; and the ethical issues surrounding these pragmatic trial designs, such as ethical oversight and consent. Karla has recently led the CONSORT extension for the stepped-wedge cluster randomised trial.

#### **Charity Patterson (Co-Chair)**



Charity G. Patterson, PhD, MSPH, is a biostatistician at the University of Pittsburgh and Director of the School of Health and Rehabilitation Sciences Data Center. She has worked in academic clinical trials for over 10 years and currently collaborates on multicenter trials for exercise or rehabilitation in multiple ligament knee injury, Parkinson's disease, low back pain, hearing health services, disability, and concussion.

## **Education Committee:**

Larisa Tereshchenko (Chair)



Larisa Tereshchenko, MD, PhD, is a clinical investigator, biostatistician, and data scientist with broad expertise in randomized controlled trials, epidemiology, clinical cardiology, cardiac electrophysiology, clinical pharmacology, genomics, and healthcare value. She is an Associate Staff at the Cleveland Clinic, Department of Quantitative Health Sciences, and an Associate Professor of Medicine. She is a Fellow of the Heart Rhythm Society, American Heart Association, and American College of Cardiology. Dr. Tereshchenko is an inventor on two patents, author of more than 150 manuscripts, 5 book chapters, and a member of an Editorial Board of Circulation: Arrhythmia and Electrophysiology, and Heart Rhythm Journal.

### Gustavo Jimenez-Maggiora (Co- Chair)



Gustavo Jimenez-Maggiora, MBA, is the Director of Informatics for the Alzheimer's Therapeutic Research Institute (USC ATRI), Keck School of Medicine, at the University of Southern California, providing the informatics leadership for all research programs conducted and managed by the Institute. As an informatician with an

applied research interest in the field of neurology, he provides informatics leadership as a co-investigator on several national and international initiatives and programs.

Gustavo's research interests include Clinical Research Informatics, Remote Data Capture Systems, and Natural Language Processing.

### **Communications Committee:**

#### Mei-Yin Polley (Chair)



Mei-Yin Polley, Ph.D., is Associate Professor in the Department of Public Health Sciences at The University of Chicago. She also serves as the Head of the Statistics Division and Co-Chair of the Brain Tumor Committee for NRG Oncology, a National Cancer Institute (NCI) sponsored member of the clinical trials network group. Dr. Polley is a highly regarded expert in cancer clinical trials. Her methodological interests include the design, conduct, and analysis of all phases of clinical trials, prognostic and predictive modeling, and biomarker reproducibility. She has served on many scientific governing bodies including NCI Steering Committees, the Scientific Committee of American Society of Clinical Oncology, and the US Veterans Affairs Oncology Review Panel.

#### Andrew Althouse (Co-Chair)

Andrew Althouse is a clinical trial statistician based at the University of Pittsburgh, with a particular interest in novel and emerging methods including win-ratio analyses for hierarchical composite endpoints and Bayesian adaptive clinical trial designs. He enjoys lifting weights, cooking, and drinking craft beer and cocktails. He currently resides in Pittsburgh with his wife and two sons.



#### **Development Committee:**

William Wang (Chair)



William Wang, PhD, is an Executive Director in Clinical Safety and Late Develop Statistics, Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories. Bill has 25+ years of global clinical development and statistical leadership experiences. He cochaired the ASA Safety Working Group and served as the deputy topics leader for the ICH E17 Working Group. He is an elected ASA Fellow.

#### Pralay Mukhopadhyay (Co-Chair)



Dr. Mukhopadhyay is an experienced statistician with a proven track record in drug development. He currently works as the Vice President and Head of Biometrics at Otsuka. Prior to that, he was the Head of late-stage immuno-oncology (IO) Statistics at AstraZeneca (AZ). During this period, he has made significant contributions in the development of Durvalumab, an anti-PDL1 agent, in Urothelial and Lung Cancer. Prior to joining AZ, he was at Bristol Myers Squibb, where he was involved in their late-stage oncology development program. During this time, he was instrumental in the development of several anti-cancer agents in both solid tumors and hematologic malignancies. Dr. Mukhopadhyay has represented his organization in advisory committee meetings with health authorities (HA) across the globe. He has participated in discussions with FDA, Health Canada and ANVISA (Brazilian HA) in broader development challenges of IO agents. He has been an invited speaker at the EMA's workshop on immunotherapy, ISPOR annual meetings, Duke Margolis health policy conference, Duke-Industry Statistics Workshop, Society for Clinical Trials, International Indian Statistical Association (IISA) and at the International Society for Biopharmaceutical Statistics (ISBS). He is also a core member of the FDA-industry cross-PhRMA working group evaluating statistical challenges in the design and analysis of IO trials. He has published in several peer reviewed statistical and clinical journals and has also served as a referee in reputed statistical journals. He received his PhD in statistics from North Carolina State University.

