SOCIETY FOR CLINICAL TRIALS

VOLUME 32,#3 NOVEMBER 2021

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CALENDAR OF EVENTS

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SCT 2021 Invited Session Proposals	Due November 15, 2021	To submit your proposal, please click here
SCT 2021 Contributed Abstracts	Due December 6, 2021	To submit your proposal, please click here
SCT 2021 Educational Workshop Proposals	Due December 6, 2021	To submit your proposal, please click here
Thomas Chalmers Student Scholarship Applications	Due December 6, 2021	To submit your proposal, please click here
Sylvan Green Physician/ Dentist Investigator Award Applications	Due December 6, 2021	To submit your proposal, please click here
SCT 2021 Trial of the Year Nominations	November 2, 2021 through January 21, 2022	To submit your nomination, please click here
Society for Clinical Trials 42nd Annual Meeting	May 15-18, 2022	http://www.sctweb.org/meeting/

Proposals/Abstracts for the SCT 43rd ANNUAL MEETING
"Informing Public Health Policy with Compelling Evidence "
MAY 15-18 2022 San Diego, CA

Invited Sessions Proposals

due November 15, 2021 by 11:59 pm CT

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 an key aspect of clinical trials design, conduct, analysis or reporting, are very welcome.
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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 successful formats used in the past.
- 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

due December 6, 2021 by 11:59 pm CT

To submit your proposal, please click **here**

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

Proposals/Abstracts for the SCT 42nd ANNUAL MEETING (continued)

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 pro-gram.
- 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 un-derstanding. 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

due December 6, 2021

To submit your proposal, please click here

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.

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

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)

2021 Award and Scholarship Programs

SCT Thomas C. Chalmers Student Scholarship

due December 6, 2021 by 11:59 pm CT

To submit your proposal, please click here

For more information about the award, please click here

Who is Eligible

Students currently enrolled in a graduate degree program (Masters, PhD, or DrPH) of an accredited college or university, or post-doctoral fellows (2 years from completing their PhD/DrPH). 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; diversity and inclusion in clinical trials; data entry, management, monitoring, sharing, informatics, software development, and computing as it relates to clinical trials; review of the results or methods of a class of trials; or scholarship in the history of clinical trials. Important papers illustrating applications of novel methodology in clinical trials are particularly encouraged.

Application Requirements

- Applicant must be first author on manuscript.
  At the time of submission, the manuscript should not be published or accepted for publication in a peer- reviewed journal.
- Applicant must be willing to attend the SCT meeting in San Diego (May 15-18, 2022) to present the paper if selected as a finalist.

Submissions should include:

- An abstract of maximum 500 words.
- A short manuscript of maximum 3500 words, not including title, author names, tables/figures or bibliography; the total number of figures and tables is limited to 4.
- A letter from the student's advisor/mentor or department chair confirming status as a student enrolled in a graduate degree program (full or part-time) or post-doctoral fellow at the time of submission. The manuscript and letter should be uploaded as a single (zipped) file on the submission portal.
- You must 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.

How to Apply

Visit the online submission form by clicking here, then click **Contributed Sessions**.

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 expenses to present their papers at the SCT meeting in San Diego, CA in May 2022. 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.

2021 Award and Scholarship Programs (continued)

SCT Sylvan Green Award

Deadline

December 6, by 11:59 pm CT

To submit your proposal, please click here

For more information about this award, please click here

Who is Eligible:

Physicians, dentists or other health professionals who are engaged as investigators or co-investigators 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; diversity and inclusion 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.

Application Requirements

- Applicant must be first author on manuscript.
- At the time of submission, the manuscript should not be published or accepted for publication in a peer-reviewed journal.
- Applicant must be willing to attend SCT 2022 meeting in San Diego (May 15-18, 2022) to present the paper if selected as the winner of this award.

Submissions should include:

- An abstract of maximum 500 words.
- A short manuscript of maximum 1000 words not including title, author names, table/figure or bibliography limit to only 1 table or figure. Preliminary results of the study should be included in the summary where applicable.
- The manuscript should be uploaded as a separate file on the submission portal.
- Indicate your credentials for eligibility.
- 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.

How to Apply:

Visit the online submission form by clicking here, then click **Contributed Sessions**.

What the Winner Receives:

The winner will receive an Award covering travel and hotel expenses to present at the SCT meeting in San Diego, CA in May 2022.

