Program Guide

SCT

Society for Clinical Trials

43rd Annual Meeting

May 15-18, 2022 • San Diego

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Welcome

SCT President
Mithat Gönen, PhD,
Memorial Sloan-Kettering
Cancer Center

Welcome to the 2022 Annual Meeting of the Society for Clinical Trials, our first in-person gathering since 2019. It has been a long two years for everyone. Our lives have been altered, mostly in unwelcome ways, and, permanently, for some of us. We know that women, minorities, and lower income groups have borne a disproportionately large burden. We have also seen our profession play a central role in shaping pandemic response, help filter efficacious and safe vaccinations and treatments from the rest. We have had two successful online meetings in 2020 and 2021, thanks to yeoman efforts from our then-Presidents **Dean Fergusson** and **Susan Halabi**, and their teams. These meetings taught us something new but, unsurprisingly, were unable to replicate the numerous benefits of human interaction, much like the other online meetings most of us attended.

So again: Welcome to the 2022 Annual Meeting of the Society for Clinical Trials, our first in-person gathering since 2019. This meeting continues to be the premier place for scholars involved in designing, conducting, reporting, ethicizing, and regulating clinical trials. Our membership and the meeting attendees are a diverse group in their personal and scientific backgrounds, as well as their day jobs. The meeting program reflects this diversity. We have scientific and educational sessions covering all aspects of clinical trials and two fantastic keynote speakers who will authoritatively speak to us from community and regulatory perspectives.

This rich program is the result of many minds and hands working together. First and foremost, we have the Program Committee Chair **Sharon Yeatts**, and Education Committee Chair **Sonia Jain** to thank. They each assembled great committees, well-mixed in clinical trial specialty and geographic representation. Both committees worked very hard to solicit proposals and review submissions, and they reflected the dedication and the temperament of their leaders, and it was a true pleasure to work with them. Trial of the Year and Student Scholarship Committees, chaired by **Debra Hill** and **Cody Chiuzan**, also worked hard to choose the winners from several qualified candidates. There are three committees that touch on everything SCT does, and the Annual Meeting preparations are no exception: Membership, Communications, and Equity, Diversity, and Inclusion Committees. This year, they were chaired by **Jody Ciolino**, **Lee McDaniel**, and **Kaleab Abebe**. They participated in many of the preparations, advertised the meeting on newsletters, email blasts, and tweets (have you not been following @SCTOrg?), advocated on members' behalf in all aspects of the Annual Meeting. **Wendy Parulekar**, **Roger Lewis**, **Ivan Chan**, and **Rick Chappell**, all giants of the Society, stepped up to shoulder the burden by chairing the Nominations, Fellows, Development, and Outreach Committees. The **Executive Committee** was the hand that steered the wheel. Through weekly meetings, they provided advice, criticism, motivation, and encouragement to me and all those I mentioned. Last, but not least, the **Board of Directors** oversaw all of this. It was a labor of love for all involved, and I thank them from the bottom of my heart. Our partners from the management company EAI, **Kevin Bragaw** and **Lisa Aguado**, who replaced **Angie Stark**, provided endless logistical support, implemented the ideas emerging from various committees and played a major role in shaping the Annual Meeting. You might be wondering what I claim responsibility for; that

would be the inevitable errors, the imperfections and the rough edges.

The meeting theme is "Informing Public Health Policy with Compelling Evidence," and we are fortunate to have attracted two incredibly accomplished keynote speakers. **Dr. Worta McCaskill-Stevens** is the Chief of the Community Oncology and Prevention Trials Research Group, which houses the National Cancer Institute (NCI) Community Oncology Research Program, a community-based clinical trials network launched in 2014. In this role, she oversees the program supporting community hospitals, physicians, and others to participate in NCI-approved cancer treatment, prevention, screening, and control clinical trials, as well as cancer care delivery studies. She will talk about the approaches, successes, and challenges of diverse populations in clinical trials, touching upon ways in which trial design plays a role in the conduct of trials in community settings. **Dr. Robert Califf** is a long-time member of the Society, was elected a Fellow in 2015 and has been serving as an Associate Editor for our journal *Clinical Trials*. He is the current FDA Commissioner, having assumed office just two months ago. It is a post he is familiar with; he also served as Commissioner from 2016-2017. Dr. Califf is an experienced clinical trialist and an accomplished clinical researcher recognized as one of the most cited in the field of medicine. He has a unique perspective as an investigator and a regulator. He will share his vision on the role of clinical trials shaping regulatory science and public health.

This year's meeting is likely to be smaller in terms of in-person attendance due to residual concerns over the pandemic. We are providing a virtual option for those who cannot make it to San Diego. Help us by making the meeting just as energetic and stimulating despite this by asking questions during the sessions, connecting with old friends, making new friends, socializing with other attendees by the water right outside the hotel, and taking advantage of the lovely sunshine and warm temperatures.

While we expect a drop in total attendance, early registration numbers suggest we will have a strong presence from non-members. I am elated to hear this. I have always thought of non-member attendance as a metric for measuring the reach of the Society and an opportunity to increase membership. To the non-members in the crowd, please introduce yourself when you see me. I would like to hear how you learned about the Society and the Annual Meeting, how you decided to attend, and how your experience has been. I will tell you what the Society has done for me and why I have been trying to give some of that back by serving in various roles.

So once again I welcome you to the Society for Clinical Trials' 2022 Annual Meeting and conclude by rephrasing the words of the great sufi poet Rumi: Welcome, welcome, whoever you are. Wanderer, wonderer, lover of learning. Ours is a caravan of trials.

SCT
Society for Clinical Trials

Announcements

Disclaimer

The primary purpose of the SCT Annual Meeting is educational. Information, as well as technologies, products and/or services discussed, is intended to inform participants about the knowledge, techniques and experiences of presenters who are willing to share such information with colleagues. A diversity of professional opinions exists and the views of SCT disclaims any and all liability for damages to any individual attending this conference and for all claims which may result from the use of information, technologies, products and/or services discussed at this conference.

Exhibit Area

This year, seven organizations will be exhibiting in the Indigo West Foyer (Level 2). We encourage all registrants to visit these booths and thank the organizations' representatives for their participation.

Exhibit Hours:

Monday. . . . . 7:30 am – 5:30 pm

Tuesday. . . . . 9:00 am – 5:00 pm

Livestream Sessions LIVESTREAM

The following sessions will be livestreamed from the main session room during the meeting. **Please note that all times listed are Pacific Time (PT).**

Monday

8:00 – 9:30 am	SCT President's Welcome & Curtis Meinert Keynote
10:00 – 11:30 am	Invited Session 5: Strategies to Mitigate the Impact of the COVID Pandemic on Trial Implementation, Closeout, Data Quality and Analysis of a Large Multicenter Clinical Trial: The Glycemia Reduction Approaches in Diabetes Comparative Effectiveness Study (GRADE)
12:45 – 2:00 pm	Chalmers & Green Award Presentations
2:30 – 3:30 pm	Contributed Session 4: Dose-Finding
4:00 – 5:30 pm	Trial of the Year

Livestream Sessions *(continued)*

Tuesday

9:30 – 10:30 am	Contributed Session 11: Outcomes
11:00 am – 12:30 pm	Invited Session 11: Clinical Trials of COVID-19 Vaccines: Overcoming the Challenges
12:30 – 2:00 pm	SCT Business Session Lunch & Presentation of the Class of 2022 Fellows
2:00 – 3:00 pm	Contributed Session 15: Data Monitoring
3:15 – 4:45 pm	Invited Session 18: All for One, One for All: How to Run Multiple Networks of COVID-19 Clinical Trials on a Common Platform Using Bayesian Method
5:00 – 6:30 pm	Founders Lecture

Meeting App

We encourage you to download the SCT Annual Meeting Mobile App to help maximize your time at the meeting. The app is available for all smart phone and tablet platforms and includes the program schedule, list of exhibitors, speakers, and more. To download the app, search for SCT 2022 in your app store.

Meeting on Demand

The sessions being livestreamed from the general session, as well as other select content, will be available on the SCT website for complimentary viewing by registrants approximately one month after the conclusion of the meeting. We encourage you to view these sessions to watch presentations you may have missed, or wish to revisit.

Photography

By registering for this meeting, attendees acknowledge and agree that SCT or its agents may take photographs during events and may freely use those photos in any media for SCT purposes. You may not photograph, videotape, audiotape or otherwise record or reproduce any of the presentations without the express written permission from SCT.

Announcements

Poster Presentations

Posters will be displayed throughout the meeting in Indigo A (Level 2) and will have scheduled presentation times where attendees can ask the authors questions about their research. Authors are requested to be at their posters during their designated date and time. The poster sessions are as follows:

Poster Session 1 (P1-P15): Monday 9:30 – 10:00 am

Poster Session 2 (P17-P34): Monday 3:30 – 4:00 pm

Poster Session 3 (P35-P48): Tuesday 10:30 – 11:00 am

See pages 24-26 for more information.

Please Note: Posters with an asterisk (*) after the presentation title will be made available to attendees after the meeting on demand.

Registration Desk Hours

The SCT Registration Desk is located along the Indigo Light Wall on Level 2 and will be open:

Sunday . . . . . 7:00 am – 5:00 pm

Monday. . . . . 7:00 am – 5:00 pm

Tuesday. . . . . 8:30 am – 5:00 pm

Wednesday . . . . . 7:00 am – noon

Networking Welcome Reception

All attendees are encouraged to attend the Welcome Reception on Monday from 6:00 – 7:30 pm on the Indigo Terrace (Level 2). It's the perfect place to catch up with old friends and make new acquaintances. A raffle drawing for first time attendees to win 1 of 3 $100 Visa Gift cards will be held during the event.

Wireless Internet

Complimentary Wi-Fi is provided in the meeting space for all SCT attendees.

