47TH Annual Meeting

PHOENIX

May 17-20, 2026

SCT

SOCIETY FOR CLINICAL TRIALS

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SCT acknowledges the following companies for their generous support of our 2026 Annual Meeting:

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Welcome to the SCT 47th Annual Meeting

Valerie Durkalski-Mauldin, PhD, MPH
SCT President

Welcome to the 47th Annual Meeting of the Society for Clinical Trials! We are thrilled that you are attending this year's meeting and hope you enjoy the program and opportunities to connect with colleagues, expand your knowledge on various clinical trial topics, and meet new colleagues and collaborators. The 2026 meeting theme is centered around the conduct of clinical trials in an era of cutting-edge information capabilities. We continue to explore the utilization and integration of artificial intelligence (AI) in the clinical trial setting, but there are also so many other technological capabilities and resources that we need to consider as we continue to advance clinical trial design, operations, data analysis, and dissemination of results. Wearable devices to capture daily activity, real-time remote monitoring of vitals such as blood pressure or glucose levels, study resupply and shipment algorithms, and utilization of the electronic health records are just a few data aspects that come to mind; but there are also innovations in protocol and consent development, study design, database and statistical programming, recruitment and retention and dissemination of study results. We are excited to hear from our presenters on these topics and much more as they share the successes and challenges that have been encountered. I hope the sessions and conversations spark new ideas and help enhance existing methods/approaches so together, we can continue to move research development forward and improve outcomes for patients.

The meeting kicks off on Sunday with pre-conference workshops covering topics on: AI-Powered Adaptive Designs; Embedded Pragmatic Trials; and, an 'Essentials of Clinical Trials' workshop that will be free for students/postgraduates and new members. Our Early Career Special Interest Group will host an Early Career & First-Time Attendee Gathering Sunday evening. Monday morning will begin with the presentation of the SCT Class of Fellows followed by our first keynote speaker, Dr. Cyrus Hoseyni from Johnson & Johnson Innovative Medicine who will be sharing how quantitative sciences and AI can be strategically and responsibly used in clinical development and evidence-based decision making. We will also host our roundtable luncheons on Monday that cover a diverse set of topics. The Monday portion of the meeting will end with a Networking Welcome Reception at 4:45 pm. Our second keynote speaker will start the day on Tuesday with the SCT Founders Lecture. Dr. Brandy Fureman, Chief Outcomes Officer at the Epilepsy Foundation of America, will be presenting how cutting-edge information capabilities, population health management and co-production can enable a new era for clinical trials. The Annual Business Session, which is open to all attendees, will be at noon on Tuesday, followed by the Trial of the Year presentation in the afternoon. Tuesday will end with a gathering hosted by our Academic DCC Special Interest Group for those that are interested in finding out more about DCCs. The meeting will close on Wednesday at 12:30 pm after a series of Contributed and Invited Sessions.

I would like to extend sincere appreciation to our SCT committee members who generously volunteered their time to contribute to the planning of this year's annual meeting. These meetings require an extraordinary amount of effort to plan and coordinate, and I greatly appreciate the time that committee members gave towards meeting planning. A special thanks to our Program and Education Committee Chairs and Co-Chairs for their careful preparation of the program. And a big thank you to our Communications Committee for keeping our members and the public informed about SCT activities. I also want to thank our management company at Executive Administration, Inc. (EAI) for their careful preparation and dedication to making this event possible, and for their overall administrative support of SCT.

Thank you for attending the SCT annual meeting. I hope you enjoy the program and your time in Phoenix.

Announcements

Abstracts
Abstracts for many of the annual meeting presentations are available on the SCT mobile app. To view, go to the "Schedule" icon and select the title of the Contributed Session/Poster Session you're interested in and click the paperclip icon that says "Handouts."

Business Session Materials
Materials for the Tuesday Business Session are available on the SCT mobile app. To view, go to the "Schedule" icon and select the Business Session and click the paperclip icon that says "Handouts."

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 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, six organizations will be exhibiting in the Grand Ballroom Foyer. We encourage all registrants to visit these booths and thank the organizations' representatives for their participation. See page 36 for more information.

Exhibit Hours:

Monday	9:15 am – 6:15 pm
Tuesday	8:45 am – 3:00 pm

Invited Sessions
Invited Sessions are 90-minute plenary sessions that are open to all meeting registrants. There is no need for a special invitation to attend these sessions and tickets are not required.

To view the Invited Session descriptions, go to the "Schedule" icon in the mobile app and select the title of the session you're interested in and click the paperclip icon that says "Handouts."

LinkedIn Page
Stay connected and informed about clinical trial methodologies, upcoming events, educational opportunities, and networking by following the SCT LinkedIn page (https://www.linkedin.com/company/society-for-clinical-trials/). We encourage everyone to share our public page to help expand awareness of clinical trials and the Society.

Luggage Check
SCT does not have a dedicated luggage check area and cannot be responsible for holding meeting attendees' luggage. Please visit the bell desk in the hotel lobby for luggage check or holding options.

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 2026 in your app store or scan the QR code.

Networking Welcome Reception
All attendees are invited to the Networking Welcome Reception on Monday from 4:45 – 6:15 pm in the Grand Ballroom Foyer & Palm Court. It's the perfect place to catch up with old friends and make new acquaintances. Please also plan to spend some time interacting with our exhibiting partners.

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. Meeting attendees 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 in the Grand Ballroom Foyer 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 (P2-P22).....Monday 9:30 – 10:15 am
Poster Session 2 (P23-P43).....Monday 2:45 – 3:30 pm
Poster Session 3 (P45-P63).....Tuesday 9:00 – 9:45 am

See pages 23-28 for more information. Authors are also required to remove their posters shortly after the conclusion of their assigned poster session(s).

Program Tracks

To make it easier for participants to identify Annual Meeting sessions that are relevant to them, SCT has identified four critical areas of clinical trials.

Design D
Ethics E
Operations
Statistics S

Please look for the designated icon that's been assigned to each Invited Session and Contributed Session.

Registration Desk Hours

The SCT Registration is located in the Grand Ballroom Foyer and will be open:

Sunday .....7:00 am – 5:00 pm
Monday.....7:00 am – 5:00 pm
Tuesday.....7:30 am – 5:00 pm
Wednesday .....7:30 – 11:15 am

Targeted Sessions

Targeted Sessions are 90-minute plenary sessions that are open to all meeting attendees. There is also no need for a special invitation to attend these sessions and tickets are not required.

To view the Targeted Session descriptions, go to the "Schedule" icon in the mobile app and select the title of the session you're interested in and click the paperclip icon that says "Handouts."

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 "ArizonaGrandMeetingRooms" wireless network
- Enter password: sct2026

Assumption of Risk

Participating in the SCT Annual Meeting carries risk due to the contagious nature of COVID-19 and other contagious viruses. All attendees agree to release SCT, its business partners, and the Annual Meeting venue from any liability related to their participation in the Annual Meeting. 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 city of Phoenix, 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 meeting sessions/events if symptomatic of any contagious virus or disease.

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

Grand Ballroom Foyer

Registration

8:00 am – noon

Acacia

Pre-Conference Workshop 1

AI-Powered Adaptive Designs: Bringing Innovative Clinical Trials Designs into Practice

Session Organizer & Speaker:
Feifang Hu, George Washington University

Speaker:
Will Ma, HopeAI, Inc.

Noon – 1:00 pm

Lunch (On Your Own)

1:00 – 5:00 pm

Acacia

Note: This workshop is only available to first-time attendees, students, and post-graduates.

Pre-Conference Workshop 4

Essentials of Clinical Trials

Session Organizer:
Yves Rosenberg, NHLBI/NIH

Session Chair:
Christopher Coffey, University of Iowa

Speakers:
Dixie J. Ecklund, University of Iowa, **Trevis Huff**, University of Iowa

1:00 – 5:00 pm

Copperwood

Pre-Conference Workshop 5

Innovations in Embedded Pragmatic Clinical Trials Workshop

Session Organizer & Session Chair:
Emily O'Brien, PhD, Duke Clinical Research Institute

Speakers:
Patrick Heagerty, University of Washington. **Wendy Weber, ND, PhD, MPH**, National Center for Complementary and Integrative Health

Panelists:
Nana Martinson, MPH, National Center for Complementary and Integrative Health, **P. Michael Hu, MD, PhD**, Kaiser Permanente Colorado, **Sebastian Tong, MD, MPH**, University of Washington, **Angelo Volandes, MD, MPH**, Harvard Medical School

5:15 – 6:15 pm

Ocotillo B

Early Career & First-Time Attendee Gathering
(Pre-registration, no cost. Ticket required.)

