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NEWSLETTER

MAY 2022

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## From SCT President Mithat Gönen



**Mithat Gönen**

**Society for Clinical Trials President 2021-2022**

It is with mixed feelings that I am writing this last newsletter column as your president. I am relieved because I was humbled to be elected and carried the weight of being entrusted with this responsibility throughout my term. I am sad to see my term end because I learned many new things, met new people and to know better others. Either way I am happy that I was able to give back to the Society that did so much for me, and I am also happy to be passing the baton to an exceptionally qualified President, Lehana Thabane. This week before the Annual Meeting is the calm before the storm. Most preparations that are expected of the society leadership are complete and last-minute logistics are handled by our able partners at EAI. It is the perfect time to take stock of the past year. I had an easier environment as the Society President than my two predecessors Dean Fergusson and Susan Halabi who found themselves restrained by a full-blown pandemic. They nevertheless kept the lights on, organized on-line meetings and kept the society afloat. In contrast to 2020 and 2021, we

are able to meet in person this year and hopefully reap the many benefits of our annual meeting.

Presidents have an iconic presence but leading the society for a year is a true team effort. Committees are always very active, filling specific roles that range from organizing the annual meeting program to being grassroots components that keep us in touch with the membership at large. Executive Committee is a president's best friend, meeting weekly and providing advice, and decision-making power. The Board of Directors give us direction and provide oversight for all society activities. Last, but not least, EAI is the glue that holds this together. Whatever credit is due, it is to this entire team.

I am finishing my term with optimistic thoughts and predictions for the society. The pandemic has placed clinical trials at the center of all societal discussions. Resources for designing and conducting trials are on the rise. Our younger members are rising in the society, chairing committees, and putting their hats in the ring for our elections. Much more needs to be done to elevate the number and diversity of our members, increase our footprint, and create additional resources. I am happy to say that the next two presidents and the incoming board are very well-prepared to meet these challenges. I thank all of you again for entrusting me to run your society and I look forward to seeing you in San Diego.

*Mithat*



## **Live & Virtual Meeting Registration is open for the 43rd Annual Meeting of the Society for Clinical Trials!**

Please join us! This year's theme is:

### ***"Informing Public Health Policy with Compelling Evidence"***

The Annual Meeting of the Society for Clinical Trials is a multidisciplinary program with broad participation. The Meeting brings together the clinical trials community from academia, the pharmaceutical and device industries, government agencies, medical groups, and centers and clinical research entities.

**May 15 - 18, 2022**

**at the**

**San Diego Hilton Bayfront Resort**

**1 Park Boulevard San Diego, CA, 92101**

**Phone: (619) 564-3333 or 1-800-HILTONS (1-800-445-8667)**

**[Click Here to Learn More About SCT's 43rd Annual Meeting](#)**

#### **Highlights of the live meeting include:**

- Networking with your colleagues
- Plenary sessions, in-conference workshops, invited sessions, contributed presentations, and posters presentations
- Pre-meeting workshop courses by leaders in the field
- Annual Thomas C. Chalmers Student Scholarship competition
- Presentation by the Sylvan Green Award Winner
- Exhibitors showcasing publications, technology and other resources for clinical trials
- Discussions of timely issues and research experiences among colleagues in the field
- Presentation of the 2021 David Sackett Trial of the Year Award
- Presentation of the SCT Class of 2022 Fellows
- Roundtables which are moderator led, small group discussions focused on specific industry related topics

#### **SCT is also offering a Virtual Meeting Option this year which includes online access via zoom to virtual meeting events including::**

- Curtis Meinert Keynote Lecture
- Annual Dave Sackett Trial of the Year Award
- Thomas C. Chalmers Scholarship & Sylvan Green Award
- Founders Keynote Lecture
- Presentation of Class of Fellows

## Society for Clinical Trials 2022 Keynote Speaker

**Dr. Robert M. Califf**



SCT is pleased to announce the  
Keynote Speaker for the Founders Lecture  
will be

**Dr. Robert M. Califf**  
*FDA Commissioner*

Dr. Califf's presentation titled  
**"The Time is Now to Fix the Evidence Generation System"** will take  
place on Tuesday, May 17 at 5:00 pm PT.

## Society for Clinical Trials 2022 Keynote Speaker

**Worta McCaskill-Stevens, MD, MS**



SCT is pleased to announce the  
Keynote Speaker for the Curtis Meinert Lecture  
will be

**Worta McCaskill-Stevens, MD, MS**  
*National Cancer Institute, NIH*

Dr. McCaskill-Stevens' keynote speech titled  
**"Lessons Learned from NCI's Community Based Clinical Trials"**  
will take place on Monday, May 16 at 8:15 AM immediately following the  
President's welcome.

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

### April, 2022 Issue Highlights

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



In the **April** issue of *Clinical Trials* **Stewart Anderson** catalogues the remarkable contributions to cancer clinical trials of Bernie Fisher and the astonishing NCI efforts to discredit him.

