SOCIETY FOR CLINICAL TRIALS

VOLUME 31,#8 NOVEMBER 2020

INSIDE THIS ISSUE:

Calendar of Events	1
SCT 42nd Annual Meeting Submissions	2-4
SCT 2020 Virtual Program	5-6
SCT Committee Chairs	7-10
CTTI News	10-11
13th Annual U Penn Conference	11
ICTMC 2022 - date change	11
Call for 2021 Fellows Nominations	12
SCT Officer Nominations	12
Trial of the Year Nominations	13
IMPACT-AD Webinar	13
SCT Spotlight—Paul Meier and the Polio Vaccine pare 2	14-15
SCT Long-Standing Members 5-9 years	16
SCT Sponsors	17
Future SCT Meetings	18
Information About SCT	18

CALENDAR OF EVENTS

Event	Date	For More Information
2020 SCT Virtual Program	Through April 30, 2021	Register Here For the Virtual Meeting Program
IMPACT-AD Webinar	December 15, 2020	See page 12
SCT 2021 Session Proposals	New Date! Due January 8, 2021	To submit your proposal, please click here
SCT 2021 Contributed Abstracts	New Date! Due January 8, 2021	To submit your proposal, please click here
SCT 2021 Educational Workshop Proposals	New Date! Due January 8, 2021	To submit your proposal, please click here
Thomas Chalmers Student Scholarship Applications	New Date! Due January 8, 2021	To submit your proposal, please click here
Sylvan Green Physician/Dentist Investigator Award Applications	New Date! Due January 8, 2021	To submit your proposal, please click here
SCT 2021 Fellow Nominations	Due January 15, 2021	To submit your proposal, please click here
SCT 2021 Trial of the Year Nominations	Due January 15, 2021	To submit your proposal, please click here
13th Annual U Penn Conference on Statistical Issues in Clinical Trials	April 21, 2021	https://www.cceb.med.upenn.edu/events/13th-university-pennsylvania-conference-statistical-issues-clinical-trials
Society for Clinical Trials 42nd Annual Meeting	May 16-19, 2021	http://www.sctweb.org/meeting/

DUE TO THE CHALLENGES OF THE PANDEMIC SCT IS PLEASED TO ANNOUNCE WE ARE EXTENDING THE DEADLINES FOR ABSTRACTS FOR THE SCT ANNUAL MEETING MAY 16-19, 2021 Chicago, IL

The theme for the 42nd Annual Meeting will be "Advancing Rigorous and Ethical Trials in the Pandemic Era"

Submissions relevant to COVID-19 clinical trials, the impact of COVID-19 upon non-COVID-19 clinical trials, and also non-COVID-19 clinical trials related research are welcome

All submissions must be made via the SCT website

Session Proposals *(previously called "Invited Sessions")*

Updated Deadline for further submissions January 8, 2021

To submit your proposal, please click here

Proposals for a session which bring together a set of speakers and discussants to present the latest findings on an important and emerging issue in an area of clinical trials research, or which provide an up to date overview of a key aspect of clinical trials design, conduct, analysis or reporting, are very welcome.

Key Information

- Session formats can vary; however, the duration should be 90 minutes in length and there should be a session chair.
- A session typically includes 3-5 participants including the chair.
- Two of the most successful formats used in the past are having 2-3 speakers with a discussant, or a structured and planned panel discussion with 3-4 panelists from different perspectives.

Your proposal should contain the following information

- Title
- Speakers with affiliation and e-mail addresses for each
- Session organizer (please add this individual's details in the additional contributors' section)
- Session chair (please add this individual's details in the additional contributors' section)
- Proposed session type (Invited talks, Panel, other)
- Written description of session to include focus, content, timeliness, appeal, and relevance to the theme, as well as specific titles for each speaker's talk (if applicable)

Contributed presentations for an Oral or Poster

Deadline extended to January 8, 2021

To submit your proposal, please click here

An abstract for a short presentation of a topic relevant to the clinical trials community is requested.

Key Information

- Submitter will be requested to specify if they wish to be considered for both an oral and a poster presentation or only a poster presentation.
- Those selected for an oral presentation will be grouped with other oral presentations with a similar theme in the program.
- Papers are usually allotted 15 to 20 minutes (including time for questions).

- Submitted abstracts should be as accurate and specific as possible as they will be included in the conference program.
- Preference will be given to abstracts that report completed investigation, analyses, designs, or methodological work over those that promise to report a work in progress if accepted. Similarly, preference will be given to new work and novel topics over reviews without any clear development or progression from previous research and understanding. Training or learning focused submissions should be submitted as educational submissions.

Your proposal should contain the following information

- Title in all capital letters with no abbreviations
- Full names of authors without degrees or titles
- Institutional affiliation, city, state or country of first author (additional contributors or authors can be added in space provided)
- Text of the abstract (500 word limit)

Educational Workshop Proposals

Deadline extended to January 8, 2021

To submit your proposal, please click here

Some of the themes we are interested in for workshops/tutorials include:

- Clinical trial conduct: recruitment and retention, ethics, study start up/close-out in multi-center trials, international trials, trial evolution over time.
- Patient reported outcomes and patient perspectives in clinical/trials decision making Trial design and/or analysis: innovations in trial methods and outcomes Artificial intelligence and 'data deluge'
- Data sharing: Preparing, submitting and accessing trial data from data sharing platforms

Pre-Conference Educational Workshop Proposals are courses on topical methods or issues related to clinical trials typically lasting around 4-hours, though 2-hour sessions will also be considered. The focus will be on education and training and will include hands-on work and plenty of time for questions and discussion. Please include a bullet point description of how the workshop will be structured (e.g. 10-min presentation followed by 30-mins of small group work with hands-on use of software etc).

