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42ND ANNUAL MEETING

MAY 17-20, 2021



Advancing Rigorous and Ethical Trials in the Pandemic Era

REGISTRATION IS NOW OPEN



FOUNDERS KEYNOTE SPEAKER
H. Clifford Lane, M.D.
Clinical Director
 National Institute of Allergy and Infectious Diseases



CURTIS MEINERT KEYNOTE SPEAKER
Martin Landray, MB ChB, Ph.D.
Professor of Medicine & Epidemiology
 Oxford University

SCT has partnered with Vision Matrix for the online meeting platform and welcomes you to join us

**May 17th through the 20th
 from 10:00 am - 3:00 pm ET.**

The SCT Annual Meeting Task Force has planned a robust program for our attendees and we welcome you to experience Educational Workshops, On-Demand and Simulive Sessions and so much more!

Please visit our Annual Meeting [website](#) for all the latest up to date information!

Please click [here](#) to register

Registration Policy

All payments must be made in USD (\$) to ensure that the full amount is received. Entry to the conference will not be permitted unless full payment has been received.

Cancellation Policy

Written cancellations received via email to registration@sctweb.org by May 10th and will be refunded less a \$50 administrative fee. There will be no refunds issued after May 10th. Failure to attend without notice will not result in a refund.

PLATFORM VENDOR: VISION MATRIX

Vision Matrix's unique blend of large-scale creativity with meticulous project management produces turn-key solutions for our clients at a remarkable value. Each production provides us with a new vision, a new challenge, and a new opportunity to provide unique results that not only meet, but consistently exceed, our clients' expectations. Vision Matrix operates with the best that advanced equipment has to offer, and with a level of imagination and competency you won't find elsewhere. Vision Matrix brings your visions to light.

**Join NIH's Dr. H. Clifford Lane for a Compelling
SCT Founders Keynote Address
May 17, 2021 at 10:00 AM EST**

Get ready for a dynamic kickoff to the Society for Clinical Trials (SCT) 2021 Virtual Annual Meeting with the Founders Lecture, the first of three special Keynote presentations.

On Monday, May 17, 2021 at 10:00 AM EST, join us virtually for "Conducting Clinical Research in the Setting of an Outbreak: From HIV to Ebola to COVID-19." This Founders Lecture Keynote will be delivered by H. Clifford Lane, MD, Clinical Director and Deputy Director for Clinical Research and Special Projects for the National Institute of Allergy and Infectious Diseases.

**Join SCT for the
Curtis Meinert Keynote Lecture
May 18, 2021 at 10:00 AM EST**

A "can't miss" second Keynote presentation!

Make plans today to join Professor Martin Landray, Professor of Medicine and Epidemiology at the University of Oxford, as he delivers the Curtis Meinert Keynote Lecture entitled "Better Trials for Better Health."

This special presentation will be delivered on Tuesday, May 18 at 10 AM ET. This lecture will be the second of two thought-provoking Keynote presentations offered as part of the Society for Clinical Trials 42nd Annual Meeting with the theme "Advancing Rigorous and Ethical Trials in the Pandemic Era," to be held virtually May 17 - 20, 2021.

Be sure to register by May 10 -to secure your place at this dynamic, multidisciplinary symposium.

**Join SCT for the
David Sackett Trial of the Year Presentation
On International Clinical Trials Day
May 20, 2021 at 10:00 AM EST**

International Clinical Trials Day will highlight the immense and positive impact trials have on the world. In recognition of this annual celebration, make plans today to attend the Society for Clinical Trials' (SCT) David Sackett Trial of the Year presentation.

At 10:00 AM EST on May 20, SCT will present the prestigious Trial of the Year award as part of its 42nd Annual Meeting, "Advancing Rigorous and Ethical Trials in the Pandemic Era." Each year since 2008, SCT has bestowed this award to a randomized, controlled trial in honor of David L. Sackett, a dedicated long-time SCT member and a pioneer in evidence-based medicine and champion of clinical trials.