Society for Clinical Trials
is Pleased to Announce the Launch of the
DATA MONITORING COMMITTEE INITIATIVE

Dear SCT Members and Clinical Trials Community:

I am pleased to announce that SCT is launching the Data Monitoring Committee (DMC) initiative. It was born out of our recognition that there is a dearth of people qualified to serve on DMCs. Dr. Dave DeMets, a long-time SCT member and Dr. Dean Fergusson, Past SCT President, initiated this discussion in 2019 and a planning committee was formed by our then-president Dr. Susan Halabi including key opinion leaders from SCT leadership, industry, academ-ia, and government. At the same time, TransCelerate Biopharma, a non-profit biopharmaceutical research and devel-opment organization, was working towards a similar goal for some time and we decided to join forces. Copyrights for this initiative were transferred from TransCelerate to SCT in 2021.

The initiative we are launching today is the product of these efforts and contain three components:

(1) Training: Several lectures were developed under the leadership of Dr. Dave DeMets featuring speakers who are world leaders in the science and practice of DMCs. Their videos are available free of charge at SCT's web site (www.sctweb.org/dmctraining).

(2) Registry: There is a registry for individuals who are interested in serving as DMC members (www.sctweb.org/dmcregistry). Dr. Haley Hedlin and Dr. Andreas Sashegyi, both members of the planning committee led the charge to develop this registry with significant effort from TransCelerate. Any individual can register indicating their interest and providing information on how much, if any, experience they have on this topic.

(3) Mentoring: Using the information from the registry we will offer mentoring opportunities to those who need it provided by experienced members.

We envision that this initiative will help to serve the unmet need in creation and functioning of DMCs, and serve as a resource for our members as well as the clinical trials community. This would not have happened without Dr. Dave DeMets' vision, intellectual and organizational leadership, and Dr. Susan Halabi's vigorous support of the initiative and channeling of the necessary resources. On behalf of SCT's Executive Committee and Board of Directors I am thanking them and all the members of the planning committee listed at the end of this message.

I invite all of you to participate by enrolling in the DMC registry, using the training modules, and partaking in the mentoring component. We welcome any feedback that you might have on this initiative.

Mithat Gönen
SCT President

Members of the Planning Committee:
Dave DeMets, PhD (University of Wisconsin-Madison)
Andreas Sashegyi, PhD (E. Lilly)
Haley Hedlin, PhD (Stanford University)
Ray Bain, PhD (Merck)
Karim Calis, PharmD (National Institute for Child Health and Human Development /NIH)
Barry Davis, MD, PhD (University of Texas in Houston School of Public Health)
Susan Ellenberg, PhD (University of Pennsylvania)
Scott Evans, PhD (George Washington University)
Thomas Fleming, PhD (University of Washington-Seattle)
Chris Granger, MD (Duke University /Duke Clinical Research Institute)
Mithat Gönen, PhD (Memorial Sloan Kettering Cancer Center)
Susan Halabi, PhD (Duke University)
Ed Korn, Ph.D. (National Cancer Institute)
William Meurer, MD (University of Michigan Medical School)
Pralay Mukhopadhyay, PhD (Otsuka America Pharmaceuticals, Inc.)
James Neaton, PhD (University of Minnesota)
Michael Proschan, PhD (National Institute for Allergy and Infectious Diseases)
Jean Rouleau, MD (University of Montreal)
Frank Rockhold, PhD (Duke University/DCRI)
Peter Sandercock MD, (University of Edinburgh)
Janet Wittes, PhD (Statistics Collaborative)

Society for Clinical Trials Committees

Program Committee

Sharon Yeatts
Program Chair

Sharon Yeatts is Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC). After receiving her PhD in Biostatistics from Virginia Commonwealth University in 2006, she joined the Data Coordination Unit to focus on the design, conduct, and analysis of multicenter clinical trials in neurological disorders and emergency medicine. Dr. Yeatts is multiple PI of the Data Coordinating Center for the SIREN (Strategies to Innovate Emergency Care Clinical Trials) network. She is PI of the DCC for several clinical trials conducted within the SIREN network: C3PO (Clinical Trial of COVID-19 Convalescent Plasma of Outpatients), ICECAP (Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients), and BOOST-3 (Brain Oxygen Optimization in Severe TBI Phase-3). Dr. Yeatts is also PI of the Data Management Center for SATURN (Statins in Intracerebral Hemorrhage), conducted within the StrokeNet network. Dr. Yeatts actively serves on grant review panels as well as DSMBs and is Statistical Editor of Stroke

Monica Taaljard
Program Co-Chair

Monica Taljaard is a Senior Scientist in the Clinical Epidemiology Program at the Ottawa Hospital Research Institute (OHRI) and Professor in the School of Epidemiology and Public Health at the University of Ottawa. Having immigrated from South Africa, she received her PhD degree in Epidemiology and Biostatistics at Western University in London, Ontario, Canada, in 2006. Her main research interests are in the design, analysis and ethics of pragmatic and cluster randomized trials. As a methodologist with the Ottawa Methods Centre, she works with clinicians and researchers from a variety of backgrounds in the design and analysis of cluster randomized trials, standard clinical trials, and observational studies. She is Deputy Editor of Clinical Trials: Journal of the Society for Clinical Trials.