In-Conference Tutorials are interactive sessions on a method or topic related to clinical trials. Tutorial sessions may include small-group work, hands-on use of tools and software, troubleshooting and 'ask-the-expert' time. In-conference tutorial sessions typically last 90 minutes.

Your proposal should contain the following information

- Primary contact (with affiliation and email address)
- Whether the proposal is tied to the overall theme (including a brief description)
- Category
- Target Audience
- Description of how the tutorial will be structured (e.g. 10-min presentation followed by 30-mins of small group work with hands-on use of software etc)

SCT Thomas C. Chalmers Student Scholarship

Deadline extended to January 8, 2021

To submit your proposal, please click here

For more information about the award, please click here

Who is Eligible

Full-time students enrolled in a graduate degree program (Masters and PhD) of an accredited college or university, or post-doctoral fellows. Previous finalists are not eligible.

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; 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 schol-

arship in the history of clinical trials. Important papers illustrating applications of novel methodology in clinical trials are particularly encouraged.

How to Apply

- Visit the online submission form by clicking **here,** then click **Contributed Sessions**. Submit an abstract (400 word limit), a short manuscript (maximum of 3500 words, not including title, author names, tables, figures or bibliography; maximum four figures and tables) and a letter from the student's advisor or mentor confirming status as a full-time student or post-doctoral fellow at the time of submission.
- Applicant must be first author on manuscript
- Indicate Thomas Chalmers Student Scholarship for abstract type.
- You may specify that if your submission is not chosen for this award, you would like it to be considered by the Program Committee for an oral or poster presentation.

NOTE: Each candidate can only submit one entry. However, candidates can be co-authors (not first author) on other entries.

What the Three Finalists and One Winner Receive:

Three students will be designated Thomas C. Chalmers Student Scholarship Finalists and will receive travel and hotel expense support to present their papers at the 2021 SCT meeting in Chicago, IL. The three finalists will present their papers at the meeting. The winner will then be selected by the SCT scholarship committee and be presented the Thomas C. Chalmers Student Scholarship Award in addition to a $500 cash prize.

SCT Sylvan Green Award

Deadline extended to January 8, 2021

To submit your proposal, please click here

For more information about this award, please click here

Who is Eligible:

Physicians and dentists engaged in clinical trials or epidemiology projects.

Appropriate topics for Submission:

All clinical trial-related issues such as study design and data analysis methods; meta-analysis; medical, ethical or legal issues in clinical trials; data entry, management, monitoring, sharing, informatics, 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 are particularly encouraged.

How to Apply:

- Visit the online submission form by clicking **here,** then click **Contributed Sessions**.
- Submit a short paper (1000-word limit, excluding author names, title, table, figure or bibliography; limit 1 table or figure) on the online abstract submission form.
- Applicant must be first author on manuscript
- Indicate your physician or dental degree for eligibility

NOTE: Each candidate can only submit one entry. However, candidates can be co-authors (not first author) on other entries.

What the Winner Receives:

The winner will receive an Award covering travel and hotel expenses to present at the 2021 SCT meeting in Chicago, IL. If your submission is not chosen for this award, it will still be considered by the Program Committee for an **oral or poster presentation.**

Join us December 14th from 10:00 am-11:30 am ET for the next 2020 Virtual Meeting Webinar

Methodological advances in the conduct of behavioral clinical trials: an international behavioural trials network (IBTN) update

This session will highlight some of the key advances in the field of behavioral intervention methodology that are unique to behavioral trials. Given the large numbers of behavioral interventions and clinical trials that have been entering the research literature, as well as growing interest in developing a solid evidence base for the efficacy of health-related behavioral interventions, this session is targeted to both seasoned clinical trial methodologists and well as behavioral trialists.

Presenters

Dr. Susan M. Czajkowski, PhD, FABMR
Dr. Susan Czajkowski is Chief of the Health Behaviors Research Branch (HBRB), Behavioral Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute (NCI).

Dr. Czajkowski is an expert on psychosocial and behavioral risk factors for disease, including the development and testing of interventions for behavioral risk factors such as obesity, physical inactivity, adverse diets, and non-adherence to medical regimens. Other interests include research on the roles of social support and depression in disease risk and recovery and the assessment of health-related quality of life and psychosocial functioning in patients with chronic diseases.

Dr. Simon L. Bacon, PhD, FTOS, FCCS, FABMR
Dr. Simon Bacon is a full professor in the Department of Health, Kinesiology, and Applied Physiology at Concordia University, Canadian Institutes of Health Research (CIHR) Strategy for Patient-Oriented Research (SPOR) Chair in Innovative, Patient-Oriented, Behavioural Clinical Trials, and FRQS Chair in Behavioural Medicine. He is also Co-Director of the Montréal Behavioural Medicine Centre, a researcher at the Centre intégré universitaire de santé et service sociaux du Nord-de-l'Île-de-Montréal and co-lead of the International Behavioural Trials Network.

Dr. Bacon has had extensive training in the delivery of behavioural randomised controlled trials and has been a PI and co-I on multiple different studies involving behavioural interventions, including exercise, weight management, stress management, and motivational communication.

Dr. Kenneth Freedland, PhD, FAHA, FABMR
Dr. Kenneth Freedland is a Professor of Psychiatry and Psychology at Washington University School of Medicine in St. Louis.

Dr. Freedland chaired the NIH/OBSSR Expert Panel on Comparator Group Selection in Behavioral and Social Science Clinical Trials and has published several papers and chapters on comparators in behavioral trials. He is also the principal developer of the Purpose-Guided Trial Design (PGTD) framework. His research focuses primarily on the role and treatment of depression, stress, and anxiety in patients with heart disease. He has been involved in clinical research on patients with other chronic medical conditions as well.