To make sure you have the latest information for this special live presentation, be sure to register by May 10. As an added benefit, don't forget all content from the Annual Meeting, to be held May 17 - 20, 2021, will be available up to 90 days after the live event.

[Register here](#)

Society for Clinical Trials Forms New Committee on Outreach



By Rick Chappelle
Outreach Committee Chair

I am pleased to announce that the Society, under the leadership of President Susan Halabi, has created an Outreach Committee in order to collaborate with other societies and with trialists around the world. The purpose is to broaden our profile, attract new members, and improve the conduct of clinical trials. Our mission statement, as recently approved by the Executive Committee, is:

'The mission of the Outreach Committee is to establish and advance relationships between the SCT and other societies and organizations at the national and international levels for the purposes of expanding the programs, activities and membership of the SCT in a man-

ner which is mutually beneficial to both the SCT and collaborating organizations. These societies and organizations include but are not limited to medical, operational, regulatory, academic, and statistical groups.

Such activities can include, but again are not limited to, joint organization or sponsorship of educational, training and outreach activities.'

The Committee's membership currently includes Ivan Chan, Rick Chappell (chairman), Li Chen, Scott Evans, Susan Halabi, Amarjot Kaur, Anne Lindblad (cochair), Mathew Sydes, and Pam Tenaerts. We are currently considering collaborations with societies and academic groups in China, England, the European Union, Korea, Latin America, and China. Initial ideas including access to webinars giving introductions to data safety monitoring boards and clinical trials in general. As conditions allow, in-person opportunities and exchanges will also be pursued. Anyone with useful contacts and ideas are encouraged to contact me at chappell@stat.wisc.edu.

The SCT 2021 Call for Volunteers Portal is open!

Submit your interest by May 31, 2021

SCT Members,

SCT Volunteers are the heart of our professional society. Your skills, talents and perspectives are welcomed to continue to build a strong, energetic and a dynamic society.

If you are interested in serving as a Volunteer, we welcome you to the 2021 SCT Volunteer Portal and invite you to submit your interest by 11:59 pm CT on May 31st.

Committee Chair and Co-Chair roles serve a One-Year Term. Committee Members serve a Three-Year term, and Board of Directors Members serve a Four-Year Term.

Please complete the following steps to submit your interest:

- Submit your interest to serve by going to <http://www.sctweb.org/>
- Log in the **Member area** with your user name and password
- Navigate to the right of your screen and **click on Member Volunteering**
- Follow the prompts in the portal and please be sure to answer all questions
- Please download the Conflicts of Interest document and disclose financial and other relationships in accordance with the SCT Conflict of Interest (COI) Policy. You can also upload the form once complete!

The whole process will take you less than 5 minutes to complete, and it is only necessary to complete these steps once for your term of service.



Highlights of Recent Issues

Dec 2020 & Feb 2021



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



By Colin Begg, Editor

December 2020

The December issue of *Clinical Trials* contained, as usual, papers on an eclectic set of topics of concern to clinical trialists. **Behnood Bikdeli** and colleagues compile data to demonstrate the increasing trend of using surrogate endpoints in non-inferiority cardiovascular clinical trials, a method that is prone to misinterpretation.

Oswald Tetteh and colleagues have studied problems associated with successful registration of clinical trials to ClinicalTrials.gov, demonstrating how difficult it is to accomplish this successfully. They present a checklist that has radically improved compliance at their own institution.

Dave Wendler has examined ethical issues concerning the use of vulnerable subjects in clinical trials, coming up with a six-step decision procedure to help decide when this is appropriate.

Finally, **Anthony Hatswell** and colleagues study the age-old question of the use of historical controls, providing guidance when this represents the only control option. 2020 has been a challenging year for the editors, as submissions of articles to the journal have increased by approximately 40% over the preceding year. It remains

to be seen whether this represents a one-time COVID-19 blip, or a longer-term trend.

February 2021

The February issue of *Clinical Trials* featured several articles on informed consent and clinical trial participation. **Hannes Kahrass** and colleagues evaluate details of risk-benefit communication in informed consent documents for phase I/II trials, describing shortcomings and suggesting improvements.