Jonathan Cook
Program Past Chair

Jonathan Cook is an Associate Professor based at the Centre for Statistics in Medicine within the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) at the University of Oxford. His main research interest is in the design, conduct, analysis and reporting of randomised controlled trials (particularly surgical trials). Specific areas of interest include specification of the target difference in the sample size calculation, addressing interventional expertise, and methods for improving recruitment. He also has extensive experience in systematic reviews of randomised controlled trials and diagnostic research. He has collaborated on numerous projects including randomised trials, observational and diagnostic studies, methodological projects and systematic reviews in a variety of clinical areas (anaesthesia, cardiovascular research, obstetrics and gynaecology, ophthalmology, orthopaedics, primary care, general surgery and urology amongst others). He is a Lead Statistician in Oxford Clinical Trials Research Unit (OCTRU) and is a Deputy Director of the Surgical Intervention Trials Unit (SITU).

Jonathan graduated from the University of Aberdeen with a BSc in Statistics. Following this he undertook a PhD on the statistical assessment of learning curve effects in randomised controlled trials. Subsequently, he worked at the Health Services Research Unit, University of Aberdeen as a Statistician. In August 2007, he started a MRC UK Fellowship focusing upon methodology related the design, conduct and analysis of surgical randomised trials. In 2012, he was awarded a MRC UK Methodology Fellowship focusing upon expertise-based trial designs and in August that year became a Senior Research Fellow. He joined the Centre for Statistics in Medicine in 2013 initially on a secondment during which he was appointed to a University Lectureship in the NDORMS, University of Oxford.

Jonathan holds a number of external responsibilities. These include serving on and chairing Data Monitoring and Steering committee for a number of clinical trials, being a Deputy Editor of Clinical Trials, and a Statistical Editor for the British Journal of Surgery. He has over 150 full text publications including more than 50 as first or senior author

Education Committee

Sonia Jain
Education Chair

Dr. Sonia Jain is a Professor of Bio-statistics at the Herbert Wertheim School of Public Health and Human Longevity Science at the University of California, San Diego. Dr. Jain received her PhD in Statistics from the University of Toronto in Toronto, Canada.

Her methodological statistical interests include Bayesian biostatistics, with special emphasis on nonparamet-ric Bayesian models. Her research interests include adap-

Society for Clinical Trials Committees (continued)

tive clinical trial designs and precision medicine trial designs.

Dr. Jain is the lead biostatistician for many collaborative projects in several disciplines, including HIV/AIDS, infectious diseases, pediatric cardiology, posttraumatic stress disorder, and traumatic brain injury.

Larisa Tereshchenko

Education Co-Chair

Larisa Tereshchenko Is an Associate Professor of Medicine at the Oregon Health & Science University, Knight Cardiovascular Institute. Dr. Tereshchenko is a clinical investigator and data scientist with broad expertise in cardiac electrophysiology, electrocardiology, epidemiology, biostatistics, and randomized controlled trials. She is a Fellow of Heart Rhythm Society, American Heart Association, and American College of Cardiology. She 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, Heart Rhythm Journal, Cardiovascular Digital Health Journal, and several other journals.

Michael Grayling

Education Past Chair

Michael Grayling is a Research Fellow in Biostatistics at Newcastle University. His position involves a mix of research on the development of efficient methods for designing and analysing clinical trials and collaborating on applying such methods to real trials in practice. His interests include adaptive trial design, early phase drug development, and longitudinal study designs

Communications Committee

Lee McDaniel

Communications Chair

Dr. McDaniel is an Associate Professor of Biostatistics at the LSU Health Sciences Center. He received his PhD in Statistics from the University of Wisconsin-Madison in 2014. Dr. McDaniel's areas of interest include non-inferiority trials and time-to-event endpoints.