Dr. Kim Lavoie, PhD, FCPA, FABMR
Dr. Kim Lavoie is a full professor in the Department of Psychology at the University of Quebec at Montreal and holds the Tier 1 Canada Research Chair in Behavioural Medicine.

Dr. Lavoie is internationally recognized for her research on the impact of psychological and behavioural factors on the development and progression of cardiovascular and lung diseases, and the impact of behavioural interventions, e.g., motivational communication, exercise, and behavioural weight loss, on key health behaviours and outcomes in chronic lung disease.

December 14th , 2020 Virtual Meeting Webinar (continued)

How do I access the webinar and the Virtual Meeting program?

All current members of SCT can register for this webinar and the Virtual Meeting Program for free!

All verified Students can register for this webinar and the Virtual Meeting Program for the low price of just $50!

Non-Members can register for this webinar and the Virtual Meeting Program for the low price of $170!

What happens after I register for the Virtual Meeting Program?

Once you have registered for the 2020 Virtual Program, SCT will register you for each webinar that is scheduled through April 2021.

You will receive an email confirmation on a monthly basis from SCT (via Go To Webinar) that will contain your dial-in information as well as a personalized link to access that month's webinar(s).

Please note that SCT will not send out calendar invites for the webinars that you have been registered for. We encourage you to add the webinar that you have been registered for to your own calendar via your confirmation email.

Register Here For the Virtual Meeting Program

Virtual Invited Sessions		
Methodological advances in the conduct of behavioral clinical trials: an international behavioural trials network (IBTN) update	Simon Bacon, Susan Czajkowski, Kenneth Freedland, Kim Lavoie	December 14, 2020 10:00 am -11:30 am ET
The design and implementation of master protocols using examples from oncology clinical trials	Timothy Chen, Shauna Hillman, Sumithra Mandrekar, Amy Stark, Pamela Tenaerts	January 12, 2021 12:00 pm - 1:00 pm ET
Strategies to collaboratively manage protocol deviations in multi-site clinical trials	Dikla Blumberg, Ashley Case, Phoebe Gauthier, Mitra Lewis, Carmen Rosa, Dagmar Salazar	January 27, 2021 12:00 pm - 1:30 pm ET
Virtual Educational Workshops Sessions		
Improving Quality and Controlling Costs in Clinical Trials Using Responsive Survey Design	James Wagner and Brady West	April 6, 2021 11:00 am ET – 12:30 pm ET
How to design and run an adaptive clinical trial: new resources and easy-to-use software	Munya Dimairo, Michael Grayling, and Graham Wheeler	TBD

Meet our Society for Clinical Trials Committees

Wendy London, Chair Communications Committee

Members of the Committee
Domenic J. Reda - Newsletter Editor
Lee S. McDaniel - Social Media Editor
Jody Ciolino - Website Oversight
Roisheen A. Doherty
Samiran Ghosh
Ashley Elizabeth Kuniholm
John David Norrie
Mei-Yin Polley
Chengjie Xiong

The mission of the Communications Committee is to administer policy and standard operating procedures for the SCT website, to promote awareness of the Society through social media, provide public comment (including responses to queries from journalists) regarding clinical trial issues, and inform the membership -at-large of Society activities via the newsletter.

The Communications Committee is:

- supporting other SCT committees, facilitating announcements and soliciting input from the membership.
- Tweeting/announcing requests for nominations

Ivan Chan, Chair Development Com-

Nicole Close, Co-Chair Development Committee

Members of the Committee
Joshua Chen
Kent Koprowicz

The mission of the Development Committee is to raise corporate/ institution sponsorship, consistent with the professional integrity of the Society, to support educational and program goals.

Recent and upcoming work:

- Review past corporate and institutional donors
- Work to identify additional prospective donors and the appropriate contact within the organization
- Prepare letters of sponsorship and contact prospective sponsors

Elizabeth Thom, Chair Fellows Committee

J. Jack Lee, Co-Chair Fellows Committee

Members of the Committee
Raymond P. Bain
Christopher Coffey
Roger J. Lewis
Anne S. Lindblad
John David Norrie
Carol K. Redmond
Scott Rushing
Lehana Thabane

The purpose of the Fellows Committee is to facilitate the selection of annual recipients of the award 'Fellow of the Society for Clinical Trials'.

The recipients must be members of the Society who have made substantial contributions to the advancement of clinical trials in one or more of the following areas:

- Methodological development
- Trial coordination, conduct or leadership
- Education
- Ethics
- Information technology, data management or data quality
- Promoting a better understanding by the general public of the importance of randomized clinical trials
- Service to the Society

Recent and upcoming work:

- The committee has held two meetings to clarify details of eligibility and ground rules for the selection process.
- A call for nominations has been made, through an e-blast to all members, and e-mail to current Fellow and an article in the Newsletter.
- The portal on the SCT website is open for nominations until January 15th, 2021.
- The committee will review nominations and we expect to put forward up to three candidates for approval by the Board of Directors.

Society for Clinical Trials Committees (continued)

Virginia Howard, Chair Nominating

Members of the Committee

Kaleab Abebe
Mithat Gönen
Susan Halabi
Alexia Iasonos
Chengjie Xiong

The responsibility of the Nominating Committee is to develop and vet a slate of nominations for the President-Elect and positions on the Board of Directors (BOD) for voting by the Society membership in February-March 2021 .

