FINAL AGENDA

FEBRUARY 2-5, 2026 | ORLANDO, FLORIDA
ROSEN SHINGLE CREEK

17th Annual

SCOPE

POWERING THE FUTURE OF CLINICAL RESEARCH

CONFERENCE PROGRAMS:

- TRIAL DESIGN & PROTOCOL DEVELOPMENT
- FEASIBILITY & SITE SELECTION
- RECRUITMENT & ENGAGEMENT
- SITE ENGAGEMENT & OPERATIONS
- BUDGETING & RESOURCES
- OUTSOURCING
- SMALL BIOPHARMA STRATEGIES
- DATA
- ADVANCING TRIAL DELIVERY
- DIGITAL MEASURES IN CLINICAL TRIALS
- REAL WORLD EVIDENCE
- AI IN CLINICAL RESEARCH
- QUALITY & MONITORING
- SAFETY & PHARMACOVIGILANCE
- BIOSPECIMEN MANAGEMENT & OPERATIONS
- CLINICAL SUPPLY & LOGISTICS
- MARKET ACCESS
- INVESTOR CONFERENCE
- TA SPOTLIGHTS
- POST-CON TRAINING SEMINARS

FEATURED SPEAKERS:

Eliav Barr
Head, Global Clinical Development and Chief Medical Officer, Merck Research Laboratories

Rosemary Rebuli
Global Head, Study & Site Operations, Novartis Pharma AG

Karen Correa, PhD
Vice President Development Operations, Boehringer Ingelheim

Demetris Zambas
Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Dave Stevenson
COO & Managing Director, Merck Global Health Innovation Fund

Jie Zhang, PhD
Head, Global Pipeline Market Access, CSL

Kevin Bugin, PhD
Head, Regulatory Policy and Intelligence, Amgen

Ken Getz
Executive Director and Professor, Tufts Center for the Study of Drug Development

Patrick Floody
Vice President, Global Clinical Trial Services, Regeneron Pharmaceuticals

Valerie Reynaert
Vice President, Global Clinical Operations, Immunocore

Yun Lu, PhD
Deputy Division Director, CBER/OBPV/DABRA, FDA

Rosalie Filling
Vice President, Senior Global Head, R&D Operations, Endo

REGISTER BY NOVEMBER 14 AND SAVE UP TO $450

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CONFERENCE PROGRAMS:

A FEW SHORTCUTS TO HELP YOU AT SCOPE:

CONFERENCE AT-A-GLANCE

CONFERENCES	MONDAY, FEBRUARY 2–WEDNESDAY, FEBRUARY 4 Coverage Includes:	WEDNESDAY, FEBRUARY 4–THURSDAY, FEBRUARY 5 Coverage Includes:
C1: TRIAL DESIGN & PROTOCOL DEVELOPMENT	Patient and Site Voice in Protocol Design	Technology, Data and AI/ML for Intelligent Trial Design
C2: FEASIBILITY & SITE SELECTION	Data-Informed Feasibility and Investigator Selection	Tech and Collaboration to Streamline Start-Up and Reduce Operational Burden
C3: RECRUITMENT & ENGAGEMENT	Enrollment Planning and Patient Recruitment	Diversity and Retention through Communities and Technology
C4: SITE ENGAGEMENT & OPERATIONS	Collaborative Strategies to Improve Trial Execution	Tech and Collaboration to Streamline Start-Up and Reduce Operational Burden
C5: BUDGETING & RESOURCES	Clinical Trial Forecasting, Budgeting and Contracting	Resource Management and Capacity Planning for Clinical Trials
C6: OUTSOURCING	Mastering an Outsourcing Strategy	Relationship and Alliance Management in Outsourced Clinical Trials
C7: SMALL BIOPHARMA STRATEGIES	Building Smart Trial Foundations	Scaling Operations with Impact
C8: DATA	Clinical Data Strategy	Integrating AI into Clinical Data Analysis
C9: ADVANCING TRIAL DELIVERY	Enhancing Point-of-Care Research: Solutions & Partnerships	eClinical Evolution
C10: DIGITAL MEASURES IN CLINICAL TRIALS	Digital Endpoints and Biomarkers	Digital Measures across Studies and Labels
C11: REAL WORLD EVIDENCE	Accessing and Generating RWD	Leveraging RWD for Clinical Research
C12: AI IN CLINICAL RESEARCH	Agentic AI in Clinical Research	AI for Trial Optimization
C13: QUALITY & MONITORING	Risk-Based Quality Management	Central Monitoring and Signal Detection
C14: SAFETY & PHARMACOVIGILANCE (NEW)	Innovation and Operational Excellence in Drug Safety (NEW)	Central Monitoring and Signal Detection
C15: BIOSPECIMEN MANAGMENT & OPS	Modernizing Lab, Biospecimen & Data Management Operations	Biomarker & Biospecimen Technology & Innovation
C16: CLINICAL SUPPLY & LOGISTICS	Communication & Digitization for End-to-End Clinical Supply Management	Clinical Supply Chain Strategies to Align Process, Products and Patients
C17: MARKET ACCESS (NEW)	Trial Design & Real World Evidence	Market Access, Pricing & Reimbursement (NEW)
INVESTOR CONFERENCE	Clinical Trial Venture, Innovation & Partnering* *(Monday, February 2 – Tuesday, February 3)*	
THERAPEUTIC AREA SPOTLIGHTS (NEW) (in-person only)	CNS and Mental Health Trials* (NEW); Obesity and Metabolic Trials* (NEW)	Oncology Trials* (NEW); Cell and Gene Therapy* (NEW)
	THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 PM FRIDAY, FEBRUARY 6, 2026 9:00 AM – 4:00 PM	THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 PM FRIDAY, FEBRUARY 6, 2026 9:00 AM – 12:00 PM
POST-CON TRAINING SEMINARS (in-person only)	• TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams* • TS2: Quality and Process Improvement Techniques and Tools*	• TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications*

*Separate Registration Required

DAILY HIGHLIGHTS

Join 4,500+ clinical research leaders at SCOPE Summit 2026—Feb 2–5 in Orlando, FL—for four dynamic days of collaboration, innovation, and insight across 30 conference tracks, 350+ exhibitors, and a host of awards and networking events. Now in its 17th year, SCOPE continues to lead the conversation on patient-centric design, site engagement, AI, and the future of clinical trials. Be part of the momentum.

Day 1 — MONDAY FEBRUARY 2

AM

- Welcome to Florida!
- SCOPE's 5th Annual Masters of Clinical Research Golf Tournament*
- Golf Luncheon*
- Pre-Conference Workshops (IN-PERSON ONLY)

PM

- Yoga *(Sponsorship Opportunities Available)*
- Monday Kickoff Plenary Keynote
- 3rd Annual Site Innovation Award
- 10th Annual Participant Engagement Award
- SCOPE's Winter Games Opening Reception *(Sponsorship Opportunities Available)*
- Clinical Trial Venture, Innovation & Partnering

Day 2 — TUESDAY FEBRUARY 3

AM

- Sunrise Yoga (In-Person Only) *Sponsored by: CISCRP*
- SCOPE's Morning Fun Run *(Sponsorship Opportunities Available)*
- Morning Coffee
- Clinical Trial Venture, Innovation & Partnering
- Tuesday Morning Opening Keynotes
- Grand Opening Coffee & Plenary Refreshment Break in the Exhibit Hall
- Conference Tracks (1-17)
- **TA Spotlight*:** CNS and Mental-Health Trials (11:00 AM – 1:10 PM)
- 1-on-1 Networking

PM

- Sponsored Networking Luncheon
- Networking Coffee & Dessert Break in the Exhibit Hall
- Conference Tracks (1-17)
- Clinical Trial Venture, Innovation & Partnering
- **TA Spotlight*:** Obesity and Metabolic Trials (3:00 PM – 5:30 PM)
- Welcome Reception in the Exhibit Hall
- SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle

Day 3 — WEDNESDAY FEBRUARY 4

AM

- Sunrise Yoga (In-Person Only) *Sponsored by: CISCRP*
- Breakfast Presentations
- Conference Tracks (1-17)
- **TA Spotlight*:** Oncology Trials (8:30 AM – 12:55 PM)
- Coffee Break in the Exhibit Hall
- 1-on-1 Networking

PM

- Sponsored Networking Luncheon
- Networking Coffee & Dessert Break in the Exhibit Hall
- Conference Tracks (1-17)
- Wednesday Afternoon Plenary Keynotes
- SCOPE Best of Show Awards
- SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available). Last Chance for Exhibit Viewing*
- 1-on-1 Networking
- SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle

Day 4 — THURSDAY FEBRUARY 5

AM

- Breakfast Presentation
- Conference Tracks (1-17)
- **TA Spotlight*:** Cell and Gene Therapy (8:30 AM – 11:00 AM)
- 1-on-1 Networking
- Interactive Working Groups *(Sponsorship Opportunity Available)*

PM

- Sponsored SCOPE Send-Off Luncheon Presentations
- Post-Conference Training Seminars*

**Limited space available, separate & advanced registration required*

SCOPE: WHERE CLINICAL RESEARCH CONNECTS

Clinical trials are the engine of medical progress—driving new treatments, improving patient outcomes, and expanding scientific knowledge. Their success depends on **collaboration, innovation, and strategic execution** at every step. SCOPE returns for its 17th year of cross-stakeholder collaboration, February 2–5 at Rosen Shingle Creek in Orlando, FL. Over **four stimulating days** of in-depth **discussions and networking**, SCOPE features **30 different conferences** (3 new), a bustling **exhibit hall with 300+ companies** (45 more than last year), 3 plenary keynote sessions, the 10th annual Participant Engagement Award, the 3rd annual Site Innovation Award, the Best of Show Awards, special cross-department panels, multiple receptions, the 5th annual Master of Clinical Research **Golf Tournament**, morning Fun Run, and Yoga. SCOPE keeps gaining momentum (**14% YoY Growth** last year alone!). At the request of our attendees, we have **extended the coverage in 2026** on Patient-Centric Trial Design, Site Engagement, Recruitment, Generative AI, Small Biopharma Strategies, ClinTech Investment, and other key topics. The programming focuses on advances and innovative solutions in all aspects of **clinical trial innovation**, planning, management, operations, and investment. SCOPE welcomes more than **4,500 attendees and 1,200 different organizations from 30 countries** — in clinical research, operations, innovation, technology, and investment — and we want you and your company to join the community!

IN 2025...

4,500+ ATTENDEES

350+ INDUSTRY-LEADING SPONSORS/EXHIBITORS

58%+ OF DELEGATES TITLED AS EXECUTIVES

Attention Pharma
50 for 25

Team Discounts for Small Biopharma

Special discounts for Top 50 Pharma, as well as Team Discounts for small pharma, biotech start-up, or virtual pharma companies.

Melissa Dolen, Account Manager
T: (+1) 781-972-5418
E: mdolen@healthtech.com

2025 ATTENDEE DEMOGRAPHICS

- 23% Biotech
- 19% Pharma
- 16% CRO
- 16% Services
- 13% Healthcare
- 9% Financial
- 3% Academic
- 1% Societies

- 57% Executive
- 24% Sales & Marketing
- 11% Manager
- 7% Scientist
- 1% Other

For additional information, please contact:

Companies A-E

Ilana Quigley
Director, Sales
(+1) 857-636-2334
Email

Companies F-N

Katelin Fitzgerald
Sr. Manager, Business Development
(+1) 781-247-1824
Email

Companies O-V

Jon Stroup
Lead Business Development Manager
(+1) 781-972-5483
Email

Companies W-Z

Patty Rose
Vice President, Sales
(+1) 781-972-1349
Email

VENTURE, INNOVATION & PARTNERING

Brian Caine
Manager, Strategic Partnerships
(+1) 908-809-0946
Email

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PLENARY KEYNOTE PRESENTATIONS

MONDAY, FEBRUARY 2

6:30 am **Golf Check-In & Breakfast Buffet***

8:00 am **SCOPE's 5th Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.