To access the Wi-Fi, simply:

- Open your wireless network connections
- Connect to the "SCT" wireless network
- Enter password: **sctsandiego**

Assumption of Risk

Participating in the Annual Meeting during the ongoing pandemic carries risk due to the contagious nature of the COVID-19 virus. All attendees agree to release SCT, the Annual Meeting organizers, and venues from any liability related to their participation. In addition, attendees must agree to follow all required health and safety guidelines, protocols, policies, regulations, and mandates relating to attendance at the Annual Meeting, including, but not limited to, Centers for Disease Control guidelines, statutes, regulations, and other mandates applicable to the State of California and the City of San Diego, as well as any additional requirements imposed by SCT or the Annual Meeting venue (regardless of whether federal, state, or local laws allow otherwise).

Attendees must monitor their own health status and are not allowed to attend the Annual Meeting if symptomatic of COVID-19 or believe they have been exposed to someone with COVID-19. An attendee's failure to comply with required safety protocols or follow the direction of SCT staff on site may result in the loss of their right to attend or participate in the Annual Meeting, including forfeiture of any registration fees paid.

Sunday Pre-Conference Schedule

Please Note: A separate registration fee is required to attend these optional workshops. Tickets are required.

7:00 am – 5:00 pm

Indigo Light Wall (Level 2)

Registration

7:30 – 8:00 am

Indigo West Foyer (Level 2)

Coffee/Tea

8:00 am – noon

202B (Level 2)

Pre-Conference Workshop 1

Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables

Session Organizer:
Michael Rosenblum, Johns Hopkins School of Public Health

Speakers:
Kelly Van Lancker, Johns Hopkins University; **Joshua Betz,** Johns Hopkins University

8:00 am – noon

202A (Level 2)

Pre-Conference Workshop 2

Clinical Trial Data Monitoring Committees and Reporting Statistical Centers: The Basics and Emerging Issues

Session Organizer:
Kevin Buhr, University of Wisconsin – Madison

Speakers:
Susan Ellenberg, University of Pennsylvania Perelman School of Medicine; **David DeMets,** University of Wisconsin – Madison

8:00 am – noon

204B (Level 2)

Pre-Conference Workshop 3

Model-Assisted Designs: Make Adaptive Clinical Trials Easy and Accessible

Session Organizer:
Ying Yuan, The University of Texas MD Anderson Cancer Center

Speaker:
J. Jack Lee, The University of Texas MD Anderson Cancer Center

9:45 – 10:15 am

Indigo West Foyer (Level 2)

Refreshment Break

Noon – 1:00 pm

Lunch (On Your Own)

1:00 – 5:00 pm

202B (Level 2)

Pre-Conference Workshop 4

Introduction to Efficient Preparation, Access, and Sharing of Trial Data in REDCap Using the API

Session Organizer:
Abigail Baldridge, Northwestern University

Speakers:
Heather Byrd, Northwestern University; **Ravi Chowdhury**, Northwestern University

1:00 – 5:00 pm

202A (Level 2)

Pre-Conference Workshop 5

Essentials of Clinical Trials

Session Organizer:
Yves Rosenberg, National Heart, Lung, and Blood Institute, NIH

Speakers:
Christopher Coffey, University of Iowa College of Public Health; **Dixie Ecklund**, Clinical Trials Statistical & Data Management Center, University of Iowa; **Trevis Huff**, Clinical Trials Statistical & Data Management Center, University of Iowa

1:00 – 5:00 pm

204B (Level 2)

Pre-Conference Workshop 6

Design Clinical Trials With Non-Inferiority Hypothesis: Methods and Applications

Session Organizer:
Sheng Iuo, Duke University

Speakers:
Ying Yuan, The University of Texas MD Anderson Cancer Center; **Li Tang**, St. Jude Children's Research Hospital

2:45 – 3:15 pm

Indigo West Foyer (Level 2)

Refreshment Break

5:00 – 6:45 pm

300 (Level 3)

SCT Board Meeting

By invitation only.

7:00 – 10:00 pm

204A (Level 2)

Fellows Dinner

Tickets required.

Conference Schedule at a Glance

Time	Monday, May 16
7:00 am – 5:00 pm	Registration
7:30 – 8:00 am	Continental Breakfast
8:00 – 9:30 am	SCT President's Welcome & Curtis Meinert Keynote
9:30 – 10:00 am	Poster Presentations and Exhibits – With Refreshments
10:00 – 11:30 am	Invited Sessions
10:00 – 11:30 am	In-Conference Workshop 1 (Tickets required.)
11:30 am – 12:45 pm	Lunch
11:30 am – 12:45 pm	Roundtable Discussions – With Lunch (Tickets required.)
12:45 – 2:15 pm	Invited Sessions
12:45 – 2:15 pm	Chalmers and Green Award Presentations
12:45 – 2:15 pm	In-Conference Workshop 2 (Tickets required.)
2:00 – 2:30 pm	Chalmers Scholarship Judging
2:15 – 2:30 pm	Break
2:30 – 3:30 pm	Contributed Sessions
3:30 – 4:00 pm	Poster Presentations and Exhibits – With Refreshments
4:00 – 5:30 pm	Trial of the Year
6:00 – 7:30 pm	Networking Welcome Reception

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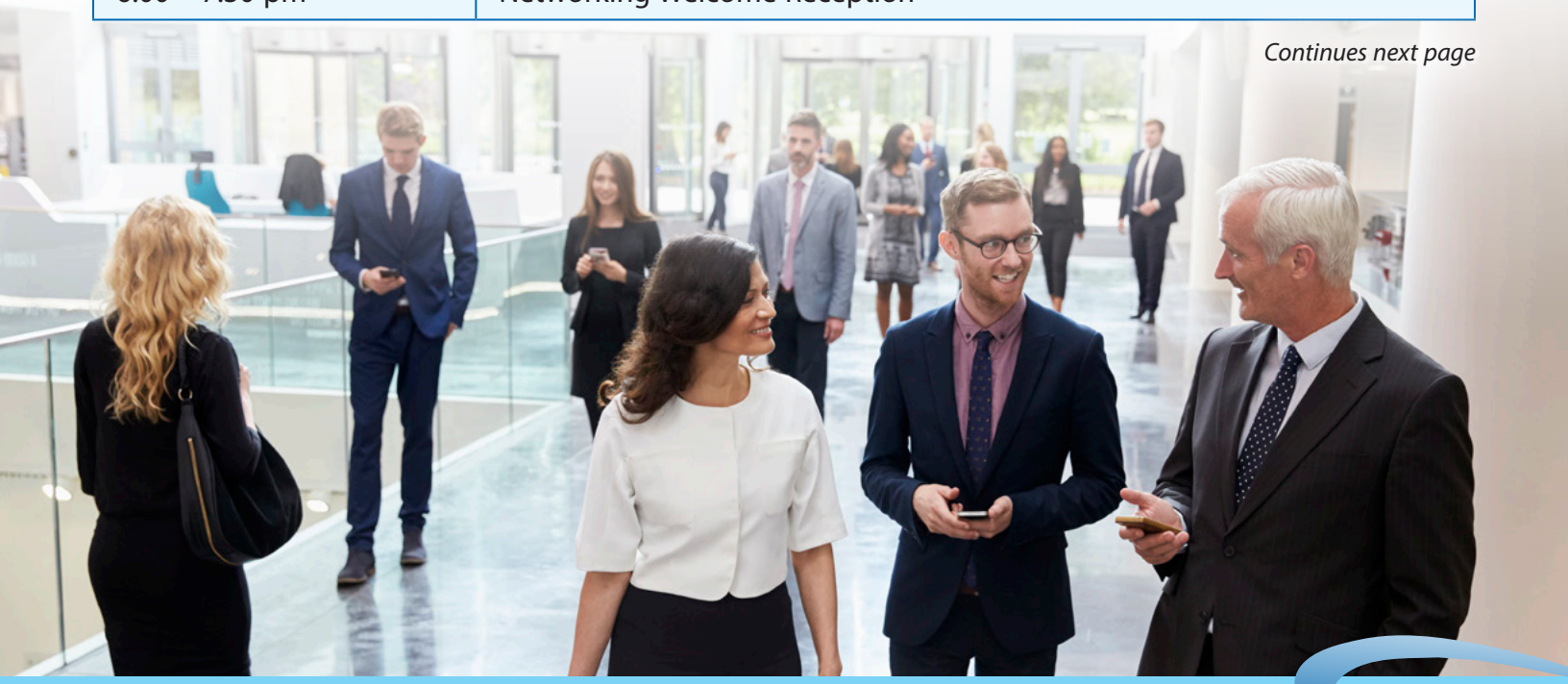

Conference Schedule at a Glance

Time	Tuesday, May 17
8:30 am – 5:00 pm	Registration
9:00 – 9:30 am	Refreshment Break
9:30 – 10:30 am	Contributed Sessions
10:30 – 11:00 am	Poster Presentations and Exhibits – With Refreshments
11:00 am – 12:30 pm	Invited Sessions
11:00 am – 12:30 pm	In-Conference Workshop 3 (Tickets required.)
12:30 – 2:00 pm	SCT Business Session Lunch & Presentation of the Class of 2022 Fellows
2:00 – 3:00 pm	Contributed Sessions
3:00 – 3:15 pm	Refreshment Break
3:15 – 4:45 pm	Invited Sessions
3:15 – 4:45 pm	In-Conference Workshop 4 (Tickets required.)
4:45 – 5:00 pm	Break
5:00 – 6:30 pm	Founders Lecture
6:30 – 7:30 pm	ED&I Committee Meeting With SCT Committee Chairs and Co-chairs
Time	**Wednesday, May 18**
7:00 am – noon	Registration
7:30 – 8:00 am	Continental Breakfast
8:00 – 9:00 am	Contributed Sessions
9:00 – 9:15 am	Refreshment Break
9:15 – 10:45 am	Invited Sessions
10:45 – 11:00 am	Break
11:00 am – 12:30 pm	Invited Sessions
11:00 am – 12:30 pm	In-Conference Workshop 5 (Tickets required.)
12:30 pm	Annual Meeting Adjourned