Recent and upcoming work:

- Reviewed our charge with SCT Leadership Meeting Sept 18
- First meeting of Committee Oct 6th
- First call for nominations went out Nov 2 – blast email
- Nominations are coming in – **please continue to submit**
- Need 2 nominations for President-Elect and 6 for BOD
- Plans to work with Communications Committee for wider solicitation, especially for self-nominations
- Next Committee meeting to be held in December
- Deadline for nominations is January 15, 2021
- Committee will meet end of Jan to review and confirm slate
- Final ballot and candidate biosketches to be submitted to

Marc Buyse, Chair Trial of the Year Committee

Debra Condon, Chair Trial of the Year Committee

Members of the Committee

Suzanne Dahlberg
Dean Follmann
Jessica Overbey
Frank W. Rockhold
Yves D. Rosenberg

The responsibility of the Trial of the Year (TOY) Committee is to advertise the David Sackett Trial of the Year Award, collect nominations for trials that are thought to deserve the Award, evaluate these nominations, select the recipient, and prepare a presentation of the Trial of the Year at the Annual Meeting.

Recent and upcoming work:

- October – 1) Prepared nomination announcement and liaised with Communications Committee to ensure wide distribution; 2) Revised submission portal
- November / December – Monitor and encourage nominations on submission portal
- January – Review nominations February – Decide on, and contact, award recipient
- April – 1) Prepare for presentation at Annual Meeting with award recipient; 2) prepare report for the Boar

Liz-Garrett Mayer, Chair Student Scholarship Committee

Cody Chiuzan , Co-Chair Student Scholarship Committee

Members of the Committee

Marcin Dudek
Denise Esserman
Michael Grayling
Yu Lan
Ruitao Lin
Lee S. McDaniel
Chaoqun Mei
Ludovic Trinquart
Xiaofei Wang

The committee is responsible for the announcement, review and selection of student awards made at the SCT annual meeting, namely the Sylvan Green Travel Award and the Thomas Chalmers Student Scholarships.

Recent and upcoming work:

- The committee developed the award announcement.
- An assessment rubric was created to define rating criteria and streamline the evaluation of submissions.
- The committee will begin reviewing applications upon the January 8, 2021 deadline.

Society for Clinical Trials Committees (continued)

Jonathan Cook, Chair
Program Committee

Toshi Hamasaki. Co-Chair
Program Committee

Members of the Committee

Dikla Blumberg	Sameer Parpia
Andrew Cook	Charity Patterson
Gustavo Jimenez-Maggiora	Julie Qidwai
Kent Koprowicz	Joseph R. Rausch
Rebecca Lewis	Kyle Rudser
Clement Ma	Matthew Sydes
Pam Mangat	Juliana Tolles
Ann Meeker-O'Connell	Charles Weijer
John Nichols	Sharon Yeatts

The Program Committee would like to highlight some points regarding the program for the SCT 2021 Annual Meeting. As you will likely be aware, due to the impact of the COVID-19 deadline on planning, it has been decided to push back deadlines to Jan 8, 2021.

We are keen to receive proposals on COVID-19 studies, the impact of COVID-19 on clinical trials in whatever way that might be, and also "regular" great research as we have had at the meeting in a typical year.

Furthermore, we would like to highlight that we are interested in receiving submissions covering all areas of research and any relevant topics related to clinical trials are eligible. A couple of key points to highlight are:

• We are very grateful to those who submitted to the recent deadline for a session proposals proposal submission. A good number of exciting proposals were received. However, we are welcoming further additional session proposal submissions for the Jan 8 deadline. Session proposals which bring together a set of speakers and discussants to present the latest findings on an important and emerging issue in an area of clinical trials research, or which provide an up to date overview of a key aspect of clinical trials design, conduct, analysis or reporting, are very welcome.

• The deadline for contributed oral and poster for standalone presentations has been extended to January 8, 2020. An abstract for a short presentation of a topic relevant to the clini-

Michael Grayling,
Education Chair

Sin-Ho Jung
Education Co-Chair

Members of the Committee

Hayley Belli	Stephanie L. Pugh
Maria Ciarleglio	Logan P. Sirline
Sarah Gaussoin	Larisa Tereshchenko
Sonia Jain	Pedro Torres-Saavedra
Kelley Kidwell	

The responsibility of the Education Committee is to coordinate the pre-conference workshops (typically 4 hours) and in-conference tutorials (typically 2 hours) for the SCT Annual Meeting, as well as to organise the SCT Webinars (typically held quarterly).

Both the pre-conference workshops and in-conference tutorials are intended to be interactive educational sessions on a method or topic related to trials. Submissions should, in particular, include a timed agenda and a list of goals – further information can be found at the SCT Annual Meeting website.

So far this year, a number of webinars organised by the Education Committee have been very well received. These include:

• A three-part series on 'Aggregate Safety Assessments for Learning and Decision-Making', by Dr Greg Ball and colleagues;

• And 'SPIRIT-Outcomes and CONSORT-Outcomes: Enhanced trial outcome transparency, less bias, improved systematic reviews, better health', by Prof Martin Offringa and Dr Nancy Butcher.

Furthermore, a number of highly successful Education Ses-

Society for Clinical Trials Committees (continued)

sions have been held as part of the 2020 Virtual Meeting:
• 'Web-based applications for early-phase trial designs', by Dr Cody Chiuzan and colleagues;
• 'From Ideas to Efficacy: Designing & Optimizing Behavioral Treatments for Chronic Diseases', by Dr Susan Czajkowski and colleagues;
• and 'Using Meta-Analysis to Combine Results from Clinical Trials', by Dr Yulia Marchenko and colleagues.

We expect several additional sessions will also run in the coming months. Currently, one such session is confirmed:
• 'Improving Quality and Controlling Costs in Clinical Trials using Responsive Survey Design', by Dr James Wagner and Dr Brady West, which will be held on April 6 2021.

Be sure to keep an eye out in year emails for confirmations on other sessions!