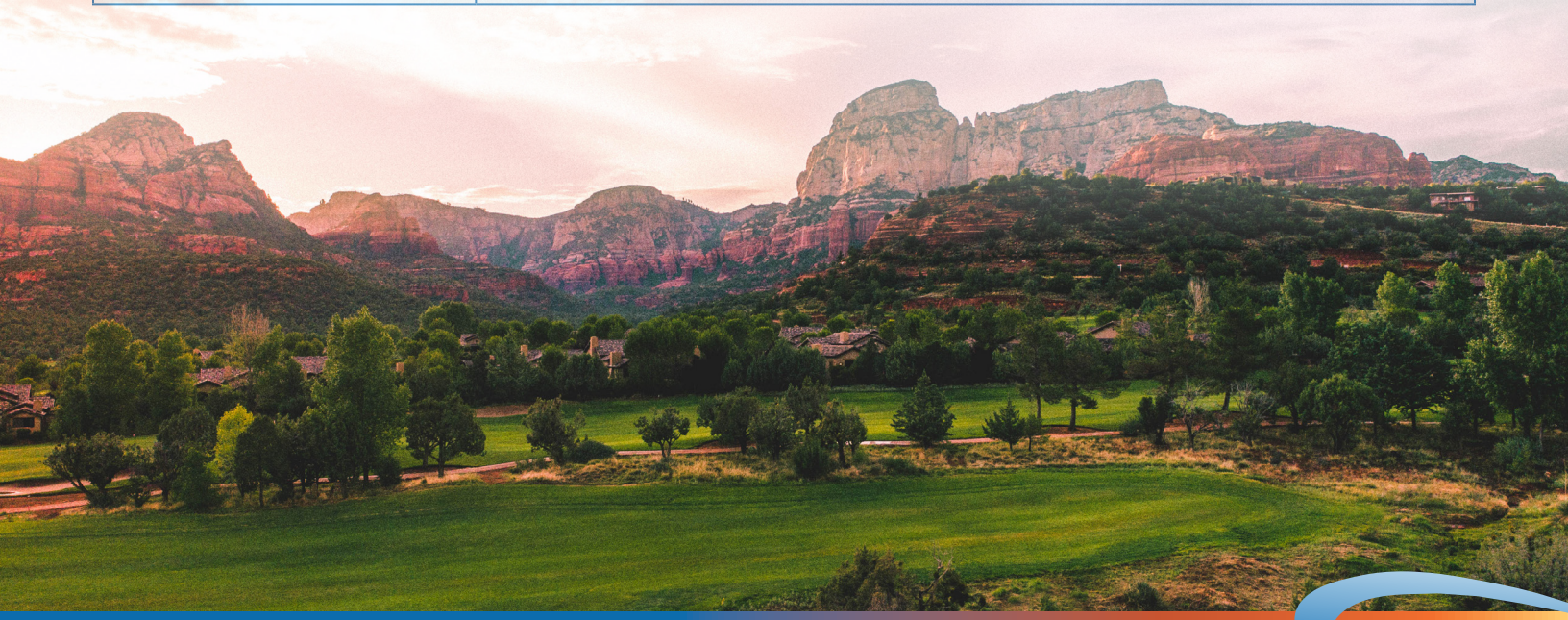
Conference Schedule at a Glance

The SCT Annual Meeting will take place in the Conference Center at the resort.

Time	Monday, May 18
7:00 am – 5:00 pm	Registration
7:00 – 8:00 am	Coffee/Tea
8:00 – 8:15 am	SCT President's Welcome
8:15 – 8:30 am	Presentation of the Class of 2026 Fellows
8:30 – 9:30 am	Curtis Meinert Keynote
9:15 am – 6:15 pm	Exhibit Hours
9:30 – 10:15 am	Poster Presentations (P2-P22) & Exhibits – With Refreshments
10:15 – 11:15 am	Contributed Sessions 1-4
11:30 am – 1:00 pm	Roundtable Discussions With Lunch
1:15 – 2:45 pm	Invited Sessions 1-4
1:15 – 2:45 pm	Targeted Session 1
2:45 – 3:30 pm	Poster Presentations (P23-P43) & Exhibits – With Refreshments
3:30 – 4:30 pm	Contributed Sessions 5-9
4:45 – 6:15 pm	Networking Welcome Reception
Time	**Tuesday, May 19**
7:30 am – 5:00 pm	Registration
7:30 – 8:00 am	Coffee/Tea
8:00 – 9:00 am	Founders Lecture
8:45 am – 3:00 pm	Exhibit Hours
9:00 – 9:45 am	Poster Presentations (P45-P63) & Exhibits – With Refreshments
10:00 – 11:30 am	Invited Sessions 5-7
10:00 – 11:30 am	Targeted Session 2
11:30 am – noon	Luncheon

Conference Schedule at a Glance

Time	Tuesday, May 19 *(continued)*
Noon – 12:45 pm	SCT Business Session
1:00 – 2:00 pm	Contributed Sessions 10-14
2:00 – 2:45 pm	Networking Break With Refreshments – Visit Exhibits
2:45 – 3:45 pm	Trial of the Year
3:45 – 4:00 pm	Break
4:00 – 5:30 pm	Invited Sessions 8-12
5:30 – 6:30 pm	UNICORN Special Interest Group Gathering (Pre-registration, no cost. Ticket required.)
Time	**Wednesday, May 20**
7:30 – 11:15 am	Registration
7:30 – 8:00 am	Coffee/Tea
8:00 – 9:00 am	Contributed Sessions 15-19
9:00 – 9:15 am	Break
9:15 – 10:45 am	Invited Sessions 13-16
9:15 – 10:45 am	Targeted Session 3
10:45 – 11:00 am	Break
11:00 am – 12:30 pm	Invited Sessions 17-21
12:30 pm	Annual Meeting Adjourned



Monday Conference Schedule

7:00 am – 5:00 pm

Grand Ballroom Foyer

Registration

7:00 – 8:00 am

Grand Ballroom Foyer & Palm Court

Coffee/Tea

8:00 – 8:15 am

Foxtail

SCT President's Welcome

Speaker:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

8:15 – 8:30 am

Foxtail

Presentation of the Class of 2026 Fellows

Speakers:
William Meurer, University of Michigan-Emergency Medicine,
Li Chen, Amgen

8:30 – 9:30 am

Foxtail

Curtis Meinert Keynote

Moderator:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

Quantitative Sciences and Artificial Intelligence: Opportunities and Considerations for Strategic and Responsible Application in Clinical Development

Speaker:
Cyrus Hoseyni, PhD, Johnson & Johnson Innovative Medicine

9:15 am – 6:15 pm

Grand Ballroom Foyer

Exhibit Hours

9:30 – 10:15 am

Grand Ballroom Foyer

Poster Presentations (P2-P22) & Exhibits – With Refreshments

10:15 – 11:15 am

Eucalyptus

Program Track:

Contributed Session 1: Trial Operations

Moderator:
Masha Kocherginsky, Northwestern University

Dual Coordination Center Strategies for Centralized and Efficient Vendor Contracting in the ALL ALS Consortium

Speaker:
Brandi Negron, Massachusetts General Hospital

From Prediction to Performance: Comparing Site Feasibility Enrollment Estimates to Actual Enrollment in Multicenter Clinical Trials

Speaker:
Catherine Dillon, Medical University of South Carolina

Feasibility of Remote Research Staff for Clinical Trials

Speaker:
Abbey Staugaitis, University of Minnesota

The End of Privacy in Clinical Trials? A Deep Learning Framework to Recover Protected Health Information from Artificial Intelligence

Speaker:
Brian Egleston, Fox Chase Cancer Center

10:15 – 11:15 am

Acacia

Program Tracks:

Contributed Session 2: Trial Operations

Moderator:
Alejandro Gerardo Villasante-Tezanos, University of Texas Medical Branch

Advancing Multiregional Investigator-Initiated Trials: Capability Assessment and Collaborative Development through the ATLAS Network

Speaker:
Chiharu Mizoguchi, National Cancer Center Hospital

Public Perspectives on the Ethics and Acceptability of Decision Architecture Randomized Trials (DART)

Speaker:
James Flory, Memorial Sloan Kettering Cancer Center

The Ethics of Shifting Norms in Medical and Scientific Communications

Speaker:
Rafael Escandon, DGBI Clinical Research and Ethics Consulting

Formation of the NeuroNEXT Patient Advisory Council: Challenges and Lessons Learned

Speaker:
Erin Steinhart, Massachusetts General Hospital

Monday Conference Schedule

10:15 – 11:15 am

Copperwood

Program Track: S

Contributed Session 3: Survival Analysis and Non-Proportional Hazards

Moderator:
Lu Mao, University of Wisconsin-Madison

A Practical Guide on How to Use the Innovative Framework of Flexible Parametric Models for the Primary Analysis of a Trial Using a Time-to-Event Outcome

Speaker:
Elena Frangou, MRC Clinical Trials Unit at UCL

Using the 'Average Hazard Ratio' When Designing Survival Trials Under Non-Proportional Hazards

Speaker:
Michael Grayling, Johnson & Johnson

Operationalizing the PREVENTABLE Study Extension: Automating Consent and Participant Decision Workflows

Speaker:
Emily Rives, Wake Forest University School of Medicine

Sample Size Determination for Win Statistics in Cluster-Randomized Trials

Speaker:
Xi Fang, PhD, Yale School of Public Health
(Chalmers Finalist)

10:15 – 11:15 am

Honeysuckle

Program Tracks: D S

Contributed Session 4: Cluster-Randomized Trial

Moderator:
Charity Patterson, University of Pittsburgh

Designing Cluster Randomized Trials: A Practical Guide for Investigators

Speaker:
Kendra Plourde, Yale School of Public Health

Optimal Sample Size Calculation in Cost-Effectiveness Longitudinal Cluster Randomized Trials

Speaker:
Fan Li, Yale School of Public Health

A Shiny App for Sample Size Re-Estimation of Parallel-Arm Cluster-Randomized Trials

Speaker:
Heather Gunn, Mayo Clinic

AMPT: An Open-Source R Shiny Platform to Amplify Mental Health Precision Trials

Speaker:
Aoqi Xie, Division of Biostatistics, Dalla Lana School of Public Health, University of Toronto

11:30 am – 1:00 pm

Foxtail

Roundtable Discussions With Lunch

Please refer to the SCT mobile app for a full list of roundtable topics, moderators, descriptions, and to find the location of the roundtable topic you registered for. Lunch is provided for all meeting attendees regardless of Roundtable Discussion registration.