9:00 am **Registration Open**

12:00 pm **Golf Lunch Buffet** *(Sponsorship Opportunities Available)**

1:00 pm **Close of Masters of Clinical Research Golf Tournament**
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm **OPEN WORKSHOP: Talk Title to be Announced** *(Sponsorship Opportunity Available)*

2:00 – 3:30 pm **OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials**
INSTRUCTOR:
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC
As clinical trials grow in complexity and scale, the role of informed consent becomes more critical—and more challenging—than ever. This interactive workshop explores the evolving landscape of consent in the digital age, from the automation of consent form development to navigating global ethics and privacy regulations. We'll examine the responsibilities embedded in consent language, new international policies designed to uphold participant rights, and the use of AI-powered tools to review, manage, and search consent documents for transparency and compliance. Designed for the broader clinical operations community, this session will be especially valuable for professionals focused on consent processes, patient recruitment, study start-up, site activation, decentralized trials, clinical technology, and clinical data. Attendees will leave with actionable insights into how technology can safeguard ethics while streamlining consent workflows across diverse trial environments.

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 pm **Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway!** *Must be present to win.*

3:50 pm **Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing**
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 pm **Chairperson's Introduction**
Speaker to be Announced, PAREXEL International

4:00 pm **FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience**



Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 pm **Tips for Getting the Most out of SCOPE**
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 pm **Chairperson's Introduction** *(Sponsorship Opportunity Available)*

4:35 pm **SCOPE's 3rd Annual Site Innovation Awards**





Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara
We are excited to announce our 3rd Annual Site Innovation Award, recognizing sites and partnerships pioneering new approaches to improve clinical trials. This is an opportunity to highlight your successes and be recognized by your peers for your dedication to advance clinical research. By sharing your actionable solutions, you will inform the broader Clinical Operations Community at SCOPE. Our definition of innovation is inclusive of low-tech or high-tech solutions, or any site operations-related process improvements that effectively reduce site burden and improve a site's ability to advance clinical research while providing patient-centered care. The Site Innovation Awards program is brought to you by Cambridge Healthtech Institute (CHI)'s SCOPE and is accepting submissions at: https://www.scopesummit.com/site-innovation-award

PLENARY KEYNOTE PRESENTATIONS

5:05 pm SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 pm KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards

PANEL MODERATORS:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Now in its 10th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. PEA embodies the values and personal accomplishments of Jerry Matczak, who sadly passed away soon after receiving the inaugural 2017 award. We dedicate this award to Jerry in the hopes that it will serve as a reminder of his ideals and accomplishments. SCOPE's 2026 Participant Engagement Award program is brought to you by Cambridge Healthtech Institute (CHI)'s SCOPE and is accepting submissions at: https://www.scopesummit.com/participant-engagement-award
PANELISTS:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Global Clinical Trial Diversity, Equity, and Inclusion, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 pm SCOPE's Winter Games Opening Reception *(Sponsorship Opportunities Available)*
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 pm Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)
Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. Yoga begins at 6:30 am. Registration Link: https://www.ciscrp.org/sunrise-yoga

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 am Registration Open

7:30 am Morning Coffee *(Sponsorship Opportunities Available)*
Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 am Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*
Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—*must be present to win!

8:30 am Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 am Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research
Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 am KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.
Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 am SCOPE's Stretch Break & Annual T-Shirt Toss
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 am KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?
PANEL MODERATOR:
Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners
Clinical development timelines remain one of the biggest barriers between breakthrough innovation and patients in need. Incremental process tweaks won't cut it—what's required is a step-change in how trials are designed, executed, and financed. This keynote will push beyond theory into bold, actionable strategies for compressing timelines, rethinking operational models, and deploying capital where it can have the greatest impact. Leaders will examine how smarter investment, data integration, and operational transformation can turn years into months—and what will truly move the needle for the future of clinical research.

9:45 am Grand Opening Coffee & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Voting Opens**
Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

WEDNESDAY, FEBRUARY 4

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 pm SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

PLENARY KEYNOTE PRESENTATIONS

SCOPE's Producer Team (Meet the Team!)
https://www.scopesummit.com/meet-the-team

2:40 pm Chairperson's Introduction: Rethinking Trial Design
Meenakshi Sinha, Director, Pharmaceutical and Life Sciences, PwC N/A

2:42 pm KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




PANEL MODERATOR:
Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from Medical Affairs, Market Access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, supports feasibility, and aligns clinical development with real-world needs—ultimately creating a competitive edge. Learn how forward-thinking teams are redefining roles and relationships across the clinical-commercial continuum.
PANELISTS:
Karen Correa, PhD, Vice President Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 pm SCOPE Award Winners & Announcements
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 pm Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 pm KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




PANEL MODERATOR:
Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
PANELISTS:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 pm SCOPE's Closing Ceremony Booth Crawl ***(Sponsorship Opportunities Available)*****. Last Chance for Exhibit Viewing.**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 pm Close of Day

5:00 pm SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* ***(Sponsorship Opportunities Available)***
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

"I have been involved with SCOPE since 2020 as a participant, track advisor and speaker. I think SCOPE is by far the best cross functional conference for biotechnology and pharmaceutical companies."

– Director Clinical Informatics & Innovation, Tango Therapeutics

Cambridge Healthtech Institute's 3rd Annual

Patient and Site Voice in Protocol Design

Harnessing Patient and Site Intelligence for Executable, Inclusive Trials

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 3rd Annual

Technology, Data and AI/ML for Intelligent Trial Design

Leveraging Techology and Data for Design Excellence

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

INCORPORATING PATIENT INSIGHTS INTO TRIAL DESIGN

11:00 Chairperson's Remarks

Ariel Katz, CEO & Co Founder, H1

11:05 PANEL DISCUSSION: How to Transform an Organization from Sporadic to Systematic Patient-Centricity in Clinical Research

Moderator: Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG

Many organizations embrace patient-centricity in theory—but struggle to embed it in practice. This panel explores how to move beyond one-off initiatives and build scalable, repeatable strategies that put patients at the heart of clinical research. Learn how leading teams are aligning culture, infrastructure, and partnerships to operationalize patient-centricity across the trial life cycle—and walk away with practical ideas to make it a true organizational advantage.

Panelists:

Speaker to be Announced, Surgo Health
Angela Bilkhu, Senior Global Patient Partnership Director, Sickle Cell Disease and aHUS, Roche
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Sema Sgaier, Co-founder & CEO, Surgo Health

11:30 Elevating the Patient Voice in Clinical Trials: What Patients Want Us to Know

Christina Brennan, MD, MBA, Senior Vice President, Clinical Research, Northwell Health
Jesse Hoffman, Chief Business Officer, AMR Clinical

This session shares findings from a national study capturing what clinical trial participants believe is most important for sponsors, sites, and CROs to know about their experiences. Attendees will hear patient-derived insights on care, support, and respect in trials—offering actionable guidance to improve quality, engagement, and patient-centered trial design.

11:55 Future-Proofing Clinical Trials: Designing Protocols for Flexibility

Speaker to be Announced, Science 37

Modern clinical trials face growing operational, regulatory, and patient engagement complexities, making early planning essential. Early protocol development is key to building adaptability that can make the difference between a smooth pivot and a costly overhaul.

This panel explores strategies for embedding flexibility in early trial design, allowing sponsors to incorporate alternative operational models or approaches without extensive amendments. Hear from sponsors, investigators, technology, and logistics partners on how to proactively design trials that are robust and agile, setting the stage for future optionality and seamless execution.

12:20 pm PANEL DISCUSSION: From Insight to Impact: Bringing Patient Voice into Our Clinical Trials

Moderator: Tuba Bas, PhD, Senior Director, Clinical Center of Excellence, Bristol Myers Squibb Co.

This panel explores how Bristol Myers Squibb integrates patient voice and advocacy insights into clinical trial design. Experts will present a framework aligned with diversity and inclusion regulations, supported by real-world examples. Attendees will gain practical strategies for enhancing study design, improving recruitment, and advancing health equity—demonstrating how patient-informed approaches strengthen scientific rigor and drive global trial success.

Panelists:

Amy Fesmire-Baus, Global Patient Recruitment, Research & Drug Development, Global Patient Outreach, Bristol Myers Squibb
Josee Pelletier, Senior Director, Research & Drug Development, Global Patient Advocacy, Bristol Myers Squibb
Ashish Shah, Director, Clinical Science Lead, Neurosciece, Bristol Myers Squibb

12:45 Bridging the Gap: Using AI and Real-World Evidence to Optimize Clinical Trial Protocols

Tabby Khan, MD, MPH, Senior Director, Analytics, Komodo Health

As the integration of Real-World Data (RWD) accelerates across the industry, forward-thinking sponsors are moving beyond post-approval applications to utilize Real-World Evidence (RWE) at the earliest stages of clinical development. This presentation examines the evolution of RWE and its critical role in informing protocol development to create trials that are more efficient, patient-relevant, and aligned with market access requirements.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall
Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

DIGITAL PROTOCOLS AND DATA-DRIVEN DESIGN

3:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

3:05 Optimizing Protocol Data Collection to Reduce Site and Patient Participation Burden
Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck
Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine
This session shares results from a TransCelerate-Tufts CSDD study analyzing 105 protocols across 15 pharma companies. Findings reveal rising protocol data volume and complexity, shifts in procedures by endpoint type, and a new variable: non-essential data collected despite supporting core endpoints. The session explores impacts on site/patient burden, data use in study reports, and why non-core procedures persist—offering strategies to optimize protocol design.

3:30 Implementation of Digital Protocols Enables Automation and Analytics-Powered Study Designs...It's Here and It's Now!
Chris Decker, President & CEO, CDISC
Robert DiCicco, Vice President, Portfolio Management, TransCelerate BioPharma, Inc.
The digital transformation of clinical research is revolutionizing protocol development and execution. Digital protocols integrate analytics, automate processes, and streamline collaboration, improving efficiency, data quality, and patient recruitment. This session explores key industry initiatives driving digital protocols, their impact on regulatory review, and reducing redundancies. A real-world case study demonstrates how one organization uses digital protocols to accelerate study startup and improve success across clinical trials.

3:42 Driving Speed and Efficiency in Clinical Development with Digital Protocols
Monica Bartucci, Associate Director, Clinical Capabilities, Bristol Myers Squibb
Neha Begum, Associate Director, Drug Development IT, Bristol Myers Squibb
Discover how BMS is transforming clinical operations by adopting Digital Protocols powered by Digital Data Flow (DDF). This approach accelerates study startup, enhances collaboration, and delivers measurable business value, shortening timelines and improving trial quality through a standardized data model.

3:55 The Unified Digital Protocol: One Solution for Operational Planning, Cost Control, and Site Feasibility
Luke Mann-O'Hallaran, Senior Director, Product, Evidence Generation, Medidata, a Dassault Systemes Co.
The clinical protocol is a trial's blueprint, yet its operational, financial, and logistical impacts are often assessed in silos leading to unpredictable enrollment, budget overruns, and reactive decisions. This session shows how to turn a static protocol into an agile asset by uniting activity-based modeling for budgeting and enrollment timelines with site-level feasibility data – enabling proactive risk mitigation and more predictable, smarter trials.

4:20 Presentation to be Announced

4:32 Sponsored Presentation *(Opportunity Available)*

4:45 Amplifying Patient Voice: Optimizing Clinical Trial Design through Analytics & Patient Insights
Hugh Dai, Director, Patient Engagement, Clinical Trial Design Capability, Eli Lilly & Company
Jade Dennis, Executive Director, Patient Engagement, Eli Lilly and Company
Patients' perspectives are critical yet often underrepresented in clinical trial design. This session shows how combining real-world data, patient-reported outcomes, and engagement analytics with direct patient insights can reveal pain points like visit burden, eligibility barriers, and adherence challenges. By bridging analytics and patient voices, we can design trials that improve recruitment, retention, and accessibility—ensuring protocols are scientifically rigorous, patient-centered, and better aligned with real-world needs.

5:10 Presentation to be Announced

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.**
Registration Link: https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials
Tobias Kruse, PhD, Managing Director, Europe, SubjectWell
Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment
Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health
Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health
As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)
MODERATOR:
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.
Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

ADVANCING EVIDENCE-BASED PATIENT-CENTERED PRACTICES

8:30 Chairperson's Remarks
Anthony Gulotta, Director, Clinical Solutions, EC USA, Commercial, Biorce

8:35 Talk Title to be Announced
Jill Pellegrino, CEO, AutoCruitment

8:47 The Future of Global Patient Engagement: A Patient Experience Platform to Accelerate Clinical Trials through Creativity, Global Reach, Site Support Services, and Technology
Fred Martin, CEO, SubjectWell
Patient recruitment and engagement are major bottlenecks in clinical research. This session reveals how a Patient Experience Platform—integrating creative strategy, global reach, site/patient support, and advanced technology—transforms

these challenges. Discover proven strategies to build trust, improve trial access, and retain patients. Learn how this approach leads to faster, more inclusive, and successful global clinical trials, with real-world examples.