**Scott Kim** and **Jonathan Kimmelman** address the ethical oversight of pragmatic randomized clinical trials of standard of care interventions, offering a structured process for evaluating the research risks.

**Helena Aschmann** and colleagues call for large scale prevention trials to be designed to make assessment of benefit-harm balance the primary aim. In a commentary **Andrew Vickers** states that doing

so would contravene established principles and would do more harm than good.

**Philip Westgate** and colleagues argue for the advantages of using negative binomial regression for analyzing cluster randomized trials when clusters are large and events are rare.

Finally, **Sarai Keestra** and colleagues examine compliance with trial reporting rules at universities, showing that political pressure can have a positive impact. As always, Society members are encouraged to submit their work to *Clinical Trials*.



By Colin Begg, Editor

## Register Onsite for Pre-Conference Workshops, In-Conference Workshops, and Roundtable Discussions While Seats Last!

If you have not already registered for a pre-conference workshop, an in-conference workshop, or a roundtable discussion, time is quickly becoming of the essence as seats are filling up fast!

The following workshops and roundtables are still available:

- Pre-Conference Workshop 1: Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables (Hybrid Format Workshop)
- Pre-Conference Workshop 2: Clinical Trial Data Monitoring Committees and Reporting Statistical Centers: The Basics and Emerging Issues
- Pre-Conference Workshop 3: Model-Assisted Designs: Make Adaptive Clinical Trials Easy and Accessible
- Pre-Conference Workshop 4: Introduction to Efficient Preparation, Access, and Sharing of Trial Data in RED-Cap Using the API
- Pre-Conference Workshop 5: Essentials of Clinical Trials
- In-Conference Workshop 1: Behavioural Trial Design: Using Stakeholder-Driven Processes to Develop Interventions and Assessment Tools Using a Public Health Intervention Example
- In-Conference Workshop 2: Causal Interference for Complex Data
- In-Conference Workshop 3: Demystifying Statistics in Clinical Trials
- In-Conference Workshop 4: TrialTree: A Novel Application for Interactive Trial Design
- In-Conference Workshop 5: It Takes a Village: Multi-Disciplinary Approach to Designing Stellar Data Collection Forms
- Roundtable 1: DSMB
- Roundtable 4: How to Get Involved with SCT (Complimentary registration.)
- Roundtable 5: New Efficiencies & Lessons Learned in a Pandemic Time
- Roundtable 6: Precision Trial Medicine
- Roundtable 7: Supplemental Clinical Trial Data vs. Real World Data
- Roundtable 8: The Statistician as an Investigator and Educator, Not Just a Power Calculator, on Clinical Research Protocols
- Roundtable 9: Fostering Equity, Diversity, and Inclusion within the Society

## The SCT 2022 Call for Volunteers Portal is open! Submit your interest by May 31, 2022

SCT Members,

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

**If you are interested in serving as a Volunteer, we welcome you to the 2022 SCT Volunteer Portal and invite you to submit your interest by 11:59 pm ET on May 31st.**

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

Please complete the following steps to submit your interest:

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

The whole process takes less than five minutes to complete, and it is only necessary to complete these steps once for your term of service.

## Society for Clinical Trials Officers Election Results

SCT is pleased to announce that **Dixie J. Ecklund, BSN, RN, MSN, MBA, CCRC** was voted in as President-elect of the Society and **Masha Kocherginsky, PhD** and **Jody D. Ciolino, PhD** were voted in as new Board Members.



**Dixie J. Ecklund,**  
**BSN, RN, MSN, MBA, CCRC**

Director of Operations,  
Clinical Trials Statistical &  
Data Management Center,  
University of Iowa



**Jody D. Ciolino, PhD**

Associate Professor;  
Director of Master of Science  
in Biostatistics Program  
Department of Preventive  
Medicine – Biostatistics;  
Northwestern University



**Masha Kocherginsky, PhD**

Professor, Department of  
Preventive Medicine,  
Division of Biostatistics;  
Director, Quantitative Data  
Sciences Core (QDSC), Robert H.  
Lurie Comprehensive Cancer  
Center, Northwestern University

## Society for Clinical Trials 2022 Class of Fellows

The Society for Clinical Trials established the title of "Fellow of the Society for Clinical Trials" in 2005 to honor Society members who have made significant contributions to the advancement of clinical trials and to the Society. This title is granted to a number of Society members each year at the Annual Meeting.



**Thomas Cook, PhD**  
University of Wisconsin,  
Madison



**Alexia Iasonos, PhD**  
Memorial Sloan Kettering  
Cancer Center

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. 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:

- Design, coordination, analysis and/or reporting of oversight of individual or multiple clinical trials.
- Education and promotion of a better understanding by the general public of the importance and interpretation of randomized clinical trials.
- Ethical considerations and human subjects' protections in the conduct of clinical trials.
- Information technology, data management, data quality, or data sharing.
- Service to the Society.