Monday Conference Schedule

7:00 am – 5:00 pm

Indigo Light Wall (Level 2)

Registration

7:30 – 8:00 am

Indigo West Foyer (Level 2)

Continental Breakfast

8:00 – 9:30 am

Indigo BCFG (Level 2) LIVESTREAM

SCT President's Welcome

Speaker:
Mithat Gönen, Memorial Sloan-Kettering Cancer Center

Curtis Meinert Keynote

Lessons Learned From the National Cancer Institute's Community Based Clinical Trials

Speaker:
Dr. Worta McCaskill-Stevens, National Cancer Institute, NIH

9:30 – 10:00 am

Indigo A & Indigo West Foyer (Level 2)

Poster Presentations (P1-P15) & Exhibits – With Refreshments

10:00 – 11:30 am

Indigo D (Level 2)

Invited Session 1

Optimizing Precision Medicine Cancer Clinical Trials

Session Organizer:
Pam Mangat, American Society of Clinical Oncology

Session Chair:
Richard Schilsky, American Society of Clinical Oncology

Speakers:
Timothy Cannon, Inova Schar Cancer Institute; **Susan Halabi**, Duke University Medical Center; **Edward Kim**, City of Hope; **Jane Perlmutter**, Patient Advocate/Gemini Group; **Christine Walko**, H. Lee Moffitt Cancer Center and Research Institute

10:00 – 11:30 am

Indigo E (Level 2)

Invited Session 2

Inclusive Recruitment Strategies in Clinical Trials: Insights From Rehabilitation Research

Session Organizer:
Allyn Bove, University of Pittsburgh

Speakers:
Christine McDonough, University of Pittsburgh; **Sara Piva**, University of Pittsburgh; **Charity Patterson**, University of Pittsburgh

10:00 – 11:30 am

202A (Level 2)

Invited Session 3

The Promise and Challenges of Integrating Real-World Evidence in Clinical Research

Session Organizer:
Cody Chiuzan, Northwell Health

Speakers:
Ben Ackerman, Flatiron Health; **Kara Rudolph**, Columbia University; **Madison Stoms** Columbia University; **Elizabeth Garrett-Mayer**, American Society of Clinical Oncology

10:00 – 11:30 am

Indigo H (Level 2)

Invited Session 4

Real World Experience in Conducting Adaptive Platform Trials

Session Organizer:
Christina Saunders, Berry Consultants, LLC

Session Chair:
Giorgio Paulon, Berry Consultants, LLC

Speakers:
Ed Mills, Cytel; **Michelle Detry**, Berry Consultants, LLC; **Anna McGlothlin**, Berry Consultants, LLC; **Hong Yu**, Massachusetts General Hospital

10:00 – 11:30 am

Indigo BCFG (Level 2) LIVESTREAM

Invited Session 5

Strategies to Mitigate the Impact of the COVID Pandemic on Trial Implementation, Closeout, Data Quality and Analysis of a Large Multicenter Clinical Trial: The Glycemia Reduction Approaches in Diabetes Comparative Effectiveness Study (GRADE)

Session Organizer:
Heidi Krause-Steinrauf, The George Washington University

Speakers:
Michaela Gramzinski, The George Washington University Biostatistics Center, Milken Institute School of Public Health; **Chantal Underkofler**, University of Colorado Anschutz Medical Campus; **Stephanie Hall**, The George Washington University Biostatistics Center, Milken Institute School of Public Health; **Margaret Tiktin**, Cleveland Veterans Affairs Medical Center, Case Western University; **Nicole Butera**, The George Washington University Biostatistics Center, Milken Institute School of Public Health

10:00 – 11:30 am

202B (Level 2)

In-Conference Workshop 1

Tickets required.

Behavioural Trial Design: Using Stakeholder-Driven Processes to Develop Interventions and Assessment Tools Using a Public Health Intervention Example

Session Organizer:
Anda Dragomir, Concordia University

Speakers:
Brigitte Voisard, Université du Québec à Montréal; **Vincent Gosselin Boucher**, University of British Columbia

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Monday Conference Schedule

11:30 am – 12:45 pm

Indigo BCFG / Indigo Terrace South (Level 2)

Lunch

11:30 am – 12:45 pm

Indigo Terrace (Level 2)

Roundtable Discussions – With Lunch

Tickets required.

1. DSMB

Moderator:
David DeMets, University of Wisconsin – Madison

2. Introduction to Clinical Trial Career Paths + Guest Attendee From Leadership (Members are encouraged to attend from diverse field backgrounds.)

Moderator:
Cristina Murray-Krezan, University of Pittsburgh

3. 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, Praxis Precision Medicines, Inc.

4. 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, Northwestern University

5. New Efficiencies & Lessons Learned in a Pandemic Time

Moderator:
Margaret Tiktin, VA Northeast Ohio Healthcare System

6. Precision Trial Medicine

Moderator:
Pam Mangat, American Society of Clinical Oncology

7. Supplemental Clinical Trial Data vs. Real World Data

Moderator:
Ben Ackerman, Flatiron Health

8. The Statistician as an Investigator and Educator, Not Just a Power Calculator, on Clinical Research Protocols

Moderator:
Alexia Iasonos, Memorial Sloan Kettering Cancer Center

9. Fostering Equity, Diversity, and Inclusion Within the Society

Moderator:
Kaleab Abebe, University of Pittsburgh

12:45 – 2:15 pm

202A (Level 2)

Invited Session 6

Innovative Approaches to Data Collection Needs in Clinical Trials: Considerations, Lessons Learned and Future Directions

Session Organizer:
Kathryn Hefner, National Institute on Drug Abuse Data and Statistics Center, The Emmes Company

Speakers:
Matisyahu Shulman, New York State Psychiatric Institute and Columbia Irving Medical Center; **Onumara Opara**, New York State Psychiatric Institute and Columbia Irving Medical Center; **Christina Scheele**, National Institute on Drug Abuse Data and Statistics Center, The Emmes Company

12:45 – 2:15 pm

Indigo D (Level 2)

Invited Session 7

Complex Innovative Design in the Modern Drug Development Era

Session Organizers:
Heng Zhou, Merck; **Ruitao Lin**, MD Anderson Cancer Center

Session Chair:
Heng Zhou, Merck

Speakers:
Yong Zang, Indiana University; **Rachael Liu**, Takeda

12:45 – 2:15 pm

Indigo H (Level 2)

Invited Session 9

Analysing Clinical Trials Disrupted by the COVID-19 Pandemic

Session Organizer:
Richard Emsley, King's College London

Speakers:
Kelly Van Lancker, Johns Hopkins Bloomberg School of Public Health; **Diane Uschner**, George Washington University

12:45 – 2:15 pm

Indigo E (Level 2)

Invited Session 10

How Different Communication Pathways Impact the Success of a Clinical Trial, A Multifaceted Perspective

Session Organizer:
Peyton Kline, The Medical University of South Carolina

Speakers:
Abbey Staugaitis, University of Minnesota; **Alaa Kassir**, University of Chicago; **Sara Butler**, The Medical University of South Carolina; **Valerie Stevenson**, University of Michigan; **Jessica Staloch**, University of Minnesota

Monday Conference Schedule

12:45 – 2:15 pm

202B (Level 2)

In-Conference Workshop 2

Tickets required.

Causal Inference for Complex Data

Session Organizer & Speaker:
Chuck Huber, StataCorp LLC

12:45 – 2:00 pm

Indigo BCFG (Level 2) LIVESTREAM

Chalmers and Green Award Presentations

Enhancing Patient-Partnership in Clinical Trials

Speaker:
Andrea Viecelli, Princess Alexandra Hospital

Simultaneous Hypothesis Testing for Multiple Competing Risks in Comparative Clinical Trials

Speaker:
Jiyang Wen, Johns Hopkins Bloomberg School of Public Health

Estimating Interactions and Subgroup-Specific Treatment Effects in Meta-Analysis Without Aggregation Bias: A Within-Trial Framework

Speaker:
Peter Godolphin, University College London

A Permutation Procedure to Detect Heterogeneous Treatments Effects in Randomized Clinical Trials While Controlling the Type-I Error Rate

Speaker:
Jack Wolf, University of Minnesota School of Public Health

2:00 – 2:30 pm

Indigo BCFG (Level 2)

Chalmers Scholarship Judging

2:15 – 2:30 pm

Break

2:30 – 3:30 pm

Indigo E (Level 2)

Contributed Session 1: Applied 1

The Inclusion of Covariates in Constrained Longitudinal Data Analysis for Pre-Post Randomized Clinical Trials

Speaker:
Joseph Rausch, Nationwide Children's Hospital

The Benefits of Covariate Adjustment for Adaptive Multi-Arm Designs

Speaker:
Richard Emsley, King's College London

Twintelligent RCT: Leveraging External Data, Artificial Intelligence, and Covariate Adjustment

Speaker:
Jose Luis Olmos-Serrano, Unlearn.AI

Bayesian Random Change Point Mixed Model Analysis of Cognitive Performance Trajectories to Identify Eligible Patients for Randomized Clinical Trials

Speaker:
Lianlian Du, The University of Wisconsin - Madison

2:30 – 3:30 pm

Indigo H (Level 2)

Contributed Session 2: Ethics 1

Grownish: How and When To Include Adolescents in Adult Research

Speaker:
Martine Dehlinger-Kremer, ICON Plc

Considerations When Collecting Real World Data in Expanded Access Programs

Speakers:
Hayley Belli, New York University Grossman School of Medicine; **Alison Bateman-House**, New York University Grossman School of Medicine

The Problem of Identifying Vulnerable Research Participants in Pragmatic Cluster Randomized Trials

Speaker:
Cory Goldstein, Western University

Dotting Your I's and Crossing Your T's: An Informed Consent Documentation Tool for Clinical Trials