In a subsequent commentary **Jonathan Kimmelman** laments the general absence of quantitative information characterizing risks and benefits.

Jason Silberlust and colleagues report that patients are more willing to give informed consent to participate in clinical trials under the guidance of their specialty physicians rather than their primary care physicians.

Sze Choong Wong and colleagues report that for patients with Duchenne muscular dystrophy, their parents/guardians and especially their doctors are unwilling to recommend participation in placebo-controlled trials.

We note that for the year 2020 there were 495 submissions to the journal, versus 350 in the previous year, reflecting an unusual consequence of the COVID-19 pandemic witnessed also by many other scientific journals.

Next issue of this newsletter we will cover the April, 2021 issue.

Society for Clinical Trials Announces a New Student Award Opportunity

SCT Members,

We are pleased to announce a new award opportunity that is being managed by the newly formed SCT Equity, Diversity and Inclusion Committee in an effort to extend invitations to students from underrepresented groups in the fields of biostatistics, statistics, epidemiology, nursing, data sciences and computer science to promote a racially and ethnically diverse SCT membership.

This new Award category will be guided by the definitions of race and ethnicity used by the National Institutes of Health and will serve as a pipeline for students from underrepresented groups to have a one year mem-

bership of SCT and registration for the Annual Meeting sponsored by SCT.

In addition, all awardees will be invited to attend a welcome reception with the SCT President, Chair and Members of the ED&I committee and will have an opportunity to network with SCT Leadership.

Announcements for this award went out in March and nominations were due April 23, 2021.

Nominees did not need to be current or previous members of SCT, and each institution was allowed to nominate up to two students.

Awardees will be notified by May 7, 2021.

Are You Following the Society for Clinical Trials Twitter Feed?

SCTorg @SCTorg · Apr 26

More and more clinical trials are considering multiple endpoints. Learn about the state-of-the-art methods for designing trials with multiple endpoints by joining Sheng Luo and Ying Yuan for their workshop on Wed 19 May at 1pm ET #SCT2021 Register: sctweb.org/meeting/#regi...

SCTorg Retweeted

Kaleab Abebe, PhD @coachabebe · Apr 24

Pro tips for anyone who still hasn't recorded their invited session @SCTorg (which is due on Monday): 1) 15min seems like a lot, but it isn't; 2) 15min is greater than 10min, which is what contributed sessions have to deal with; and 3) dress comfortable yet professional.



SCTorg @SCTorg · Apr 23

Interested in #ValueofInformation, a method for research prioritization and design that ensures value for money from research? Then join @NataliaKunst, @WeltonNicky and @ConVOIgroup on May 19 10am ET for an introduction to these methods #SCT2021. Register: sctweb.org/meeting/#regi...

SCTorg @SCTorg · Apr 21

Join @HMoradiMD, Ann Meeker-O'Connell & Ted Lystig Thurs May 20 at 1pm ET for their workshop as they discuss accelerating evidence generation through @CTTI_Trials's #qualitybydesign (#QbD) approach. #clinicaltrials #SCT2021

SCTorg @SCTorg · Apr 20

International Clinical Trials Day is May 20! In one month, SCT will highlight the immense and positive impact trials have on the world. Make plans today to attend the SCT Annual Meeting and learn about the David Sackett Trial of the Year.

SCTorg @SCTorg · Apr 16

SCTorg @SCTorg · Oct 20, 2020

Human challenge trials include deliberately infecting some of the participants. Could they be used safely and effectively in covid-19 research? @KimmelmanJ @Stevelfoffe @charlesweijer @SpencerPHeay

Dozens to be deliberately infected with coronavirus in UK 'human chall... Proponents of the trials say they can be run safely and help to identify effective vaccines, but others have questioned their value. [nature.com](https://www.nature.com)

SCTorg @SCTorg · Apr 16

Recruitment and retention in #clinicaltrials for substance use disorder treatment is hard! Lucky for you, representatives from @NIDAnews will discuss challenges, lessons from the pandemic, and best practices. Tune in May 19, 2-3pm EST. Register at sctweb.org/meeting/#regis...