Dixie Ecklund, Chair
Membership Committee

Jody Ciolino, Co-Chair
Membership Committee

Members of the Committee
Kaleab Abebe
Dikla Blumberg
Julia Collins
Janel Fedler
Julie Qidwai
Maggie Spencer
Zhaoyang Teng

The goals of the Membership Committee are to 1) increase and sustain membership; 2) increase membership diversity, including diversity across fields represented within the Society; and 3) increase collaboration between SCT committees

Recent and upcoming committee work :

- Invited committee members and established monthly meeting schedule through Spring of 2021
- Participated in task force to realign the 2020 annual meeting to virtual format
- Continuously monitor membership numbers on a weekly basis
- Participating in newly formed DEI committee
- Crafted email blast to invite back non-renewing members and highlighted benefit of membership including access to all of the virtual meeting content through April 2021
- Crafted more personalized email blast to reach out to non-renewing members who are known to committee members and encouraged all committee members to reach out to known colleagues who had not renewed membership
- Met with Exec Board to discuss strategies to encourage membership such as continuing $50 student membership and uncoupling meeting registration from membership
- Currently developing a survey instrument to learn more about our membership

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Master Protocols Webinar Recording Available

CTTI's October 13th webinar released a new set of robust resources that can be used to collaborate, communicate and design master protocol studies. The webinar recording and associated materials are now available.
Thank you to the speakers: Abby Bronson (Edgewise Therapeutics), Marianne Chase (Massachusetts General Hospital), Daniel Millar (J&J/Janssen), and Nick Richardson, (FDA/CDER), and to the Master Protocol Studies team for their work on this project. Please contact Zach Hallinan if you would like more information on the resources created through this project.

Webinar Recording Available: Resources for Implementing QbD in Trials

A recording is now available of CTTI's recent webinar unveiling new QbD resources developed by the QbD Adoption project team. Thank you to the team leaders, team members, and others who have contributed to these resources, as well as presenters Greg Pennock (EMD Serono), David Rodin (Amici Clinical Research), Ansalan Stewart (FDA), Karlin Schroeder (Parkinson's Foundation) and Steve Young (CluePoints) for the launch webinar. Please contact Zach Hallinan if you have any questions or would like additional information about the new resources.

FDA to Host Webinar on Diversity in Clinical Trials

On Dec. 16 from 1-2:30pm ET, the FDA will host a free webinar, where they will share CDER's most recent assessment of clinical trial diversity and discuss efforts to advance diverse participation in clinical trials to include relevant FDA guidance and regulations. For more on CTTI's diversity work, see here.

SAVE THE DATE!
Monday, April 12, 2021 (8:30 A.M. to 4:30 PM)
13th Annual University of Pennsylvania
Conference on Statistical Issues in Clinical Trials:
Cluster Randomized Clinical Trials: Challenges and Opportunities
Registration opens January 2021

SCT is continuing its longstanding collaboration with the Department of Biostatistics, Epidemiology and Informatics at the University of Pennsylvania and is delighted to announce the 13th Annual Conference on Statistical Issues in Clinical Trials:

CLUSTER RANDOMIZED TRIALS (CRTs) - CHALLENGES AND OPPORTUNITIES. REGISTRATION WILL OPEN IN EARLY JANUARY.

The conference will be virtual and the program is given below. The University of Pennsylvania website will be updated as plans are formalized.

Please visit https://www.cceb.med.upenn.edu/events/13th-university-pennsylvania-conference-statistical-issues-clinical-trials for up to date information as it becomes available.

Program

13th Annual Clinical Trials Conference
VIRTUAL

SAVE THE DATE!
Monday, April 12, 2021 (8:30 A.M. to 4:30 PM)
13th Annual University of Pennsylvania
Conference on Statistical Issues in Clinical Trials:
Cluster Randomized Clinical Trials: Challenges and Opportunities
Registration opens January 2021

SPEAKERS AND TOPICS	
DAVID MURRAY, NIH	*Overview: Innovations in the Design and Analysis of Group- or Cluster-Randomized Trials*
VICTOR DeGRUTTOLA, Harvard	*Using Network-level (and Individual-level) Information in Design and Analysis*
LUKE J. KEELE, University of Pennsylvania	*Complexities Caused by Noncompliance in Cluster Randomized Trials*
JAMES P. HUGHES, University of Washington	*Current Issues in the Design and Analysis of Stepped Wedge Trials*
LAWRENCE H. MOULTON, Johns Hopkins University	*Randomization: Beyond the Closurization Principle*
NATALIE E. DEAN, University of Florida	*The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness During Infectious Disease Outbreaks*
DEBORAH J. DONNELL, University of Washington	*Challenges in Implementing CRTs: from Hawthorne Effect to Measurement Bias*
WEILI HE, AbbVie	*Practical Considerations in Utilizing Cluster Randomization Trials in Medical Research*
PANELISTS	
Andrew Copas	University College London
Karla Hemming	University of Birmingham
David Murray	NIH
Mike Proschan	NIH
Jeffrey Roberts	FDA CBER
Alisa J. Stephens-Shields	University of Pennsylvania

Up to date information at:
https://www.cceb.med.upenn.edu/events/13th-university-pennsylvania-conference-statistical-issues-clinical-trials

For additional information, contact:
Janine Pritchard
Phone: 215-573-4045 | Email: jpritcha@pennmedicine.upenn.edu

Save The Date - Date Change

ICTMC 2022
6th International Clinical Trials Methodology Conference. Harrogate, UK 3 - 6 October

International Clinical Trials Methodology Conference Organising Committee would like to announce the change of date for the ICTMC conference which will now take place **Monday 3rd - Thursday 6th October 2022** at Harrogate Convention Centre, Yorkshire, UK.

ICTMC 2022 promises to be a unique opportunity for those working in clinical trials to meet and discuss the current issues within trials and trials methodology. ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology research.