Speaker:
Lauren Shirley, Boston Children's Hospital

2:30 – 3:30 pm

202A (Level 2)

Contributed Session 3: Operations 1

Increasing the Generalizability of Pain Study Results

Speaker:
Emine Bayman, University of Iowa

OlympiA – A Complex but Successful Model for a Large Global Trial

Speaker:
Eleanor McFadden, Frontier Science (Scotland) Ltd

The Protocol Review Checklist: A Tool to Ensure Protocol Completeness, Consistency, and Accuracy

Speaker:
Lauren Dresser, Emmes

Lifestyle Intervention Delivery During the COVID Era

Speaker:
Katelyn Garcia, Wake Forest University School of Medicine Department of Biostatistics and Data Science

Continues next page

Monday Conference Schedule

2:30 – 3:30 pm

Indigo BCFG (Level 2) LIVESTREAM

Contributed Session 4: Dose-Finding

A Unified Decision Framework for Phase I Dose-Finding Designs

Speaker:
Yunshan Duan, University of Texas at Austin

Early Phase Dose-Finding Trials in Virology

Speaker:
Hakim-Moulay Dehbi, University College London

Dose-Finding Based on Feasibility and Late-Onset Toxicity in Adoptive Cell Therapy Trials

Speaker:
Evan Bagley, University of Virginia

A Biomarker-Based Dose-Finding Design for Immunotherapy

Speaker:
BeiBei Guo, Louisiana State University

2:30 – 3:30 pm

Indigo D (Level 2)

Contributed Session 5: Recruitment & Retention 1

A Novel Approach Employing Readability Metrics and Crowdsourcing to Improve Randomised Clinical Trial Information Leaflets

Speaker:
Fernando Santos Sanchez, University of Southampton

Using Informational Videos to Support Recruitment for Parenting Trials

Speaker:
Maiken Pontoppidan, *VIVE - The Danish Center for Social Science Research*

A Culturally and Contextually Situated Multimedia Approach to Recruiting, Consenting, and Randomizing a Hard-to-Reach Spanish-Speaking Population for a Randomized Controlled Trial

Speaker:
Cristina Murray-Krezan, University of Pittsburgh

Predicting Patients' Willingness to Participate in Clinical Trials: A Simulation Tool Using Patient Choice Data

Speaker:
Caitlin Thomas, Evidera

2:30 – 3:30 pm

204B (Level 2)

Contributed Session 6: Trial Design 1

Randomization Schemes Using Electronic Health Systems to Facilitate Emergency Department-Based Pragmatic Clinical Trials of Public Health Screening Interventions

Speaker:
Jason Haukoos, Denver Health Medical Center & University of Colorado School of Medicine

Involving Patients in the Design of Randomized Clinical Trials

Speaker:
Mark Harrison, The University of British Columbia

Novel Method of Using JavaScript Encoding and QR (Quick Response) Codes in Remotely Managed Randomization of Blinded Studies in Low-Resource Environments

Speaker:
Aditya Pabba, Research Triangle Institute

3:30 – 4:00 pm

Indigo A & Indigo West Foyer (Level 2)

Poster Presentations (P17-P34) & Exhibits – With Refreshments

4:00 – 5:30 pm

Indigo BCFG (Level 2) LIVESTREAM

Trial of the Year

The TOGETHER Trial: An Adaptive Platform International Trial

Speakers:
Edward Mills, McMaster University;
Gilmar Reis, Pontifica Universidade Catolica de Minas Gerais

6:00 – 7:30 pm

Indigo Terrace (Level 2)

Networking Welcome Reception

Tuesday Conference Schedule

8:30 am – 5:00 pm

Indigo Light Wall (Level 2)

Registration

9:00 – 9:30 am

Indigo West Foyer (Level 2)

Refreshment Break

9:30 – 10:30 am

Indigo H (Level 2)

Contributed Session 7: Applied 2

Accounting for Differential Uptake of Treatment-as-Usual in Open-Label RCTs: A Comparison of Methods and Illustration in Mental Health Trials

Speaker:
Richard Emsley, King's College London

Quantifying the Impact of Enrichment in Pre-Post Randomized Controlled Clinical Trials

Speaker:
Navneet Hakhu, University of California, Irvine

SuperLearner Enforced Treatment Effect Estimation in Pediatric Trials

Speaker:
Azzolina Danila, University of Ferrara

Bayesian Network Enforced Super Learner Treatment Effect Estimation in Clinical Trial: A Proposal and Application

Speaker:
Azzolina Danila, University of Ferrara

9:30 – 10:30 am

Indigo D (Level 2)

Contributed Session 8: Operations 2

Implementation of Substudies in Multi-Center Clinical Trials: The Grade Study Experience

Speaker:
Heidi Krause-Steinrauf, The George Washington University

The What, How, When and Who of Sharing Trial Results Summaries With Trial Participants: Stakeholder Informed Guidance From the RECAP Project

Speaker:
Katie Gillies, University of Aberdeen

Challenges Implementing a Clustered Randomized Behavioral Clinical Trial in a Community Based Participatory Research Framework

Speaker:
Elizabeth Avery, Rush University Medical Center

Advantages, Disadvantages, and Other Considerations for Trials in Cohorts: A Decade In

Speaker:
Richard Henry, McGill University

9:30 – 10:30 am

Indigo E (Level 2)

Contributed Session 9: Cluster Trials

Estimating Marginal Treatment Effect in Cluster Randomized Trials With Multilevel Missing Outcomes

Speaker:
Chia-Rui (Jerry) Chang, Harvard University T.H. Chan School of Public Health

A SAS Macro for the Power of Generalized Estimating Equations Analysis of Cluster Randomized Trials With the Application to Stepped Wedge Designs

Speaker:
Ying Zhang, University of North Carolina at Chapel Hill

Maximin Optimal Cluster Randomized Designs Accounting for Treatment Effect Heterogeneity

Speaker:
Mary Ryan, Yale University

Power Analysis for Stepped Wedge Cluster Randomized Trials With Continuous Co-Primary Endpoints

Speaker:
Kendra Plourde, Yale University

9:30 – 10:30 am

202A (Level 2)

Contributed Session 10: Mediation & Trial Design 3

The Good, The Bad and The Hidden Bias in Mediation Analyses of Clinical Trials

Speaker:
Mollie Payne, King's College London

Challenges for Conducting Mediation Analyses in Multi-Arm Trials

Speaker:
Danielle Edwards, King's College London

Combining Non-Adherence and Mediation in a Unified Causal Analysis: A Methodological Review and Application to the AVATAR Trial

Speaker:
Anca Chis Ster, King's College London

Continues next page

Tuesday Conference Schedule

The CREID: Complementary Randomized Controlled Trial and Real-World Study for Efficacy, Effectiveness, and Implementation Design, With Illustrations of One Published and Two Proposed Large Studies for Sequential and Parallel Designs

Speaker:
Chengwu Yang, UMass Chan Medical School

9:30 – 10:30 am

Indigo BCFG (Level 2) LIVESTREAM

Contributed Session 11: Outcomes

Integrating Patient Values Into Clinical Trials Using a Patient-Centered Composite Endpoint: A Case Study Using the Control of Hypertension in Pregnancy Study (CHIPS) Trial

Speaker:
Nick Bansback, University of British Columbia

Virtual Clinical Outcome Ascertainment in a Prostate Cancer Treatment Trial

Speaker:
J. Athene Lane, University of Bristol

Challenges of Data Collection for a Fully Remote Clinical Trial With a Multi-Component Outcome: Virtual ELM Pilot Study

Speaker:
Kelly Karavolos, Rush University Medical Center

9:30 – 10:30 am

204B (Level 2)

Contributed Session 12: Trial Design 2

Landscape of Phase 2 Trials in Alzheimer's Disease: A Systematic Review of Trial Characteristics

Speaker:
Clement Ma, Centre for Addiction and Mental Health

A Structured Framework for Adaptively Incorporating External Evidence in Sequentially Monitored Clinical Trials

Speaker:
Evan Kwiatkowski, Rice University and MD Anderson Cancer Center

Multi-Arm Multi-Outcome Clinical Trial Design and Analysis With Bayesian Spike-and-Slab Priors

Speaker:
Jun Yin, Mayo Clinic

How Are Progression Decisions Made Following External Randomised Pilot Trials? A Qualitative Interview Study and Framework Analysis

Speaker:
Katie Mellor, University of Oxford

10:30 – 11:00 am

Indigo A & Indigo West Foyer (Level 2)

Poster Presentations (P35-P48) & Exhibits – With Refreshments

11:00 am – 12:30 pm

Indigo BCFG (Level 2)

Invited Session 11 LIVESTREAM

Clinical Trials of COVID-19 Vaccines: Overcoming the Challenges

Session Organizer:
Susan Ellenberg, University of Pennsylvania

Speakers:
Jacqueline Miller, Moderna, Inc.; **Sally Hunsberger**, National Institute of Allergy & Infections Diseases, NIH; **Steven Joffe**, University of Pennsylvania

11:00 am – 12:30 pm

Indigo H (Level 2)

Invited Session 12

Using a Single IRB for NIH-Funded Multisite Trials

Session Organizer:
Tina Neill-Hudson, University of Iowa

Session Chair:
Maxine Koepp, University of Iowa

Speakers:
Jarrod Feld, University of Iowa; **Catherine Gladden**, Mass General Brigham; **Cynthia Diltz**, University of Iowa

11:00 am – 12:30 pm

202A (Level 2)

Invited Session 13

Perspectives on Real World Data and Evidence Collection Through Expanded Access

Session Organizer:
Hayley Belli, New York University Grossman School of Medicine

Speakers:
Alison Bateman-House, New York University Grossman School of Medicine; **Andrew McFadyen**, The Isaac Foundation; **Tom Watson**, Bionical Emas

11:00 am – 12:30 pm

Indigo D (Level 2)

Invited Session 14

When and How to Use Covariate Adjustment to Improve Precision in Randomized Trials

Session Organizer:
Kelly Van Lancker, Johns Hopkins Bloomberg School of Public Health

Session Chair:
Xiudi Li, University of Washington, Seattle

Tuesday Conference Schedule

Speakers:
Min Zhang, University of Michigan, Ann Arbor; **Mark van der Laan**, University of California, Berkeley, School of Public Health; **Frank Bretz**, Novartis Pharma AG

11:00 am – 12:30 pm

Indigo E (Level 2)

Invited Session 15

Optimizing the Interdisciplinary Design of Adaptive Platform Trials

Session Organizer:
Roger Lewis, Berry Consultants, LLC; Harbor-UCLA Medical Center; and David Geffen School of Medicine at UCLA

Speakers:
Juliana Tolles, Berry Consultants, LLC; Harbor-UCLA Medical Center; and David Geffen School of Medicine at UCLA; **Kert Viele**, Berry Consultants, LLC; **Will Meurer**, Department of Emergency Medicine, University of Michigan

11:00 am – 12:30 pm

202B (Level 2)

In-Conference Workshop 3
Tickets required.