9:00 From Engagement to Strategy: An Evidence Based Framework for Operationalizing Patient-Centeredness in Pharma

Jen Miller, Co-Director, Program for Biomedical Ethics; Associate Professor, Yale School of Medicine; Founder, Bioethics International; Interim CEO, Good Pharma Scorecard

Pharmaceutical companies emphasize patient centricity, yet consensus on a comprehensive corporate strategy and standardized evaluation frameworks is lacking. We present a framework and performance indicators, developed through a systematic literature review and focus groups with patients and clinicians. Findings highlight definitions, initiatives, outcomes, implementation strategies, barriers, facilitators, metrics, and case examples. Together, these insights provide an evidence-based foundation to guide, benchmark, and advance patient-centered practices across the pharmaceutical sector.

9:20 Begin at the Beginning: Integrating Patient Voices to Accelerate ICH E6/E8 Implementation

Amy Fesmire-Baus, Global Patient Recruitment, Research & Drug Development, Global Patient Outreach, Bristol Myers Squibb

ICH E6/E8 guidelines are enabling a new era of innovation in trial design. Operationalizing the guidelines is spurring a shift in mindsets and processes in the early stages of trial design, including rethinking when and how to engage patients. This session shares how early consideration of patient perspectives can support the development of fit-for purpose, quality-by-design trials, and spotlights tools to help organizations accelerate the move from guidance to implementation.

9:35 Extracting Insights from Clinical Study Data—Two Reverse-Translation Case Studies

Radhesh Nair, Director, Data Science and Analytics, Clinical Development, AbbVie, Inc.

Edward Price, PhD, Principal Research Scientist, Abbvie, Inc.

Reverse translational approaches are rapidly gaining ground as a means to identify drug targets, segment patients, and validate unmet medical needs. Clinical study data is one of the richest sources of data to support such analyses. Using two "Reverse Translational", also known as "bedside to bench", projects, we will highlight where scientific insights can be derived through the secondary use of clinical study data and documents.

9:50 From Parents to Participants: Precision Recruitment Strategies Powered by First-Party Data

Megan Preovolos, Director, Partner Operations, Patient Recruitment, Everyday Health Group

In an age of increasing pharma skepticism, vaccine hesitancy, and fragmented rare disease care, how can sponsors succeed in enrolling the most complex audiences in clinical research? Drawing from new proprietary research, the team behind What to Expect and BabyCenter will share findings powered by an unmatched reach to 9 in 10 first-time pregnant women in the US and 36 million new and expecting parents globally each month. This session will reveal key behavioral and attitudinal indicators of trial participation across critical segments. We'll explore factors such as vaccine confidence, interest in specific content topics, and use of digital health tools that signal openness to clinical research. Discover how these deep audience insights grounded in first-party data translate into actionable strategies for successful recruitment and ultimately get life-changing therapies to families faster.

10:02 Designing for Real People: How a Pharma Company and Biorce Using AI to Build Truly Patient-Centric Trials

Dennis Velasquez, Head, Clinical Solutions, Commercial, Biorce

Tired of hearing "patient-centric" with no real change? This session shows how a top pharma and Biorce are actually doing it, using AI to co-design trials with patients in mind. Think faster protocols, fewer burdens, real-world inclusivity, and documents people can understand. Join us to see what happens when empathy meets automation.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

OPERATIONALIZING PATIENT-CENTRICITY (cont)

11:10 Chairperson's Remarks

Kent Thoelke, CEO, Paradigm Health, Inc.

11:15 Sponsored Presentation *(Opportunity Available)*

11:40 Translating Patient Insights into Action

Trish Davidson, PALADIN Consortium Director, Tufts Center for the Study of Drug Development

Ellyn Getz, MPH, Director, Patient Partnerships, CSL Behring

Hollie Schmidt, Vice President, Scientific Operations, Accelerated Cure Project for MS

Hear how insights from patients and advocates shaped study designs and materials across three indications. This session will highlight how patient insights informed protocol development, addressed study burden, and improved recruitment. Attendees will walk away with a roadmap for replicating this success in their own programs.

12:05 pm Leveraging Innovation to Optimize the Protocol Development Process

Jennifer Poon, Director, Clinical Capabilities Lead, Clinical Center of Excellence, Bristol Myers Squibb Co.

Hillary Rose, Associate Director, Product Manager, Global Clinical Development, Bristol Myers Squibb Co.

In this session, BMS presents its innovative development and application of AI to streamline and automate clinical protocol development. As industry data reveals increasing protocol complexity, frequent amendments, and prolonged timelines, BMS's approach addresses these challenges head-on. Protocol automation enables time savings, reduces manual effort, and enhances consistency and quality across documentation. This presentation will highlight how AI supports operational efficiency and elevates the standard of clinical protocol development.

12:30 Presentation to be Announced

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:

Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim

Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi

Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl (Sponsorship Opportunities Available). Last Chance for Exhibit Viewing

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

STREAMLINING OPERATIONS TO SUPPORT SITES AND PATIENTS

8:30 Chairperson's Remarks

Suzanne Harris, Senior Vice President, Marketing & Communications, SubjectWell

8:35 Implementing AI Solutions for Driving Patient- and Site-Centric Clinical Trials

James Falcous, Patient & Site Engagement Lead, Boehringer Ingelheim

Boehringer Ingelheim has been working with patient and site advisors as standard for a long time to inform our clinical trial design. In some cases, we have held relationships with advisors for 15+ years. We have developed an AI chatbot to power these interactions, identifying previously received insights to ensure future discussions with advisors are efficient and effective. This powers the sponsor-advisor interaction, to drive patient- and site-centric clinical trials.

9:00 AI & Innovation in Clinical Trial Financial Management

Zahiah Gueddar, Senior Director Commercialization, Clinical Trial Financial Suite, IQVIA Technologies

Join industry leaders to discover how innovation is transforming clinical trial financial management and accelerating site and patient success. Hear firsthand about the key features and tools they're most excited to implement and get an insider's look at early improvements, including streamlined payment automation and stronger site outcomes. Whether you're exploring AI in clinical trial financial management or seeking ways to boost results for sites and patients, this session delivers forward-looking insights and practical lessons from the field.

9:25 Optimizing Clinical Trials with Process Change and AI Innovation

Ophelia Mok, Senior Manager, Business Analytics and Insights, Global Development Organization, Takeda Pharmaceuticals, Inc.

Discover how quantifying patient burden through the Schedule of Activities (SOA) can transform protocol design at Takeda. This session will showcase how actionable insights on study burden informed early discussions, have guided complexity reduction, and minimized protocol amendments; explore strategies for leveraging competitive intelligence to optimize protocols and improve patient experience.

9:50 Patient Centricity in the Broader Context of Protocol Feasibility Assessments

Speaker to be Announced, PwC
Eduardas Valaitis, Managing Director Pharma & Life Sciences Analytics, PwC
Mary Carroll, Director, Protocol Optimization, Clinical Acceleration & Performance, AbbVie, Inc.

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation. After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

IN-PERSON ONLY WORKING GROUPS: Simplify to Elevate: Designing Leaner, Smarter Clinical Protocols

Tuba Bas, PhD, Senior Director, Clinical Center of Excellence, Bristol Myers Squibb Co.
Ann Hegarty, Clinical Project Manager, Clinical Center of Excellence, Bristol Myers Squibb Co.
Vibhuti Mehta, Associate Director, PRC Lead, Bristol Myers Squibb Co.
Kissondra Morris, Associate Director, Protocol Review Committee Lead, Bristol Myers Squibb Co.

This workshop brings together cross-functional teams to identify actionable ways to simplify protocols while preserving scientific integrity and regulatory rigor. Through collaborative exercises and real-world case examples, participants will explore strategies to reduce complexity, improve execution, and enhance the patient and site experience.Participants will explore key focus areas including: Data Optimization, Reducing Burden, and Smart Assessment Planning. Together, we'll explore ways to achieve leaner protocol design.

11:00 Networking Coffee Break

Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

COLLABORATIVE INNOVATION IN TRIAL DESIGN

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 PANEL DISCUSSION: Site Input to DCT Use in Trials: Pathways to Protocol Input and Implementation Insights

Moderator: Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)

Site adoption of DCT elements is critical to the success of driving these new methods to scale. Sites shared they often don't learn that DCT elements are included until the investigator meeting or initiation meeting. Two initiative teams focused on how to include the site voice in protocol design and planning, by collecting retrospective data and prospective input. The aim is to increase collaboration to optimize DCT use in trials.

Panelists:
Deena E. Bernstein, Vice President, Site Choice Account Development, TPS Global
Caroline Redeker, Chief Strategy & Commercial Officer, Advanced Clinical
Michelle Shogren, CEO & Owner, Innovate in What You Do!; former Senior Director of Innovation, Pharma R&D Clinical Operations, Bayer

12:00 pm Presentation to be Announced

12:25 PANEL DISCUSSION: Many Voices, One Goal: Responsible AI in Clinical Trials across Stakeholders

Moderator: Sharlene Carnegie, Senior Vice President, Engineering, Medidata Platform, Medidata a Dassault Systemes Co.

This multi-stakeholder panel, featuring perspectives from a sponsor, patient, and site, examines responsible integration of AI and its impact on clinical trials. Key topics include balancing innovation, privacy, and regulatory concerns, with practical implementation of AI tools. We'll explore patient-centric strategies for trust, transparency, and equitable access, as well as industry best practices for data integrity and compliance that can streamline operations, enhance data, and improve patient engagement.

Panelists:
Shashidar Abbidi, Senior Manager, Clinical Data Management, Global Data Operations, Bristol Myers Squibb Co.
Deborah K. Jones-Hertzog, PhD, CIO & Chief Privacy Officer, Catalyst Clinical Research
David M. Vulcano, Vice President, Research Compliance & Integrity, HCA Healthcare

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm

TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm

TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 17th Annual

Data-Informed Feasibility and Investigator Selection

Data-Informed, Site-Centric Approaches to Improve Feasibility and Investigator Selection

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 13th Annual

Tech and Collaboration to Streamline Start-Up and Reduce Operational Burden

New Processes and Technologies to Improve Trial Execution and Operational Outcomes

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

PREDICTIVE PLANNING & DATA-DRIVEN FEASIBILITY

11:00 Chairperson's Remarks

Speaker to be Announced, Advarra

11:05 Site Feasibility of the Future—Site Intelligence from the Source

Ashley Davidson, Vice President, Product Lead, Advarra

Access to site performance data is transforming how we evaluate and qualify clinical trial sites. By integrating these insights with feasibility workflows, sponsors and CROs can achieve a more holistic, data-driven approach that reduces site burden, accelerates decision-making, and redefines site feasibility for the future.

11:30 Reshaping Feasibility: Actions to Accelerate the Process

Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi

In an increasingly complex clinical research landscape, traditional start-up timelines and feasibility assessments often delay progress. A new initiative reimagines early-phase planning by integrating data analytics, country insights, and indication-level strategies to streamline operations and reduce start-up timelines.

11:55 Adopting Predictive Methods to Drive Geostrategy, Site Selection, and Timelines

Kieran Whelton, Data Scientist, Data Science & Analytics, AbbVie, Inc.

Learn how AbbVie continues to advance predictive methods to inform study feasibility, geostrategy, and site selection during start-up to drive more accurate timelines and set organizational expectations. We continue to build trust, increase adoption, and overcome the change management curve with our clinical teams and governance.

12:20 pm Integrated Data, AI Modeling and Digital Platform for Site Recommendation

Daoying Hu, PhD, MBA, Director, Data Science and Digital Health, Johnson & Johnson Innovative Medicine

Effective site selection is vital for the success of clinical trials. This presentation outlines an innovative and multi-model data driven site recommendation framework, along with a digital platform developed by J&J's data science team. The platform seamlessly integrates quantitative metrics from both internal and external data sources, leveraging AI and machine learning models to enhance site selection process and optimize clinical trial outcomes.