1:15 – 2:45 pm

Eucalyptus

Program Track: S

Invited Session 1

Recent Advances in Statistical Methods for Hierarchical Composite Endpoints

Session Organizer & Session Chair:
Yuliya Lokhnygina, Duke University

Speakers:
Huiman Barnhart, Duke University, **Lu Mao**, University of Wisconsin-Madison, **Eric Leifer**, National Institutes of Health/Department of Health and Human Services

Discussant:
Roland Matsouaka, Duke University

1:15 – 2:45 pm

Foxtail

Program Tracks: D E S

Invited Session 2

Shaping the Next Generation of Clinical Trialists: Perspectives on Opportunities, Challenges, and Innovations in Training the Clinical Trials Workforce

Session Organizer & Panelist:
Megan McCabe, University of Alabama at Birmingham

Session Chair:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

Panelists:
Anna Snavely, Wake Forest University, **Heidi Munger Clary**, Wake Forest University, **Christopher Coffey**, University of Iowa, **Letitia Weigand**, NIH NINDS

Continues next page

Monday Conference Schedule

1:15 – 2:45 pm

Copperwood

Program Tracks: D ⚙

Invited Session 3

Research Done Differently®: Cutting-Edge Tools for Patient-Centered Trials

Session Organizer & Speaker:
Claudia Grossmann, PCORI

Session Chair:
Nora McGhee, PCORI

Speakers:
Jason Gerson, PCORI, **Mabel Crescioni**, PCORI

1:15 – 2:45 pm

Honeysuckle

Program Tracks: D S

Invited Session 4

Challenges in the Communication of Results From Randomized Clinical Trials

Session Organizer & Session Chair:
Roger Lewis, MD, PhD, Journal of the American Medical Association (JAMA)

Moderator:
Colin Begg, Memorial Sloan Kettering Cancer Center

Panelist:
Patrick J. Heagerty, PhD, University of Washington

1:15 – 2:45 pm

Acacia

Targeted Session 1

Investigator-Initiated Clinical Trial Funding Opportunities – What Is on the Horizon for US Federal Funding Programs

Session Organizer & Moderator:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

Speakers:
Clinton Wright, PhD, National Institute of Neurological Disorders and Stroke, **Yves Rosenberg, MD**, NHLBI/NIH, **Pedro Torres-Saavedra, PhD**, National Cancer Institute, **Seema Nayak, MD**, National Institute of Allergy and Infectious Diseases

2:45 – 3:30 pm

Grand Ballroom Foyer

Poster Presentations (P23-P43) & Exhibits – With Refreshments

3:30 – 4:30 pm

Eucalyptus

Program Tracks: D S

Contributed Session 5: Adaptive Designs

Moderator:
Patrick PJ Phillips, University of California, San Francisco

Bayesian Response-Adaptive Randomization for Cluster Randomized Controlled Trials

Speaker:
Yunyi Liu, UC San Diego
(Chalmers Finalist)

CADET: Covariate-aware Adaptive Design for Efficient Trials

Speaker:
Yi Lian, University of Pennsylvania

Adaptive Seamless Phase 2/3 Designs with Contribution of Components Demonstration

Speaker:
Ruoqi Song, University of Cincinnati

Early Phase Adaptive Platform Trials: Current Practice, Challenges and Opportunities

Speaker:
Sabine Dreibe, The Institute of Cancer Research

3:30 – 4:30 pm

Copperwood

Program Track: ⚙

Contributed Session 6: Improving Clinical Trial Conduct and Monitoring

Moderator:
Yves Rosenberg, NHLBI/NIH

Enhanced Regional Study Coordinator Model for Centralized Long-Term Follow-Up: The Colonoscopy vs. Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer (CONFIRM)

Speaker:
Beata Planeta, Cooperative Studies Program Coordinating Center

NINDS Promotes its Innovative Approach for Funding Clinical Trials in Adult and Pediatric Populations using Other Transactions Authority

Speaker:
Joan Ohayon, NIH

Changing Behaviours to Change Trials: Leveraging Cutting Edge Capabilities From Behavioural Science to Improve Trial Conduct

Speaker:
Katie Gillies, University of Aberdeen

Monday Conference Schedule

PROFILE Trial – Disease Modification With Early Treatment in Newly-Diagnosed Crohn's Disease

Speaker:
Nurulamin Noor, University of Cambridge
(Sylvan Green Award Winner)

3:30 – 4:30 pm

Foxtail
Program Tracks: E ⚙

Contributed Session 7: Consent and Trial Conduct

Moderator:
Emily Rives, Wake Forest University School of Medicine

Development of SPIRIT and CONSORT Extensions for Reporting Climate and Environmental Outcomes in Randomised Trials (SPIRIT-ICE and CONSORT-ICE)

Speaker:
Johanne Petersen, Copenhagen Trial Unit

International Regulatory Comparison of Emergency Consent Models and Emerging Directions in Japan: Public Acceptance and Policy Implications

Speaker:
Mayumi Fukuda-Doi, National Cerebral and Cardiovascular Center

Rethinking Informed Consent: A "Staged-and-Tailored" Approach for Pragmatic Trials

Speaker:
Beverley Nickolls, Queen Mary University of London

Streamlining Multicenter Trauma Research: Insights From the LITES Network and University of Pittsburgh IRB

Speakers:
Lisa DeSantes, University of Pittsburgh, **Alexandra Merti**, University of Pittsburgh Medical Center

3:30 – 4:30 pm

Honeysuckle
Program Tracks: D S

Contributed Session 8: Subgroup and Heterogeneous Populations

Moderator:
Kendra Plourde, Yale School of Public Health

Pre-Planned Subgroup Analyses: Great on Paper, Tricky in Practice

Speaker:
Ian Rines, Medical University of South Carolina

Methods for Formally Testing in a Prespecified Subpopulation in a Confirmatory Trial

Speaker:
Michael Grayling, Johnson & Johnson

Bayesian Meta-Analysis of Comparative Drug Safety

Speaker:
Zizhong Tian, PhD, Eli Lilly and Company **(Chalmers Finalist)**

SMART-Vent: A Bayesian Adaptive Platform Trial for Evaluating Mechanical Ventilation Strategies Using Patient-Centered Endpoints in Heterogeneous ICU Populations

Speaker:
Domenico Iervolino, University of Padova

3:30 – 4:30 pm

Acacia
Program Track: S

Contributed Session 9: Complex Endpoint and Survival Analysis

Moderator:
Jingyi Lin, Merck

Covariate-Adjusted Win Statistics in Randomized Clinical Trials With Ordinal Outcomes

Speaker:
Guangyu Tong, Yale University

From Biomarkers to Benefit: A Mediation-Based Framework for Surrogate Endpoints in Cardiovascular Outcome Trials

Speaker:
Pasquale Dolce, University of Naples Federico II

When to Enrich? Enrollment Strategy Trade-Offs in Time-to-Event Studies With Heterogeneous Treatment Effects

Speaker:
Kyle Rudser, University of Minnesota

Analyzing Cardiovascular Outcomes Using Multi-State Models Beyond Time-to-First Analysis

Speaker:
Shun Fu Lee, McMaster University

4:45 – 6:15 pm

Grand Ballroom Foyer & Palm Court

Networking Welcome Reception

Continues next page

Tuesday Conference Schedule

7:30 am – 5:00 pm

Grand Ballroom Foyer

Registration

7:30 – 8:00 am

Grand Ballroom Foyer & Palm Court

Coffee/Tea

8:00 – 9:00 am

Foxtail

Founders Lecture

Moderator:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

How Cutting-Edge Information Capabilities, Population Health Management and Co-production Can Enable a New Era for Clinical Trials

Speaker:
Brandy Fureman, PhD, FAES, American Epilepsy Society

8:45 am – 3:00 pm

Grand Ballroom Foyer

Exhibit Hours

9:00 – 9:45 am

Grand Ballroom Foyer

Poster Presentations (P45-P63) & Exhibits – With Refreshments

10:00 – 11:30 am

Eucalyptus

Program Tracks: D

Invited Session 5

Regaining Trust in Clinical Trials – Fellows' Session

Session Organizer & Panelist:
William Meurer, University of Michigan

Session Chair:
Anne Lindblad, Retired/Formerly of Emmes Corp.