SCTorg @SCTorg · Apr 16

Want to gain hands on experience and insights from a cross-industry international working group on how the Estimand Addendum to ICH E9 helps interdisciplinary teams to formulate clinical trial objectives? Sign up for the workshop on Thurs May 20 1pm ET #SCT2021

SCTorg Retweeted

Liz Garrett-Mayer, PhD @LGM_Biostats · Apr 12

#SCT2021 invited session: Different Clinical Trial Analyses for Different Stakeholders. Opportunities for "persuasive evidence" to drive a more personalized risk/benefit discussion of product use. Ball, Herson, Hendrickson, Gaffney, Garrett-Mayer. Join us 5/17, 2pm EDT! @SCTorg

SCTorg @SCTorg · Mar 29

Do you still think a double-masked covid trial means everyone wears two masks? Then you should register for SCT's annual meeting and sign up for Yves Rosenberg's workshop to learn all the basics.

SCTorg @SCTorg · Mar 25

The #RECOVERYtrial aims to identify treatments for COVID. If you want to learn more, you can hear about it from PI @MartinLandray at the annual @SCTorg (virtual) meeting. Will his presentation exceed 280 characters? Register to find out: sctweb.org/meeting/#prog...

SCTorg @SCTorg · Apr 17

Basket or umbrella? There is still time to choose which design for your clinical trial, no matter the weather. Join SCT prez Susan Halabi and Mary Redman for a workshop on biomarker driven trials for precision medicine on May 17. Register today: sctweb.org/meeting/#regis...

SCTorg 763 Tweets Follow

Detection of atypical data in multicenter clinical trials using unsupervis... Background/Aims A risk-based approach to clinical research may include a central statistical assessment of data quality. We investigated... journals.sagepub.com

SCTorg Retweeted

Colin Begg @ColinBBegg · Nov 8, 2019

Phase I/II clinical trials aim at identifying active agents at a dose that is safe. This study establishes the importance of re-estimating the maximum tolerated dose during the expansion phase. @SCTorg #clinicaltrials @FDAOncology

journals.sagepub.com/doi/pdf/10.117...

Sequential or combined designs for Phase I/II clinical trials? A simulation study

Caroline Rosson^{1,2}, Aurélie Bardet^{1,3}, Birgit Goeger³ and Xavier Paoletti^{1,2}

Society for Clinical Trials 2021 Virtual Annual Meeting Schedule

Listed Times are Eastern Time Zone in the United States

MONDAY, MAY 17 TUESDAY, MAY 18 WEDNESDAY, MAY 19 THURSDAY, MAY 20

SCT Annual Meeting - Monday, May 17, 2021				
9:00 - 10:00	New Member Welcome & Orientation Session			
10:00 - 11:30	Welcome - SCT President - <i>Dr. Susan Halabi</i> Founders Lecture Keynote <i>Dr. Lane - Conducting Clinical Research In The Setting Of An Outbreak: From HIV To Ebola To Covid-19</i>			
11:30 - 12:30	Session Proposal 1 Seema Shah & Charles Weijer <i>Ethics and future of human challenge trials with SARS-CoV-2 to speed vaccine development</i>	Session Proposal 2 Qilu Yu <i>Managing Pragmatic Clinical Trials in the Time of COVID-19</i>	Session Proposal 3 Sonia Jain <i>Design, Implementation, and Analysis of N-of-1 Clinical Trials</i>	Session Proposal 4 SCT Committee Updates
12:30 - 1:00	Lunch			
1:00 - 2:00	Contributed Sessions 1 <i>Statistical Design I</i>	Contributed Sessions 2 <i>Statistical Analysis I</i>	Contributed Sessions 3 <i>Data Management I</i>	Contributed Sessions 4 <i>Study Co-ordination I</i>
2:00 - 3:00	Session Proposal 6 James Albert <i>Design and Implementation of a Vaccine Trial in a Pandemic - mRNA-1273 Phase I Trial</i>	Session Proposal 7 Greg Ball <i>Different Clinical Trial Analyses for Different Stakeholders</i>	Session Proposal 8 Saurabh Mukhopadhyay <i>Leveraging External Evidence in Clinical Research using Novel Statistical Methods</i>	Session Proposal 9 Shahrul Mt-Isa <i>Benefit-Risk Assessment in Clinical Trials with Individual Patient Needs in Mind</i>
3:00 - 3:30	Networking			