## Equity, Diversity & Inclusion Committee:

#### Kaleab Abebe (Chair)



Kaleab Abebe is an Associate Professor of Medicine, Biostatistics, and Clinical & Translational Science at the University of Pittsburgh. He directs the Center for Research on Health Care Data Center as well as the Center for Clinical Trials & Data Coordination. Dr. Abebe joined the faculty in 2009 after receiving his PhD in Statistics from the University of Pittsburgh. His collaborative research focuses on design, conduct, coordination, and analysis of multicenter randomized controlled trials (RCTs). He is the PI of two, large NIH-funded consortiums: the COPE-AKI Consortium Scientific & Data Research Center, which is developing and testing interventions to reduce morbidity and mortality in AKI survivors; and the Data Coordinating Center (DCC) for the REBIRTH Study, which will assess the effect of bromocriptine on left ventricular ejection fraction in women with peripartum cardiomyopathy. He is the Co-PI for the CaRISMA study, which is a pragmatic trial examining the effectiveness of computerized cognitive behavioral therapy (vs pain education) on pain intensity in adults with sickle cell disease (SCD). Dr. Abebe leads the DCC for the STERIO-SCD study, a phase II trial evaluating safety and tolerability of riociguat in SCD. Most recently, he led the DCC for the TAME-PKD study, which was a phase II RCT assessing safety and tolerability of metformin in polycystic kidney disease (PKD). Additionally, Dr. Abebe collaborates with the Adolescent Medicine Division on the design and analysis of cluster randomized trials in sexual violence prevention. In addition to his research collaborations, Dr. Abebe is the director of the Clinical Trials Track for the MS in Clinical Research at the Institute for Clinical Research Education. He is a standing member of the Kidney, Nutrition, Obesity, and Diabetes (KNOD) Study Section, and he is a member of the Board of Directors and chair of the Equity, Diversity, and Inclusion committee for the Society for Clinical Trials.

#### Mitra Lewis (Co-Chair)

Mitra Lewis is a Principal CSM at Emmes, supporting trials in substance use disorders throughout the lifecycle from protocol development to closeout. She collaborates closely with internal and external stakeholders to ensure cohesive protocol management, management of IP and supplies, and compliance with regulatory requirements and ICH guidelines. Prior to Emmes, she served as a Senior Research Coordinator and then Senior Research Supervisor



in the Johns Hopkins Department of Emergency Medicine. Ms. Lewis supported various NIH-funded studies, notably the Center of Excellence for Influenza Research and Surveillance and The Center for Point-of-Care Tests for Sexually Transmitted Diseases.

## **Fellows Committee:**

### Carol Redmond (Chair)



Carol K. Redmond is a biostatistician known for her research on breast cancer. She is Distinguished Service Professor Emerita in the Department of Biostatistics at the University of Pittsburgh.

Redmond graduated from Waynesburg College in 1962, with a bachelor's degree in mathematics. She completed a master's degree in 1963 and a doctorate in 1966 in biostatistics from the University of Pittsburgh. She remained at Pittsburgh as a faculty member, and chaired the department from 1983 to 1996, when she took a second adjunct position in the Department of Biometry and Epidemiology at the Medical University of South Carolina. In 1997 she became Distinguished Service Professor of Public Health at Pittsburgh, and from 1997 to 2002 she served as a vice dean, first for faculty and later for academic affairs. She retired in 2012. She became a fellow of the American Statistical Association and of the American College of Epidemiology in 1982. She was elected as a fellow of the American Association for the Advancement of Science in 2005, and of the Society for Clinical Trials in 2013.

## Valerie Durkalski (Co-Chair)



Valerie Durkalski-Mauldin is Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina and serves as the Director of the Data Coordination Unit (DCU), a unit that specializes in the design, coordination and analysis of multicenter clinical trials. She has a track record of collaboration and DCC leadership on several large multicenter clinical trials in various therapeutic areas and continues to pursue her research interests in statistical methods for the design and analysis of clinical trials. She is an active member in the Society serving as Chair of the Strategic Planning Committee, named Fellow in 2019 and was a Board member 2015-2019.

# Membership Committee:

### <u>Dikla Blumberg (Chair)</u>



Dr. Blumberg is a social psychologist with a background in self-regulation and health behavior change. She has over 16 years of experience in the field of clinical research, and for the last 12 years has worked at a global CRO, the Emmes Company. She served as the Co-PI of the Clinical Coordinating Center for the National Institute on Drug Abuse (NIDA) National Drug Abuse Treatment Clinical Trial Network (CTN) studies, and is currently the Director of the Project Leader Department at Emmes, supporting the leadership across all therapeutic areas of the company.