Panelists:
Robert M. Califf, Duke University, **Marion Campbell**, University of Aberdeen, **Scott Evans**, Georgetown University, **Dixie Ecklund**, University of Iowa

Discussant:
Frank Rockhold, Duke University

10:00 – 11:30 am

Copperwood

Program Track: S

Invited Session 6

The Principal Stratum Strategy in Action: Addressing Intercurrent Events in Modern Clinical Trials

Session Organizer & Speaker:
Kimberley Goldsmith, King's College London

Session Chair & Discussant:
Graeme MacLennan, University of Aberdeen

Speakers:
Richard Emsley, King's College London, **Fan Li**, Yale School of Public Health

10:00 – 11:30 am

Honeysuckle

Program Track: S

Invited Session 7

Innovative Methods for Composite Endpoints: Statistical and Clinical Perspectives

Session Organizer:
Lai Wei, The Ohio State University

Session Chair & Other/Contributor:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

Speakers:
Md Rejuan Haque, The Ohio State University, **James Troendle**, National Heart, Lung, and Blood Institute (NHLBI), **Guoqing Diao**, The George Washington University

Discussant:
Huiman Barnhart, Duke Clinical Research Institute

Other/Contributor:
Madison Hyer, The Ohio State University

10:00 – 11:30 am

Acacia

Targeted Session 2

Data Monitoring Committees - Advancing Best Practices and Developing Next Generation Experts

Session Organizer:
Fanni Natanegara, PhD, Eli Lilly and Company

Session Chair:
Li Chen, PhD, ScD, Amgen

Panelists:
Pandurang Kulkarni, PhD, Eli Lilly and Company, **Kun He, PhD**, Independent Statistical Consultant, **Janet Wittes, PhD**, Wittes LLC, **Karen Higgins, ScD**, FDA, **Roger Lewis, MD, PhD**, Berry Consultants, David Geffen School of Medicine at UCLA

Tuesday Conference Schedule

11:30 am – noon

Palm Court

Luncheon

Noon – 12:45 pm

Foxtail

SCT Business Session (See page 22)

1:00 – 2:00 pm

Foxtail

Program Tracks: D ⚙

Contributed Session 10: Outcome Assessment and Discrete Choice Models

Moderator:
Tolulope Sajobi, University of Calgary

Evolving Outcome Measures in Rehabilitation Trials: From Legacy Scales to Modern Metrics

Speaker:
Christy Cassarly, Medical University of South Carolina

Remote Versus In-Person Cognitive Outcome Assessments in a Randomized Trial of Community-Dwelling Older Women

Speaker:
Alison Huang, University of California San Francisco

Assessing the Efficiency of Platform Trials with Long-Term Primary Outcomes

Speaker:
Aritra Mukherjee, Newcastle University

Designing Trials to Facilitate Recruitment: Insights From a Discrete Choice Experiment

Speaker:
Melissa Crane, Rush University Medical Center

1:00 – 2:00 pm

Eucalyptus

Program Track: ⚙

Contributed Session 11: Trial Operations and Monitoring

Moderator:
Logan P. Williams, George Washington University

Creating Report Dashboards Using Dynamic and Flexible SQL Generation for U.S. POINTER

Speaker:
Brandon Bukas, Advocate Atrium Health Wake Forest Baptist University

Cutting the Clutter: Streamlining Data Reports to Maximize Accountability and Boost Operational Efficiency

Speaker:
Brandon Napoleon, ASCO

Enhancing Data Cleaning and Monitoring through Interactive Dashboards: Implementation of a Power BI Framework for Quality Monitoring in a Multi-Center Clinical Study

Speaker:
Helena Blumenau, University of Iowa

Patterns and Timing of Protocol Deviations in a Time-Sensitive Stroke Trial

Speaker:
Mayumi Fukuda-Doi, National Cerebral and Cardiovascular Center

1:00 – 2:00 pm

Copperwood

Program Tracks: D ⚙

Contributed Session 12: Randomization and Baseline Balance

Moderator:
Guangyu Tong, Yale School of Medicine

Randomization at Crossroads: Advancing Methods, Modernizing Systems, and Updating Guidance

Speaker:
Wenle Zhao, Medical University of South Carolina

Integrating Minimal Sufficient Balance Randomization Into an Automated REDCap Workflow: Practical Considerations and Lessons Learned from an Active Clinical Trial

Speaker:
Madison Hyer, Center for Biostatistics, The Ohio State Medical Center

Minimal Sufficient Balance Randomization for Multi-Arm Randomized Clinical Trial Designs

Speaker:
Tolulope Sajobi, University of Calgary

Mitigating Baseline Imbalance in the MAGiNE Trial for GNE Myopathy

Speaker:
Dosten Kpozehouen, Clinical Trials Statistical and Data Management Center

Continues next page

Tuesday Conference Schedule

1:00 – 2:00 pm

Acacia

Program Track: S

Contributed Session 13: Challenges in Modern Clinical Trials

Moderator:
Bingkai Wang, University of Michigan

Estimands in Practice: Attitudes and Barriers to Implementation in UK Academic Clinical Trials Units

Speaker:
Morgaine Stiles, The Institute of Cancer Research

Disentangling Clinical Rescue From True Treatment Effect: SEM and Propensity-Score Approaches for Intercurrent Events Under ICH E9(R1)

Speaker:
Pasquale Dolce, University of Naples Federico II

Assessing Baseline Variable Imbalance in Cancer Randomized Controlled Trials: A Methodological Systematic Review

Speaker:
Alyssa Antonini, The Ohio State University

Improving the Reporting and Feasibility Assessment of Clinical Trials With Online Components: Findings From a Scoping Review of Terminology and Methodological Challenges

Speaker:
Tega Ayerume, Queen Mary University of London

1:00 – 2:00 pm

Honeysuckle

Program Track: S

Contributed Session 14: Composite Endpoint and Survival Analysis

Moderator:
John VanBuren, University of Utah

While-Alive Regression Analysis of Composite Survival Endpoints

Speaker:
Xi Fang, Yale School of Public Health

Methodology and Practical Considerations for Point Estimation of Novel Composite Time-To-Event Endpoints

Speaker:
Subodh Selukar, St. Jude Children's Research Hospital

Phase 2 Time-to-Event Small Bayesian Hybrid-Controlled Design in Metastatic Ocular Melanoma

Speaker:
David Zahrieh, Department of Quantitative Health Sciences, Mayo Clinic, Rochester

2:00 – 2:45 pm

Grand Ballroom Foyer & Palm Court

Networking Break With Refreshments – Visit Exhibits

2:45 – 3:45 pm

Foxtail

Trial of the Year

Moderator:
Jonathan Cook, University of Oxford

HepB-CpG vs HepB-Alum Vaccine in People With HIV and Prior Vaccine Nonresponse: The BEe-HIVe Randomized Clinical Trial (BEe-HIVe) Trial

Speaker:
Kristen Marks, MD, Weill Cornell Medicine

3:45 – 4:00 pm

Break

4:00 – 5:30 pm

Eucalyptus

Program Tracks: D S

Invited Session 8

Designing and Delivering Robust System-Level Evaluations (Using the Evaluation of Robot-Assisted Surgery as a Motivating Example)

Session Organizer & Session Chair:
Marion Campbell, University of Aberdeen

Speakers:
Graeme MacLennan, University of Aberdeen, **Katie Gillies**, University of Aberdeen, **David Beard**, University of Oxford & University of Sydney

Tuesday Conference Schedule

4:00 – 5:30 pm

Foxtail

Program Tracks: D E ⚙ S

Invited Session 9

Behind Multisite Trials Coordinating Center: Building and Sustaining Effective Data Coordinating Centers (DCCs)

Session Organizer:
Hyoshin Kim, Center for Biostatistics, Ohio State University

Session Chair:
Philip Hart, Ohio State University

Speakers:
Soledad Fernandez, Center for Biostatistics, Ohio State University, **Kaleab Z. Abebe**, Center for Biostatistics & Qualitative Methodology (CBQM), University of Pittsburgh, **Christopher Lindsell**, Duke Clinical Research Institute, Duke University, **Cathie Spino**, Statistical Analysis, Biomedical and Educational Research (SABER) unit, University of Michigan

4:00 – 5:30 pm

Honeysuckle

Program Track: ⚙

Invited Session 10

Lessons Learned: Preventing and Correcting Common Challenges in Clinical Trials

Session Organizer & Panelist:
Sally Jo Zuspan, University of Utah

Session Chair:
Barbara H. Braffett, PhD, George Washington University

Panelists:
Bryan Blette, Vanderbilt University, **Dixie Ecklund**, University of Iowa, **Michelle Lancet**, University of Pittsburgh, **Brian Mittman**, Kaiser Permanente

4:00 – 5:30 pm

Acacia

Program Track: ⚙

Invited Session 11

The NN111 Extinguish Trial: Lessons Learned in Trial Implementation, Recruitment, and Retention for a Rare Disease in an Acute Care Setting, International Clinical Trial

Session Organizer:
Erin Steinhart, Massachusetts General Hospital

Session Chair:
Michele Costigan, University of Iowa - NeuroNEXT DCC

Speakers:
Ka-Ho Wong, University of Utah, **Brenda Pearson**, University of Iowa - NeuroNEXT DCC, **Zackary Lemka**, University of Iowa - NeuroNEXT DCC

4:00 – 5:30 pm

Copperwood

Program Track: S

Invited Session 12

Extending the Reach and Impact of Randomized Clinical Trials (RCTs) through Causal Inference

Session Organizer & Session Chair:
Roger Lewis MD, PhD, Journal of the American Medical Association (JAMA) and David Geffen School of Medicine at UCLA

Speakers:
Yu-Hun Chiu, MD, ScD, Brown University School of Public Health, **Issa Dahabreh, MD, MS, ScD**, Harvard T.H. Chan School of Public Health

5:30 – 6:30 pm

Palm 2AB

UNICORN Special Interest Group Gathering
(Pre-registration, no cost. Ticket required.)