12:45 How Data-Driven Sites Are Proving Patient Access to Win Trials and Accelerate Enrollment

Liz Beatty, Chief Strategy Officer, Inato

Clinical research is entering a new era, where data transparency and AI are beginning to reshape how sponsors evaluate and select site partners. As sites start to invest in AI-powered tools and explore ways to leverage their own patient-level data, they're positioning themselves to demonstrate proven patient access, differentiate their capabilities, and build sponsor confidence — even before a trial begins.

This session will explore how forward-thinking sites are laying the groundwork to become more data-driven. Panelists will discuss the value of investing in AI and patient data, share how they're beginning to approach this shift, and reflect on how these efforts can support faster, more informed decisions with sponsors.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

SITE PERFORMANCE & START-UP EFFICIENCY

3:00 Chairperson's Remarks

Speaker to be Announced, Citeline

3:05 FIRESIDE CHAT: Third Era of Feasibility—The AI-Enabled Workforce

Moderator: Ronald Du, Associate Principal, ZS Associates

Feasibility has evolved from experience-driven to data-informed and now to AI-enabled. Learn how trial optimization and feasibility organizations are evolving the workforce and the work-to-be-done in this new era of AI while keeping patients and the human element at the center.

Panelists:
Katie Bonner, Director of Strategic Feasibility, AstraZeneca
Dana Iommazzo, Global Head, Clinical Operations Program Management, Novartis
Alex Weir, Senior Director, Head of Operational Deisgn, Amgen
Morgan Wooten, Director, Head of Patient Engagement, Recruitment and Retention, Daiichi Sankyo
John Yannone, Director, Feasibility Strategy, Innovative Health Engagement and Advocacy, Johnson and Johnson

3:30 PANEL DISCUSSION: Breaking Down Barriers: Streamlining CDAs to Accelerate Clinical Research

Moderator: Christine Senn, Senior Vice President, Site-Sponsor Innovation, Advarra
Study start-up delays hinder clinical research and patient access. The Site-Sponsor Consortium—a collaboration of sponsors, CROs, institutional and commercial sites—presents its first whitepaper on streamlining CDA processes. Panelists will share ethical and operational drivers for reform, explore master and bilateral CDA models, and offer practical strategies to accelerate start-up timelines through transparency and shared responsibility.
Panelists:
Jennifer Byrne, CEO, Javara, Inc.
Patrick A. Floody, Vice President, Global Clinical Trial Services, Regeneron Pharmaceuticals, Inc.
Alison Liddy, Senior Vice President, Patient and Site Cenric Solutions, IQVIA
Kristie Moffett, Senior Director, Moffitt Cancer Center

3:55 Presentation to be Announced

4:20 Talk Title to be Announced

Tom Johnson, Senior Director Life Sciences & Health IT , Life Sciences, Exostar

4:32 Five-Minute Feasibility—Too Good to Be True?

Alexandra Rosario, Clinical Director, Scientific, Biorce
Traditional feasibility in clinical trials is slow, manual, and costly—often delaying study start-up and driving frequent amendments. This session will explore how innovative, data-driven approaches can transform feasibility assessments into faster, smarter, and more accurate processes, reducing timelines, optimizing budgets, and ultimately accelerating patients' access to new treatments.

4:45 PANEL DISCUSSION: Practical Insight on Site-Led Clinical Trial Innovations

Moderator: Sean Lynch, Clinical Innovation Head, Innovative Trial Operations, Novartis Pharmaceuticals
This discussion explores how the collaborative role between Sponsor Innovation teams and clinical trial sites drive innovation through real-world feedback, tech adoption, and design collaboration. Panelists will share insights on tactics, sponsor-provided tools, and site-led technology. Learn how sites may influence user acceptance testing, engage with vendor design teams, and pitch their own ideas.
Panelists:
Kaye Doiron, Founder, CEO, Samaras & Research Works INC
Jamie Bendrick-Peart, Senior Director, Innovation and Strategic Projects, AstraZeneca
Arpana White, Site Partnership Head, US Study & Site Operations, Novartis

5:10 "When the Data Talks Back – Rethinking Feasibility through Site Tech Insights"

Speaker to be Announced, Evinova An AstraZeneca Healthtech Co
Highlighting the recent Tufts study and publication by expanding our discussion with insight into site preferences, how do we modify our feasibility approaches?

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell
Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health
Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health
As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.
Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

EVOLVING TOOLS AND FRAMEWORKS FOR SMARTER, MORE INCLUSIVE CLINICAL TRIALS

8:30 Chairperson's Remarks

Scott Arceri, Vice President, Strategic Solutions, Commercial, Science 37

8:35 Feasibility & Start-Up Risk in Practice: Managing What Emerges

Donna Hanson, VP Strategy & Optimization, Strategy & Optimization, Advanced Clinical
Cheryle Evans, President, Advanced Clinical
In clinical development, the path from feasibility to first patient is like entering a dense forest—you rarely see the full trail from the start. Blind spots such as compressed feasibility, tech gaps, and overreliance on imperfect data derail timelines. This session reveals the myths, risks, and practical plays to keep studies on track. Join us to learn how to spot hidden obstacles and build adaptive strategies before delays appear.

9:00 Engaging Community Sites in Oncology Clinical Trials: Obstacles and Solutions

Tameika Graham, Head, Feasibility Strategy & Analytics, Pfizer Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
When it comes to cancer research, academic medical centers (AMCs) are a valuable mainstay. However, data shows us greater than 70% of cancer patients live over 2 hours away from their nearest AMC—making clinical trials far less accessible to some. We will discuss the obstacles sponsors may face when seeking to bring more oncology trials to a community setting and methods implemented to overcome them.

9:25 PANEL DISCUSSION: A Fresh Look at Data Sharing for Study Planning and Site Selection

Moderator: Nick Whitney, Senior Director, Trial Management, IQVIA

Feasibility & Site Selection

Data sharing consortium and the Data Query System (DQS) were launched more than a decade ago by a handful of the largest pharmaceutical companies to reduce site burden and accelerate clinical trials. In this presentation, you'll learn how the data, technology, and companies behind DQS are evolving to match today's needs for study planning, site identification, feasibility, investigator/site selection, and master data management.

Panelists:
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Sarah McClure, Global Data Engagement Lead, Feasibility Management, R&D, Sanofi
Jane Twitchen, Head Clinical Trial Accelerator Unit & Executive Director, Global Clinical Operations, Biogen Ltd.

9:50 Laying the Process Groundwork to Achieve a 24-Hour Study Build

Mark Laney, Senior Director, Sales Engineering & Partnerships, Sales, Zelta by Merative
Chris Walker, Senior Director, Clinical Data Sciences, Data Sciences, Alimentiv

Zelta by Merative, in partnership with Alimentiv, will explore how to optimize study-start-up processes as a key enabler and accelerator in creating an end-to-end vision for how Digital Data Flow (DDF) can impact the industry. Discover practical strategies to reimagine your clinical trial processes through advanced technology that supports protocol ingestion, AI-informed design, smart validation, and standards-informed data flow—accelerating validated study builds within 24 hours.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

NAVIGATING THE SITE LANDSCAPE

11:10 Chairperson's Remarks

Jeff Golden, Vice President, Strategic Solutions, Strategic Solutions, Elixia Health

11:15 Why Your Site Feasibility Strategy Is Failing—and What to Do Instead

Robert Buka, Senior Director, Product Management , Medidata a Dassault Systemes Co.

Feasibility teams operate on outdated assumptions, like experience equals better performance and public site data is reliable. Analysis of 12,000 clinical trial sites reveals 43% never enroll a single patient and in 80% of studies, site experience doesn't correlate to enrollment success. This session debunks myths and shows why site-specific, indication-level performance data is necessary to improve site selection, reduce non-enrollers, and turn feasibility into a competitive advantage.

11:40 PANEL DISCUSSION: Strategic Site Relationship Management: Tailoring Engagement Models for Diverse Site Needs

Moderator: Rachel Ovens, Director, Patient & Site Engagement, Boehringer Ingelheim Pharmaceuticals,

The site landscape is increasingly diverse, from academic centers and community practices to multi-site organizations and decentralized models. Each type brings unique strengths and challenges. This panel will explore strategies for managing these relationships effectively, including building trust, ensuring clear communication, and tailoring support to each model. Speakers will share lessons learned and best practices to foster stronger partnerships that drive more efficient, patient-centered clinical trials.

Panelists:
Shannon Duffany, Clinical Trial Early Planning Lead – Global Oncology, Sanofi
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Christina Greene, PhD, Head, Global Site Agreements, Merck

12:05 pm PANEL DISCUSSION: Optimizing Clinical Research through Strategic Site Collaboration: Tools and Tactics for Success with MSRCs

Moderator: Carlos E. Orantes, CEO, Alcanza Clinical Research

This panel explores how to collaborate effectively with Multi-Site Research Corporations (MSRCs). Panelists will share practical tactics for site selection, onboarding, communication, and performance management, while highlighting the Association of Multi-Site Research Corporations (AMRC) framework for effective MSRC partnerships. The discussion will also address integrating MSRCs with Sponsors and CROs to strengthen collaborations, streamline operations, and optimize recruitment across the clinical trial ecosystem, while maintaining the quality standards we expect.

Panelists:
Jamie Bendrick-Peart, Senior Director, Innovation and Strategic Projects, AstraZeneca
Kari Delahunty, CEO, AMR Clinical
Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda

12:30 Precision Feasibility: Data-Driven Planning across Program, Trial & Site to Reduce Burden and Optimize Site Selection

Cristin MacDonald, Vice President, Client Delivery, WCG

Explore how strategic data use across program, trial, and site-level feasibility planning can streamline clinical trial execution. Learn how to reduce site burden by eliminating repetitive queries and ensure site selection aligns with the unique needs of the molecule and trial strategy. This session highlights how differentiated feasibility layers—program, trial, and site—can work together to drive smarter, more efficient planning.

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced propharma

8:25 Transition to Sessions

AI ENABLED SITE SELECTION & ENGAGEMENT

8:30 Chairperson's Remarks
Kaye Doiron, Founder, CEO, Samaras & Research Works INC

8:35 Project Radiate: Unlocking Community Site Potential through Geo-Clustered Referral Networks in Oncology Trials
Sharri Gilloxhani, Data Scientist, Pfizer
Javiera Kettlun, Director, Pfizer Chile SA
Project Radiate addresses the underutilization of community oncology sites in clinical trials by using real-world data, trial history, and geospatial analytics to identify high-potential site clusters. By mapping patient flow and referral patterns, it enables a scalable, geo-clustered model where community sites act as referral hubs. This approach broadens access, accelerates start-up, and enhances diversity—positioning community sites as empowered partners in precision oncology.

9:00 Presentation to be Announced ICON

9:25 Optimizing Site Engagement through Strategic Portfolio Management and AI-Driven Trial Matching
Milijana Ugrenovic-Petrovic, MPM Director, Clinical Research Operations, Clinical Trials Office, Moffitt Cancer Center
Explore how clinical research operations can be transformed by integrating strategic portfolio oversight with AI-powered trial matching tools and standardized feasibility workflows. Drawing on real-world examples from Moffitt Cancer Center, we will highlight how data-driven decision-making, dashboard tools, and structured intake processes improve trial selection, resource allocation, and site engagement. Attendees will gain actionable insights into aligning trial feasibility with institutional priorities and enhancing operational efficiency across disease programs.