Demystifying Statistics in Clinical Trials

Session Organizer:
Jody Ciolino, Northwestern University

Speakers:
Lauren Balmert Bonner, Northwestern University

12:30 – 2:00 pm

Indigo BCFG (Level 2) LIVESTREAM

SCT Business Session Lunch & Presentation of the Class of 2022 Fellows

2:00 – 3:00 pm

Indigo D (Level 2)

Contributed Session 13: Applied 3

Accounting for Unequal Cluster Sizes in Designing Cluster Randomized Trials to Detect Treatment Effect Heterogeneity

Speaker:
Guangyu Tong, Yale School of Public Health

Accounting for Correlation Among the Total Events of Composite Outcomes in Cardiovascular Trials

Speaker:
Shun Fu Lee, McMaster University

A Hybrid Approach to Comparing Parallel-Group and Stepped-Wedge Cluster Randomized Trials When There Is Uncertainty in the Intra-Cluster Correlation

Speaker:
Samuel Kwakye Sarkodie, Newcastle University

Statistical Assessment of Unplanned Crossover Effect in Surgical Trials

Speaker:
Zhibao Mi, VA Cooperative Studies Program Coordinating Center, Perry Point

2:00 – 3:00 pm

Indigo E (Level 2)

Contributed Session 14: Operations 3

ClinicalTrials.gov Tracking With Do-It-Yourself Application Programming Interface (DIY API)

Speaker:
Wendy Seiferheld, NRG Oncology

Overview of CDER BIMO Compliance and Enforcement

Speaker:
Rachelle Swann, U.S. Food and Drug Administration

Modifications to Surgical Procedures: A Scoping Review and Preliminary Framework to Promote Transparent Reporting and Efficient Sharing

Speaker:
Christin Hoffmann, University of Bristol

Disseminating Phase I Vaccine Trial Data in a Pandemic to Inform the Scientific Community – mRNA-1273 Phase I Trials

Speaker:
Mat Makowski, The Emmes Company, LLC

2:00 – 3:00 pm

Indigo BCFG (Level 2) LIVESTREAM

Contributed Session 15: Data Monitoring

Assessment of a Risk-Based Quality Management Approach to Protocol Deviations - A Data Coordinating Center's Experience

Speaker:
Marie Kay, University of Utah - Clinical Research Enterprise

Dynamically Generating Study Monitoring Reports via Email

Speaker:
Eric MW. Fischer, Wake Forest School of Medicine

Analysis of Adverse Event and Serious Adverse Event Data From Randomized Controlled Trials

Speaker:
Min Zhan, Department of Veterans Affairs

Data Visualization Approaches to Presenting Harms in Clinical Trials

Speaker:
Riaz Qureshi, University of Colorado Anschutz Medical Campus

Continues next page

Tuesday Conference Schedule

2:00 – 3:00 pm

202A (Level 2)

Contributed Session 16: Historical Controls

Local Multisource-Exchangeability Model for Adaptive Information Borrowing From Multiple Historical Controls

Speaker:
Wei Wei, Yale University

A Bayesian Exact Adaptive Platform Design With Continual Reassessment for Trials Utilizing Real World Data

Speaker:
Wei Wei, Yale University

Dynamic Borrowing From Historical Controls via the Synthetic Prior With Covariates in Randomized Clinical Trials

Speaker:
Daniel Schwartz, University of Chicago

Benefits and Risks in Leveraging Historical Control Data in Clinical Trials

Speaker:
Sara Urru, University of Padua

2:00 – 3:00 pm

Indigo H (Level 2)

Contributed Session 17: Personalized Medicine

A RSHINY APPLET for Sequential, Multiple Assignment, Randomized Trials With a Time-to-Event Final Endpoint

Speaker:
Sasha Kravets, University of Illinois at Chicago

Developing and Externally Validating Clinical Dynamic Prediction Joint Models for Localised Prostate Cancer

Speaker:
Harry Parr, The Institute of Cancer Research

Estimating the Impact of Patient Preference in Two-Stage Clinical Trials for Binary Outcomes When Some Patients are Indifferent to Treatment

Speaker:
Wenjing Meng, Yale University

Implementing Personalised Treatment Recommendations to Determine Optimal Treatment Decisions Using Data From a Three-Arm Trial When Both Active Treatments Show Positive Results

Speaker:
Danielle Edwards, King's College London

3:00 – 3:15 pm

Indigo West Foyer (Level 2)

Refreshment Break

3:15 – 4:45 pm

Indigo D (Level 2)

Invited Session 16

A Partnership Between Clinical Safety and Statistics for Aggregate Safety Assessment – Year Two

Session Organizer:
Gabrielle Murashova, Merck & Co.

Session Chair:
Greg Ball, Merck & Co.

Speakers:
Todd Gruber, Merck & Co.; **Nelson Lee Afanador**, Merck & Co.

3:15 – 4:45 pm

Indigo BCFG (Level 2) LIVESTREAM

Invited Session 18

All for One, One for All: How to Run Multiple Networks of COVID-19 Clinical Trials on a Common Platform Using Bayesian Method

Session Organizer:
Dong-Yun Kim, NHLIB/NIH

Speakers:
Scott Berry, Berry Consultants LLC; **Sonia Thomas**, Research Triangle Institute (RTI) International; **Christopher Lindsell**, Vanderbilt University Medical Center

3:15 – 4:45 pm

Indigo H (Level 2)

Invited Session 19

A Pragmatic Path to Direct Delivery of Drug to Participants

Session Organizer:
Letitia Perdue, Wake Forest School of Medicine

Speakers:
Julissa Almonte, Wake Forest School of Medicine; **Adam Henrie**, Cooperative Studies Program Clinical Research Pharmacy Coordinating Center; **Laura Lovato**, Wake Forest School of Medicine; **Sheronda Peeples**, VAMC Memphis-Research, Inc.

Tuesday Conference Schedule

3:15 – 4:45 pm

Indigo E (Level 2)

Invited Session 20

Dose Optimization in Oncology: Why, When and How

Session Organizers:
Kentaro Takeda, Astellas Pharma Global Development, Inc.; **Ying Yuan**, The University of Texas MD Anderson Cancer Center

Session Chair:
Kentaro Takeda, Astellas Pharma Global Development, Inc.

Speaker:
Rachael Liu, Takeda Pharmaceuticals International Co.

3:15 – 4:45 pm

202B (Level 2)

In-Conference Workshop 4

Tickets required.

TrialTree: A Novel Application for Interactive Trial Design

Session Organizer:
Lawrence Mbuagbaw, McMaster University

Speaker:
Daeria Lawson, McMaster University

4:45 – 5:00 pm

Indigo West Foyer (Level 2)

Break

5:00 – 6:30 pm

Indigo BCFG (Level 2) LIVESTREAM

Founders Lecture

Speaker:
Dr. Robert Califf, FDA Commissioner

6:30 – 7:30 pm

300 (Level 3)

ED&I Committee Meeting With SCT Committee Chairs & Co-Chairs

Wednesday Conference Schedule

7:00 am – noon

Indigo Light Wall (Level 2)

Registration

7:30 – 8:00 am

Indigo West Foyer (Level 2)

Continental Breakfast

8:00 – 9:00 am

Indigo D (Level 2)

Contributed Session 18: Applied 4

Outcome Variance After Dropout as an Indicator of Missing-Not-At-Random Bias in Randomized Clinical Trials

Speaker:
Audinga-Dea Hazewinkel, University of Bristol

Optimality of Testing Procedures for Survival Data in the Non-Proportional Hazards Setting

Speaker:
Andrea Arfe, Memorial Sloan Kettering Cancer Center

How Much Is that Data in the Window? A Comparison of Strategies for Analysing Data Recorded Outside Pre-Specified Visit Windows in Randomised Controlled Trials

Speaker:
Nick Beckley-Hoelscher, King's College London

The Application of ACCEPT Software in Retrospective Analysis of Specimen Data (SWOG S0500 Translational Medicine Project)

Speaker:
Jieling Miao, Fred Hutchinson Cancer Research Center

8:00 – 9:00 am

Indigo E (Level 2)

Contributed Session 19: Operations 4

One Line on a Manuscript: Operationalizing Ecological Momentary Assessment (EMA) in Clinical Trials

Speaker:
Brian Neumann, Rush University Medical Center

The CURED Framework: A Data-Driven Management Tool to Aid Successful Delivery of Clinical Research Projects

Speaker:
David Bryde, Liverpool John Moores University

Effectiveness of Interventions to Share Trial Results With Health Workers and Policymakers: Results of a Systematic Review

Speaker:
Annabelle South, UCL

Communicating Overall Results to Trial Participants: The Perspective of Site Staff From the Show RESPECT Study

Speaker:
Annabelle South, UCL

8:00 – 9:00 am

Please Note: All presentations in this session will be made available after the meeting on demand.