We look forward to welcoming you in 2022!

The meeting will also offer valuable networking and training opportunities, with over 750 delegates from 22 countries attending ICTMC 2019.

Register Your Interest

Please feel free to visit the conference website where details will be updated regularly.

www.ictmc.org

Our mailing address is:
In Conference, Unit 1, Q Court,
Edinburgh, Midlothian EH54BP
United Kingdom

Call for 2021 Fellow Nominations due by January 15, 2021

Dear SCT Fellows,

We are calling for nominations for the next class of SCT Fellows to join your illustrious group! As Fellows yourselves, you may already know the process and you are certainly aware of the type of excellent candidates we are seeking. We encourage you to put forward deserving colleagues for consideration.

Candidates must have been an SCT member for at least five of the last 10 years or for a total of at least 10 years. Both the nominator and the nominee should be a member of SCT.

Each nominee will be evaluated by the SCT Fellows Committee on the basis of contributions to the advancement of clinical trials in one or more of the following areas:

- Methodologic development
- Trials coordination, conduct, or leadership of individual clinical trials
- Education
- Ethics
- Information technology, data management, or data quality
- Promotion of a better understanding by the general public of the importance of randomized clinical trials
- Service to the Society

How to Submit a Nomination

If you know someone who meets these qualifications and is deserving of this particular Society honor, please follow this three-part process:

1. Check with the SCT office at info@sctweb.org to confirm the eligibility of your intended nominee
2. Prepare a Nomination Packet, which should include:
   - Candidate's current full curriculum vitae (CV)
   - Three or more letters of support from individuals qualified to describe the candidate's contributions. At least two of the letters should be from individuals at an institution, agency, or organization other than that of the candidate. The letters may include a letter of support from the nominator.
   - Cover letter from the nominator to document that the packet is complete and that the candidate meets criteria. (If the nominator writes a letter of support, documentation of meeting criteria may be incorporated into the letter of support instead.)
3. Submit the nomination on the SCT website **here**

Complete nomination packets are due by January 15, 2021

Thank you,

The 2020-2021 Fellows Committee

Call for Nominations for the SCT Board of Directors due by January 15, 2021

SCT Members,

We are soliciting nominees for President-Elect for 2021-2022 and for three members of the Board of Directors for 2021-2025.

The President-Elect serves a one-year term before becoming President and one additional year as Past President. Board members serve a four-year term.

Call for nominations to fill positions of President-Elect and members of the Board of Directors are due by January 15, 2021 and the ballot will be distributed in early February 2021 for voting by the SCT Membership.

For us to fill these positions, we are reliant on the members of the Nominating Committee and the general members of the Society in identifying candidates willing to stand for election.

To qualify as a candidate, the nominee should be:

- A member of the Society in good standing by having been an SCT member for five years or longer consecutively and preferably one who is or has been an active participant in SCT activities and/or committees.
- Someone who is well respected in their area of clinical trial activities, whether it be in information technology, patient care, statistics, project management, regulatory affairs, epidemiology, laboratory sciences, or any of the other disciplines that are important for the planning, conduct, analysis, interpretation and reporting of clinical trials.

If you have suggestions for possible nominations, please reach out to Virginia Howard, Chair of the SCT Nominating Committee via **email**

Thank you for your Nominations.

The 2020-2021 Nominating Committee
Virginia J. Howard, Chair
Mithat Gönen, 2020-2021 President-Elect
Susan Halabi, 2020-2021 President
Kaleab Abebe, Committee Member
Alexia Iasonos, Committee Member
Chengjie Xiong, Committee Member

Call For The David Sackett Trial Of The Year Nominations
Deadline is January 15, 2021

The Society for Clinical Trials presents an annual award to the randomized clinical trial published (either electronically or in print) in the previous year (2020 in this case) that best fulfills the following standards:

- It improves the lot of humankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcame obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

The deadline for nominations is January 15, 2021.

The award will be presented at the 42nd SCT Annual Meeting held May 16-19, 2021, in Chicago, IL.

Nominations can be submitted online at **http://www.sctweb.org/meeting/#abstract** until January 15, 2021.

For questions, please contact Marc Buyse (**marc.buyse@iddi.com**), Chair of the David Sackett Trial of The Year Committee.

Read more about the Trial of the Year at: **http://www.sctweb.org/toty.cfm**.

IMPACT-AD

Institute on Methods and Protocols for Advancement of Clinical Trials in ADRD

INFORMATIONAL WEBINAR

DECEMBER 15TH 2020

12-1PM(PT)

SCAN CODE TO REGISTER

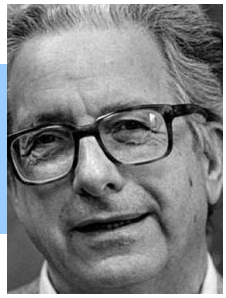
Presentations and a Q&A session hosted by the course co-directors Dr. Rema Raman & Dr. Joshua Grill

Dr. Rema Raman
University of Southern Caliifornia

Dr. Joshua Grill
University of Califiornia, Irvine

SUPPORTED BY: alzheimer's association NIH NIA ACTC ALZHEIMER'S CLINICAL TRIALS CONSORTIUM

SCT Spotlight – Paul Meier's Role in the Discovery and Evaluation of The Cutter Incident—part 2



Paul Meier

By Chris Barker

(continued from the October, 2020 newsletter)

Meier's evaluation of the safety recommendations following The Cutter Incident

I commend readers of this note to obtain a copy of Pauls' article in Science 1957. (I have a copy if this proves to be insurmountable problem – I can't post due to copyright issues). Paul reviewed recommendations for the detection of live virus in the "vaccine lots". Paul considers issues ranging from first order kinetics in virology to the societal public health implications. Paul's review I can only describe as a deeply thoughtful, calm assessment and re-assessment of manufacturing and vaccine safety evaluation.