Continues next page

Wednesday Conference Schedule

7:30 – 11:15 am

Grand Ballroom Foyer

Registration

7:30 – 8:00 am

Grand Ballroom Foyer & Palm Court

Coffee/Tea

8:00 – 9:00 am

Copperwood

Program Tracks: E ⚙

Contributed Session 15: Consent and Trial Conduct

Moderator:
Cristina Murray-Krezan, University of Pittsburgh

FASTEST Trial: A Collaborative Approach to Automated Drug Distribution Tracking in a Global Emergency Trial Setting

Speaker:
Noor Sabagha, NIH StrokeNet National Coordinating Center

Introducing the Informed Consent Design Decisions (ICDD) Framework

Speaker:
Beverley Nickolls, Queen Mary University of London - Wolfson Institute of Population Health, Centre for Evaluation and Methods, Methodology Research Unit

Operational Challenges in a Large-Scale Pragmatic Clinical Trial in Routine Care: Lessons From a Centralized Clinical Research Nurse Team in the Diuretic Comparison Project

Speaker:
Colleen Hynes, U.S. Department of Veterans Affairs

Recurrence: Considering the Timing and Reappearance of Adverse Events for Greater Insight into Patient Safety

Speaker:
Richard Zink, JMP Statistical Discovery

8:00 – 9:00 am

Foxtail

Program Tracks: E ⚙

Contributed Session 16: Monitoring and Event Adjudication

Moderator:
Grecio J. Sandoval, The George Washington University Biostatistics Center

A Research Nurse-Led Model for Next Generation Safety Event Monitoring in Clinical Trials

Speaker:
Annette Martinez-Rioux, Boston Cooperative Studies Program Coordinating Center (CSPCC), Department of Veterans Affairs

Remote Centralized Adverse Events Adjudication in Multicenter Trials

Speaker:
Alexandra Gil, University of Pittsburgh

Centralized Safety Monitoring and Endpoint Review: Streamlining Multicenter Trial Oversight

Speaker:
Catherine Dillon, Medical University of South Carolina

Leveraging Patient Advocacy Groups to Optimize the Clinical Trial Experience

Speakers:
Hana Ballard, Rho, Inc. (CRO), **Kaitlin Enger**, Rho, Inc. (CRO)

8:00 – 9:00 am

Honeysuckle

Program Tracks: D ⚙

Contributed Session 17: Trial Adaptation and Implementation

Moderator:
Sumihiro Suzuki, Rush University Medical Center

Master Protocols in 2025: Myths, Realities, and Practical Guidance for Implementation

Speaker:
Bryan McComb, Pfizer

Implementation of a Standardized Staffing Ratio Model and Its Associated Impact on Clinical Research Site and Network Performance in the VA Health Care System: A 3-Year Assessment

Speakers:
Marcus Johnson, Durham VA Health Care System, **Aliya Uddin**, VA Long Beach Healthcare System

Project Optimus vs Master Protocols: A Comparison of Randomization Adaptations and IRT Implementation

Speaker:
Kevin Venner, Almac Clinical Technologies

Wednesday Conference Schedule

8:00 – 9:00 am

Acacia

Program Tracks: D S

Contributed Session 18: Innovative Study Designs

Moderator:
Xi Fang, Yale School of Public Health

Targeting What Matters in Pediatric Trials: Bayesian Basket and Umbrella Trials for Heterogeneous Airway Disease

Speaker:
Mohd Rashid Khan, University of Padova

Continuous Monitoring of Delayed Outcomes in Basket Trials

Speaker:
Marcio Diniz, Icahn School of Medicine

Zero Inflated Outcomes in SMART Designs

Speaker:
Hanna Venera, University of Michigan

Using Clinical Trial Data in Combination With Pharmacokinetics to Inform Novel Study Designs

Speaker:
Alison Coyne, University of California, San Francisco

8:00 – 9:00 am

Eucalyptus

Program Track: S

Contributed Session 19: Methods for Complex Intervention

Moderator:
Yongdong Ouyang, Roswell Park Comprehensive Cancer Center

Addressing Cluster-Level Treatment Effect Heterogeneity in Sample Size Determination for Hierarchical 2x2 Factorial Designs

Speaker:
Guangyu Tong, Yale University

Identification and Estimation of Causal Effects of Components of a Bundled Intervention

Speaker:
Jeffrey Albert, Case Western Reserve University

Study Designs and Methods for Intervention Delivery, Data Analysis, and Sample Size Proposed in NIH-Supported Phase 2 and 3 Clinical Trials

Speaker:
David Murray, National Institutes of Health

9:00 – 9:15 am

Break

9:15 – 10:45 am

Honeysuckle

Program Tracks: D S

Invited Session 13

Beyond Blocks: A New Era of Randomization

Session Organizer & Panelist:
Wenle Zhao, Medical University of South Carolina

Session Chair & Panelist:
Diane Uschner, F. Hoffmann-La Roche Ltd. Basel, Switzerland

Panelist:
Jennifer Ross, Almac Clinical Technology

9:15 – 10:45 am

Eucalyptus

Program Tracks: D

Invited Session 14

Avoid Data Indigestion: Ingestion and Management of Complex and Novel Data at Academic Data Centers

Session Organizer & Session Chair:
John VanBuren, University of Utah

Speakers:
Shawn Ballard, University of Pennsylvania, **Denise Scholtens**, Northwestern University, **Haley Hedlin**, Stanford University, **Chris Arnaud**, Medical University of South Carolina, **Lisa Young**, University of Utah

Continues next page

Wednesday Conference Schedule

9:15 – 10:45 am

Foxtail

Program Tracks: D S

Invited Session 15

Statistical and Practical Issues in Implementation Trials

Session Organizer & Speaker:
Judith J. Lok, Boston University Department of Mathematics and Statistics

Session Chair:
Scott Evans, Georgetown University

Speakers:
Erinn M. Hade, Department of Population Health, Division of Biostatistics, New York University Grossman School of Medicine, **Donna Spiegelman**, Yale School of Public Health Director, Center on Methods for Implementation and Prevention Science (CMIPS), Yale School of Public Health

Discussant:
Eve M. Nagler, Harvard TH Chan School of Public Health

9:15 – 10:45 am

Copperwood

Program Tracks: D

Invited Session 16

Design and Operational Considerations for Long COVID Clinical Trials

Session Organizer & Session Chair:
Chao-Kang Jason Liang, National Institute of Allergy and Infectious Diseases, Office of Biostatistics Research

Speakers:
Carolyn Bramante, University of Minnesota**, Julie Holub**, Yale, **Sean Hanlon**, RTI International, **Justin Lin**, Patient Caregiver

Discussants:
Lori Dodd, National Institute of Allergy and Infectious Diseases, **Tracy Nolen**, RTI International

9:15 – 10:45 am

Acacia

Targeted Session 3

Bridging Innovation and Impact: Uniting the Statistical Innovation Community With the Society for Clinical Trials

Session Organizer & Session Chair:
Chenguang Wang, Regeneron

Panelists:
Chen Hu, Johns Hopkins University, **Satrajit Roychoudhury**, Pfizer, **May Mo**, Amgen, **David Ohlssen**, Novartis, **Lei Nie**, FDA

10:45 – 11:00 am

Break

11:00 am – 12:30 pm

Acacia

Program Track:

Invited Session 17

From Data to Decisions: Why Investing in MedDRA Coding and Quality Reviews Pays Off

Session Organizer & Speaker:
Sara Meyer, Data Coordination Unit (DCU) at the Medical University of South Carolina

Session Chair:
Valerie Durkalski-Mauldin, PhD, MPH, Medical University of South Carolina

Speakers:
Ian Rines, Medical University of South Carolina, **Robert Silbergleit**, The Clinical Coordinating Center at the University of Michigan

11:00 am – 12:30 pm

Foxtail

Program Tracks: D S

Invited Session 18

Non-Inferiority Trials Yield Results that are Arbitrary, Obscure, and Unreliable. What are the Alternatives?