## David Sackett Trial of the Year

On May 16, 2022 the Society for Clinical Trials (SCT) will bestow the prestigious David Sackett Trial of the Year Award and is proud to announce the 2021 winning trial:

### The TOGETHER Trial: An Adaptive Platform International Trial

Accepting the award and presenting the trial about the largest placebo-controlled clinical trial for the evaluation of COVID-19 therapeutics in the world will be Co-principal Investigators, Drs. Edward J. Mills, from McMaster University; and Gilmar Reis, Pontifica Universidade Catolica de Minas Gerais.

Each year The Society for Clinical Trials presents an award to the randomized clinical trial published in the previous year 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.

## Society for Clinical Trials 2022 Equity, Diversity & Inclusion Student Travel Awards

The Society for Clinical Trials (SCT) is pleased to announce this year's ED&I Student Travel Award recipients!



**Sandra Castro-Pearson**  
University of Minnesota



**David-Erick Lafontant**  
University of Iowa



**Jacqueline Thompson**  
University of Birmingham














**Ariany Marques Vieira**  
Concordia University

All awardees will be recognized during the Business Session Lunch on Tuesday, May 17 as part of SCT's 43rd Annual Meeting (May 15-18, 2022) in San Diego, CA. They will also have the opportunity to network with SCT leadership and members of the Equity, Diversity, & Inclusion (ED&I) Committee.


















Each year, SCT's ED&I Committee chooses travel award recipients to help promote a diverse SCT membership. Each student receives complimentary meeting registration, one-year membership, and up to a \$1,600 grant for travel and hotel expenses to attend the Annual Meeting.

Congratulations to all

## Sunday, May 15, 2022

7:00 AM - 5:00 PM	<ul style="list-style-type: none"> <li>• <b>REGISTRATION</b>  Indigo Light Wall (2nd Floor)</li> </ul>
8:00 AM - 12:00 PM	<ul style="list-style-type: none"> <li>• <b>PRE-CONFERENCE WORKSHOP 1</b>   Indigo 202 B (2nd Floor) Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables</li> <li>• <b>PRE-CONFERENCE WORKSHOP 2</b>   Indigo 202 A (2nd Floor) Clinical Trial Data Monitoring Committees and Reporting Statistical Centers: The Basics and Emerging Issues</li> <li>• <b>PRE-CONFERENCE WORKSHOP 3</b>   Indigo 204 B (2nd Floor) Model-Assisted Designs: Make Adaptive Clinical Trials Easy and Accessible</li> </ul>
9:45 AM - 10:15 AM	<ul style="list-style-type: none"> <li>• <b>BREAK</b></li> </ul>
12:00 PM - 1:00 PM	<ul style="list-style-type: none"> <li>• <b>LUNCH (ON YOUR OWN)</b></li> </ul>
1:00 PM - 5:00 PM	<ul style="list-style-type: none"> <li>• <b>PRE-CONFERENCE WORKSHOP 4</b>   Indigo 202 B (2nd Floor) Introduction to Efficient Preparation, Access, and Sharing of Trial Data in REDCap Using the API</li> <li>• <b>PRE-CONFERENCE WORKSHOP 5</b>   Indigo 202 A (2nd Floor) Essentials of Clinical Trials</li> </ul>
2:45 PM - 3:15 PM	<ul style="list-style-type: none"> <li>• <b>BREAK</b></li> </ul>

## Monday, May 16, 2022

7:00 AM - 5:00 PM	<ul style="list-style-type: none"> <li>• <b>REGISTRATION</b>  Indigo Light Wall (2nd Floor)</li> </ul>
8:00 AM - 9:30 AM	<ul style="list-style-type: none"> <li>• <b>SCT PRESIDENT WELCOME</b>  Indigo BCFG (2nd Floor) Mithat Gönen, PhD   Memorial Sloan-Kettering Cancer Center</li> <li>• <b>CURTIS MEINERT KEYNOTE LECTURE</b>  Indigo BCFG (2nd Floor) "Lessons Learned from the National Cancer Institute's Community-Based Clinical Trials"   Dr. Worta McCaskill-Stevens</li> </ul>
9:30 AM - 10:00 AM	<ul style="list-style-type: none"> <li>• <b>POSTER SESSION 1</b>   Indigo A (2nd Floor)</li> </ul>
10:00 AM - 11:30 AM	<ul style="list-style-type: none"> <li>• <b>INVITED SESSION 1</b>   Indigo D (2nd Floor) Optimizing Precision Medicine Cancer Clinical Trials</li> <li>• <b>INVITED SESSION 2</b>   Indigo E (2nd Floor) Inclusive Recruitment Strategies in Clinical Trials: Insights from Rehabilitation Research</li> <li>• <b>INVITED SESSION 3</b>   Indigo 202 A (2nd Floor) The Promise and Challenges of Integrating Real-World Evidence in Clinical Research</li> <li>• <b>INVITED SESSION 4</b>   Indigo H (2nd Floor) Real World Experience in Conducting Adaptive Platform Trials</li> <li>• <b>INVITED SESSION 5</b>   Indigo BCFG (2nd Floor) Strategies to Mitigate the Impact of the COVID Pandemic on Trial Implementation, Closeout, Data Quality and Analysis of a Large Multicenter Clinical The Glycemia Reduction Approaches in Diabetes Comparative Effectiveness Study (GRADE)</li> <li>• <b>IN-CONFERENCE WORKSHOP 1</b>   Indigo 202 B (2nd Floor) Behavioural Trial Design: Using Stakeholder-Driven Processes to Develop Interventions and Assessment Tools Using a Public Health Intervention Example</li> </ul>