MONDAY, MAY 17 TUESDAY, MAY 18 WEDNESDAY, MAY 19 THURSDAY, MAY 20

SCT Annual Meeting - Tuesday, May 18, 2021				
10:00 - 11:30	Curtis Meinert Keynote <i>Professor Martin Landray</i>			
11:30 - 12:30	Session Proposal 10 Ashley Wegel <i>Adaptive COVID-19 Treatment Trial (ACTT) Data Management: Ensuring Success in a Constantly-Evolving, High-Demand Pandemic Environment</i>	Session Proposal 11 Erinn Hade <i>Sample size re-estimation: Reflections on implementation and extensions to complex designs</i>	Session Proposal 12 Jonathan Cook <i>The ASPIRE guidance on surgical placebo controls in randomised trials</i>	Session Proposal 13 Lehana Thabane <i>INCREASING DIVERSITY IN CARDIOVASCULAR CLINICAL TRIALS: ENGAGEMENT, RECRUITMENT, LEADERSHIP</i>
12:30 - 1:00	Lunch			
1:00 - 2:00	Chalmers Student Scholarship Finalists: Subodh Selukar Xiaoyu Tang Siyun Yang	Contributed Sessions 5 <i>Statistical Design II</i>	Contributed Sessions 6 <i>Outcomes I</i>	Contributed Sessions 7 <i>Study Co-ordination II</i>
2:00 - 3:00	Session Proposal 14 Kert Viele <i>Bayesian Modeling in COVID-19 - Disease Modelling, Therapeutics, and Vaccines</i>	Session Proposal 15 Janel Fedler <i>The Impact of COVID-19 on the Conduct of Trials in the NeuroNEXT Network</i>	Session Proposal 16 Monica Taljaard <i>Pragmatic trials: key unresolved ethical issues and the need for guidance</i>	Session Proposal 17 Susan Halabi <i>SCT New Committees and DMC Training Initiative</i>

In-Conference Workshop 2
Sheng Luo
Design Clinical Trials with Multiple Endpoints: Methods and Applications

Society for Clinical Trials 2021 Virtual Program (continued)

Listed Times are Eastern Time Zone in the United States

MONDAY, MAY 17 TUESDAY, MAY 18 WEDNESDAY, MAY 19 THURSDAY, MAY 20

SCT Annual Meeting - Wednesday, May 19, 2021					
9:00 - 10:00	Presentation of the Class of 2021 Fellows				
10:00 - 11:00	Contributed Sessions 8 <i>Statistical Analysis II</i>	Contributed Sessions 9 <i>Statistical Design III</i>	Contributed Sessions 10 <i>Ethics</i>	Contributed Sessions 11 <i>Study conduct during COVID-19</i>	In-Conference Workshop 3 Anna Heath <i>Designing Clinical Research to Inform Decision-Making using Value of Information</i>
11:00 - 12:00	Session Proposal 18 Tyler Bonnett <i>Design and Implementation of Clinical Trials in a Pandemic - Reflecting on the ACTT Studies</i>	Session Proposal 19 Chen Hu <i>Recent developments in quantitative benefit-risk assessment in clinical trials</i>	Session Proposal 20 Laura Levit <i>It Can Be Done! Equitable, Accessible, and Efficient Clinical Trials Through Streamlined Protocol Designs and Requirements</i>	Contributed Sessions 12 <i>Statistical Analysis III</i>	(Continued from previous session)
12:00 - 1:00	Business Meeting with Lunch				
1:00 - 2:00	Contributed Sessions 13 <i>Statistical Design IV</i>	Contributed Sessions 14 <i>Statistical Analysis IV</i>	Contributed Sessions 15 <i>Misc I</i>	Contributed Sessions 16 <i>Study Co-ordination III</i>	In-Conference Workshop 4 Yves Rosenberg <i>Essentials of Clinical Trials</i>
2:00 - 3:00	Session Proposal 21 Dee Blumberg <i>Challenges and Best Practices for Recruitment and Retention During the COVID Pandemic</i>	Session Proposal 22 Holly Janes <i>Current issues in the design and analysis of COVID-19 vaccine efficacy trials</i>	Session Proposal 23 Darren Courtney <i>Choices, choices: Selecting, defining, and measuring outcomes for young people with depressive disorders</i>	Session Proposal 24 Pralay Mukhopadhyay <i>Challenges with COVID-19 Vaccine Development and Assessing Impact of the Pandemic on Oncology Trial Outcomes</i>	(Continued from previous session)