Session Organizer & Speaker:
Patrick Phillips, University of California San Francisco

Session Chair & Discussant:
Lori Dodd, NIH/NIAID

Speakers:
Dave Glidden, University of California San Francisco, **Suzanne Dufault**, University of California San Francisco, **Johann Verbeeck**, Hasselt University, Belgium ***(Pre-recorded)***

Wednesday Conference Schedule

11:00 am – 12:30 pm

Eucalyptus

Program Tracks: D E S

Invited Session 19

Innovating Trial Design and Analysis for Discovery Medicine: Clinical, Statistical and Regulatory Perspectives and Lessons From Early-Phase Trials of Broadly Neutralizing Antibody-Inducing HIV Vaccines

Session Organizer & Speaker:
Yunda Huang, Fred Hutchinson Cancer Center, University of Washington

Session Chair & Discussant:
Dean Follmann, National Institutes of Health

Speakers:
William Hahn, Fred Hutchinson Cancer Center, University of Washington, **Craig Sturgeon**, National Institutes of Health ***(Pre-recorded)***

11:00 am – 12:30 pm

Copperwood

Program Tracks: D S

Invited Session 20

Rethinking the Stepped-Wedge Design amid Time-Varying Treatment Effects: Implications, Modeling Strategies, and Practical Evidence

Session Organizer & Session Chair:
Yongdong Ouyang, Roswell Park Comprehensive Cancer Center

Speakers:
Bingkai Wang, University of Michigan, Ann Arbor, **Danni Wu**, Pfizer, **Fan Li**, Yale School of Public Health, **Emily Voldal**, Fred Hutchinson Cancer Center

11:00 am – 12:30 pm

Honeysuckle

Program Tracks: D S

Invited Session 21

From Integration to Dissemination: Data and Statistical Management in a Perpetual ALS Platform Trial

Session Organizer & Session Chair:
Brittney Harkey, Healey & AMG Center for ALS at Mass General

Speakers:
Hong Yu, Healey & AMG Center for ALS at Mass General, **Lori Chibnik**, Healey & AMG Center for ALS at Mass General, **Lindsay Heyd**, Healey & AMG Center for ALS at Mass General

12:30 pm

Meeting Adjourns

Business Session Agenda

Tuesday, Noon – 12:45 pm

Foxtail

President's Welcome ..... **Valerie Durkalski-Mauldin**, President

Approval of 2025 Business Meeting Minutes ..... **Valerie Durkalski-Mauldin**, President
(In the SCT mobile app, please select the "Handouts" icon to access the minutes from the 2025 Business Session.)

President's Report ..... **Valerie Durkalski-Mauldin**, President

- Year-in-Review
- Recognition of Program Committee Chair
- Recognition of Education Committee Chair
- Sponsor Acknowledgements
- Exhibitor Acknowledgements
- Election Results

Financial Report ..... **Christopher Coffey**, Treasurer

***Clinical Trials* Journal Report** ..... **Colin Begg**, Editor

First-Time Attendee Raffle ..... **Emine Bayman**, Membership Chair

Chalmers Student Scholarship Winner & Sylvan Green Award Winner ..... **Sumihiro Suzuki**, Student Scholarship Chair

RISE Emerging Leader Award Recipients ..... **Codruta Chiuzan**, RISE Chair

Best Poster Presentation Award ..... **Fan Li**, Program Chair

Remarks from Incoming President ..... **Alexia Iasonos**, President-Elect

- Recognition of Outgoing Board Members
- Award to Outgoing President
- 2027 Annual Meeting

Closing Remarks ..... **Alexia Iasonos**, President-Elect

- Open Discussion / Q&A
- Adjournment

Poster Presentations

Monday, May 18 | 9:30 – 10:15 am | Grand Ballroom Foyer				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
1	**P2**	Bias of Treatment Effect Estimation in Hybrid Goldilocks Adaptive Design: A Simulation Study	**Yang Wang**	McMaster University
1	**P3**	Bayesian Dynamic Borrowing Approaches for Incorporating Patient Treatment Preferences in SMART Designs	**Sarah Ferlito**	University of Michigan
1	**P4**	Data Quality Assurance Tool for the Acute to Chronic Pain Signatures Study (A2CPS): An Interactive R Shiny Web Application	**Briha Ansari**	Johns Hopkins University; School of Public Health
1	**P5**	The "Clinical Trial Effect" in Randomized Controlled Secondary Stroke Prevention Trials: A Systematic Review	**Kompal Kumar**	University of Minnesota
1	**P7**	Treatment Effect Estimation in the Presence of Cluster Size Dependent Treatment Heterogeneity in Stepped Wedge Designs	**Fandi Chang**	The Ohio State University
1	**P8**	Commercial Bias in Plastic Surgery: Impact of Device Interventions on Transparency in Mastopexy Clinical Trials	**Cameron Hrabak**	Midwestern University (AZCOM)
1	**P9**	Flexible Parametric Survival Modeling of Post-Relapse Outcomes in a National Clinical Trial Cohort of Wilms Tumor	**Anahita Saeedi**	University of Massachusetts Chan Medical School in Worcester, MA
1	**P10**	Intervention Type as a Primary Determinant of Result Transparency in Reduction Mammoplasty	**Ashley Brudzinski**	Arizona College of Osteopathic Medicine
1	**P11**	Utility-Based Outcome-Adaptive Sequential Multiple Assignment Randomized Trial Design for Bivariate Categorical Outcomes	**Xinyue Mao**	University of Rochester
1	**P12**	Navigating the Consent Dilemma: Biometric Identification and Ethical Integrity for Non-Literate Participants in The Gambia	**Gibbi Sey**	Medical Research Council Unit The Gambia at the London School of Hygiene and Tropical Medicine

Continues next page

Poster Presentations

Monday, May 18 | 9:30 – 10:15 am | Grand Ballroom Foyer				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
1	**P14**	Recruitment Strategies and Barriers in Pediatric Heart Transplant Trials: Insights from the PEACE Study	**Dana Feng**	Boston Children's Hospital
1	**P16**	Optimizing Staffing Models Capacity for Statistics and Data Management Centers (SDMC) Amidst Diminishing Funding and Increasing Complexity of Oncology Trials	**Kristina Laumann**	Alliance Statistics and Data Management Center and Mayo Clinic Quantitative Health Sciences, Rochester, MN
1	**P18**	World's First Automated, Adaptive, End-to-End, Open-Source, AI-Enabled Framework for Risk Based Quality Management (RBQM) of Clinical Trials	**Zhongkai Wang**	Gilead Sciences Inc.
1	**P19**	Streamlining Data Collection in Oncology Clinical Trials: The Alliance Approach Demonstrated through PROSPECT-Lung	**Allison Booth**	Alliance Statistics and Data Management Center, Mayo Clinic
1	**P20**	REACON: Hybrid Framework Leveraging REDCap and Custom DEACON Applications for Systems Efficiency	**John Hepler**	Wake Forest University School of Medicine
1	**P21**	When Patients Don't Click "Submit": A Comparative Evaluation of Site-Entered eCRFs vs Direct ePRO for Patient-Reported Outcomes in a Contemporary Phase 2 Study	**Nicole Close**	EmpiriStat, Inc.
1	**P22**	Developing a Physiologic Transgression Score for Predicting Outcomes in Cardiac Arrest Patients Undergoing Temperature Management	**Akash Roy**	Medical University of South Carolina
Note: Posters #2-22 must be removed from the Poster Session area no later than 10:30 am.				

Poster Presentations

Monday, May 18 | 2:45 – 3:30 pm | Grand Ballroom Foyer				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
2	**P23**	Providing Source to Stay the Course: Leveraging Coordinating Center Tools to Improve Clinical Trial Visit Execution	**Laura Baird**	Rho, Inc.
2	**P24**	The Fibromyalgia TENS in Physical Therapy Study (FM-TIPS): Results of a Cluster-Randomized Pragmatic Clinical Trial	**David-Erick Lafontant**	University of Iowa
2	**P25**	Utilization of eConsent Platform in Aging Populations	**Lauryn Barrett**	University of Minnesota
2	**P26**	Creation and Implementation of a Clinical Trial Data Monitoring Metric Tool	**Valerie Stevenson**	University of Michigan
2	**P27**	Does the Use of a Novel Emergency Medical Services Mobile Application Improve Trauma Care in a Simulated Crossover Randomized Controlled Trial?	**Jake Toy**	Harbor-UCLA Medical Center, The Lundquist Institute, UCLA David Geffen SOM, Los Angeles County EMS Agency
2	**P29**	Evaluation of Translation and Interpretation Services Implemented by Clinical Trial Units (CTUs) to Increase Recruitment of People with Limited English Proficiency in Pragmatic Randomised Controlled Trials (The INVITE Study)	**Kirsty Roberts**	Bristol Trials Centre, University of Bristol, Bristol, UK
2	**P31**	The mGlide Trial Effect Study: Preliminary Findings	**Kompal Kumar**	University of Minnesota
2	**P32**	Trends of Clinical Trial Designs Over the Last Decade	**Ashlyn Butkowski**	Massachusetts General Hospital
2	**P33**	Handling Safety Information in Multi-Regional Clinical Trial – Current Status and Future Outlook	**Takako Hitomi**	National Cancer Center Hospital
2	**P34**	A Holistic Approach for Pre-Powering Subgroup Analyses in Time-to-Event Trials; From Interaction Testing to Claiming Efficacy	**Elena Frangou**	MRC Clinical Trials Unit at UCL