Mei-Yin Polley

Communications Co-Chair

Mei-Yin C Polley, Ph.D, holds a doctoral degree in Biostatistics from Columbia University. Currently, she is Associate Professor of Biostatistics at The University of Chicago and the Head of the Statistics Division for NRG Oncology (a National Cancer Institute sponsored member of the national clinical trials network group). Her methodological interests include the design, conduct, analysis and monitoring of all phases of cancer clinical trials, biomarker reproducibility, innovative group sequential methods for biomarker validation, prognostic and predictive modeling, and biomarker-based clinical trial designs. Dr. Polley has been actively involved in a broad spectrum of cancer research with a particular focus on breast cancer and brain cancer. She has served on many scientific governing or advisory bodies including the National Cancer Institute Steering Committees, the Scientific Program Committee of American Society of Clinical Oncology (ASCO), and the US Veterans Affairs (VA) Oncology A Study Section

Development Committee

Ivan Chan

Development Chair

Dr. Ivan S.F. Chan has more than 25 years of experience in the pharmaceutical industry. He is VP and Head of Hematology Biostatistics, Global Biometrics & Data Sciences at Bristol Myers Squibb. Previously, Ivan was VP and Head of Statistical Sciences at AbbVie. Prior to that, Ivan was Executive Director at Merck Research Laboratories where he led the global statistical support for vaccines and early oncology. Throughout his career, Ivan has built strong partnership across organization to influence decision making. He also has a passion for statistical innovation leading to accelerated development of drugs and vaccines.

Ivan received his B.S. in Statistics from the Chinese University of Hong Kong and Ph.D. in Biostatistics from the University of Minnesota. He is an elected Fellow of the American Statistical Association (ASA) and an elected Fellow of the Society for Clinical Trials (SCT). He currently serves as the Chair of the SCT Development Committee and has previously served on the Board of Directors and the Program Committee.

Meet our Society for Clinical Trials Committees (continued)

Equity, Diversity & Inclusion Committee

Kaleab Abebe

ED&I 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.

Dixie Ecklund

ED&I Co-Chair

Ms. Ecklund is Director of Operations of the CTSDMC. She has over 30 years of combined experience in conduct-ing clinical trials through the CTSDMC and in her previous role as Nurse Manager of the General Clinic Research Center (GCRC). She has been involved in various capacities in hundreds of clinical trials, ranging from small Phase 1 studies to multi-center Phase 3 studies. Ms. Ecklund has served as an IRB member for 25 years and was appointed an IRB chair in 2009. She has administrative experience with responsibilities including protocol implementation, protocol compliance, resource allocation, budgetary implications, and collaboration with many partners. Ms. Ecklund is responsible for overseeing all day-to-day activities of the DCC. She participates in all of the NeuroNEXT study team meetings and all of the operational meetings. She functionally supervises all DCC team leaders, monitors their progress, and provides guidance for operational questions. Ms. Ecklund serves as the direct liaison from the DCC Leadership to the CCC Leadership. She serves on the Site Support team and is a direct contact to the NeuroNEXT PIs and Coordinators. She serves as the DCC liaison for many of the Committees and is an ad-hoc member of NEC. Ms. Ecklund serves as the liaison to the NINDS DSMB on behalf of all of the NeuroNEXT investigators. She also serves on the Protocol Steering Committees as the blinded DCC member.

Fellows Committee

Roger Lewis

Fellows Chair

Dr. Lewis received his PhD in Biophysics and his MD from Stanford University. He is the former Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center, Professor of Emergency Medicine at the David Geffen School of Medicine at UCLA, and the Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in innovative clinical trial design. Dr. Lewis's expertise centers on adaptive and Bayesian clinical trials, including platform trials; translational, clinical, health services and outcomes research methodology; data and safety monitoring boards, and the oversight of clinical trials. Dr. Lewis was elected to membership in the National Academy of Medicine in 2009.

Dr. Lewis has served as a member of the Blood Products Advisory Committee of the US Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services, and on multiple consensus committees of the National Academy of Medicine. He has chaired data and safety monitoring boards (DSMBs) for numerous federally funded, industry-sponsored, and multinational clinical trials. He is a research methodology reviewer for *JAMA* and an editor of the *JAMA* series entitled "JAMA Guides to Statistics and Methods." Dr. Lewis

Meet our Society for Clinical Trials Committees (continued)

has served as a content reviewer for many other peer reviewed journals. He has authored or coauthored over 270 original research publications, reviews, editorials, and chapters.

Dr. Lewis has served as a grant reviewer for the Agency for Healthcare Research and Quality (AHRQ), the Canadian Institutes of Health Research (CIHR), the Centers for Disease Control and Prevention (CDC), the UK Medical Research Council (MRC), the National Cancer Institute of France, the National Institutes of Health (NIH), the Patient Centered Outcomes Research Institute (PCORI), and foundations.