# Society for Clinical Trials 2022
















## Program (continued)

Monday, May 16, 2022

11:30 AM - 12:45 PM	<ul style="list-style-type: none"> <li>▪ <b>LUNCH</b> ➔ Indigo BCFG (2nd Floor)</li> <li>▪ <b>ROUNDTABLE 1</b> ➔ Indigo Terrace (2nd Floor) DSMB Moderator: David DeMets, PhD</li> <li>▪ <b>ROUNDTABLE 2</b> ➔ Indigo Terrace (2nd Floor) Introduction to Clinical Trial Career Paths + with Guest Attendee from Leadership (Members are encouraged to attend from diverse field backgrounds.) Moderator: Cristina Murray-Krezan</li> <li>▪ <b>ROUNDTABLE 3</b> ➔ Indigo Terrace (2nd Floor) On Navigating Common Issues in Clinical Trials (e.g., protocol deviations, adverse events, ethical considerations) (Members are encouraged to attend from diverse field backgrounds.) Moderator: Julia Collins</li> <li>▪ <b>ROUNDTABLE 4</b> ➔ Indigo Terrace (2nd Floor) How to Get Involved with SCT (This session will provide some background on the society and structure along with ideas for networking and professional growth within the society.) Moderator: Jody Ciolino, PhD</li> <li>▪ <b>ROUNDTABLE 5</b> ➔ Indigo Terrace (2nd Floor) New Efficiencies &amp; Lessons Learned in a Pandemic Time Moderator: Margaret Tikin, DNP, CNP, MBA</li> <li>▪ <b>ROUNDTABLE 6</b> ➔ Indigo Terrace (2nd Floor) Precision Trial Medicine Moderator: Pam Mangat</li> <li>▪ <b>ROUNDTABLE 7</b> ➔ Indigo Terrace (2nd Floor) Supplemental Clinical Trial Data vs. Real World Data Moderator: Ben Ackerman, PhD</li> <li>▪ <b>ROUNDTABLE 8</b> ➔ Indigo Terrace (2nd Floor) The Statistician as an Investigator and Educator, Not Just a Power Calculator, on Clinical Research Protocols Moderator: Alexia Iasonos, PhD</li> <li>▪ <b>ROUNDTABLE 9</b> ➔ Indigo Terrace (2nd Floor) Fostering Equity, Diversity, and Inclusion within the Society Moderator: Kaleab Abebe, PhD</li> </ul>
12:45 PM - 2:00 PM	<ul style="list-style-type: none"> <li>▪ <b>CHALMERS AWARD FINALISTS</b> ➔ Indigo BCFG (2nd Floor) Simultaneous Hypothesis Testing for Multiple Competing Risks in Comparative Clinical Trials Estimating Interactions and Subgroup-Specific Treatment Effects in Meta-Analysis Without Aggregation Bias: A Within-Trial Framework A Permutation Procedure to Detect Heterogeneous Treatments Effects in Randomized Clinical Trials While Controlling the Type-I Error Rate</li> <li>▪ <b>SYLVAN GREEN AWARD WINNER</b> ➔ Indigo BCFG (2nd Floor) Enhancing Patient-Partnership in Clinical Trials</li> </ul>
12:45 PM - 2:15 PM	<ul style="list-style-type: none"> <li>▪ <b>INVITED SESSION 6</b> ➔ Indigo 202 A (2nd Floor) Innovative Approaches to Data Collection Needs in Clinical Trials: Considerations, Lessons Learned and Future Directions</li> <li>▪ <b>INVITED SESSION 7</b> ➔ Indigo D (2nd Floor) Complex Innovative Design in the Modern Drug Development Era</li> <li>▪ <b>INVITED SESSION 9</b> ➔ Indigo H (2nd Floor) Analysing Clinical Trials Disrupted by the COVID-19 Pandemic</li> <li>▪ <b>INVITED SESSION 10</b> ➔ Indigo E (2nd Floor) How Different Communication Pathways Impact the Success of a Clinical Trial, A Multifaceted Perspective</li> <li>▪ <b>IN-CONFERENCE WORKSHOP 2</b> ➔ Indigo 202 B (2nd Floor) Causal Inference for Complex Data</li> </ul>
2:15 PM - 2:30 PM	<ul style="list-style-type: none"> <li>▪ <b>BREAK</b></li> </ul>