Continues next page

Poster Presentations

Monday, May 18 | 2:45 – 3:30 pm | Grand Ballroom Foyer				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
2	**P35**	REDCap Innovations to Empower Discrete Choice Experiments	**Chen Yeh**	Rush University Medical Center
2	**P36**	Design, Implementation and Analysis of Pragmatic Clinical Trials in Changing Disease Landscapes	**Bareng Aletta Nonyane**	Johns Hopkins Bloomberg School of Public Health
2	**P37**	Aspirations Meet Reporting: Results from a Scoping Review of Sequential Multiple Assignment Randomized Trials (SMARTs) from 2009-2024	**Nikki Freeman**	Duke University
2	**P38**	Bridging the Gap Between Monitoring and Data Management: Using Targeted Reporting Tools to Enhance On-Site Data Cleaning	**Nicole Close**	EmpiriStat, Inc.
2	**P39**	Leveraging Survey Insights to Enhance Clinical Research, Regulatory and Compliance Workflows Using Artificial Intelligence: A Pilot Study	**Ramya Krishna Chunduru**	Baylor Scott and White Research Institute
2	**P41**	Neighborhood-Level Measures Associated with Medication Adherence in a Personalized Glaucoma Coaching Randomized Controlled Trial	**Patrice Hicks**	University of Michigan
2	**P42**	Optimizing Clinical Operations for Complex Innovative Trial Designs: Strategies and Lessons Learned	**Bambi Smith**	Almac Group
2	**P43**	Automating Clinical Trial Data Collection to Improve Data Quality: The SWOG–nCartes Collaboration	**Chris Cook**	SWOG Statistics and Data Management Center

Note: Posters #23-43 must be removed from the Poster Session area no later than 6:15 pm.

Poster Presentations

Tuesday, May 19 | 9:00 – 9:45 am | Grand Ballroom Foyer				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
3	**P45**	The PREVENTABLE Action Card: A Tool for Monitoring Site Performance and Trial Quality	**Julissa Almonte Santana**	Wake Forest University School of Medicine
3	**P46**	Ensuring Participant Safety: Tracking COVID-19 Cases in an Intervention-Based Clinical Trial	**Marjorie Howard**	Wake Forest University School of Medicine
3	**P47**	A Strategy for Uneven Events Collection. Ascertained vs. Volunteered Events in Multi-Arm Trials with Uneven Participant Contact (e.g., Lifestyle Interventions)	**Debbie Felton**	Atrium Wake Forest Advocate Health
3	**P48**	Biosample Management for the HEALEY ALS Platform Trial	**Taylor Stimpson**	Massachusetts General Hospital, Boston
3	**P49**	Co-Design of Resources to Support Researchers to Develop Accessible and Inclusive Patient Information Leaflets for Randomised Controlled Trials: The MAPLE Project	**Kirsty Roberts**	Bristol Trials Centre, University of Bristol, Bristol, UK
3	**P50**	Phase I Dose Finding Considerations for Cell Therapeutics Studied as Part of a Drug Combination	**Evan Bagley**	Medical University of South Carolina
3	**P51**	A Generalized Method for the Construction of Non-Inferiority P-Value Computations	**Hongqiu Gu**	Beijing Tiantan Hospital
3	**P53**	Centralized Screening and Tracking in a Pragmatic Trial	**Letitia Perdue**	Wake Forest University School of Medicine
3	**P54**	Practice Doesn't Always Make Perfect: Simulating Clinical Research in a Biocontainment Unit	**Jessica Gieseke**	University of Minnesota
3	**P55**	Using Electronic Health Records to Support Study Recruitment Sourcing	**Paul Glover**	Rush University Medical Center
3	**P56**	Implementing Decentralized Clinical Trials to Expand Access for Rare Cancer Patients	**Chiharu Mizoguchi**	Department of International Clinical Development, National Cancer Center Hospital

Continues next page

Poster Presentations

Tuesday, May 19 | 9:00 – 9:45 am | Grand Ballroom Foyer				
Poster Session	**Poster ID#**	**Title**	**Presenter Name**	**Affiliation**
3	**P57**	Finding the Sweet Spot: Optimizing Site Activation for Efficient Enrollment	**Lia Tamburello**	Massachusetts General Brigham, Massachusetts General Hospital
3	**P58**	Developing Guidance for Bayesian Survival Analyses in Rare Disease Clinical Trials	**Arlene Jiang**	The Hospital for Sick Children
3	**P59**	Surrogate Evaluation for Cancer Screening Trials	**Arnold Johnsen**	Fred Hutchinson Cancer Center
3	**P60**	Application of a Customized GPT to Address Inquiries and Facilitate Conduct of a Large Randomized Controlled Trial	**Devin Brown**	University of Michigan
3	**P62**	Three-Arm Clinical Trials: Choosing Between Fixed and Adaptive Design Options	**Michael Grayling**	Johnson & Johnson
3	**P63**	Managing the Unexpected: Practical Solutions to Central Laboratory Data Transfer Challenges in Real-World Clinical Trial Settings	**Nicole Close**	EmpiriStat, Inc.
Note: Posters #45-63 must be removed from the Poster Session area no later than 1:00 pm.				

Thomas C. Chalmers Student Scholarship

2026 Thomas C. Chalmers Student Scholarship Finalists

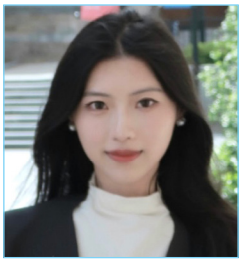
This Scholarship was named in honor of Dr. Thomas C. Chalmers, who was a founding member of the SCT, served on the Board and was President in 1984. It recognizes his lifetime of service to the Society. Please visit the SCT website for further information.

The finalists for the 2026 Student Scholarship will present their abstracts during Monday's Contributed Sessions. The finalists and winner will receive commemorative award certificates during the Tuesday Business Session.

Xi Fang, PhD
Yale School of Public Health

Sample Size Determination for Win Statistics in Cluster-Randomized Trials

(See page 11 for presentation details.)



Yunyi Liu (PhD Student)
UC San Diego

Bayesian Response-Adaptive Randomization for Cluster Randomized Controlled Trials

(See page 12 for presentation details.)

Zizhong Tian, PhD
Eli Lilly and Company

Bayesian Meta-Analysis of Comparative Drug Safety

(See page 13 for presentation details.)

Sylvan Green Award

This award was created in 2011 to honor Dr. Sylvan Green for his service to the Society. He served as 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.

Dr. Nurulamin Noor
University of Cambridge

The 2026 Sylvan Green Award Winner, Dr. Nurulamin Noor, will present his talk titled **"PROFILE Trial – Disease Modification With Early Treatment in Newly-Diagnosed Crohn's Disease"** on Monday at 3:30 pm during Contributed Session 6 (pages 12-13). He'll be presented with his commemorative award certificate during the Tuesday Business Session.

2026 Representation, Inclusion, Support & Engagement (RISE) Emerging Leader Award

Tuesday, Noon – 12:45 pm (presented during the SCT Business Session)

Foxtail

The SCT Representation, Inclusion, Support & Engagement Committee (RISE) started this award in 2025 to recognize and support outstanding early-career professionals who demonstrate remarkable potential in clinical trials methodology, development, conduct, or dissemination, and a strong commitment to expanding engagement and representation.

Eligibility and criteria for this award include that applicants must be early career individuals (e.g., within 5 years of beginning a career in the clinical trials profession, within 5 years of completion of postgraduate training (e.g., residency or fellowship) after a terminal degree, or within 5 years of their most recent degree (considering pauses in career or periods of flexible working), currently pursuing a graduate degree in a relevant field (e.g., epidemiology, biostatistics, statistics, data science, computer science, medicine, nursing, pharmacy, dentistry, social science)) and can either be members or non-members of SCT. Priority will be given to applicants who are either new to SCT or current members who may not otherwise have access to participate in the SCT annual meeting. Information regarding the country of citizenship/origin, first generation-student status, disability status, and demographics will be collected on the application to ensure a broad pool of applicants. Applications must include two letters: 1) an application letter from the applicant, and 2) a support letter from someone other than the applicant. Applications must also include the applicant's resume/curriculum vitae and confirmation from the applicant's employer of their early career status.

The award is presented across two professional tracks: Public Health and Clinical Research (e.g., biostatisticians/statisticians, epidemiologists, physician-scientists, nurse investigators, other clinician researchers) and Study Coordination and Operations (e.g., study coordinators, project managers, data managers, IT programmers). Each awardee receives complimentary meeting registration, a one-year SCT membership, and up to $1,600 for travel and hotel expenses to attend the meeting.

The following award recipients will be recognized during the SCT Business Session.