Excerpting Paul's concluding remarks and advice from his 1957 paper, advice that remains valid today

From the viewpoint of the relationships between scientists and the general public, the consequences of this policy may be much more serious than the harm done by faulty vaccine. It is understandable that, having decided to proceed with a program, all concerned should wish to have it presented in the most favorable light. However, failure adequately to inform the public, more particularly the physicians who must largely accept the responsibility for advising the rest of the public, seems likely to lead to the deterioration of the confidence and respect which scientists should enjoy. In view of the questions raised about the general policies adopted in the safety-testing program for poliomyelitis vaccine, a searching study of the entire program conducted by an appropriate body, such as the National Academy of Sciences, seems called for. Such a study could lead to recommendations for future programs which would provide for more complete access to information and, consequently, to more adequate protection from errors in judgment.

Polio Vaccine Side effects

The polio vaccine side effect arising from lots with active virus is called Vaccine-associated paralytic poliomyelitis (VAPP)
https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

CDC historical concerns with Polio Vaccines

1955, some batches of polio vaccine given to the public contained live polio virus, even though they had passed required safety testing. Over 250 cases of polio were attributed to vaccines produced by one company: Cutter Laboratories. This case, which came to be known as the Cutter Incident, resulted in many cases of paralysis. The vaccine was recalled as soon as cases of polio were detected.

The Cutter Incident was a defining moment in the history of vaccine manufacturing and government oversight of vaccines and led to the creation of a better system of regulating vaccines. After the government improved this process and increased oversight, polio vaccinations resumed in the fall of 1955.

At the time, there was no system in place to compensate people who might have been harmed by a vaccine. Today we have the National Vaccine Injury Compensation Program (VICP), which uses scientific evidence to determine whether a vaccine might be the cause of an illness or injury, and provides compensation to individuals found to have been harmed by a vaccine. The VICP remains a model method for ensuring that all persons harmed by vaccines are compensated quickly and fairly, while also protecting companies that make lifesaving products from financially unsustainable liability claims through the tort system.

For more information, see Food and Drug Administration (FDA)'s Science and the Regulation of Biological Products page.

Legislation resulting from Cutter

At the time, there was no system in place to compensate people who might have been harmed by a vaccine. Today we have the

National Vaccine Injury Compensation Program (VICP), which uses scientific evidence to determine whether a vaccine might be the cause of an illness or injury, and provides compensation to individuals found to have been harmed by a vaccine. The VICP remains a model method for ensuring that all persons harmed by vaccines are compensated quickly and fairly, while also protecting companies that make lifesaving products from financially unsustainable liability claims through the tort system.

Conclusion

A fundamental principle of vaccine for a lethal illness is the trust by the population of people at risk in the adequacy of the evaluation of efficacy and safety and the honesty and integrity of the scientists involved. The Cutter Incident is considered to be the largest biological disaster in the history or vaccine development. Paul Meier was a central figure in the discovery, methodical reporting and interpretation of the findings of the investigation. Paul identified "root causes". Remarkably, Pauls' published interview comments (Marks) seems to suggest that Paul believes his 1957 paper in Science may have been ignored.

Paul certainly collaborated with many others in the discovery of the Cutter Incident. Paul left no stone unturned in his 1957 assessment in Science. In 2020, about 63 years later, in the middle of an unprecedented pandemic by covid19, Pauls' evaluation of Cutter manufacturing and his publication is a pillar in the process of establishing vaccine safety.

References

Betts, Kellyn. "Paul Meier A Man Behind the Method." *American journal of public health* 102.11 (2012): 2026-2029.

Brownlee, K. Alexander. "Statistics of the 1954 polio vaccine trials." *Journal of the American Statistical Association* 50.272 (1955): 1005-1013.

Dublin, Thomas D. "1954 Poliomyelitis Vaccine Field Trial: Plan, Field Operations, and Follow-up Observations." *Journal of the American Medical Association* 158.14 (1955): 1258-1265.

Fitzpatrick, Michael. "The cutter incident: How america's first polio vaccine led to a growing vaccine crisis." *Journal of the Royal Society of Medicine* 99.3 (2006): 156-156.

Halpern, Sydney A. *Lesser harms: The morality of risk in medical research*. University of Chicago Press, 2006.

Hinman, Alan R., and Stephen B. Thacker. "Invited Commentary on "The Cutter Incident: Poliomyelitis following Formaldehyde-inactivated Poliovirus Vaccination in the United States during the Spring of 1955. II. Relationship of Poliomyelitis to Cutter Vaccine"." *American Journal of Epidemiology* 142.2 (1995): 107-108.

Marks, Harry M. "A conversation with Paul Meier." *Clinical Trials* 1.1 (2004): 131-138.

Marks, Harry M. "The 1954 Salk poliomyelitis vaccine field trial." *Clinical Trials* 8.2 (2011): 224-234.

Meier, Paul. "TIIE BIGGEST PUBLIC IIEALTH EXPERIMENT EVER: The 1954 Field Trial of the Salk Poliomyelitis Vaccine."

Monto, Arnold S. "Francis field trial of inactivated poliomyelitis vaccine: background and lessons for today." *Epidemiologic reviews* 21.1 (1999): 7-23.

Nathanson, Neal, and Alexander D. Langmuir. "The Cutter Incident. Poliomyelitis following Formaldehyde-Inactivated Poliovirus Vaccination in the United States during the Spring of 1955. II. Relationship of Poliomyelitis to Cutter Vaccine." *American journal of hygiene* 78.1 (1963): 29-60.

Offit, Paul A. The Cutter incident: how America's first polio vaccine led to the growing vaccine crisis. Yale University Press, 2007.

