

47<sup>TH</sup>  
Annual Meeting

PHOENIX

May 17-20, 2026



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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 
- Ethics 
- Operations 
- Statistics 

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.)



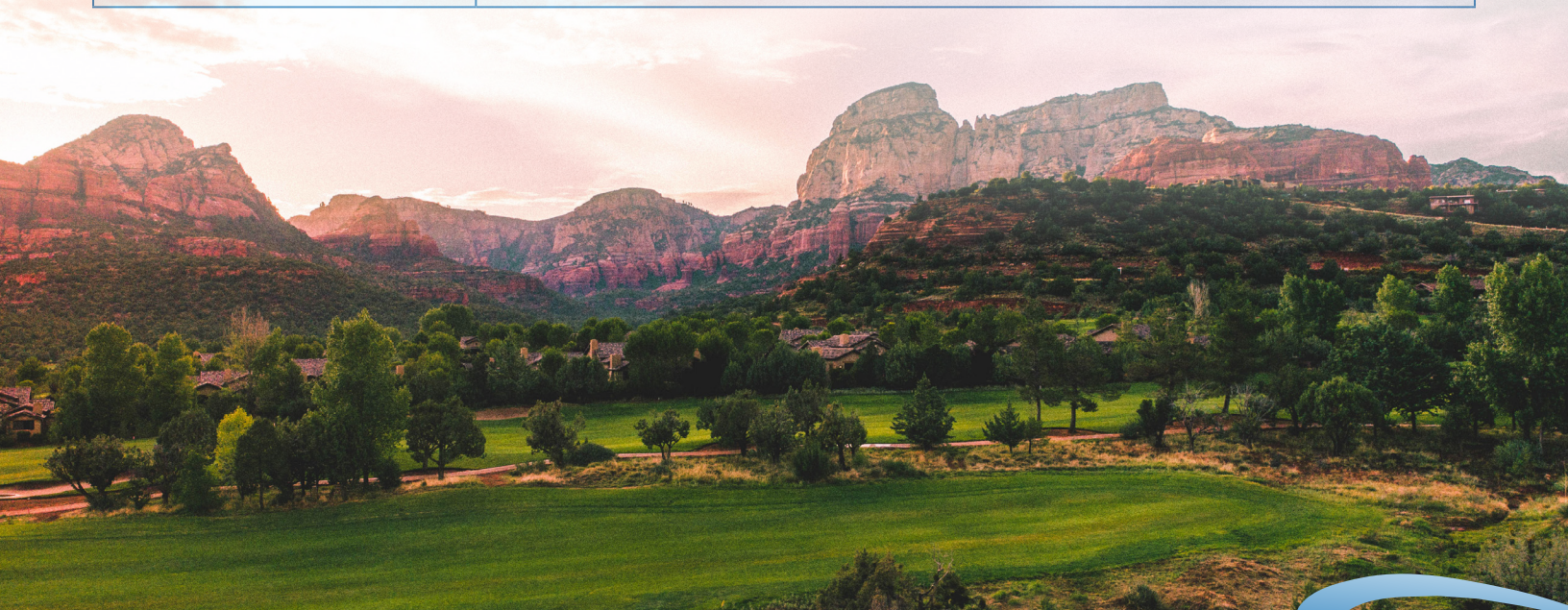
# CONFERENCE SCHEDULE AT A GLANCE

*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 <i>(continued)</i>
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 Likhnygina**, 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** **S**

**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: **S**

**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** **G**

## 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** **G**

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** **G**  
**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: **G**  
**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** **G**  
**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,

**Kaleb 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: **S**

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: **S**

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** **G**

**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** **G**

**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** **G**

**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** **S**

## 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** **G**

**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: **G**

**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**



# SCT 2026 BUSINESS SESSION

## 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.

# REPRESENTATION, INCLUSION, SUPPORT & ENGAGEMENT (RISE) EMERGING LEADER AWARD

## 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 2025 TRIAL OF THE YEAR AWARD

## 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**  
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Austin, Texas



**Letitia Perdue, MS, BA**  
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# THANK YOU TO OUR EXHIBITORS

*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

101 NE 3rd Avenue, Suite 320  
Fort Lauderdale, FL 33301  
Corina Dobinda-Dzwill  
cdobinda@citiprogram.org  
citiprogram.org

CITI Program is the trusted standard in research, ethics, and compliance training. We are dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.