Nikki Freeman, PhD
Duke University
Durham, North Carolina

Kelcy Klein
Johns Hopkins Center for Psychedelic and Consciousness Research
Baltimore, Maryland

SCT David Sackett Trial of the Year Presentation

"HepB-CpG vs HepB-Alum Vaccine in People With HIV and Prior Vaccine Nonresponse: The BEe-HIVe Randomized Clinical Trial (BEe-HIVe) Trial"

Tuesday, 2:45 – 3:45 pm

Foxtail

AALL1731 was a RCT conducted by the Children's Oncology Group across over 220 centres in four countries. Hepatitis B virus is a leading cause of liver-related mortality worldwide. People with HIV often do not develop protective antibodies after standard HBV vaccines. The BEe-HIVe trial tested whether HepB-CpG (HBV vaccine formulated with TLR-9 agonist adjuvant) improves immunogenicity compared with conventional HepB-alum in adults with HIV who previously failed to respond to vaccination. The trial enrolled 561 adults at sites across Africa, Asia, North America, and South America. Participants were randomized to receive 2 doses HepB-CpG, 3 doses HepB-CpG, or 3 doses HepB-alum. The primary analysis demonstrates that 99% of those receiving 3 doses and 93% receiving 2 doses of the HepB-CpG vaccine achieved seroprotection compared to 81% receiving 3 doses of HepB-alum. The HepB-CpG vaccine led to higher levels of protective antibodies which resulted in more durable seroprotection at end of study. Adverse events were generally mild and comparable across groups, with no unexpected safety signals.

Kristen Marks, MD
Weill Cornell Medicine

Dr. Marks is an Associate Professor of Medicine at Weill Cornell Medicine (WCM) where she conducts clinical trials related to HIV and viral hepatitis prevention and treatment. She received Internal Medicine residency and Infectious Diseases fellowship training at New York-Presbyterian Hospital (Cornell) and completed Weill Cornell's Master's Degree in Clinical Investigation. She serves as a co-director of the Cornell HIV/AIDS Clinical Trials Unit, where she conducts clinical trials related to HIV and hepatitis viruses. She is vice chair of the ACTG Hepatitis Transformative Science Group and has also served on the ACTG Scientific Agenda Steering Committee. She was co-chair of IDSA/AASLD's joint guidelines panel for "Recommendations for testing, managing and treating hepatitis C" and a member of New York State's HCV guidelines panel. When the COVID pandemic hit New York City, she led the phase 3 studies of remdesivir at Weill Cornell and phase 3 studies of vaccines for the prevention of COVID at Weill Cornell. She is co-program director of a T32 training grant and prior Program Director for Weill Cornell Infectious Diseases fellowship.

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 clinical 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.
- The peer reviewed trial publication date (be that on paper or electronic) must be within the 2025 calendar year.

Nominations are welcome regardless of trial setting, investigator, or patient group. Nominations are welcome from anyone (Society members, nonmembers, and committee members). The David Sackett Trial of the Year Selection Committee will issue a call for nominations later this year.

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2026 – 2027 Election Results

SCT is proud to announce our incoming President-Elect and Board Members.

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Elizabeth Garrett-Mayer
Vice President, Center for Research and Analytics (CENTRA), American Society of Clinical Oncology

Incoming Board Member
Emine Bayman
Professor of Biostatistics and Anesthesia, and the Deputy Director of the Clinical Trials Statistical and Data Management Center (CTSDMC), University of Iowa

Incoming Board Member
Katie Gillies
Professor of Clinical Trials Methodology, University of Aberdeen, United Kingdom

Class of 2026 Fellows

The SCT Board of Directors invites all meeting attendees to join in saluting the Class of 2026 Fellows on Monday, 8:15 – 8:30 am in Foxtail.

Karim Anton Calis, PharmD, MPH
National Institutes of Health
Bethesda, Maryland

Kelley Kidwell, PhD, BS
University of Michigan School of Public Health
Ann Arbor, Michigan

Jessica Overbey, DrPH
Berry Consultants
Austin, Texas

Letitia Perdue, MS, BA
Wake Health University School of Medicine
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Please visit the exhibits in the Grand Ballroom Foyer.

Exhibit Hours:
Monday: 9:15 am – 6:15 pm
Tuesday: 8:45 am – 3:00 pm

CITI Program, a division of BRANY — Booth #1

101 NE 3rd Avenue, Suite 320
Fort Lauderdale, FL 33301
Corina Dobinda-Dzwill
cdobinda@citiprogram.org
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Eli Lilly and Company — Booth #6/7

893 S. Delaware Street
Indianapolis, IN 46285
Jennifer Jones
Jennifer.jones@lilly.com

The Clinical Talent Development Program (CTDP) at Eli Lilly aims to open the door to career opportunities within the clinical space of the pharmaceutical industry by offering early talent a unique blend of immersive, hands-on experience, mentorship, and professional development.

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Gilead Sciences — Booth #2

2026 NE 65th Street
Seattle, WA 98115
Tricia Reese
Tricia.reese1@gilead.com
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McMaster University – Population Health Research Institute — Booth #8

20 Copeland Ave
Hamilton L8L 2X2
Canada
Kumar Balasubramanian
Kumar.balasubramanian@phri.ca

The Population Health Research Institute (PHRI) is a world leader in large clinical trials and population health observational studies, involving over 1.3 million participants across 105 countries. PHRI's research has led to breakthroughs in treatments, disease prevention, and understanding risk factors, thus improving health outcomes and informing global healthcare guidelines.

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Yunu — Booth #3

1605 Montvale Grant Way
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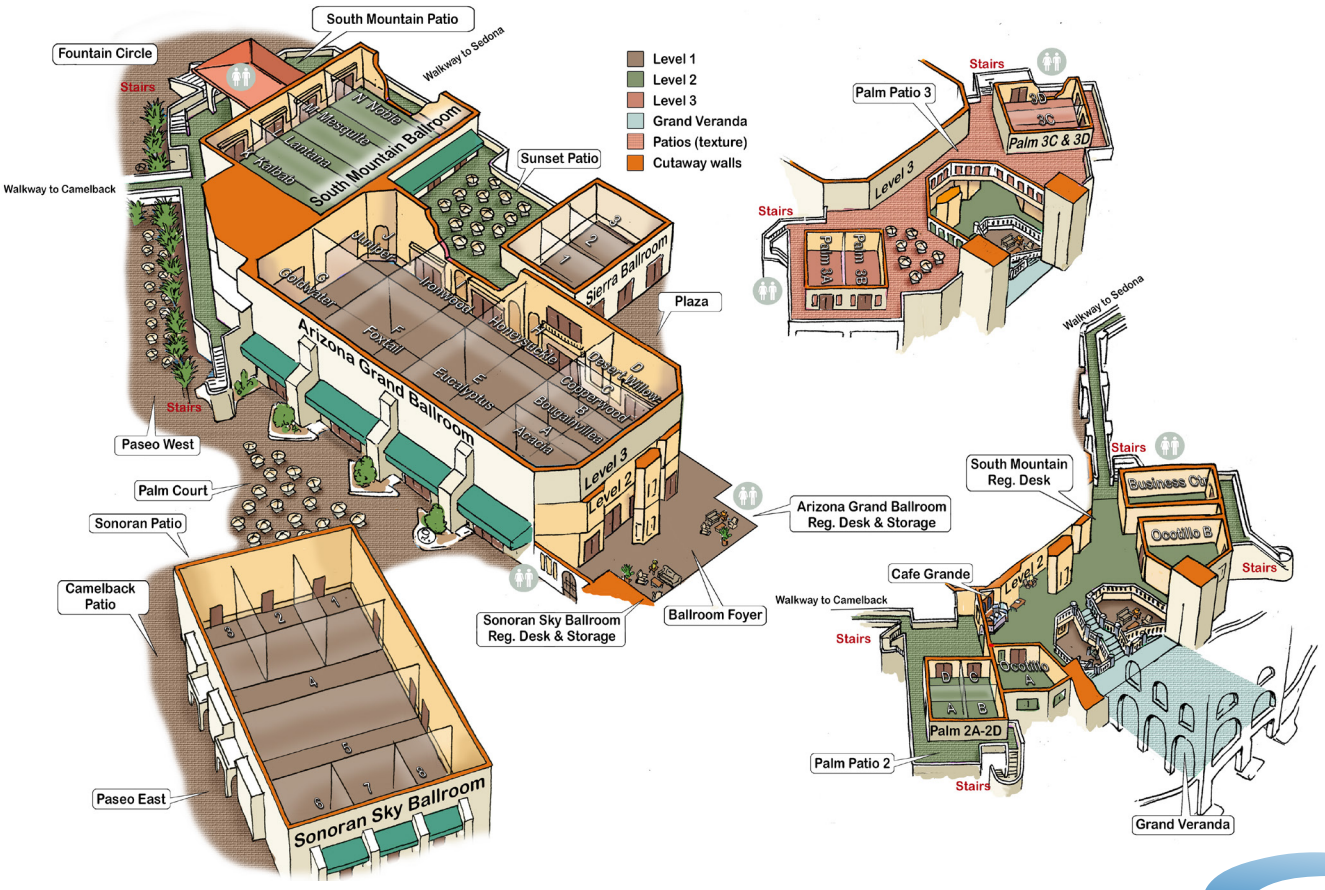

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May 16 – 19, 2027	May 21 – 24, 2028	May 20 – 23, 2029	May 19 – 22, 2030
48th Annual Meeting	49th Annual Meeting	50th Annual Meeting	51st Annual Meeting
Chicago, IL	**Charlotte, NC**	**Toronto, ON, Canada**	**Baltimore, MD**

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