U.S. Public Health Service, Technical Report on Salk Poliomyelitis Vaccine (mimeographed) (June 1955).

Reference URLs

Washington Post, April 4, 2020, https://www.washingtonpost.com/history/2020/04/14/cutter-polio-vaccine-paralyzed-children-coronavirus/

History.com https://www.history.com/this-day-in-history/salk-announces-polio-vaccine

Science history.com https://www.sciencehistory.org/historical-profile/jonas-salk-and-albert-bruce-sabin

SCT Honor's It's Long-Standing Members (continued from July, 2020 issue)

In previous issues we featured current members who have maintained continuous membership for at least 10 years. In this newsletter, we list current members who have held continuous membership for 5 to 9 years. Among current members, some have held continuous membership since 1979! SCT would like to thank all of you distinguished and faithful members for your support of the Society. If your name is not listed below and you believe it should be, please contact our management office at info@sctweb.org

Many of our members renew their membership at the annual meeting. Since this year's meeting was cancelled due to the pandemic, we'd like to remind you that if you have not renewed your membership for this year there is still time. You can renew at http://www.sctweb.org/. Log in to the members only section with your membership credentials and renew today to continue your members benefits.

5 - 9 Years

Robert Annechiarico
Kaitlyn Antonelli
Simon Bacon
David Beard
Melanie Bell
Tracy Bergemann
William Blackwelder
Barbara Braffett
Siobhan Brown
Iris Castro
Rick Chappell
Yiyi Chen
Cody Chiuzan
Mace Coday
Debra Condon
Andrew Cook
Victor Crentsil
Janet Dale
Lori Dodd
Vladimir Dragalin
Brian Egleston
Denise Esserman
Ross Fleischman

Eric Foster
Kenneth Freedland
Mark Gosnell
Dario Gregori
Michael Hancock
Brett Hanscom
Dietrich Haubenberger
Chen Hu
Trevis Huff
Rani Jayswal
Gustavo Jimenez-Maggiora
Steven Julious
Joseph Koopmeiners
Kent Koprowicz
Edward Korn
Lisa Kowarski
Gillian Lancaster
Sharon Lawlor
Martin Lesser
Donna Levy
Sarah Leatherman
Jennifer Le-Rademacher

Fan Li
Na Li
Yuanyuan Liang
Theodore Lystig
Graeme MacLennan
Pam Mangat
Michael McDermott
William Meurer
Steven Mondia
Cristina Murray-Krezan
John Norrie
Kieran O'Brien
Kurt Olson
Fang-Shu Ou
Norberto Pantoja-Galicia
Sameer Parpia
Gregory Pond
Rema Raman
Lindsay Renfro
Amber Salter
Richard Schilsky
Nicholas Seewald
Abigail Shoben

Kirsten Shuler
Laura Smeaton
Claire Snowdon
Deokumar Srivastava
Matthew Sydes
Monica Taljaard
Donald Taves
Pamela Tenaerts
Larisa Tereshchenko
Sonia Thomas
Juliana Tolles
Thomas Travison
Ludovic Trinquart
Andrea Troxel
Lynda Ugwu
Alison Urton
John VanBuren
Donald Vena
Michael Wininger
Kathryn Winter
Jose-Miguel Yamal
Maryna Yaskina
Ying Yuan

THANK YOU TO OUR CORPORATE SPONSORS!

Platinum Sponsors

Gold Sponsors

Gold Sponsor

ASTRAZENECA

AstraZeneca is a global, science-led biopharmaceutical business and our innovative medicines are used by millions of patients worldwide.

Gold Sponsor

GW BIOSTATISTICS CENTER

The GW Biostatistics Center has a 47 year history of leadership in practice-changing clinical trials and biostatistical methodology research. Center research has been recognized in reports to the US President and Congress and resulted in over 60 NEJM publications.

Gold Sponsor

FRONTIER SCIENCE FOUNDATION

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.

Silver Sponsors

Silver Sponsor

CYTEL

We provide unrivaled biostatistics and operations research knowledge to our customers. Our knowledge is available in the form of both software and services. This knowledge, supported by our trial implementation capabilities, is what makes us different. We are leaders in the design and implementation of adaptive clinical trials.

Silver Sponsor

JAEB CENTER FOR HEALTH RESEARCH

The Jaeb Center for Health Research was established in 1993 as a freestanding, nonprofit coordinating center for multi-center clinical trials and epidemiologic research. The Jaeb Center's focus is eye disorders or type 1 diabetes.

Silver Sponsor

EMMES

Emmes collaborates with clients to produce valued, trusted scientific research. We are passionate about making a difference in the quality of human health, and have supported more than a thousand studies across a diverse range of diseases since our formation in 1977.

Bronze Sponsor

Bronze Sponsor

JOURNAL OF CLINICAL MEDICINE

JCM (IF = 5.583) is an international scientific open access journal, providing a platform for advances in clinical practices, the study of direct observation of patients and general medical research. The journal is indexed by SCIE and PubMed.

Save the Dates - Upcoming SCT Annual Meetings

42nd Annual Meeting May 16-19, 2021

Chicago, Illinois USA

43rd Annual Meeting May 15-18, 2022

San Diego, California USA

Information About SCT

SOCIETY FOR CLINICAL TRIALS

85 W. 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

@SCTorg

@sct.org

Executive Committee

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

Board of Directors

Kaleab Abebe (2020-2024)
James Dignam (2017-2021)
Emily V. Dressler (2018-2022)
Alexia Iasonos (2019-2023)
Robert Lindblad (2019-2023)
Will Meurer (2017-2021)
Letitia Perdue (2020-2024)
Pamela Tenaerts (2018-2022)
Elizabeth Thom (2017-2021)

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