During the US COVID-19 epidemic, Dr. Lewis served as the Director of Covid-19 Demand Modeling for the Los Angeles County Department of Health Services, leading a multidisciplinary team developing epidemiological prediction models to aid in hospital preparedness and response.
Dr. Lewis is a Past President of the Society for Academic Emergency Medicine (SAEM) and served on the Board of Directors for the Society for Clinical Trials. He is a fellow of the American College of Emergency Physicians, the American Statistical Association, and the Society for Clinical Trials.

Carol Redmond

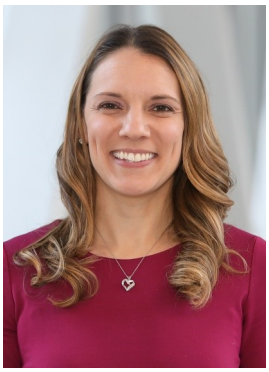
Fellows Co-Chair

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.

Membership Committee



Jody Ciolino

Membership Chair

Dr. Jody D. Ciolino is an Associate Professor in the Division of Biostatistics, Department of Preventive Medicine at Northwestern University. Her research interests include clinical study design and conduct, database development and data (quality) monitoring, interim monitoring / reporting / analyses, randomization and treatment allocation techniques (including cluster-randomization allocation techniques), and clinical trial data analyses. She is affiliated with both the Biostatistics Collaboration Center (BCC) and the Northwestern University Data Analysis and Coordinating Center (NUDACC) at Northwestern University. Dr. Ciolino's applied / collaborative research focuses on clinical studies applied to a wide range of disorders, diseases, and populations including those in the fields of perinatal depression, mood disorders, internal medicine and geriatrics, gastroenterology, and pediatrics. She also directs the MS-Biostatistics program at Northwestern University, advising students, coordinating thesis efforts, and teaching in this program.

Dr. Ciolino has been an active member of SCT for over 10 years, and has served on the Membership, Education, Communications Committees, and most recently the Equity, Diversity and Inclusion Committee. She sits on multiple Data and Safety Monitoring Boards (DSMBs) and also serves as a standing study section member for grant review.

Dee Blumberg

Membership Co-Chair

Dr. Dikla (Dee) Shmueli-Blumberg is a social psychologist with a background in self-regulation and health behavior change. She has over 14 years of experience in the field of clinical research, with earlier work examining models of self-regulation applied to the field of tobacco use and other substance use and craving. For the last 10 years she has worked at the Emmes Company, a global full service Clinical Research Organization (CRO). She serves 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) trials, where she oversees management activities for NIDA CTN studies across a variety of clinical operation domains including regulatory support, key study document development, research site staff

Society for Clinical Trials Committees (continued)

training, pharmacovigilance support, quality assurance and protocol monitoring, as well as managing pharmaceutical and laboratory services and supply logistics.

Dr. Blumberg has been an active member of SCT for 7 years and has served on the Membership and Program Committees.

Nominating Committee

Wendy Parulekar

Nominating Chair

Dr. Wendy Parulekar is a graduate of the University of Ottawa Medical School where she also completed residency training in Internal Medicine and Medical Oncology followed by post graduate training in clinical pharmacology at the University of Toronto. She currently holds a joint clinical/research position at Queen's University Cancer Research Institute and the Cancer Centre of South Eastern Ontario.

In her capacity as Senior Investigator at the internationally recognized research organization, the Canadian Cancer Trials Group, she supervises the conduct of national and international trials. These trials have contributed to treatment guidelines in breast, gynaecological and genitourinary malignancies.

Dr. Parulekar is a Fellow of the Society of Clinical Trials, past President (2015-2016) and a current Associate Editor for the Society journal *Clinical Trials*.

She also serves in an advisory/ reviewer capacity to numerous research organizations including the National Cancer Research Institute (NCRI): International Clinical Trials Awards and Advisory Panel, European Organization for Research and Treatment of Cancer, NCI US National Clinical Trial Network, Canadian Institutes of Health Research, Health Canada, Cancer Care Ontario Practice Guideline Initiative and the Ontario Institute of Cancer Research.

Outreach Committee

Rick Chappell

Outreach Chair

Rick Chappell chairs the Society's Outreach Committee and is a past president. He is Professor, Depts. of Statistics and of Biostatistics and Medi-cal Informatics, at the Univer-sity of Wisconsin.

Anne Lindblad

Outreach Co-Chair

Dr. Lindblad is the former President and CEO of Emmes, a global Contract Research Organization founded in 1977 with over 1000 staff members serv-ing both Industry and govern-ment clients. Dr. Lindblad is a biostatistician with more than 40 years of experience supporting clinical research projects. As the President and CEO of Emmes, Dr. Lindblad was responsible for providing strategic leadership for the company by working with the Board and other management personnel to establish long-range goals, strategies, plans and policies.