#### Julie Qidwai (Co-Chair)



Julie Qidwai has worked in clinical trials since 1999, beginning as a research assistant in a Phase 4 facility. She is currently a Senior Project Manager at Veristat. Much of her experience was gained in the academic setting at the University of Iowa Clinical Trials Statistical and Data Management Center. Julie has been an ACRP-certified CCRC for more than 15 years and a member of various SCT committees for the past five years. She is wellversed in project management of matrixed groups, longterm follow-up trials, transplant research, COVID trials, remote monitoring techniques, budgeting, and resource allocation.

## Nominating Committee:

### **Emily Dressler (Chair)**

Emily V. Dressler is an Associate Professor and Vice Chair in the Department of Biostatistics and Data Science at Wake Forest University School of Medicine. Her methodological interests focus on adaptive trial designs, including Phase I approaches for ordinal toxicity grading and dual toxicity/efficacy outcomes. She is lead



biostatistician with the WF NCI Community Oncology Research Program (NCORP) Research Base, which conducts multi-site trials in cancer control and cancer care delivery research. She is an active member of SCT, as current chair of the nomination committee, a former education chair, and recently completed her term on Board of Directors.

### Sameer Parpia (Co-Chair)



Dr. Sameer Parpia is a Biostatistician and Associate Professor in the Departments of Oncology and Health Research Methods, Evidence, & Impact at McMaster University, Canada. He is a senior biostatistician with the Ontario Clinical Ontario Group. His collaborative research focuses on the design, conduct, monitoring, statistical analysis and reporting of randomized clinical trials. He is the lead statistician/methodologist on randomized trials in clinical areas such as cancer, venous thromboembolism, surgery, critical care and emergency medicine. He teaches and mentors students in clinical trial methodology and applied biostatistics in the Health Research Methodology Program at McMaster University.

## **Outreach Committee:**

## **Rick Chappell (Chair)**



Rick Chappell chairs the Society's Outreach Committee and is a past president. He is Professor, Depts. of Statistics and of Biostatistics and Medical Informatics, at the University of Wisconsin.

# Student Scholarship Committee:

### **Michael Grayling (Chair)**



Dr. Grayling is a Principal Statistician in the Statistical Modeling and Methodology group at Janssen. I am currently Chair of SCT's Student Scholarship Committee and Secretary to the Board of Directors.

## Ludovic Tringuart (Co-Chair)

Ludovic Trinquart is the Director of the Center for Clinical Trials, Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, and Tufts CTSI. He also is the Director of the Data Safety and Monitoring Board program. Dr. Trinquart is a translational statistician whose scholarship is focused on innovative methods for the design and analysis of clinical trials.



# **Trial of the Year Committee:**

## Suzanne Dahlberg (Chair)



Suzanne Dahlberg is the Assistant Director of Clinical Trial Biostatistics and Data Management for the Institutional Centers for Clinical and Translational Research at Boston Children's Hospital, an Associate Professor at Harvard Medical School, and a statistician collaborating with the hospital's Division of Pulmonary Medicine. She has over 15 years of research experience, having previously worked in pediatric and thoracic oncology at Dana-Farber Cancer Institute and the ECOG-ACRIN Cancer Research Group. She holds a doctorate in Biostatistics from Harvard University.

### Andrew Cook (Co-Chair)



Andrew Cook is a public health physician by training, and a trials methodologist by accident. His main areas of interest are pragmatic trials of complex interventions, research topic prioritisation, and post award management. He currently splits his time between being Associate Director of the Southampton Clinical Trials Unit, and the UK's National Institute for Health and Care Research's Evaluation, Trials and Studies Coordinating Centre based at the University of Southampton in the UK.



# **5th TMRP Webinar Series Announced!**

We are delighted to announce that UKTMN will be hosting the 5th TMRP webinar programme starting in September 2022.

The UKTMN began hosting the TMRP methodology webinars in 2019, and we are delighted to bring you a varied and interesting programme for the fifth series. See below for more information and to access the event page for each session.

OPEN ACCESS TOOLS AND RESOURCES FOR ADAPTIVE DESIGNS IN CLINICAL TRIALS

Thursday 27 September 2022 - 14:00-15:00 Hosted by Liz Allen and Philip Pallmann

DATA INTEGRITY

Wednesday 19 October 2022 - 11:00-12:00 Macey Murray (UCL)

WOULD YOU BE HAPPY TO BE CONTACTED ABOUT RESEARCH?