9:50 Presentation to be Announced rws

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

COLLABORATIVE INNOVATION IN TRIAL DESIGN

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 PANEL DISCUSSION: Site Input to DCT Use in Trials: Pathways to Protocol Input and Implementation Insights
Moderator: Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Site adoption of DCT elements is critical to the success of driving these new methods to scale. Sites shared they often don't learn that DCT elements are included until the investigator meeting or initiation meeting. Two initiative teams focused on how to include the site voice in protocol design and planning, by collecting retrospective data and prospective input. The aim is to increase collaboration to optimize DCT use in trials.
Panelists:
Deena E. Bernstein, Vice President, Site Choice Account Development, TPS Global
Caroline Redeker, Chief Strategy & Commercial Officer, Advanced Clinical
Michelle Shogren, CEO & Owner, Innovate in What You Do!; former Senior Director of Innovation, Pharma R&D Clinical Operations, Bayer

12:00 pm Presentation to be Announced CVS Healthspire

12:25 PANEL DISCUSSION: Many Voices, One Goal: Responsible AI in Clinical Trials across Stakeholders
Moderator: Sharlene Carnegie, Senior Vice President, Engineering, Medidata Platform, Medidata a Dassault Systemes Co.
This multi-stakeholder panel, featuring perspectives from a sponsor, patient, and site, examines responsible integration of AI and its impact on clinical trials. Key topics include balancing innovation, privacy, and regulatory concerns, with practical implementation of AI tools. We'll explore patient-centric strategies for trust, transparency, and equitable access, as well as industry best practices for data integrity and compliance that can streamline operations, enhance data, and improve patient engagement.
Panelists:
Shashidar Abbidi, Senior Manager, Clinical Data Management, Global Data Operations, Bristol Myers Squibb Co.
Deborah K. Jones-Hertzog, PhD, CIO & Chief Privacy Officer, Catalyst Clinical Research
David M. Vulcano, Vice President, Research Compliance & Integrity, HCA Healthcare

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Congratulations on an incredible conference. There was so much positive energy and hope in the air. I hope you are very proud of the program you were able to put together. I hope that SCOPE continues to value the scientific importance of representation and diversity in trials.

– Chief of Staff and Strategy, Foundation for Sarcoidosis Research

Cambridge Healthtech Institute's 18th Annual

Enrollment Planning and Patient Recruitment

Tools and Techniques to Accelerate Patient Recruitment and Achieve Enrollment Goals

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 13th Annual

Diversity and Retention through Communities and Technology

Patient-Centered Approaches to Build Trust and Improve Participant Experience

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

SMARTER PLANNING TO DRIVE FASTER ENROLLMENT

11:00 Chairperson's Remarks

Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis

11:05 Reimagining Clinical Trial Recruitment: AI's Potential to Power a Global Revolution

Lauren Johnson, Director, Global Patient Recruitment & Retention, Pfizer Inc.
Christopher Rodricks, Senior Director, Strategic Partnerships, Pfizer Inc.

In this session, we'll explore how Pfizer is leveraging AI to revolutionize clinical trial recruitment. By using advanced analytics and machine learning, we can identify eligible participants more efficiently, improve outreach strategies, and enhance retention. Attendees will gain insights into how AI is accelerating study timelines, supporting diversity in trials, and ultimately driving faster, more inclusive development of life-saving therapies.

11:25 ROI-Driven Approaches to Patient Engagement

Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

Strong patient engagement is key to driving meaningful business outcomes and operational efficiencies in clinical research. With the launch of the Walgreens Clinical Trials Patient Advisory Board, Walgreens has been enhancing our recruitment approach by incorporating board members' lived experiences to improve recruitment, retention and accessibility. This session will focus on the intersection of patient engagement strategies, the use of community pharmacies as trustworthy hubs and ROI in clinical trials.

11:40 How Can We Achieve Faster Recruitment in Rare Disease

Patricia Brady, Director, Rare Disease, Novartis Pharma SAS

Currently, 300 million people around the world are affected by rare diseases, which is a significant number. While each rare disease is uncommon individually, together they have a major impact. For those of us involved in clinical research, this group represents a unique and complex challenge, as traditional approaches have not adequately addressed their needs. However, this model is now changing.

11:55 Fast-Tracking Recruitment and Data-Driven Engagement: A Sponsor-Aligned, Patient-First Strategy for Smarter, Faster, Fairer Trials

Speaker to be Announced, IQVIA Technologies

Recruitment is a persistent challenge in clinical research, and expanding access to sites and patients is key. In this session, IQVIA shares how a sponsor-aligned, patient-first model—blending data science, digital innovation, and site enablement—is redefining recruitment to accelerate enrolment and improve trial outcomes. This approach ensures that, once enrolled, participants receive tailored content to enhance their experience, driving stronger retention and more meaningful results.

12:20 pm PANEL DISCUSSION: Beyond the Screen Fail: Building a Collaborative Platform to Redirect Unmatched Participants to Clinical Trial Opportunities

Co-Moderators:

Jean Stimola-Sposaro, Director, Global Clinical Trial Industry Collaborations, Global Drug Development & Global Development Operations, Bristol Myers Squibb Co.
Ross Watson, Director, Global Site Partnerships, CSL Behring

Thousands of motivated clinical trial participants are turned away each year because they don't meet eligibility for a specific study, leaving patients searching for alternative ways to access treatment options. This session explores a cross-industry initiative to create a privacy-preserving platform that matches screen-failed individuals to alternative trials. By opening new doors for patients, the effort aims to improve access, accelerate enrollment and reduce burden for sponsors, sites, and patients.

Panelists:

Jen Miller, Co-Director, Program for Biomedical Ethics; Associate Professor, Yale School of Medicine; Founder, Bioethics International; Interim CEO, Good Pharma Scorecard

12:45 Bridging the Gap: Unifying Clinical Trial Recruitment

Seth Halvorson, Senior Vice President of Operations, Operations—Site Solutions, WCG

Study-wide recruitment often faces challenges because the process is highly variable and typically managed at the local level, with sites frequently chosen based on pattern and habit rather than strategy. This inconsistent approach often produces inconsistent outcomes. Aligning site selection and enrollment strategies with study goals is the key to achieving reliable results.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall
Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

HARNESSING PATIENT INSIGHTS AND COMMUNITY ENGAGEMENT TO DRIVE TRIAL ENROLLMENT

3:00 Chairperson's Remarks
Speaker to be Announced, Care Access

3:05 Where Trust Leads, Access Follows: A Model for Community-Centered Obesity Research in Underserved Populations
Amanda Beasley, PhD, Director, Representation in Clinical Research (RISE), Amgen
Mimi Fenton, CEO, Cedar Health Research
This panel features a Sponsor, Clinical Research Site, and Community Organization who built a trust-based partnership to deliver obesity research to those who need it most. Through deep community engagement and mutual collaboration, the site enrolled 100% of its participants from underrepresented populations. Together, they will share how trust, transparency, and shared purpose can drive inclusive enrollment and create a sustainable model for community-centered, equitable clinical research.

3:30 We Connect with Communities as Partners: Digital and On-the-Ground Strategies for Patient Support and Trial Diversity
Amanda Decoker, Senior Director, Head of Patient Recruitment and Retention, Takeda
LaShell Robinson, MS, Senior Director Diversity, Equity & Inclusion in Clinical Research, Takeda
Explore how Takeda leverages digital platforms and on-the-ground efforts to enhance our outreach to under-represented communities and how this mechanism can help measure engagement and potential impact. The WeConnectPatients.com portal has been instrumental in connecting patients with clinical trial educational resources and research opportunities. Delve into the various ways we are utilizing this tool to foster stronger community ties, improve patient recruitment, and promote diversity in clinical trials.

3:55 Talk Title to be Announced
Neil Weisman, President, Continuum Clinical

4:20 Presentation to be Announced

4:45 Patient Community Engagement: A New Model
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi

5:10 Presentation to be Announced

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants
Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials
Tobias Kruse, PhD, Managing Director, Europe, SubjectWell
Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment
Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health
Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health
As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)
MODERATOR:
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.
Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

ADVANCING EQUITY AND INCLUSION IN CLINICAL RESEARCH

8:30 Chairperson's Remarks
Cal Collins, CTO, OpenClinica LLC

8:35 What Are You Missing in Recruitment and Enrollment?
Alyssa Vincze, Principal & Director, Research & Development, Milliman IntelliScript
Current (pre-)screening methods are slow and expensive... but did you know that they also miss critical information? IntelliScript's studies show that ineligible participants are randomizing into trials in shocking numbers. Irix® can fill the information gap and speed up enrollment by retrieving and interpreting health data on trial participants in a matter of seconds. Just collect a HIPAA authorization to access our proprietary, nationwide data and make better, faster eligibility decisions.

9:00 Access = Acceleration: Why Broadening Recruitment Is the Future of Clinical Research
Garo Kiledjian, Founder & CEO, SGM Alliance
Barriers to trial participation slow recruitment, increase costs, and weaken real-world relevance. Starting with the lived experience of a BIPOC person living with HIV, this session illustrates how outdated eligibility criteria and systemic gaps affect not only HIV studies but oncology, cardiology, and beyond. Industry leaders then respond with solutions, showing how broadening access accelerates enrollment, strengthens data, and drives both scientific progress and commercial success.

9:25 PANEL DISCUSSION: Diversity in Clinical Trials—What's Working, What's Next
Moderator: Bianca Green, Clinical Program Diversity Head, UCB
Recruiting diverse populations into clinical trials is a shared goal—but what's actually moving the needle? This panel brings together industry leaders who are implementing scalable, measurable strategies to advance diversity, equity, and inclusion. Hear what's working, what's still a challenge, and what's coming next. Through real-world examples and candid discussion, walk away with actionable insights that can be applied to your own recruitment and engagement efforts.
Panelists:
Angel Akinbinu, Director, Trial Equity & Representation, Takeda Pharmaceutical Co. Ltd.

Natanya Candelario, Senior Director, Inclusive Research, Bristol Myers Squibb
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Laurie Myers, Senior Director, Health Literacy Strategy & Innovation, Merck & Co., Inc.

9:50 **Presentation to be Announced**

10:15 **Coffee Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

DRIVING ENROLLMENT THROUGH PATIENT-CENTERED EDUCATION AND HEALTH LITERACY

11:10 **Chairperson's Remarks**
Brett Kleger, CEO, Inspire

11:15 **Clinical Trials, Streamlined: How Integrated Solutions Accelerate Success**
Justin North, Vice President of Product Management, TriNetX, LLC
In today's fast-paced clinical research landscape, trial recruitment and communication remain two of the most persistent bottlenecks. This session will delve into the current pain points faced by sponsors, CROs, and sites, and showcase how innovative technologies are streamlining workflows, improving patient engagement, and accelerating trial timelines.

11:40 **Health Literacy as a Catalyst for Patient-Centric Clinical Trials: Enhancing Enrollment, Retention, and Participant Diversity**
Laurie Myers, Senior Director, Health Literacy Strategy & Innovation, Merck & Co., Inc.
Health literacy is an underappreciated factor in clinical trial success. This presentation explores how integrating health literacy principles into trial design and communication strategies can improve the experience of participants, foster diversity, and enhance enrollment and retention. Attendees will gain actionable insights to gain sponsorship and embed health literacy across all aspects of a clinical trial, ultimately driving more efficient and equitable trial outcomes.

12:05 pm **PANEL DISCUSSION: Beyond Recruitment: Optimizing Patient Experiences to Drive Enrollment & Retention**
Moderator: Mackenzie McKinney, Executive Director, Site Solutions & Patient Engagement, Jumo Health
Moving patients from identification to enrollment requires more than outreach—it demands a purposeful experience. This session explores how applying behavioral science, health literacy, and patient insights transforms recruitment into a system built around real patient and caregiver decision-making. By reducing friction and aligning education with patient needs, sponsors can create scalable experience infrastructure that accelerates enrollment, builds trust, improves comprehension, and sustains engagement throughout the trial journey.
Panelists:
Eda Baykal-Caglar, Director of Patient Engagement, The Michael J. Fox Foundation for Parkinson's Research
Tricia Buchheit, Director, Patient Recruitment, Alnylam Pharmaceuticals
Michele Falk, CCRP, Global Patient Outreach Recruitment Lead, Bristol Myers Squibb
Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML/LLS

12:30 **Presentation to be Announced**

12:55 **Sponsored Networking Luncheon**
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 **Networking Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 **SCOPE around the World, Faces from the Community**
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 **Chairperson's Introduction: Rethinking Trial Design**
Speaker to be Announced, PwC

2:42 **KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success**




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 **SCOPE Award Winners & Announcements** *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 **Chairperson's Introduction: AI Adoption in eClinical Technology**
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 **KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams**




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 **SCOPE's Closing Ceremony Booth Crawl** *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 **Close of Day**

5:00 **SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle*** *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am **Registration Open**

BREAKFAST PRESENTATION

8:00 **BREAKFAST PRESENTATION: Presentation to be Announced**

8:25 **Transition to Sessions**

BUILDING THE INFRASTRUCTURE FOR INCLUSIVE RECRUITMENT

8:30 Chairperson's Remarks
Kate Shaw, Founder & CEO, Innovative Trials Ltd

8:35 Partnering for Progress: Strengthening Sponsor–Community Site Relationships to Support Oncology Trial Enrollment
Scott Welden, Associate Director, Oncology Portfolio Delivery, Gilead Sciences, Inc.
This discussion explores how establishing partnerships between industry sponsors and community sites can advance oncology clinical trial access and recruitment. The session will highlight strategies to overcome access barriers, build trust through local engagement, and implement patient-focused tools such as navigators and advisory boards. We'll explore how these collaborative models can result in an agile trial design, ideally leading to less protocol amendments and towards a more representative enrollment population.