MONDAY, MAY 17 TUESDAY, MAY 18 WEDNESDAY, MAY 19 THURSDAY, MAY 20

SCT Annual Meeting - Thursday, May 20, 2021					
9:30 - 10:00	Pre-recorded talks Q&A - Session 1				
10:00 - 11:30	Trial of the Year TBA				
11:30 - 12:30	Session Proposal 25 Rema Raman <i>Impact of the COVID-19 Pandemic on the Design, Operations and Analysis Plans of Dementia Trials</i>	Session Proposal 26 Lehana Thabane <i>Design and conduct of pilot and feasibility trials: focus on unresolved issues</i>	Session Proposal 27 Thomas Cook <i>Missing Data in Clinical Trials: principles, planning, prevention</i>	Session Proposal 28 Lauren Balmert <i>Operational Innovations in Academic Data Analysis and Coordinating Centers</i>	(Continued from previous session)
12:30 - 1:00	Lunch				
1:00 - 2:00	Contributed Sessions 17 <i>Statistical Design V</i>	Contributed Sessions 18 <i>Data Management II</i>	Contributed Sessions 19 <i>Outcomes II</i>	In-Conference Workshop 5 Stefan Englert <i>How the estimand addendum to the ICH E9 guideline helps structure clinical objectives, analyses, and conclusions - a series of oncology case studies</i>	In-Conference Workshop 6 Zachary Hallinan <i>Accelerating evidence generation through quality by design</i>
2:00 - 3:00	Contributed Sessions 20 <i>Misc II</i>	Contributed Sessions 21 <i>Study Co-ordination IV</i>	(Continued from previous session)	(Continued from previous session)	(Continued from previous session)
3:00 - 3:30	Pre-recorded talks Q&A - Session 2				
3:00 - 4:00	End of meeting				

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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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Save the Dates - Upcoming SCT Annual Meetings



42nd Virtual Annual Meeting
May 17-20, 2021



43rd Annual Meeting
May 15-18, 2022
San Diego, California
USA

Information About



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 Algonquin Road
 Suite 550
 Arlington Heights, IL 60005
 (847) 427-8010

Executive Director
 Kevin Bragaw
Administrative Assistant
 Angie Stark

info@sctweb.org
 www.sctweb.org



Executive Committee
 Susan Halabi (President)
 Mithat Gönen (President-Elect)
 Dean Fergusson (Past-President)
 Domenic Reda (Secretary)
 Li Chen (Treasurer)

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Committee Chairs

Program:	Jonathan Cook (Chair) Toshimitsu Hamasaki (Co-Chair)
Education:	Michael Grayling (Chair) Sin-Ho Jung (Co-Chair)
Communications:	Wendy London (Chair)
Development:	Ivan Chan (Chair) Nicole Close (Co-Chair)
Fellows:	Elizabeth Thom (Chair) J. Jack Lee (Co-Chair)
Membership:	Dixie Ecklund (Chair) Jody Ciolino (Co-Chair)
Nominating:	Virginia Howard (Chair)
Student Scholarship:	Elizabeth Garrett-Mayer (Chair) Cody Chizuan (Co-Chair)
Trial of the Year:	Marc Buyse (Chair) Debra Condon (Co-Chair)
Webmaster:	John Hepler
Newsletter Editor:	Domenic Reda