Contributed Session 20: Ethics 2 (On Demand)

Identifying and Examining Ethical Considerations Facing Data Monitoring Committees

Speaker:
Seema Shah, Lurie Children's Hospital

Development of a Core Outcome Set for the Evaluation of Interventions to Enhance Proxy Consent Decisions on Behalf of Adults who Lack Capacity to Consent: A Mixed Methods Study (COnSiDER Study)

Speaker:
Victoria Shepherd, Cardiff University

Conceptualising 'Good' Proxy Consent Decisions for Clinical Trial Participation: Implications for the Development of Interventions to Improve the Quality of Proxy Consent

Speaker:
Victoria Shepherd, Cardiff University

Unpacking the 'Black Box of Horrendousness': A Qualitative Study Exploring the Barriers and Facilitators to Conducting Trials Involving Adults Lacking Capacity to Consent

Speaker:
Victoria Shepherd, Cardiff University

8:00 – 9:00 am

Indigo H (Level 2)

Contributed Session 21: Recruitment & Retention 2

Retention to Pediatric Randomized Controlled Trials During the COVID-19 Pandemic: A Qualitative Study

Speaker:
Daisy Gaunt, University of Bristol

Correcting Disparities In Adolescent Access To Medicines By Promoting Age-Inclusive Research

Speaker:
Martine Dehlinger-Kremer, ICON Plc

Wednesday Conference Schedule

Participant Retention in Pediatric Randomized Controlled Trials: Systematic Review and Meta-Analysis

Speaker:
Daisy Gaunt, University of Bristol

Strategies to Improve Retention in Randomised Trials: A Cochrane Review

Speaker:
Katie Gillies, University of Aberdeen

8:00 – 9:00 am

204B (Level 2)

Contributed Session 22: Surgical Trials

Integration of Qualitative Research Into Surgical Trials to Optimise Trial Conduct and Understanding of the Trial Results For Maximal Impact

Speaker:
Julie Croft, University of Leeds

A Core Information Set to Guide Early Phase Surgical Research

Speaker:
Christin Hoffmann, University of Bristol

The Effects of Preceding Prospective Collaborative Studies (IDEAL Stage 2b) on the Quality and Impact of Subsequent Randomized Controlled Trials (IDEAL Stage 3) Evaluating Surgical Innovations: A Systematic Review and Case-Control Study

Speaker:
Mudathir Ibrahim, IDEAL Collaboration, Nuffield Department of Surgical Sciences, University of Oxford

Trial Designs to Target the Conditional Average Treatment Effect, With Application to Operating Surgeon Learning Effects in Surgical RCTS

Speaker:
Neil Corrigan, University of Leeds

9:00 – 9:15 am

Indigo West Foyer (Level 2)

Refreshment Break

9:15 – 10:45 am

Indigo D (Level 2)

Invited Session 21

Improving Data Quality in Multi-Center Trials: Innovative Approaches Utilized Within the Wake Forest NCI Community Oncology Research Program Research Base (WF NCORP RB)

Session Organizer:
Emily Dressler, Wake Forest University School of Medicine

Speakers:
Karen Craver, Wake Forest University School of Medicine; **Bill Stanfield**, Wake Forest University School of Medicine; **Glenn Lesser**, Wake Forest University School of Medicine

9:15 – 10:45 am

202A (Level 2)

Invited Session 22

Design and Analysis of Stepped Wedge Cluster Randomized Trials Based on Marginal Models for Discrete and Continuous Outcomes

Session Organizer:
Fan Li, Yale University School of Public Health

Session Chair:
Paul Rathouz, The University of Texas at Austin

Speakers:
John Preisser, University of North Carolina at Chapel Hill; North Carolina Translational & Clinical Sciences Institute (NC TraCS); **Elizabeth Turner**, Duke University School of Medicine; **Patrick Heagerty**, University of Washington, Seattle

9:15 – 10:45 am

Indigo E (Level 2)

Invited Session 23

Analysis of Complex Time-to-Event Endpoints in Clinical Trials

Session Organizer:
Lu Mao, University of Wisconsin-Madison

Speakers:
Ting Ye, University of Washington; **Chen Hu**, Johns Hopkins University School of Medicine; **Rick Chappell**, University of Wisconsin-Madison

9:15 – 10:45 am

Indigo H (Level 2)

Invited Session 24

Developing Adaptive Trial Designs: A Collaborative Process Balancing Statistical Efficiency With Clinical Importance

Session Organizer:
Jonathan Beall, Medical University of South Carolina

Speakers:
William Meurer, University of Michigan; **Byron Gajewski**, University of Kansas Medical Center; **Gregory Campbell**, GCStat Consulting LLC

10:45 – 11:00 am

Break

11:00 am – 12:30 pm

Indigo D (Level 2)

Invited Session 25

Bad Bugs in Tough Places – Developing Capacity to Obtain Compelling Evidence In Challenging Environments

Session Organizer:
Tyler Bonnett, Frederick National Laboratory for Cancer Research

Continues next page

Speakers:
H. Clifford Lane, National Institute of Allergy and Infectious Diseases; **Placide Mbala**, National Institute of Biomedical Research, Kinshasa, Democratic Republic of the Congo; **Nsengi Ntamabyaliro**, University of Kinshasa, Kinshasa, Democratic Republic of the Congo; **Olivier Tshiani**, Frederick National Laboratory for Cancer Research Frederick, MD National Institute of Biomedical Research, Democratic Republic of the Congo; **Seydou Doumbia**, University Clinical Research Center

11:00 am – 12:30 pm

Indigo E (Level 2)

Invited Session 26

Pharmacokinetics and/or Pharmacodynamics-Informed Dose-Finding Designs

Session Organizer:
Yisheng Li, The University of Texas MD Anderson Cancer Center

Speakers:
Moreno Ursino, Hôpital Universitaire Robert-Debré, Unité d'Epidémiologie Clinique || Unité de Recherche Clinique || Inserm CIC-EC 1426; **Burak Kürsad Günhan**, Biopharma | Global Development Global Biostatistics, Epidemiology & Medical Writing, Merck Healthcare KgaABiopharma | Global Development Global Biostatistics, Epidemiology & Medical Writing, Merck Healthcare KgaA, Darmstadt, Germany

11:00 am – 12:30 pm

Indigo H (Level 2)

Invited Session 27

Accommodating "History Effects" in Long Duration, Multi-Site Clinical Trials to Ensure Relevant and Compelling Evidence

Session Organizer:
Kimberly Carlson, Edward Hines Jr. VA Hospital, Cooperative Studies Program Coordinating Center

Speakers:
David Leehey, ACOS/Clinical Affairs and Education, Edward Hines Jr VA Hospital; **Drew Moghanaki**, Radiation Oncology, Veterans Affairs Greater Los Angeles Healthcare System; **Stuart Johnson**, Infectious Disease/Research, Edward Hines Jr. VA Hospital; **Abhishek Solanki**, Radiation Oncology, Edward Hines Jr. VA Hospital

11:00 am – 12:30 pm

202A (Level 2)

Invited Session 28

Rethinking the Inclusion of Research Biopsies in the Design of Clinical Trials

Session Organizer:
Laura Levit, American Society of Clinical Oncology

Speakers:
Elizabeth Garrett-Mayer, American Society of Clinical Oncology; **R. Donald Harvey**, Emory University; **Mark Ratain**, University of Chicago; **Alda Tam**, University of Texas, MD Anderson Cancer Center; **Jane Perlmutter**, Gemini Group; **Julie Kaneshiro**, Office for Human Research Protections

11:00 am – 12:30 pm

204B (Level 2)

Invited Session 29

Planning, Prioritizing, and Conducting Clinical Research in the VA Learning Healthcare System During the COVID-19 Pandemic

Session Organizer:
Jane Zhang, VA Cooperative Studies Program Coordinating Center and VA Network of Dedicated Enrollment Sites (NODES)

Session Chair:
Tassos Kyriakides, Veterans Affairs (VA) Cooperative Studies Program Coordinating Center

Speakers:
Jeffrey Curtis, Ann Arbor VA Medical Center; **Sanjay Mehta**, San Diego VA Medical Center; **David Smith**, San Diego VA Medical Center; **Marcus Johnson**, VA Cooperative Studies Program Coordinating Center and VA Network of Dedicated Enrollment Sites (NODES); **Peter Peduzzi**, Yale; **Grant Huang**, Cooperative Studies Program Office of Research and Development

11:00 am – 12:30 pm

202B (Level 2)

In-Conference Workshop 5

Tickets required.