9:00 Presentation to be Announced
CLARINESS

9:25 Building a Strategic, Evidence-Based Support System for Representative Recruitment and Enrollment
Tyler A. Allen, PhD, Program Leader, Clinical Research Representation, Duke University
This presentation will outline a comprehensive, evidence-based framework for empowering clinical teams to successfully recruit, engage, and enroll representative patient populations in oncology clinical trials. The session will highlight practical strategies, structural considerations, and collaborative models for integrating equity into core trial operations, drawing on lessons learned from academic medical centers and real-world implementation within cancer research environments.
NGLAND

9:50 Presentation to be Announced

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

IN-PERSON ONLY WORKING GROUPS: Simplify to Elevate: Designing Leaner, Smarter Clinical Protocols
Tuba Bas, PhD, Senior Director, Clinical Center of Excellence, Bristol Myers Squibb Co.
Ann Hegarty, Clinical Project Manager, Clinical Center of Excellence, Bristol Myers Squibb Co.
Vibhuti Mehta, Associate Director, PRC Lead, Bristol Myers Squibb Co.
Kissondra Morris, Associate Director, Protocol Review Committee Lead, Bristol Myers Squibb Co.
This workshop brings together cross-functional teams to identify actionable ways to simplify protocols while preserving scientific integrity and regulatory rigor. Through collaborative exercises and real-world case examples, participants will explore strategies to reduce complexity, improve execution, and enhance the patient and site experience.Participants will explore key focus areas including: Data Optimization, Reducing Burden, and Smart Assessment Planning. Together, we'll explore ways to achieve leaner protocol design.

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

PATIENT & ADVOCACY PARTNERSHIPS DRIVING ENGAGEMENT INNOVATION

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 From Community Clinic to Clinical Trial: A Site-Readiness Framework for Engaging Historically Under-Represented Populations
Ramona Burress, Chief Development Officer, ONYX Health Collective
This session introduces a scalable Site-Readiness and Activation Framework developed by Onyx Health Collective and Diversity Health NetWoRx to transform trusted community clinics and health organizations into research-ready trial partners. Grounded in patient-focused drug development and population health principles, the framework assesses operational, regulatory, digital, and safety readiness. Attendees will learn how this approach improves feasibility, accelerates diverse recruitment, strengthens retention, and supports sustainable, equity-driven clinical trial pipelines.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:25 From Mistrust to Momentum: How the Lupus Help Center Is Reimagining Clinical Trial Engagement
Michele Falk, CCRP, Global Patient Outreach Recruitment Lead, Bristol Myers Squibb
Seth Ginsberg, Co-Founder & President, Global Healthy Living Foundation
Lupus patients face some of the toughest barriers to trial participation: systemic mistrust, confusing eligibility, and lack of culturally competent outreach. We'll share how BMS and the Global Healthy Living Foundation (GHLF) co-created the Lupus Help Center, a digital-first platform that humanizes clinical research and simplifies access. Real data, real stories, and real strategies to engage and activate the most disengaged patients will be the heart of this conversation.

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 2nd Annual

Collaborative Strategies to Improve Trial Execution

Innovative Solutions to Reduce Site Burden and Modernize Clinical Trials

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 14th Annual

Tech and Collaboration to Streamline Start-Up and Reduce Operational Burden

New Processes and Technologies to Improve Trial Execution and Operational Outcomes

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

BREAKING DOWN SILOS TO BUILD STRONGER SITE PARTNERSHIPS

11:00 Chairperson's Remarks

Speaker to be Announced, WCG Clinical

11:05 From Silos to Synergy: Driving Site Engagement through Integrated Technologies and Cross-Divisional Collaboration

Angela DeLuca, Associate Vice President, Global Study Operations, Amgen

This session explores how breaking down organizational silos and integrating technologies across pharmaceutical divisions can transform site engagement in clinical trials. By aligning tools, data, and strategies, we unlock new efficiencies and foster stronger site partnerships. Attendees will gain insights into scalable approaches that enhance collaboration, streamline operations, and accelerate trial execution—ultimately driving better outcomes for patients and stakeholders.

11:30 From Insight to Impact: Enhancing Site Engagement Strategies

Jennifer Blinn, Senior Director, Monitoring Excellence Global Process Owner, Clinical Study & Site Management, Bristol Myers Squibb Co.
Vidhya Gedela, Director, Patient & Site Engagement Products, Global Development Operations IT R&D Business Insights and Technology, Bristol Myers Squibb Co.

BMS is committed to transforming site engagement by listening to site feedback and implementing strategies that reduce process and technology burdens. Our focus is on enabling sites to prioritize patient care, resulting in smoother trial activation and conduct. In this session, we will share key approaches that BMS is using to create a frictionless experience for the sites and accelerate the delivery of innovative medicines to patients.

11:55 New Approach to Site ID: Adding a Semantic Knowledge Platform to Solid Process Foundation

Katarzyna Moscicka, Head, Feasibility, PSI CRO AG

This session will explore a roadmap to site ID in one click. We'll illustrate the importance of strong expertise-driven processes combined with the first-of-its-kind semantic knowledge platform. Using 30 years' worth of operational data, a solid process foundation, and external data from 500k+ institutions and 3M sites, this new methodology reduces the industry's 50% non-enrollment rate and empowers sponsors to accelerate timelines, cut costs, and boost trial efficiency.

12:20 pm Cross-Functional Collaboration: Breaking Silos for Clinical Trial Success

Sunee Reiner, R&D Field Medical Director, Medical Affairs, Sanofi

This presentation introduces a cross-functional collaboration model uniting Medical Affairs, Development, and Clinical Study Units to accelerate trials, engage KOLs early, and enhance risk mitigation. Attendees will gain actionable strategies to dismantle silos, foster joint accountability, and transform clinical operations into a dynamic, patient-centered ecosystem—delivering measurable impact across timelines, costs, and recruitment success.

12:45 Faster, Better, Smarter: The ROI of Simulation in Clinical Trials

Brad Stefanovic, Head of Clinical Innovation, Simulations Plus

In clinical trials, every dollar, data point, and day counts. This session explores how simulation-based training delivers measurable returns across the three metrics that matter most—cost, quality, and time. Learn how sponsors and sites are using immersive, adaptive learning and simulated protocols to reduce site/patient training burden, improve protocol compliance, and accelerate study timelines—without sacrificing quality. We'll share case examples, data insights, and practical takeaways to help you turn training from a cost center into a competitive advantage.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

TURNING DATA INTO ACTION FOR SMARTER SITE OPERATIONS

3:00 Chairperson's Remarks

Brook White, Vice President of Marketing & Commercial Operations, Sales & Marketing, CRIO

3:05 Addressing Organizational Transformation for the Successful Adoption of EMR2EDC

Michael Forst, IT Capability Lead, GMD Account R&D IT, AstraZeneca

Strategic insights from an experienced EMR2EDC implementation team that has successfully scaled the solution globally. This session moves beyond vendor roadmaps and technical specifications to address organizational change management and navigating cross-functional communication to maximize technology investments. Attendees will gain an understanding of the requisite stakeholders to engage, practical & effective communication strategies, and key asks for senior leadership.

3:30 Automated Insight Generation for Clinical Site Operations Using Reasoning LLMs and GraphRAG

Mark F. Ciaccio, PhD, Senior Biology Data Scientist, Platform Informatics & Knowledge Management, AbbVie, Inc.

Derek Wang, PhD, Director Clinical & Performance Insights, AbbVie, Inc.

We created an AI virtual assistant to answer specific queries about site and study health to proactively monitor and improve clinical operations. This assistant uses GraphRAG with reasoning LLMs, including GPT5 and Claude-Sonnet, to extract meaningful insights from our internal clinical operations dashboards. Additionally, this automated application sends stakeholders weekly reports on key milestones and real-time notifications about causes-for-concern with suggested next-best actions for sites, countries, studies, and portfolios.

3:55 Standardizing for Speed: The Blueprint for Modern Sponsor Site Partnership

Anusha Shetty, Senior Director, Strategy, Study Startup, Veeva Systems

Discover how leading biopharmas are strengthening their site partnerships through people, processes and platforms. Panelists from pharma, tech, and site networks will share how they are adopting standardized collaboration models-including restructuring roles and processes to foster genuine relationships and drive operational excellence.

Key Takeaways:

• Relationship Focus: Dedicated roles to build trust and ensure seamless execution

• Harmonization and Standardization: Streamlined surveys and unified systems to reduce redundancy.

• Operational Excellence: Leveraging standardized technology to improve efficiency and accelerate site activation.

4:20 Presentation to be Announced

4:45 PANEL DISCUSSION: Innovative Partnerships Delivering the Future of AI-Enabled Clinical Trials: Case Studies of Real-World Collaborations

Moderator: Muhammed Idris, PhD, Co-Director, Digital Health & Medicine, Morehouse School of Medicine

The future of clinical trials is being built through bold collaborations between sponsors, research sites, and AI companies. This panel showcases real-world partnerships where cutting-edge technology is not just a tool, but a catalyst for reimagining recruitment, engagement, and outcomes.

Panelists:

Andres Alvarez, MD, PhD, Director, Clinical and Translational Medicine Division, Baptist MD Anderson Cancer Center

Kesley D. Holmes, DHA, MS, CCRP, Director of Clinical Research, United Digestive

5:10 Powering Smarter Site Selection and Study Start-Up with Platform Technology

Catherine Gregor, Chief Clinical Trial Officer, Thought Leadership, Florence Healthcare

5:22 Presentation to be Announced

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

COLLABORATION & PARTNERSHIP MODELS FOR SUCCESS

8:30 Chairperson's Remarks

Scott Palmese, Executive Director, Site-Focused Solutions, Worldwide Clinical Trials

8:35 Aligning Stakeholder Priorities: A Unified Performance Framework for Clinical Trial Success

Teri Karcher, President, Global Project Leadership & Launch Excellence, Parexel

Kushal Gohil, Senior Vice President, Global Project Leadership & Launch Excellence, Parexel

Carlos Orantes, CEO, Alcanza Clinical Research

Clinical trials involve diverse stakeholders with competing priorities, often causing misaligned incentives and communication gaps that delay patient access to therapies. This interactive panel unites sponsor, site, and CRO perspectives to explore a unified performance measurement framework. Panelists will share strategies for transparency, accountability, and alignment to accelerate access while ensuring quality and compliance.

9:00 Enhancing Site Engagement during Site Initiation Visits

Marie Kromplewski, RN, MSN, Associate Director, Clinical Capabilities Manager, Clinical Center of Excellence, Bristol Myers Squibb Co.

This session will introduce an innovative approach to conducting an engaging and successful Site Initiation Visit (SIV). The SIV serves as a crucial opportunity for the sponsor to connect with site personnel and convey key protocol information. This site- and patient-focused approach ensure a clear understanding of the protocol, expectations, and implications for their patients. Join the session to explore a new way to re-imagine SIVs.