Dr Lindblad has supported clinical research throughout her career, serving as Principal Investigator of projects spanning diverse disease areas, including oncology, dialysis, transplantation, ophthalmology, speech and hearing, dentistry, and neurology. She has co-authored numerous publications in each of these areas, presented at scientific conferences and taught courses in clinical trials. She has witnessed first-hand the challenges in conducting sound research. From this experience, she has contributed to the literature in such fields as patient-reported outcome development, central statistical monitoring as part of a risk-based monitoring plan, disease classification systems, and barriers to recruiting for clinical trials.

Dr. Lindblad has a PhD in Statistics from George Washington University, a Masters degree in Biostatistics from the Medical College of Virginia, VA Commonwealth University, and a Bachelor of Science degree in Statistics from Hollins College.

Student Scholarship Committee

Cody Chiuzan

Student Scholarship Chair

Cody Chiuzan, PhD, is an Associate Professor in the Institute of Health System Science at Northwell Health, NY. Before that she was an Assistant Professor in the Department of Biostatistics at Mailman School of Public Health, Columbia University. Her research area focuses on development of early-phase clinical trial designs (applications to targeted and immunotherapeutic agents) and leveraging real-world evidence to improve trial outcomes and increase diversity of populations in clinical trials. Her honors include Junior Faculty Research Award and Co-

Society for Clinical Trials Committees (continued)

lumbia Public Health Innovation Award from the Mailman School of Public Health. Starting 2018, Dr. Chiuzan has served as the President of the American Statistical Association (ASA) NYC Chapter and an organizer member of StatFest and Diversity Mentoring Program sponsored by the ASA Committee on Minorities in Statistics.

Michael Grayling
Student Scholarship Co- Chair

Michael Grayling is a Research Fellow in Biostatistics at Newcastle University. His position involves a mix of research on the development of efficient methods for designing and analysing clinical trials and collaborating on applying such methods to real trials in practice. His interests include adaptive trial design, early phase drug development, and longitudinal study designs

Liz Garett-Mayer
Student Scholarship Past Chair

Elizabeth (Liz) Garrett-Mayer earned her PhD in Biostatistics at Johns Hopkins University in 2000. From 2000 to 2007, she served on the faculty in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. During these years, Dr. Garrett-Mayer collaborated in basic, translational, clinical and observational research in oncology, and taught courses in Biostatistics and mentored students at Johns Hopkins Bloomberg School of Public Health. In 2007, she joined the faculty of the Medical University of South Carolina and established the Biostatistics Shared Resource at the Hollings Cancer Center. In July 2017, Dr. Garrett-Mayer joined the Center for Research and Analytics at ASCO as the Division Director for Biostatistics and Research Data Governance. She currently collaborates with ASCO staff and external stakeholders on ASCO-directed research, including projects and data sources such as expanding eligibility criteria in cancer clinical trials, the TAPUR study, ASCO's COVID-19 Registry, and increasing minority enrollment in clinical trials. Her publication record includes over 280 peer-reviewed publications, the majority of which are in cancer research, two co-edited books, and nine book chapters. She has also been a member of numerous NCI committees and continues to participate on Data Safety Monitoring Committees for NIH supported clinical trials.

Trial of the Year Committee

Debra Hill
Trial of the Year Chair

Debra Hill (formally Condon), MSN, RN, CCRP has been a registered nurse since 1994 and is certified as a research professional through the Society of Clinical Research Associates (SoCRA). She has 40 years of medical and nursing experience in the areas of clinical research including medical devices, hematology/oncology, infectious disease, and gastroenterology. Furthermore, Debra has served as a board member and Co-Chair for the VA CSP-NODES Executive Committee from 2016-2018; a member of the Minneapolis VA Institutional Review Board from 2014 to present and Chair of the IRB since January 2020; and an active member of the Medical Reserve Corps of Carver County serving since 2006. In addition, Debra has been a contract faculty member of the Normandale Community College Nursing Program teaching a Nursing Refresher Course for three years. Her career at the Minneapolis VA Health Care System (MVAHCS) has spanned 31+ years. Currently, she is the Associate Director-Operations for the VA CSP-NODES program at the MVAHCS which she has held from October 2012 to present.

Suzanne Dahlberg
Trial of the Year Co-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.

SCT Member Spotlight – Sally Jo Zuspan, RN, MSN

What is your current position?