Monday, May 16, 2022

2:30 PM - 3:30 PM	<ul style="list-style-type: none"> <li> <b>CONTRIBUTED SESSION 1</b>   Indigo E (2nd Floor)           <p>Applied 1</p> <p>The Inclusion of Covariates in Constrained Longitudinal Data Analysis for Pre-Post Randomized Clinical Trials</p> <p>The Benefits of Covariate Adjustment for Adaptive Multi-Arm Designs</p> <p>TwinRCT: Leveraging External Data, Artificial Intelligence, and Covariate Adjustment</p> <p>Bayesian Random Change Point Mixed Model Analysis of Cognitive Performance Trajectories to Identify Eligible Patients for Randomized Clinical Trials</p> </li> <li> <b>CONTRIBUTED SESSION 2</b>   Indigo H (2nd Floor)           <p>Ethics 1</p> <p>Grownish: How And When To Include Adolescents In Adult Research</p> <p>Considerations When Collecting Real World Data in Expanded Access Programs</p> <p>The Problem of Identifying Vulnerable Research Participants in Pragmatic Cluster Randomized Trials</p> <p>Dotting Your I's and Crossing Your T's: An Informed Consent Documentation Tool for Clinical Trials</p> </li> <li> <b>CONTRIBUTED SESSION 3</b>   Indigo 202 A (2nd Floor)           <p>Operations 1</p> <p>Increasing the Generalizability of Pain Study Results</p> <p>OlympiA – A Complex but Successful Model for a Large Global Trial</p> <p>The Protocol Review Checklist: A Tool to Ensure Protocol Completeness, Consistency, and Accuracy</p> <p>Lifestyle Intervention Delivery During the COVID Era</p> </li> <li> <b>CONTRIBUTED SESSION 4</b>   Indigo BCFG (2nd Floor)           <p>Dose-Finding</p> <p>A Unified Decision Framework for Phase I Dose-Finding Designs</p> <p>Early Phase Dose-Finding Trials in Virology</p> <p>Dose-Finding Based on Feasibility and Late-Onset Toxicity in Adoptive Cell Therapy Trials</p> <p>A Biomarker-Based Dose-Finding Design for Immunotherapy</p> </li> <li> <b>CONTRIBUTED SESSION 5</b>   Indigo D (2nd Floor)           <p>Recruitment &amp; Retention 1</p> <p>A Novel Approach Employing Readability Metrics and Crowdsourcing to Improve Randomised Clinical Trial Information Leaflets</p> <p>Using Informational Videos to Support Recruitment for Parenting Trials</p> <p>A Culturally and Contextually Situated Multimedia Approach to Recruiting, Consenting, and Randomizing a Hard-to-Reach Spanish-Speaking Population</p> <p>Predicting Patients' Willingness to Participate in Clinical Trials: A Simulation Tool Using Patient Choice Data</p> </li> <li> <b>CONTRIBUTED SESSION 6</b>   Indigo 204 B (2nd Floor)           <p>Trial Design 1</p> <p>TBD</p> <p>Randomization Schemes Using Electronic Health Systems to Facilitate Emergency Department-Based Pragmatic Clinical Trials of Public Health Screening</p> <p>Involving Patients in the Design of Randomized Clinical Trials</p> <p>Novel Method of Using JavaScript Encoding and QR (Quick Response) Codes in Remotely Managed Randomization of Blinded Studies in Low-Resource Environments</p> </li> </ul>
3:30 PM - 4:00 PM	<ul style="list-style-type: none"> <li> <b>POSTER SESSION 2</b>   Indigo A (2nd Floor)           </li> </ul>
4:00 PM - 5:30 PM	<ul style="list-style-type: none"> <li> <b>TRIAL OF THE YEAR</b>  Indigo BCFG (2nd Floor)           <p>Coming soon</p> </li> </ul>