9:25 PANEL DISCUSSION: Sponsor-Site Collaboration: Tools, Data, and Processes for Enhanced Engagement

Moderator: Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Executive-level clinical-trial leaders explore moving beyond transactional interactions toward sustainable, value-driven partnerships across the ecosystem. Through the lens of AI and digital innovation, panelists share strategies for seamless trial rollouts and enhanced engagement with CROs, service providers, sites, and patients. Discover how emerging technologies accelerate collaboration, deliver measurable operational impact, and build trust that extends beyond single studies, creating mutually beneficial relationships among all stakeholders.
Panelists:
Kristen Dopf, MHS, PA-C Principal Investigator, Suburban Research Associates
Vani Nilakantan, PhD, Senior Research Advisor and Consultant
Adam Penna, JD, Associate Director Clinical Operations, Merck
Ginger Switzer, Senior Vice President, Clinical Operations AMR Clinical

9:50 Meeting Sites Where They Are—Key Connections in Action
Kate Yawman, Director, Product Management, Advarra
Nick Spittal, Chief Operations Officer, Velocity Clinical Research
Accelerating study start-up and improving operational outcomes requires sponsors to support sites within their established ways of working. This session explores how connected and easily accessible technology with aligned workflows can reduce inefficiencies, strengthen collaboration, and enhance visibility across study operations. Through real-world examples, we'll highlight how greater technological harmony between stakeholders contributes to more efficient start-up, stronger engagement, and the realization of connected research.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*
Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

COLLABORATION & PARTNERSHIP MODELS FOR SUCCESS (cont)

11:10 Chairperson's Remarks
Speaker to be Announced, Summit Clinical Research LLC

11:15 Sponsored Presentation *(Opportunity Available)*

11:40 Protocol Complexity and the AMC-Pharma Disconnect: A HIRO-Inspired Blueprint for Collaboration
Christopher Herrick, Vice President, Research Technology, Mass General Brigham
This session examines how Academic Medical Centers (AMCs) and pharma sponsors can address complex trial protocols. Drawing on Mass General Brigham's HIRO, speakers will share how early collaboration, feedback loops, and operational alignment reduce site burden and improve trial delivery. Site leaders will highlight challenges and present HIRO's engagement model as a replicable, evidence-based framework for designing scientifically rigorous, operationally feasible trials.

12:05 pm Partnership for Progress—A Site/Sponsor Collaboration Success Story
Sean Cunningham, Director, Study Site Engagement, Clinical Site Start-Up & Engagement, Takeda
Michelle Monosmith, Operations Administrator, Office of Clinical Trial, Mayo Clinic
Andrew Taylor, Associate Director Site Start-Up, Takeda
The cornerstones of any successful partnership are trust, transparency, and humility. In this session, representatives from Mayo Clinic and Takeda will share their approach to building a mutually beneficial partnership, which has led to reduced activation timelines, increased trial collaborations, and enhanced operational efficiency across both organizations.

12:30 Presentation to be Announced

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

Site Engagement & Operations

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

STREAMLINING OPERATIONS TO SUPPORT SITES AND PATIENTS

8:30 Chairperson's Remarks
Suzanne Harris, Senior Vice President, Marketing & Communications, SubjectWell

8:35 Implementing AI Solutions for Driving Patient- and Site-Centric Clinical Trials
James Falcous, Patient & Site Engagement Lead, Boehringer Ingelheim
Boehringer Ingelheim has been working with patient and site advisors as standard for a long time to inform our clinical trial design. In some cases, we have held relationships with advisors for 15+ years. We have developed an AI chatbot to power these interactions, identifying previously received insights to ensure future discussions with advisors are efficient and effective. This powers the sponsor-advisor interaction, to drive patient- and site-centric clinical trials.

9:00 AI & Innovation in Clinical Trial Financial Management
Zahiah Gueddar, Senior Director Commercialization, Clinical Trial Financial Suite, IQVIA Technologies
Join industry leaders to discover how innovation is transforming clinical trial financial management and accelerating site and patient success. Hear firsthand about the key features and tools they're most excited to implement and get an insider's look at early improvements, including streamlined payment automation and stronger site outcomes. Whether you're exploring AI in clinical trial financial management or seeking ways to boost results for sites and patients, this session delivers forward-looking insights and practical lessons from the field.

9:25 Optimizing Clinical Trials with Process Change and AI Innovation
Ophelia Mok, Senior Manager, Business Analytics and Insights, Global Development Organization, Takeda Pharmaceuticals, Inc.
Discover how quantifying patient burden through the Schedule of Activities (SOA) can transform protocol design at Takeda. This session will showcase how actionable insights on study burden informed early discussions, have guided complexity reduction, and minimized protocol amendments; explore strategies for leveraging competitive intelligence to optimize protocols and improve patient experience.

9:50 Patient Centricity in the Broader Context of Protocol Feasibility Assessments
Speaker to be Announced, PwC
Eduardas Valaitis, Managing Director Pharma & Life Sciences Analytics, PwC
Mary Carroll, Director, Protocol Optimization, Clinical Acceleration & Performance, AbbVie, Inc.

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

COLLABORATIVE INNOVATION IN TRIAL DESIGN

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 PANEL DISCUSSION: Site Input to DCT Use in Trials: Pathways to Protocol Input and Implementation Insights
Moderator: Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Site adoption of DCT elements is critical to the success of driving these new methods to scale. Sites shared they often don't learn that DCT elements are included until the investigator meeting or initiation meeting. Two initiative teams focused on how to include the site voice in protocol design and planning, by collecting retrospective data and prospective input. The aim is to increase collaboration to optimize DCT use in trials.
Panelists:
Deena E. Bernstein, Vice President, Site Choice Account Development, TPS Global
Caroline Redeker, Chief Strategy & Commercial Officer, Advanced Clinical
Michelle Shogren, CEO & Owner, Innovate in What You Do!; former Senior Director of Innovation, Pharma R&D Clinical Operations, Bayer

12:00 pm Presentation to be Announced

12:25 PANEL DISCUSSION: Many Voices, One Goal: Responsible AI in Clinical Trials across Stakeholders
Moderator: Sharlene Carnegie, Senior Vice President, Engineering, Medidata Platform, Medidata a Dassault Systemes Co.
This multi-stakeholder panel, featuring perspectives from a sponsor, patient, and site, examines responsible integration of AI and its impact on clinical trials. Key topics include balancing innovation, privacy, and regulatory concerns, with practical implementation of AI tools. We'll explore patient-centric strategies for trust, transparency, and equitable access, as well as industry best practices for data integrity and compliance that can streamline operations, enhance data, and improve patient engagement.
Panelists:
Shashidar Abbidi, Senior Manager, Clinical Data Management, Global Data Operations, Bristol Myers Squibb Co.
Deborah K. Jones-Hertzog, PhD, CIO & Chief Privacy Officer, Catalyst Clinical Research
David M. Vulcano, Vice President, Research Compliance & Integrity, HCA Healthcare

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

NEW at SCOPE 2026's Exhibit Hall

Oliver Patch Collective: Pediatric Champions & Advocacy Corner
A dedicated space spotlighting pediatric advocacy programs focused on clinical trial support, patient and family resources, community engagement, and meaningful partnerships. This area brings together organizations united in their commitment to pediatric care, collaboration, and championing young lives.

Cambridge Healthtech Institute's 14th Annual

Clinical Trial Forecasting, Budgeting and Contracting

Innovative Strategies for Cost-Efficient Trials

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 8th Annual

Resource Management and Capacity Planning for Clinical Trials

Strategies for Efficient Resource Forecasting and Supporting Your Workforce

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC
For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

CREATING VALUE AND REDUCING COST: ARTIFICIAL INTELLIGENCE IN CLINICAL CONTRACTING AND BUDGETING

11:00 Chairperson's Remarks

Gary Steidl, Clinical Strategies & Development, Spaulding Clinical Research

11:05 PANEL DISCUSSION: AI in Clinical Outsourcing and Procurement: Creating Value, Reducing Cost, and Accelerating Timelines

Moderator: Rene Stephens, Managing Director, CBO, Danforth Advisors

Maximizing the value of every outsourcing decision is critical as clinical trial costs continue to rise. This panel will explore how AI is impacting clinical outsourcing/procurement to deliver measurable cost savings and stronger ROI. Hear how leading clinical operations teams are using AI to optimize budgets, negotiate smarter contracts, and streamline workflows—unlocking both financial and operational value while keeping trials on track.

Panelists:
Stefanie Kuhner, Global Head of Strategic Sales Life Sciences Engagement, Medidata
Lisa La Luna, Founder, La Luna 4 Healthcare
Shawne Moran, Head, In-Country Study Operations-Americas, Merck KGaA/EMD Serono
Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.

11:55 The New Normal Is Constant Change: How to Navigate Regulation, Risk, and Trial Complexity

Holly Leslie, Executive Director, Clinical Solutions, LedgerRun

In clinical trials, contracts and payments are under pressure from all sides—global regulation, technology shifts, and operational inertia. This session explores how sponsors and CROs can adapt to increasing complexity by embracing smarter change management, improving financial workflows, and linking contracts directly to payments. Panelists will share real-world examples of what's working, what isn't, and what it will take to truly transform trial operations.

12:20 pm From Tedious to Tech-Driven: How AI is Automating Financial Review and Contract Management

Gus Davidson, Senior Director, Supplier Relationship Management, Takeda

This talk explores real-world applications of tools like ChatGPT to automate financial reviews of trial budgets, accelerate contract development, and improve vendor management. Learn how the team at BMS are reducing manual effort and errors while improving speed and compliance. Walk away with practical insights on building a strong business case for AI investment.

12:45 Sponsored Presentation *(Opportunity Available)*

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

SUPPORTING SITES THROUGH EFFECTIVE BUDGETING AND CONTRACTING

3:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

3:05 Building Site Resilience in Uncertain Times: Budgeting, Contracting, and Forecasting Amid Global Pressures

Marina Malikova, PhD, Executive Director, Surgical Translational Research, Operations and Compliance, Boston University School of Medicine

Amid rising inflation, geopolitical shifts, and shrinking budgets, clinical trial sites face mounting pressures not only on finances but also on staff recruitment and retention. This session examines current trends in budgeting, contracting, and forecasting that affect site stability—from evolving cost structures to shifting sponsor expectations. Speakers will share forward-looking strategies to support workforce sustainability, strengthen site partnerships, and safeguard trial continuity in today's climate while preparing for tomorrow's uncertainties.

3:30 Sponsored Presentation *(Opportunity Available)*

4:20 PANEL DISCUSSION: Weathering the Storm—Site, CRO, and Sponsor Perspectives on Current Trends in Budgets and Contracts

Moderator: Debora Sobral, Founder, CEO, ClinBiz

Economic uncertainty and shifting global dynamics are reshaping how clinical trial budgets and forecasts are managed. In this panel, leaders from a site, a CRO, and a sponsor share candid perspectives on today's financial pressures and the trade-offs they face. Together, they'll explore strategies for fair contracting, sustainable site support, and stronger collaboration to keep trials moving forward despite turbulent conditions.

Panelists:

Jennifer Sydney Goldman, Clinical Business Operations, Consultant

Kathy Mickel, Director, Membership & Programs, Society for Clinical Research Sites (SCRS)

5:10 From Protocol to Budget: Faster Than This Session Biorce

Clara Bernardes, Co-Founder & CSO, Scientific, Biorce

Discover how Biorce's AI-powered solution is revolutionizing the way pharmaceutical and biotech companies launch clinical trials. By fully automating contract and budget negotiations, Biorce cuts startup timelines by nearly 70%—empowering sponsors and CROs to accelerate trial activation, boost collaboration, and stay ahead in a rapidly evolving industry.

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants CISCRP

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAKFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials SUBJECTwell

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment gcihealth

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

OPERATIONALIZING SITE AND PATIENT INITIATIVES THROUGH EFFECTIVE BUDGETING AND CONTRACTING

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Sponsored Presentation *(Opportunity Available)*

9:00 CO-PRESENTATION: Exploring the Site Contracting Experience: Breaking Down Budgets, Building Relationships

Carrie Lewis, Executive Director, Clinical Program Optimization, Keenova Therapeutics

Suzy Montanye, Site Relationship Manager, Keenova Therapeutics

Endo will share its success in implementing a Site Operations Board, a strategic initiative designed to gather operational feedback directly from clinical sites. This approach enabled the team to make informed adjustments to site budgets and drive numerous operational improvements. Most importantly, it fostered stronger, more collaborative relationships with their clinical sites—ensuring that what matters most remains at the center of their work.

9:25 PANEL DISCUSSION: Beyond the Budget Line: Integrating Patient Payments and Site Strategy to Drive Trial Equity

Moderator: Shelley Douros, Senior Director, Clinical Financial Management, Product & Strategy, Medidata, a Dassault Systemes Co.

We will explore the challenges of budgeting for diversity and structuring site contracts that support the whole patient. Panelists will share insights on designing compensation models that reduce patient burden by including timely and seamless support for costs such as travel, lodging, childcare, and translation services. We will explore how to empower sites with the resources and flexibility needed to become true partners in creating equitable access to clinical trials.