Director of Research and Business for the Data Coordinating Center at the University of Utah

What are your past positions?

I began my career as an emergency department nurse and a Trauma Program Manager at a large children's hospital. Following that I worked as a lobbyist for the American College of Surgeons Committee on Trauma in Ohio and helped pass trauma legislation. Research was an important aspect of trauma care sparking my interest in clinical research. When I moved to Utah, I found a research position at the University of Utah managing the Data Coordinating Center. Our first studies were focused in pediatrics and then adults, rare disease and cardiology.

What is your training?

I have a Bachelor's degree in Nursing and a Master's degree in Emergency and Trauma Nursing.

What are your specific research interests?

I am interested in how to help investigators develop robust, practical research trials that are easily implementable at multiple sites. I am also interested in research outcomes using wearable devices and remote assessments. The topic of how to obtain clean, analyzable data from busy clinical areas is also an area of interest.

What are your hobbies (outside of work)?

I am an avid cyclist, skier and hiker and love to explore slot canyons while canyoneering in Southern Utah. I also love camping, but have recently purchased an RV which makes camping much more enjoyable. I love international travel, languages and exploring other cultures.

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

I am a member of SCT and have been for several years. I have been fortunate to present at a few meetings.

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

My favorite part of being involved in clinical trials is educating investigators about how best to organize a trial for optimal results. I enjoy being engaged with sites to learn what makes research interesting and also what challenges impact a site's ability to conduct great research.

Your least favorite?

My least favorite part of research is the challenge in finding funding for excellent research proposals. I also really hate dirty data.

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

I completely enjoy engaging with other academic research centers and I always find the presentations and abstracts to be enjoyable and educational.

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

Find an excellent mentor and work closely with that person to gain experience and confidence in clinical research. Then, never give up.

What is one strategy you have used to maintain your sanity during the pandemic?

Getting outside to enjoy nature is a huge stress reliever. Outside is a safe place to be from the pandemic standpoint and very easily accessible in Utah.

Call For The David Sackett Trial Of The Year Nominations

Deadline is January 28, 2022

We Are Accepting Nominations For The Trial Of The Year 2021!

Nominations must be submitted online (click here).

The Society for Clinical Trials presents an annual award to the randomized clinical trial published (either electronically or in print) in the previous year (2021 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 28, 2022.

The Award will be presented at the 43rd Annual Meeting

taking place in San Diego, CA

May 15-18, 2022

***Nominations can be submitted online between November 2, 2021 and January 28, 2022.**

*Nominations from the Trial of the Year planning group are also welcome.

For questions, please contact SCT via **email**

CLINICAL TRIALS

Journal of the Society for Clinical Trials

August & October, 2021 Issue Highlights

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

By Colin Begg, Editor

In the **August** issue of ***Clinical Trials*** **Elizabeth Schaeffer** and colleagues examined how to record patient-reported pain for cancer studies, finding that daily reporting is unnecessary and weekly reporting is sufficient.

Jill Fisher and colleagues studied the use of "professional" volunteers for phase 1 clinical trials, finding that the remuneration for this kind of work is very modest.

Holly Taylor and colleagues conducted a randomized trial of strategies to enhance understanding of informed consent, showing that an interview style video was significantly more effective than a fact sheet. Finally, the FDA has increasingly been using accelerated approval.

Joshua Skydel and colleagues studied the impact of this, finding that the number of required post-marketing studies has not increased to the extent we should have expected.

In the **October** issue, **Karla Hemming** and colleagues investigated the novel data monitoring challenges faced in cluster randomized trials, providing some guidelines. Also on the topic of cluster trials,

Elizabeth Korevaar and colleagues have provided a repository of intra-cluster correlations to help planning cluster trials.