It Takes a Village: Multi-Disciplinary Approach to Designing Stellar Data Collection Forms

Session Organizer:
Laura Lovato, Wake Forest University School of Medicine

Speakers:
Emily Dressler, Wake Forest University School of Medicine; **Darrin Harris**, Wake Forest University School of Medicine; **Letitia Perdue**, Wake Forest University School of Medicine; **Lindsay Tysinger**, Wake Forest University School of Medicine

12:30 pm

Annual Meeting Adjourned

Business Session Agenda

LIVESTREAM

Tuesday, May 17, 12:30 – 2:00 pm

Indigo BCFG (Level 2)

12:30 pm **President's Welcome and Report** ..... **Mithat Gönen**, President
- Approval of 2021 Business Meeting Minutes
- Year-in-Review
- Financial Report
- Sponsor Acknowledgments
- Election Results

12:45 pm **Presentation of Class of 2022 Fellows** ..... **Roger Lewis**, Fellows Chair

12:50 pm **Clinical Trials Journal Report** ..... **Colin Begg**, Editor

1:00 pm **Membership Committee Update** ..... **Jody Ciolino**, Membership Chair

1:05 pm **Communications Committee Update** ..... **Lee McDaniel**, Communications Chair

1:10 pm **Chalmers Student Scholarship** ..... **Codruta Chiuzan**, Student Scholarship Chair
Sylvan Green Winner

1:15 pm **ED&I Student Award** ..... **Kaleab Abebe**, ED&I Chair

1:20 pm **Best Poster Presentation** ..... **Sharon Yeatts**, Program Chair

1:30 pm **Remarks from Incoming President** ..... **Lehana Thabane**, President-Elect
- Award to Outgoing President and Board
- Future Annual Meetings

1:40 pm **Closing Remarks** ..... **Mithat Gönen**, President
- Open Discussion / Q&A
- Adjournment

2022 Equity, Diversity, and Inclusion (ED&I) Student Award Recipients

Ariany Marques Vieira **Jacqueline Thompson** **David-Erick Lafontant** **Sandra Castro-Pearson**

Poster Presentations

Monday, May 16 | 9:30 – 10:00 am | Indigo A (Level 2)				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
1	**P1**	Clinical Trial Facilitators: A Novel Approach to Support the Execution of Clinical Research at the Study Site Level	**Marcus Johnson**	Durham VA Health Care System
1	**P2**	OnCore and REDCap: A Comparison of Two Data Management Systems	**Shaun Bulsara**	Baylor College of Medicine
1	**P3**	The Effect of Subject Accrual on Futility Analyses in Randomized Clinical Trials with Time-To-Event Endpoints: A Simulation Study on Conditional Power	**Corinne McGill**	Medical University of South Carolina
1	**P4**	Developing At-A-Glance Workflows for Conducting Trials in Compliance With Complex Regulatory Systems and Expectations for Simplification of the System in Japan*	**Mayumi Fukuda-Doi**	National Cerebral and Cardiovascular Center
1	**P5**	A Web Application Tool for Power Calculation of Stepped Wedge Cluster Randomization Trials With Complete/Incomplete Design	**Zhuopei Hu**	University of Arkansas for Medical Sciences
1	**P6**	Estimation of Personalised Treatment Recommendations in the Survival Context Using a Restricted Mean Survival Time Outcome	**Richard Emsley**	King's College London
1	**P7**	Implementation of Platform-Enabled Fast Healthcare Interoperability Resources on Behalf of Empowered, Accelerated Discovery in Children With SARS-CoV-2 Infections	**Adam Resnick**	Childrens Hospital of Philadelphia
1	**P8**	Lessons from Implementing Practice-Level Cluster Randomized Studies Within the NCORP Setting	**Kathryn Arnold**	Fred Hutchison Cancer Research Center
1	**P9**	On the Robustness and Precision of Mixed-Model Analysis of Covariance in Cluster-Randomized Trials*	**Bingkai Wang**	University of Pennsylvania
1	**P10**	Inclusion of Progression Criteria in External Randomised Pilot Trial Funding Applications Submitted to UK NIHR Research for Patient Benefit	**Katie Mellor**	University of Oxford
1	**P11**	The Win-Ratio Approach. Some Notes on the Impact of Unbalanced Samples, Heterogeneity, and Clustering in Data	**Dario prof. Gregori**	University of Padua
1	**P12**	Validation of a New Digital Tool to Assess Physician Competency in Behaviour Change Counseling: The Motivational Communication Competency Assessment Test	**Anda Dragomir**	Concordia University
1	**P13**	Letter Tracking System Design: The Systolic Blood Pressure Intervention Trial Mind 2020	**Danielle Cunio**	Wake Forest School of Medicine
1	**P14**	Collection of Precise Reasons for Treatment Discontinuations to Allow Better Defining Estimands*	**Yongming Qu**	Eli Lilly and Company
1	**P15**	Bayesian Methods to Compare Dose Levels to Placebo in a Small n, Sequential, Multiple Assignment, Randomized Trial (snSMART) With a Continuous Outcome	**Fang Fang**	University of Michigan School of Public Health

Please Note: Posters with an asterisk (*) after the poster presentation title will be made available to attendees after the meeting on demand.

Poster Presentations

Monday, May 16 | 3:30 – 4:00 pm | Indigo A (Level 2)				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
2	**P17**	Allowing for Uncertainty in the Components Required for Sample Size Estimation for a Cluster Randomized Trial Using the Symbolic Two-Step Method	**David Zahrieh**	Department of Data Sciences & Development Strategy, Ultragenyx Pharmaceutical
2	**P18**	Bayesian Analysis of Cluster Randomized Trials With Ordinal Endpoints	**Travis Lilley**	The University of Texas at Austin
2	**P19**	Interim Data Communication Strategies for Adaptive Clinical Trial Designs	**Anna Bosse**	Berry Consultants, LLC
2	**P19**	Interim Data Communication Strategies for Adaptive Clinical Trial Designs	**Farah Khandwala**	Berry Consultants, LLC
2	**P21**	Evaluating Intermediate Clinical Endpoints for Futility Analysis in Clinical Trials	**Emily Roberts**	University of Michigan
2	**P22**	Identifying Meaningful Change on PROMIS Short Forms in Cancer Patients: A Comparison of Item Response Theory and Classic Test Theory Frameworks	**Minji Lee**	Mayo Clinic
2	**P23**	Interpreting a Bayesian Phase II Futility Clinical Trial	**Jonathan Beall**	Medical University of South Carolina
2	**P24**	Using Social Contact Data to Improve the Overall Effect Estimate of a Cluster-Randomized Influenza Vaccination Program in Senegal	**Gail Potter**	National Institute for Allergy and Infectious Diseases, National Institutes of Health
2	**P25**	A Bayesian Piecewise Exponential Phase II Design for Monitoring a Time-to-Event Endpoint*	**Yun Qing**	University of Texas MD Anderson Cancer Center and The University of Texas Health Science Center at Houston (UTHealth) School of Public Health
2	**P27**	Stopping Rules of Interim Monitoring Analyses in Clinical Trials*	**Fei Yuan**	Population Health Research Institute - McMaster University
2	**P28**	Utilization of R Markdown for Automation in Development of Participant Feedback Reports for N-of-1 Trial Designs	**Heejoon Ahn**	Northwell Health
2	**P29**	Quantifying the Prior Informativeness via ESS Approach in a Clinical Trial: An Application of a Semiparametric Prior Elicitation Phase IIA Design	**Azzolina Danila**	University of Ferrara
2	**P30**	The Use of Evidence-Based Dynamic Treatment Regimes to Improve Depression Outcomes	**Yi Dai**	Yale University
2	**P31**	Automated Real-Time Monitoring and Feedback of Shared Decision Making for Surgery: A Non-Randomised Feasibility Study*	**Christin Hoffmann**	University of Bristol
2	**P32**	SWAT Priorities to Improve the Evidence to Inform Recruitment and Retention Practice in Clinical Trials	**Cherish Eloise May Boxall**	University of Southampton
2	**P34**	A Comprehensive Simulation Study to Compare Estimators of Restricted Mean Survival Time Using Data From Clinical Trials	**Oleksandr Savenkov**	Weill Cornell Medicine

Continues next page

Please Note: Posters with an asterisk (*) after the poster presentation title will be made available to attendees after the meeting on demand.

Poster Presentations

Tuesday, May 17 | 10:30 – 11:00 am | Indigo A (Level 2)				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
3	**P35**	Addressing Challenges and Barriers to Rural Veteran Participation in Clinical Research Within the Veterans Affairs Healthcare System	**Marcus Johnson**	Durham VA Health Care System
3	**P36**	Benefits and Pitfalls of Combining Observational and Experimental Studies in Network Meta-Analyses: Implications for Public Health Policy	**Menelaos Konstantinidis**	Dalla Lana School of Public Health, University of Toronto
3	**P38**	Versatile Window Mean Survival Time: Motivating Trial Design and Analysis With Clinical Relevance	**Mitchell Paukner**	University of Wisconsin - Madison
3	**P39**	Building Infrastructure to Exploit Evidence From Patient Preference Information (PPI) Studies*	**Ileana Baldi**	University of Padova
3	**P40**	Statistical Considerations for Testing Facility Interventions in Infants With Neonatal Opioid Withdrawal Syndrome (NOWS)	**Zhuopei Hu**	University of Arkansas for Medical Sciences
3	**P41**	The I-SOCIALISE Study: A Cluster Randomised Controlled Trial Investigating the Social Competence and Isolation of Children with Autism Taking Participating in LEGO® Based Therapy ('Play Brick Therapy') Groups in Mainstream School Environments*	**Ellen Kingsley**	COMIC research, LYPFT NHS
3	**P42**	A Non-Factorial Analysis of a Factorial Phase II Trial Design to Evaluate Single Agent and Combination Consolidation Therapies Following CD19 CAR T-cell Therapy for Relapsed/Refractory Diffuse Large B cell* Lymphoma (R/R DLBCL): SWOG-S2114*	**Hongli Li**	SWOG Statistics and Data Management Center
3	**P44**	A More Efficient Approach to Clinical Trial Data Collection: The SWOG-nCartes Pilot Collaboration	**Chris Cook**	SWOG Statistics and Data Management Center
3	**P45**	Do Participants Exhibit Evidence of Respondent Fatigue After Completion of Subjective Questionnaires Multiple Times Across a Study?: Examination of Data from a Phase I Inpatient Randomized Clinical Trial	**Shawn Hirsch**	RTI International
3	**P46**	Optimization of a Training Program in Motivational Communication: Phase 1	**Brigitte Voisard**	Université du Québec à Montréal
3	**P48**	The Intervention Portal: Consolidating Study Intervention Tracking With Participant Data Management	**John Nichols**	Wake Forest School of Medicine

Please Note: Posters with an asterisk (*) after the poster presentation title will be made available to attendees after the meeting on demand..