**Booth #1**

## McMaster University – Population Health Research Institute

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.

**Booth #8**

## SILVER

### Eli Lilly and Company

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.

Our goal is to cultivate a community of emerging professionals who are inspired to become part of Team Lilly, contribute meaningfully from day one, and evolve into the next generation of leaders within clinical development.  
RippleMatch | Community

**Booth #6/7**

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### StataCorp

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Brooke Johnson  
bjohnson@stata.com  
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Stata statistical software provides everything for your data science needs – data manipulation, visualization, statistics, and automated reporting. Whether you prefer a GUI, a command line, or scripts, Stata puts the statistics you want at your fingertips. Stata is easy to use and has your back with world-class support.

**Booth #4/5**

## Gilead Sciences

2026 NE 65th Street  
Seattle, WA 98115  
Tricia Reese  
Tricia.reese1@gilead.com  
gilead.com/company

Gilead and Kite Oncology are transforming how cancer is treated by advancing next generation therapies, combinations, and technologies. As Oncology care increasingly moves into community settings within the US, we are committed to strengthening US clinical trial site participation and the broader cancer care ecosystem to improve access, quality, and value for patients nationwide.

**Booth #2**

## Yunu

1605 Montvale Grant Way  
Cary, NC 27519  
Kim Sacchetti  
events@yunu.io  
yunu.io

Yunu is redefining how imaging powers clinical research. The company's intelligent, end-to-end workflow platform streamlines every stage of imaging-based trials – from image capture and reader assignment to adjudication and data export – ensuring scientific integrity and operational efficiency. Trusted by life sciences, pharmaceutical, cancer centers, and research organizations worldwide, Yunu empowers teams to manage complex imaging studies with clarity, confidence, and speed.