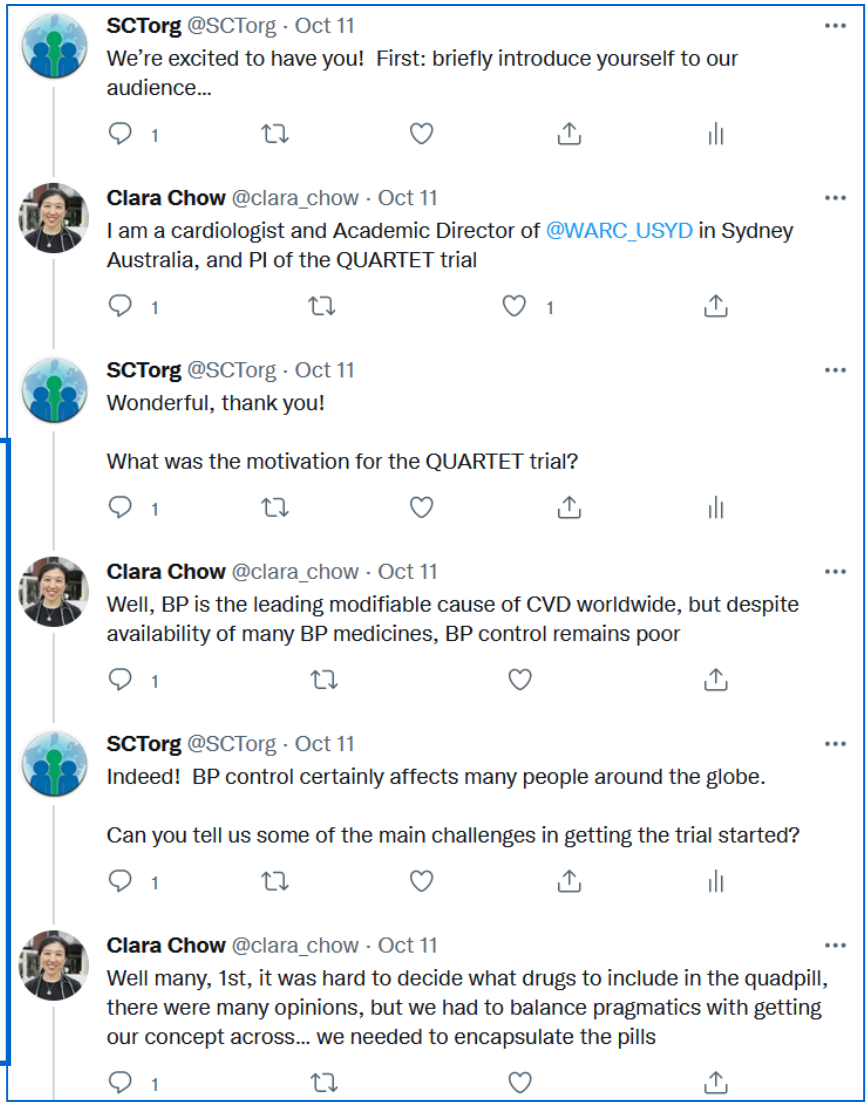
Dimitri Drekonja and colleagues show how the VA managed to successfully implement a remote trial of fecal transplantation during the pandemic.

As always, we welcome all Society members to submit their best research to the Society journal.

What's Happening on the SCT Twitter Feed?

Lee McDaniel
Communications
Committee
Chairperson

Are you interested in sharing your clinical trials experience with the SCT membership on social media? The SCT Social Media Coordinator is publishing a series of interviews on Twitter to shine a light on all different personnel involved in making clinical trials happen. If you just want to read about the experiences of others, follow @SCTorg on Twitter, but if you want to share please direct message @SCTorg and say "interview me!"



SCT's 2021 Virtual Meeting Recordings now available at www.sctweb.org !

SCT is pleased to announce that all content from our 2021 Virtual Annual Meeting is now available on the SCT website!

You can view all recordings under the Annual Meeting drop down, then navigate to 2021 Virtual to access all the content from our recent meeting.

Please note that you must log into the Member area of the website in order to access the content.

If you need assistance with logging in, please contact us at info@sctweb.org

Thank you.

CALLING ALL SCT HISTORIANS AND HISTORY BUFFS

The stated purpose of the Society is an international multidisciplinary organization dedicated to the development and dissemination of knowledge about the design, conduct, analyses, and reporting of clinical trials and related health care research methodologies. To this end, SCT is launching an initiative to capture missing newsletters and the information that they contain.

SCT is looking for copies of SCT Newsletters from 1978 when the Society was founded through 1997. Newsletters from 1998 to 2021 are currently available on the website at http://sctweb.org/newsletter.cfm

Do you have any of these Newsletters? We welcome you to scan and email them to info@sctweb.org.

If you prefer to mail your copies, please send them to:
Society for Clinical Trials
ATTN: Angie Stark
85 W. Algonquin Road – Suite 550
Arlington Heights, IL 60005

Questions? Please contact us at info@sctweb.org

Thank you for your dedication to SCT and for your help in preserving our history.

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

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The 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.

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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.

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OXFORD RECOVERY CENTER

The Oxford Recovery Model develops a targeted healing approach for each unique patient. We employ numerous therapies and healing modalities to treat a wide range of conditions.

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UNIVERSITY OF WISCONSIN DCC

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

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

44th Annual Meeting
May 21-24, 2023
Baltimore, MD

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