# Society for Clinical Trials 2022

## Program (continued)

Tuesday, May 17, 2022	
8:30 AM - 5:00 PM	<ul style="list-style-type: none"> <li>REGISTRATION Indigo Light Wall (2nd floor)</li> </ul>
9:30 AM - 10:30 AM	<ul style="list-style-type: none"> <li>CONTRIBUTED SESSION 7 ☑ Indigo H (2nd floor)               <p>Applied 2</p> <p>Accounting for Differential Uptake of Treatment-as-Usual in Open-Label RCTs</p> <p>A Comparison of Methods and Illustration in Mental Health Trials</p> <p>Quantifying the Impact of Enrichment in Pre-Post Randomized Controlled Clinical Trials</p> <p>SuperLearner Enforced Treatment Effect Estimation in Pediatric Trials</p> <p>Bayesian Network Enforced Super Learner Treatment Effect Estimation in Clinical Trial: A Proposal and Application</p> </li> <li>CONTRIBUTED SESSION 8 ☑ Indigo D (2nd floor)               <p>Operations 2</p> <p>Implementation of Substudies in Multi-Center Clinical Trials: The Grade Study Experience</p> <p>The What, How, When and Who of Sharing Trial Results Summaries with Trial Participants: Stakeholder Informed Guidance from the RECAP Project</p> <p>Challenges Implementing a Clustered Randomized Behavioral Clinical Trial in a Community Based Participatory Research Framework</p> <p>Advantages, Disadvantages, and Other Considerations for Trials in Cohorts: A Decade In</p> </li> <li>CONTRIBUTED SESSION 9 ☑ Indigo E (2nd floor)               <p>Cluster Trials</p> <p>Estimating Marginal Treatment Effect in Cluster Randomized Trials with Multilevel Missing Outcomes</p> <p>A SAS Macro for the Power of Generalized Estimating Equations Analysis of Cluster Randomized Trials with the Application to Stepped Wedge Designs</p> <p>Maximin Optimal Cluster Randomized Designs Accounting for Treatment Effect Heterogeneity</p> <p>Power Analysis for Stepped Wedge Cluster Randomized Trials with Continuous Co-Primary Endpoints</p> </li> <li>CONTRIBUTED SESSION 10 ☑ Indigo 202 A (2nd floor)               <p>Mediation &amp; Trial Design 3</p> <p>The Good, The Bad and The Hidden Bias in Mediation Analyses of Clinical Trials</p> <p>Challenges for Conducting Mediation Analyses in Multi-Arm Trials</p> <p>Combining Non-Adherence and Mediation in a Unified Causal Analysis: A Methodological Review and Application to the AVATAR Trial</p> <p>The CREED:</p> <p>Complementary Randomized Controlled Trial and Real-World Study for Efficacy, Effectiveness, and Implementation Design, with Illustrations of One I</p> </li> <li>CONTRIBUTED SESSION 11 ☑ Indigo BC/FG (2nd floor)               <p>Outcomes</p> <p>Integrating Patient Values into Clinical Trials Using a Patient-Centered Composite Endpoint:</p> <p>A Case Study Using the Control of Hypertension in Pregnancy Study (CHIPS) Trial</p> <p>Virtual Clinical Outcome Ascertainment in a Prostate Cancer Treatment Trial</p> <p>Challenges of Data Collection for a Fully Remote Clinical Trial with a Multi-Component Outcome: Virtual ELM Pilot Study</p> <p>TBO</p> </li> <li>CONTRIBUTED SESSION 12 ☑ Indigo 204 B (2nd floor)               <p>Trial Design 2</p> <p>Landscape of Phase 2 Trials in Alzheimer's Disease: A Systematic Review of Trial Characteristics</p> <p>A Structured Framework for Adaptively Incorporating External Evidence in Sequentially Monitored Clinical Trials</p> <p>Multi-Arm Multi-Outcome Clinical Trial Design and Analysis with Bayesian Spike-and-Slab Priors</p> <p>How are Progression Decisions Made Following External Randomised Pilot Trials? A Qualitative Interview Study and Framework Analysis</p> </li> </ul>
10:30 AM - 11:00 AM	<ul style="list-style-type: none"> <li>POSTER SESSION 3 ☑ Indigo A (2nd floor)</li> </ul>
11:00 AM - 12:30 PM	<ul style="list-style-type: none"> <li>INVITED SESSION 11 ☑ Indigo BC/FG (2nd floor)               <p>Clinical Trials of COVID-19 Vaccines: Overcoming the Challenges</p> </li> <li>INVITED SESSION 12 ☑ Indigo H (2nd floor)               <p>Using a Single RRT for NIH-Funded Multisite Trials</p> </li> <li>INVITED SESSION 13 ☑ Indigo 202 A (2nd floor)               <p>Perspectives on Real World Data and Evidence Collection Through Expanded Access</p> </li> <li>INVITED SESSION 14 ☑ Indigo D (2nd floor)               <p>When and How to Use Covariate Adjustment to Improve Precision in Randomized Trials</p> </li> <li>INVITED SESSION 15 ☑ Indigo E (2nd floor)               <p>Optimizing the Interdisciplinary Design of Adaptive Platform Trials</p> </li> <li>IN-CONFERENCE WORKSHOP 3 ☑ Indigo 202 B (2nd floor)               <p>Demystifying Statistics in Clinical Trials</p> </li> </ul>