SCT David Sackett Trial of the Year Presentation

LIVESTREAM

Monday, May 16, 4:00 – 5:30 pm

Indigo BCFG (Level 2)

"The TOGETHER Trial: An Adaptive Platform International Trial" is the recipient of the prestigious David Sackett Trial of the Year Award, presented annually by the Society for Clinical Trials (SCT). Dr. Edward J. Mills, Professor, Department of Health Research Methods, Evidence, & Impact, Faculty of Health Sciences at McMaster University, and Dr. Gilmar Reis, Associate Professor of Medicine at Pontifica Universidade Catolica de Minas Gerais will accept the award on behalf of the TOGETHER Trial: An Adaptive Platform International Trial team.

The TOGETHER Trial is an adaptive, multi-arm platform trial, evaluating multiple concurrent interventions (investigational products [IPs]) versus placebo among outpatients at high risk of developing COVID-19-related complications. The trial is designed to allow for multiple intervention arms to be implemented at any time and data to be merged with data from other external trials. This is a new approach for clinical trials that has occurred as a result of the COVID-19 pandemic and integrates platform adaptive trial designs with data synthesis to facilitate rapid decision-making. The overarching objective of this study is to test the hypothesis that repurposed drugs versus placebo effectively prevent worsening of COVID-19 requiring extended emergency room observation or hospitalization among high-risk adults at 28 days post-randomization. This trial is now expanding to South Africa, Pakistan, Rwanda, DRC, and Vietnam.

About the SCT David Sackett Trial of the Year

Each year since 2008, the SCT David Sackett Trial of the Year Award has been awarded to a randomized, controlled trial published (either electronically or in print) in the previous calendar year that best fulfills the following standards:

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

Nominations are accepted from Society members, investigators, and interested scholars from around the world. The 2022 Trial of the Year Committee will issue a call for nominations in late 2022.

Continues next page

SCT David Sackett Trial of the Year Presentation *(continued)*

Monday, May 16, 4:00 – 5:30 pm

Indigo BCFG (Level 2)

Edward Mills, PhD, FRCP
McMaster University

I am a clinical trialist leading the TOGETHER platform trial in Brazil, South Africa, Pakistan, DRC/Rwanda and soon Vietnam. I am also a Professor at McMaster University and lead a company named Platform Life Sciences. I have worked on clinical trials for twenty years and have seen, and naively participated, in clinical research that was wasteful, unimportant, and probably wrong. Over the last ten years I have changed my opinion on clinical trials and now am focused on adaptive, Bayesian approaches to trials with a focus on building long-term infrastructure for complex trials in previously unexpected settings, such as low income countries.

I encourage SCT Annual Meeting attendees to reach out to me with ideas about how you think clinical trials can be done in novel ways that help those who need it most. I am always keen to collaborate on important issues.

Gilmar Reis, MD, PhD
Pontifica Universidade Catolica de Minas Gerais

Dr. Reis received his Medical Degree in 1989 and completed his Internal Medicine Fellowship in 1990 and Cardiology Fellowship in 1992. He went to University of Michigan for a Cardiology Research Fellowhip from 1993-1994. He obtained his PhD in 2001 from Heart Institute, University of Sao Paulo. Dr. Reis is now serving as an Associate Professor of Medicine, Department of Medicine, Pontifical Catholic University of Minas Gerais (PUC-Minas) since 2001 and also was a Director of the PUC-Minas Medical School at Contagem, MG, Brazil, from 2015 to 2020. He built up a large cardiovascular research clinic in Belo Horizonte (CARDRESEARCH) focusing on global health evaluation, epidemiological evaluation of cardiac risk factors and patient centered clinical research with emphasis on cardiovascular chronic conditions. During pandemics he proposed the TOGETHER Trial in partnership with scientists from McMaster University and built up a large primary care clinical research frame network focusing on COVID-19 early mild disease patients.

Sylvan Green Award

This award was created in 2011 to honor Sylvan Green, MD for his service to the Society. He served as the SCT President in 1994, chaired the Education and the Student Scholarship Committees and was inducted as a Fellow in 2007. This award is open to physicians and dentists involved in clinical trials or epidemiology projects.

The 2022 Sylvan Green Award winner, Andrea Viecelli, will present her talk Monday, May 16, titled "Enhancing Patient-Partnership in Clinical Trials" from 12:45 – 1:00 pm. The award certificate will be presented during the Business Session on Tuesday, May 17, from 12:30 – 2:00 pm in Indigo BCFG (Level 2).

Andrea Viecelli
Princess Alexandra Hospital

Enhancing Patient-Partnership in Clinical Trials

Thomas C. Chalmers Student Scholarship

2022 Thomas C. Chalmers Student Scholarship Finalists

This scholarship was named in honor of Dr. Thomas C. Chalmers, who was a founding member of the SCT, served on the Board and was President in 1984. It recognizes his lifetime of service to the Society. Please visit the SCT website for further information.

The finalists for the 2022 Scholarship will present their abstracts on Monday, May 16, 12:45 – 2:00 pm in Indigo BCFG (Level 2). The winner will receive their award during the SCT Business Session on Tuesday, May 17, 12:30 – 2:00 pm in Indigo BCFG (Level 2).

Jiyang Wen
Johns Hopkins Bloomberg School of Public Health

Simultaneous Hypothesis Testing for Multiple Competing Risks in Comparative Clinical Trials

Peter Godolphin
University College London

Estimating Interactions and Subgroup-Specific Treatment Effects in Meta-Analysis Without Aggregation Bias: A Within-Trial Framework

Jack Wolf
University of Minnesota School of Public Health

A Permutation Procedure to Detect Heterogeneous Treatments Effects in Randomized Clinical Trials While Controlling the Type-I Error Rate

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2022 – 2023 Election Results

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Class of 2022 Fellows

The SCT Board of Directors invites all meeting attendees to join in saluting the Class of 2022 Fellows on Tuesday, May 17, 12:30 - 2:00 pm in Indigo BCFG (Level 2).

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University of Wisconsin, Madison
Madison, WI

Alexia Iasonos, PhD
Memorial Sloan Kettering Cancer Center
New York, NY

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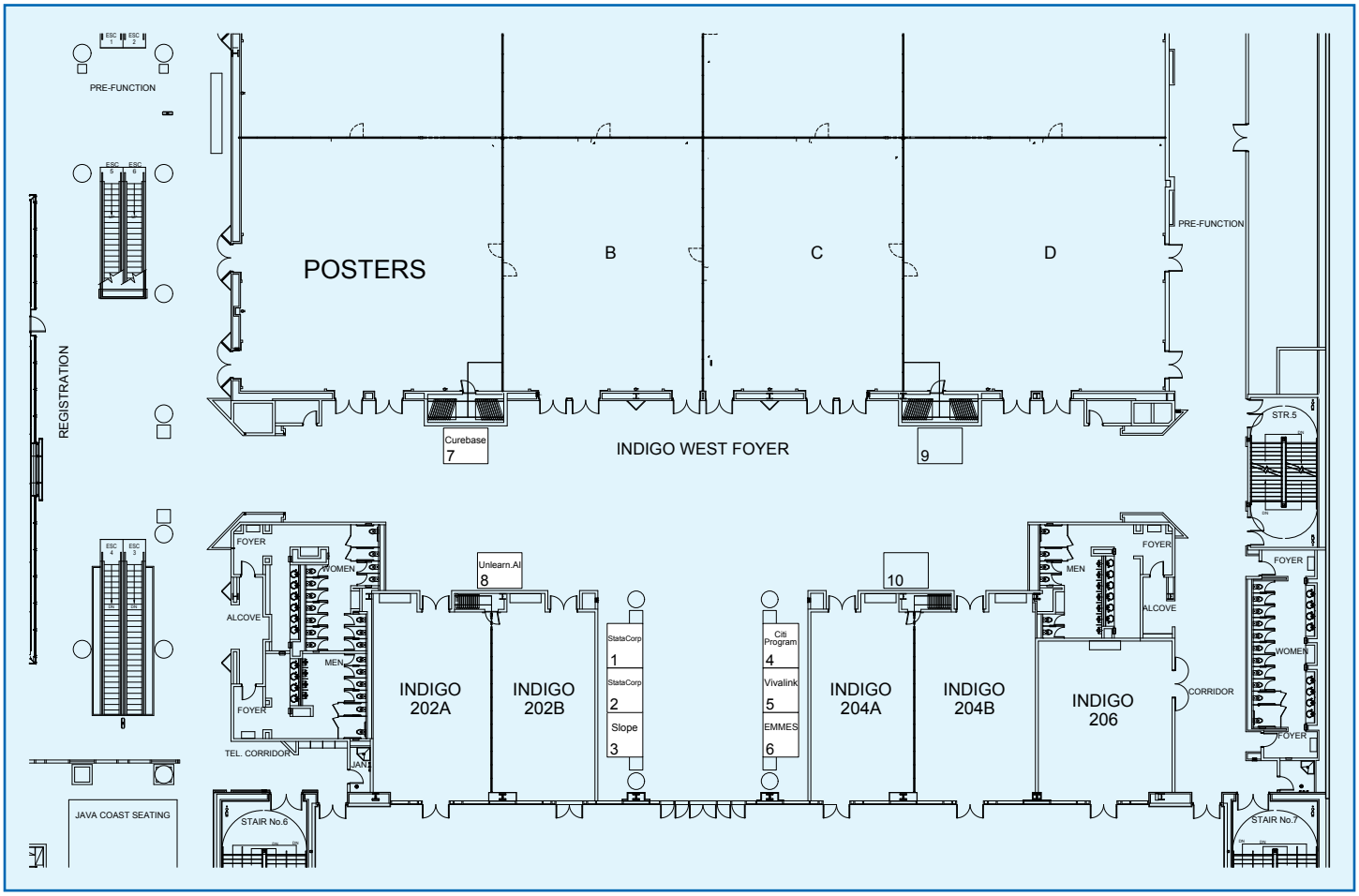

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May 21 – 24, 2023
44th Annual Meeting
Baltimore, MD

May 19 – 22, 2024
45th Annual Meeting
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May 18 – 21, 2025
46th Annual Meeting
Vancouver, Canada

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