Monday 7 November 2022 - 11:00-12:00 Sarah Lawton (Keele University)

RESULTS OF THE PERSEVERE PROJECT

Thursday 1 December 2022 - 12:00-13:00 Will Cragg (University of Leeds)

DEVELOPING AN EDUCATIONAL AND TRAINING INTERVENTION FOR NEONATAL TRIAL RECRUITERS: THE TRAIN PROJECT

Tuesday 17 January 2023 - 12:00 - 13:00 Valerie Smith (Trinity College Dublin)

**IMPLEMENTATION OF METHODS RESEARCH** 

Monday 27 February 2023 - 11:00 - 12:00 Katie Gillies (University of Aberdeen)

Best wishes Professor Paula Williamson



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).

#### Contact



In Conference Ltd Unit 1, Q Court Quality Street Edinburgh EH4 5BP Tel: +44 (0)131 336 4203 Email: ictmc@in-conference.org.uk PAGE 12



Workshops Announced for

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# ICTMC 2022!

We are pleased to announce two important updates on our International Clinical Trials Methodology Conference (ICTMC), 3<sup>rd</sup> - 6<sup>th</sup> October 2022 in Harrogate. If you can advertise to anyone you think might be interested please do!

## (1) Training workshops announced

The pre and post conference workshop schedule has now been confirmed and the workshop titles and presenters are outlined below:

# Monday 3rd October, 10:00 – 13:00

**W1.1: Finding, critically appraising, and using a core outcome set (COS) for your trial** *Paula Williamson, Declan Devane, Karen Matvienko-Sikar, Sarah Gorst, Nicola Harman* 

W1.2: Introduction to optimisation experiments for complex interventions within the Multiphase OptimisationStrategy (MOST) frameworkSamuel Smith, Michelle Collinson, Rebecca Walwyn

**W1.3:** Using the PeRSEVERE guiding principles to prepare for and manage participation changes in clinical trials *William Cragg, Katie Gillies, Lauren Moreau, Puvan Tharmanathan* 

W1.4: Implementing CDISC's SDTM retrospectively for data sharing Sharon Kean

**W1.5: Estimands in randomised trials: practical guidance to help get the right answer to the right question** *Brennan Kahan, Suzie Cro, James Carpenter* 

# Monday 3rd October, 14:00 – 17:00

W2.1: Routine Data Suzanne Hartley, Kimberley Watson, Andy Rees & Macey Murray, Sharon Love, Matt Sydes

W2.2: Clinical Trial Monitoring Sharon Love, Victoria Yorke-Edwards, Lisa Fox

W2.3: Planning & Delivering Effective and Engaging Training to Clinical Trial Staff

Sara Brookes, Razia Meer-Baloch

**W2.4: Good practice in planning, conducting and reporting pilot trials** *Sandra Eldridge, Christine Bond* 

# Thursday 6th October, 13:30 - 16:30

W3.1: Statistical and practical aspects of the design and analysis of Multi-Arm Multi-Stage (MAMS) Platform Trials Babak Choodari-Oskooei, Matt Sydes, Max Parmar

W3.2: eConsent in clinical trials UK Trial Managers' Network, Trials Methodology Research Partnership, UKCRC CTU Network Collaborative Group

**W3.3: Triangulating evidence from observational data and randomized controlled trials for precision medicine** *Jack Bowden, Beverley Shields* 

You can register now as part of the <u>main conference registration</u> or book to attend the <u>workshops only</u>. Places are limited and so you are advised to book as soon as possible to secure your place.

# Best wishes

Professor Paula Williamson

#### PAGE 14

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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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Amgen strives to serve patients by transforming the promise of science and biotechnology into theraples 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 industrysponsored RCTs. We provide expertise in planning, conduct, monitoring, and analysis of clinical trials.

#### Silver Sponsor BERRY CONSULTANTS

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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Webmaster: John Hepler Advisor to Executive Committee: Domenic Reda

#### Executive Committee (2022-2023)

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

#### Board of Directors (2021-2022)

Kaleab Abebe (2020-2024) Jody Ciolino (2022-2026) Denise Esserman (2021-2025) Alexia Iasonos (2019-2023) Masha Kocherginsky (2022-2026) Robert Lindblad (2019-2023) Theodore Lystig (2022-2025) Letitia Perdue (2020-2024) Julianna Tolles (2021-2025)

Committee Chairs (2022-2023) Program: Karla Hemming (Chair) Charity Patterson (Co-Chair) Sharon Yeatts (Past Chair) Education: Larisa Tereshchenko (Chair) Gustavo Jimenez-Maggiora (Co- Chair) Sonia Jain (Past Chair)

#### **Communication:**

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