# Society for Clinical Trials 2022

## Preliminary Program (continued)

Tuesday, May 17, 2022

12:30 PM - 2:00 PM	<ul style="list-style-type: none"> <li>▪ <b>SCT BUSINESS MEETING</b> 📍 Indigo BCFG (2nd floor)</li> <li>▪ <b>PRESENTATION OF FELLOWS CLASS</b> 📍 Indigo BCFG (2nd floor)</li> </ul>
2:00 PM - 3:00 PM	<ul style="list-style-type: none"> <li>▪ <b>CONTRIBUTED SESSION 13</b> 📍 Indigo D (2nd floor) Applied 3 Accounting for Unequal Cluster Sizes in Designing Cluster Randomized Trials to Detect Treatment Effect Heterogeneity Accounting for Correlation Among the Total Events of Composite Outcomes in Cardiovascular Trials A Hybrid Approach to Comparing Parallel-Group and Stepped-Wedge Cluster Randomized Trials When There is Uncertainty in the Intra-Cluster Correlation Statistical Assessment of Unplanned Crossover Effect in Surgical Trials</li> <li>▪ <b>CONTRIBUTED SESSION 14</b> 📍 Indigo E (2nd floor) Operations 3 ClinicalTrials.gov Tracking with Do-It-Yourself Application Programming Interface (DIY API) Overview of CDER BIMO Compliance and Enforcement Modifications to Surgical Procedures: A Scoping Review and Preliminary Framework to Promote Transparent Reporting and Efficient Sharing Disseminating Phase I Vaccine Trial Data in a Pandemic to Inform the Scientific Community - mRNA-1273 Phase I Trials</li> <li>▪ <b>CONTRIBUTED SESSION 15</b> 📍 Indigo BCFG (2nd floor) Data Monitoring Assessment of a Risk-Based Quality Management Approach to Protocol Deviations - A Data Coordinating Center's Experience Dynamically Generating Study Monitoring Reports via Email Analysis of Adverse Event and Serious Adverse Event Data from Randomized Controlled Trials Data Visualization Approaches to Presenting Harms in Clinical Trials</li> <li>▪ <b>CONTRIBUTED SESSION 16</b> 📍 Indigo 202 A (2nd floor) Historical Controls Local Multisource-Exchangeability Model for Adaptive Information Borrowing from Multiple Historical Controls A Bayesian Exact Adaptive Platform Design with Continual Reassessment for Trials Utilizing Real World Data Dynamic Borrowing from Historical Controls via the Synthetic Prior with Covariates in Randomized Clinical Trials Benefits and Risks in Leveraging Historical Control Data in Clinical Trials</li> <li>▪ <b>CONTRIBUTED SESSION 17</b> 📍 Indigo H (2nd floor) Personalized Medicine A RSHINY APPLET for Sequential, Multiple Assignment, Randomized Trials with a Time-to-Event Final Endpoint Developing and Externally Validating Clinical Dynamic Prediction Joint Models for Localised Prostate Cancer Estimating the Impact of Patient Preference in Two-Stage Clinical Trials for Binary Outcomes When Some Patients are Indifferent to Treatment Implementing Personalised Treatment Recommendations to Determine Optimal Treatment Decisions Using Data from a Three-Arm Trial When Both Arms are Active</li> </ul>
3:15 PM - 4:45 PM	<ul style="list-style-type: none"> <li>▪ <b>INVITED SESSION 18</b> 📍 Indigo D (2nd floor) A Partnership between Clinical Safety and Statistics for Aggregate Safety Assessment - Year Two</li> <li>▪ <b>INVITED SESSION 19</b> 📍 Indigo BCFG (2nd floor) All for One, One for All: How to Run Multiple Networks of COVID-19 Clinical Trials on a Common Platform Using Bayesian Method</li> <li>▪ <b>INVITED SESSION 20</b> 📍 Indigo H (2nd floor) A Pragmatic Path to Direct Delivery of Drug to Participants</li> <li>▪ <b>INVITED SESSION 21</b> 📍 Indigo E (2nd floor) Dose Optimization in Oncology: Why, When and How</li> <li>▪ <b>IN-CONFERENCE WORKSHOP 4</b> 📍 Indigo 202 B (2nd floor) TrialTree: A Novel Application for Interactive Trial Design</li> </ul>
4:45 PM - 5:00 PM	<ul style="list-style-type: none"> <li>▪ <b>BREAK</b></li> </ul>
5:00 PM - 6:30 PM	<ul style="list-style-type: none"> <li>▪ <b>FOUNDERS KEYNOTE LECTURE</b> 📍 Indigo BCFG (2nd floor) Dr. Robert Califf, FDA Commissioner</li> </ul>