**Booth #3**

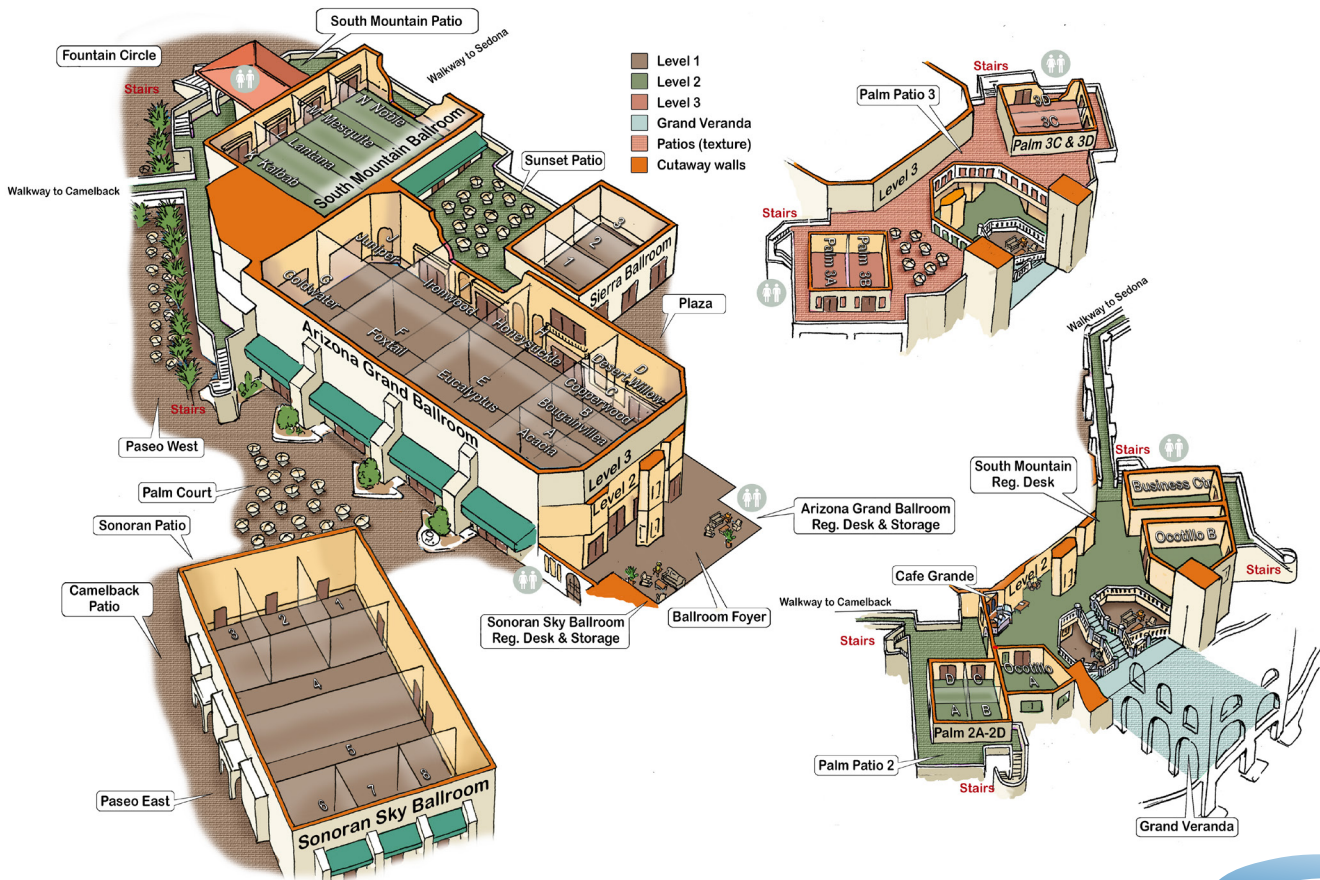
# ARIZONA GRAND RESORT & SPA



SCAN CODE FOR RESORT AMENITIES & HOURS



<p><b>1 LOBBY</b> Marketplace Cafés Lobby Bar Gift Shop Golf Shop The Villas Sales Center</p> <p><b>2 CAMELBACK</b> CAMELBACK MEETING ROOMS Camelback B, Level 1 Camelback C, Level 3 Camelback D, Level 4 Camelback F, Level 6</p> <p><b>3 VILLAS</b></p> <p><b>4 OASIS WATER PARK</b></p>	<p><b>5 SEDONA</b> SEDONA MEETING ROOMS Sedona B, Level 1 Sedona C, Level 3 Sedona D, Level 4</p> <p><b>6 CONFERENCE CENTER</b></p> <p><b>7 PASEO</b></p> <p><b>8 SONORAN SKY BALLROOM</b></p> <p><b>9 CANYON BALLROOM</b></p> <p><b>10 AUNT CHILADA'S</b></p>	<p><b>11 LAS PALMAS</b></p> <p><b>12 ATHLETIC CLUB/SPA</b></p> <p><b>13 THE VISTA</b></p> <p><b>14 RUSTLER'S ROOSTE</b></p> <p><b>15 MOUNTAINSIDE</b></p> <p><b>ELEVATOR LOCATION</b></p>
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# ARIZONA GRAND RESORT & SPA



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## SAVE THE DATES

**May 16 – 19, 2027**

48th Annual Meeting  
**Chicago, IL**

**May 21 – 24, 2028**

49th Annual Meeting  
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**May 20 – 23, 2029**

50th Annual Meeting  
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