# Society for Clinical Trials 2022

## Program (continued)

Wednesday, May 18, 2022	
7:00 AM - 12:00 PM	<ul style="list-style-type: none"> <li>REGISTRATION Indigo Light Wall (2nd floor)</li> </ul>
8:00 AM - 9:00 AM	<ul style="list-style-type: none"> <li>CONTRIBUTED SESSION 18 Indigo D (2nd floor) Applied 4 Outcome Variance After Dropout as an Indicator of Missing-Not-At-Random Bias in Randomized Clinical Trials Optimality of Testing Procedures for Survival Data in the Non-Proportional Hazards Setting How Much is that Data in the Window? A Comparison of Strategies for Analysing Data Recorded Outside Pre-Specified Visit Windows in Randomised Co The Application of ACCEPT Software in Retrospective Analysis of Specimen Data (SWOG S0500 Translational Medicine Project)</li> <li>CONTRIBUTED SESSION 19 Indigo E (2nd floor) Operations 4 One Line on a Manuscript: Operationalizing Ecological Momentary Assessment (EMA) in Clinical Trials The CURED Framework: A Data-Driven Management Tool to Aid Successful Delivery of Clinical Research Projects Effectiveness of Interventions to Share Trial Results with Health Workers and Policymakers: Results of a Systematic Review Communicating Overall Results to Trial Participants: The Perspective of Site Staff from the Show RESPECT Study</li> <li>CONTRIBUTED SESSION 20 Indigo F (2nd floor) Ethics 2 (ON DEMAND) Identifying and Examining Ethical Considerations Facing Data Monitoring Committees Development of a Core Outcome Set for the Evaluation of Interventions to Enhance Proxy Consent Decisions on Behalf of Adults who Lack Capacity to A Mixed Methods Study (CONSIDER Study) Conceptualising "Good" Proxy Consent Decisions for Clinical Trial Participation: Implications for the Development of Interventions to Improve the Quality of Proxy Consent Unpacking the "Black Box of Horrendousness": A Qualitative Study Exploring the Barriers and Facilitators to Conducting Trials Involving Adults Lacking Capacity to Consent</li> <li>CONTRIBUTED SESSION 21 Indigo H (2nd floor) Recruitment &amp; Retention 2 Retention to pediatric randomized controlled trials during the COVID-19 pandemic: a qualitative study Correcting Disparities In Adolescent Access To Medicines By Promoting Age-Inclusive Research Participant Retention in Pediatric Randomized Controlled Trials: Systematic Review and Meta-Analysis Strategies to Improve Retention in Randomised Trials: A Cochrane Review</li> <li>CONTRIBUTED SESSION 22 Indigo 204 B (2nd floor) Surgical Trials Integration of Qualitative Research Into Surgical Trials to Optimise Trial Conduct and Understanding of the Trial Results For Maximal Impact A Core Information Set to Guide Early Phase Surgical Research The Effects of Preceding Prospective Collaborative Studies (IDEAL Stage 2b) on the Quality and Impact of Subsequent Randomized Controlled Trials (IDE A Systematic Review and Case-Control Study Trial Designs to Target the Conditional Average Treatment Effect, with Application to Operating Surgeon Learning Effects in Surgical RCTS</li> </ul>
9:00 AM - 9:15 AM	<ul style="list-style-type: none"> <li>BREAK</li> </ul>
9:15 AM - 10:45 AM	<ul style="list-style-type: none"> <li>INVITED SESSION 21 Indigo D (2nd floor) Improving Data Quality in Multi-Center Trials: Innovative Approaches Utilized within the Wake Forest NCI Community Oncology Research Program Research Base (WF NCIOR RB)</li> <li>INVITED SESSION 22 Indigo 202 A (2nd floor) Design and Analysis of Stepped Wedge Cluster Randomized Trials Based on Marginal Models for Discrete and Continuous Outcomes</li> <li>INVITED SESSION 23 Indigo E (2nd floor) Analysis of Complex Time-to-Event Endpoints in Clinical Trials</li> <li>INVITED SESSION 24 Indigo H (2nd floor) Developing Adaptive Trial Designs: A Collaborative Process Balancing Statistical Efficiency with Clinical Importance</li> </ul>
10:45 AM - 11:00 AM	<ul style="list-style-type: none"> <li>BREAK</li> </ul>
11:00 AM - 12:30 PM	<ul style="list-style-type: none"> <li>INVITED SESSION 25 Indigo D (2nd floor) Bad Bugs in Tough Places - Developing Capacity to Obtain Compelling Evidence in Challenging Environments</li> <li>INVITED SESSION 26 Indigo E (2nd floor) Pharmacokinetics and/or Pharmacodynamics-Informed Dose-Finding Designs</li> <li>INVITED SESSION 27 Indigo H (2nd floor) Accommodating "History Effects" in Long Duration, Multi-Site Clinical Trials to Ensure Relevant and Compelling Evidence</li> <li>INVITED SESSION 28 Indigo 202 A (2nd floor) Rethinking the Inclusion of Research Biopsies in the Design of Clinical Trials</li> <li>INVITED SESSION 29 Indigo 204 A (2nd floor) Planning, Prioritizing, and Conducting Clinical Research in the VA Learning Healthcare System During the COVID-19 Pandemic</li> <li>IN-CONFERENCE WORKSHOP 5 Indigo 202 B (2nd floor) It Takes a Village: Multi-Disciplinary Approach to Designing Stellar Data Collection Forms</li> </ul>

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# Save the Dates - Upcoming SCT Annual Meetings



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



**45th Annual Meeting**  
**May 19-22, 2024**  
**Boston, MA**



**46th Annual Meeting**  
**May 18-21, 2025**  
**Vancouver, BC, Canada**

## Information About SCT

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