9:50 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)* Rho

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

RESOURCE MANAGEMENT: HOW TOOLS AND MODELS BOTH DRIVE EFFICIENCY

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 Sponsored Presentation *(Opportunity Available)*

11:40 From Complexity to Clarity: Leveraging Data Visualization and AI to Understand Portfolio Changes and Resource Demand

Geoff Kremer, Director, Global Resource Management, BeOne Medicines

Understanding the ripple effects of portfolio changes on resource demand is no small feat. This session explores how data visualization techniques and artificial intelligence can transform complex information into actionable insights. Attendees will gain practical takeaways through real-world use cases and lessons learned.

12:05 pm Balancing Insourcing and Outsourcing: Aligning Teams in a Hybrid FSP Model

Katherine Barboza, PhD, Associate Director, Process Development, Galderma

Nearly two years after piloting a hybrid Functional Service Provider (FSP) model, Galderma shares lessons learned about defining new roles, aligning internal teams with new outsourced members, and managing change in a lean organization. Discover how blending insourcing and outsourcing can optimize capacity planning and keep fast-paced clinical trials on track.

12:30 Sponsored Presentation *(Opportunity Available)*

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

NAVIGATING CLINICAL TRIAL LOGISTICS: WHAT CLINICAL STAGE OUTSOURCING LEADERS NEED TO KNOW

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Navigating Regulatory Requirements across Multiple US Agencies for Importing Biological Materials
Sean Smith, Biological Threat Exclusion Coordinator (BTEC), Agriculture Programs and Trade Liaison, US Customs and Border Protection
CBP will provide an overview of major U.S. regulatory authorities governing biological material importations, guidelines for acceptable and unacceptable cargo descriptions, examples of non-compliant shipments of biological materials and pharmaceutical products, and provide essential resources and important contacts for support.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 Shared Learnings on Methods to Decrease Temperature Excursions
Barbara Versage, Senior Manager, Supply Chain Sourcing, Immunocore LLC
Monitoring temperature control is a vital responsibility in clinical supply, extending beyond deep-frozen storage. Even products stored at ambient conditions require monitoring to ensure they avoid freezing or overheating. This session explains how tracking at defined supply chain touchpoints enables data collection, trending, and timely intervention. By leveraging value stream checkpoints, organizations can proactively maintain product integrity, safeguarding quality while minimizing risks across distribution and storage environments.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

THINK TANK: Specimen in Transit: Untangling the Complexities of Global Transport Logistics
Brenda Yanak, Founder & Principal, Clinical Transformation Partners LLC
Where in the world is . . . . .? Have you encountered confusion or churning around supply logistics for clinical trials? Don't know where to turn? This is your opportunity to learn from industry experts in global transport logistics, sample tracking and management, along with customs clearance on a multitude of topics. Join a Think Tank facilitated small group discussion to share experiences and solutions.

10:40 Think Tank Report Outs: Listen and Learn
During the Think Tank Table discussions, we shared our experiences and working solutions for global supply logistics. Now, as a collective community, let's hear from the table facilitators as they share key discussion points and strategies and provide a wrap-up of their table's discussion. What can we take away and apply?

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

COLLABORATIVE OUTSOURCING MODELS: BALANCING COST, GOVERNANCE, AND SITE ENGAGEMENT ACROSS STAKEHOLDERS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Strengthening Sponsor-Site Partnerships in Outsourced Trials
Liza Micioni, Senior Director, Head of Clinical Operations, Tris Pharma
In fully outsourced trials, sponsor-site relationships might seem secondary—but for small and emerging biopharmas, they can be a key differentiator. Even when using a CRO or FSP model, sites still look to sponsors for clarity, support, and partnership. This session will explore why direct sponsor-site engagement still matters, how it impacts trial success, and practical ways to build trust and alignment—regardless of your outsourcing structure.

12:00 pm **Sponsored Presentation** *(Opportunity Available)*

12:25 **PANEL DISCUSSION: Strategic Outsourcing in Biopharma: Optimizing Vendor Partnerships, Governance, and Site Engagement**

Moderator: Suzanne Vyvoda, Founder and Principal

As outsourcing continues to play a central role in clinical trial execution, biopharma leaders face increasing pressure to strike the right balance between efficiency, cost control, and stakeholder alignment. This panel will explore practical approaches to vendor selection and governance models that foster transparency, accountability, and long-term collaboration. Speakers will share strategies for engaging investigative sites as true partners, ensuring operational success while managing costs and timelines.

Panelists:
Kristin M. Ferrigno, Director of Clinical Operations, Clinical Research Site Development & Operations, Veda Clinical Trials
Tim Foley, Chief Business Officer, Scailyte
Melanie Goodwin, Director, Clinical Outsourcing, Immunocore

12:50 **Transition to Lunch**

12:55 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 **SCOPE Summit 2026 Adjourns**

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 **POST-CONFERENCE TRAINING SEMINARS***

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 10th Annual

Mastering an Outsourcing Strategy

Innovative Outsourcing Models and Determining Success through Metrics and Governance

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 12th Annual

Relationship and Alliance Management in Outsourced Clinical Trials

Strategies for Building Successful Partnerships and Alliances in a Competitive Landscape

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

MERGERS, MONEY, AND MILESTONES: NAVIGATING THE SHIFTING CLINICAL TRIAL OUTSOURCING LANDSCAPE

11:00 Chairperson's Remarks

George Sawicki, COO, KPS Life LLC

11:05 How M&A Strategies Shape the Clinical Trial Landscape

James West, Managing Director, Bourne Partners

This talk will share insights on how leading research companies' M&A strategies have defined the industry and explore the emerging trends that will shape its future. Learn how fast-growing companies are leveraging M&A and financing to gain market share and capitalize on pharma's propensity for outsourcing critical projects. Equip yourself with the knowledge to navigate the evolving clinical research vendor landscape and anticipate the M&A landscape ahead.

11:30 Talk Title to be Announced

Michelle Verhaeghe, Vice President, FSP Clinical Operations, Parexel

11:55 PANEL DISCUSSION: Navigating the Complexities of M&A and Outsourcing in Clinical Trials

Moderator: Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Keenova Therapeutics

This insightful panel discussion examines the intricate dynamics of outsourcing models, strategies, and experiences from the perspectives of both acquired and acquiring organizations in the clinical trial operations space. Leveraging real-world case studies and expert insights, this panel offers a comprehensive understanding of the challenges and best practices for biopharmaceutical executives managing the intersection of mergers, acquisitions, and outsourcing.

Panelists:

Gus Miller, Director, Clinical Labs Global Procurement, Regeneron
Stephanie Pfister, Vice President, Clinical Operations, Biohaven
Charles Semenchuk, Senior Director, Head of GCDO Business & Technology Capabilities, Global Clinical Development Operations, Jazz Pharmaceuticals
Laura Whitmore, Senior Director, Business Operations and Clinical Outsourcing, Kailera Therapeutics

12:45 pm Presentation to be Announced

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

UNLOCKING EFFICIENCY: TRANSFORMING OUTSOURCING MODELS FOR TRIALS OF TODAY AND TOMORROW

3:00 Chairperson's Remarks

Michelle Verhaeghe, Vice President, FSP Clinical Operations, Parexel

3:05 CO-PRESENTATION: Transforming Bayer's Supplier Ecosystem: Driving Efficiency and Capability in Clinical Trials

James Chennells, Strategic Alliances Lead, Product Development & Performance Excellence, Clinical Development & Operations, Bayer
Nick Lewis, Head, Clinical Vendor Management, Bayer

Discover how Bayer is revolutionizing its clinical trial outsourcing strategy by transforming its supplier ecosystem. Explore cutting-edge tools to boost operational efficiency, a robust, portfolio-aligned clinical development strategy, and future-proofing capabilities for evolving market demands. Uncover actionable insights to stay ahead in an increasingly complex outsourcing landscape.

3:30 Strategic and Operational Realities of Rethinking Preferred Partnerships

Jodi Coughlin, Senior Director, Vendor Strategy and Operations, Deciphera Pharmaceuticals, Inc.
Ashley Fitzgerald, Associate Director, Vendor Performance and Strategy, Deciphera

3:55 The AI Advantage in Clinical Business Operations

Anca Copaescu, CEO, Clinical Maestro by Strategikon

AI is transforming clinical trials by automating manual tasks, improving budget accuracy, and accelerating study planning and sourcing. It enhances—not replaces—human expertise. This session explores how AI streamlines clinical operations, strengthens oversight of vendors, timelines, and risks, and delivers practical ways to boost efficiency, cut costs, and enable faster, data-driven trial execution.

4:20 Reimagining the Resourcing FSP Continuum

Nicole Duffey, Chief Strategy & Growth Officer, KPS Life

Sponsors must have information to make the right resourcing decisions, yet many find themselves stuck between traditional staffing models and evolving delivery needs. This session outlines how a continuum-based diagnostic can help teams assess where they are today, identify internal misalignment, and shift toward modern, scalable workforce strategies that enhance speed, structure, and cross-functional collaboration.

4:45 CO-PRESENTATION: How Key Clinical-Operations Experts Can Partner to Successfully and Efficiently Deliver Outsourced Clinical Trials

Melody Aldred, PhD, Study Director Community Lead, SSO GCO Development, Novartis

Heidi Pereira, Vendor Program Strategy Director, Novartis

How does an organization strike a balance between fully insourced vs. outsourced clinical-trial-delivery models? The right balance varies amongst companies. We will hear from two roles that offer a unique collaboration and perspective on how we ensure successful delivery within our organization. This session will focus on strategic engagement, efficient processes, and robust oversight to create a sustainable outsourcing model that remains effective amidst industry changes.

5:10 Structuring Outsourcing Models for Efficiency, Clarity, and Cost Control

Nicole Stansbury, Senior Vice President, Global Clinical Operations, Premier Research

Choosing the right outsourcing model can significantly influence study efficiency, cost control, and the overall sponsor–CRO working dynamic. This session will break down the strengths and limitations of full-service, FSP, and hybrid approaches, highlighting how each model shapes resourcing planning, role clarity, and operational continuity. We will outline how sponsors can determine the most effective mix of insourced and outsourced roles and how pricing structures reflect these choices. The session will also explore how integrated oversight capabilities—such as centralized monitoring—can strengthen quality, risk detection, and visibility across models. Attendees will walk away with practical guidance to select and configure outsourcing approaches that support smoother collaboration and more reliable study delivery.

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

THE ROLE OF INNOVATION AND TECHNOLOGY IN OPERATIONAL EXCELLENCE

8:30 Chairperson's Remarks

Speaker to be Announced, Catalyst Clinical Research

8:35 Doing the Right Thing: Delivering Individual Data Records to Participants at Scale

Brian Deighan, Program Lead, Program Management, Teckro

Jane Twitchen, Executive Director, Head Clinical Trial Accelerator Unit, Global Clinical Operations, Biogen

Regulatory expectations are evolving and patient engagement continues to be a focal point in clinical trials. Global regulatory bodies, including ICH E6(R3), are stressing the importance of providing patients with access to their clinical trial data. Furthermore, there is increased interest from Patients themselves regarding access to their personalized study results, allowing them to inform their own treatment journeys. Designing a clinical trial that delivers meaningful outputs for patients while remaining focused on engaging sites and reducing their burden is a big challenge. In this session, Teckro and Biogen will explore how scalable technology can support meaningful patient insights alongside site engagement, to run operationally feasible, patient-friendly studies. We'll share practical tools and approaches for gathering and returning this data, and outline a repeatable process that bridges scientific intent with real-world execution.

9:00 Gaining AI Literacy to Drive Operational Efficiency and Excellence

Katrina Arceta, Category Manager, Development, R&D Procurement, Astellas Pharma Inc

AI literacy is rapidly becoming a core competency for outsourcing leaders. This session shows how understanding AI enables executives to evaluate CRO and vendor solutions, strengthen contract negotiations, and ensure that innovation translates into real-world efficiency. Participants will see how AI literacy drives operational excellence, enhances vendor oversight, and delivers value in outsourced clinical operations.

9:25 Accelerating Clinical Procurement with Generative AI for Market Reviews and Complex RFIs

Martina Endzhova, Global Category Lead, Clinical Trial Technologies, Bayer

Learn how a complex RFI process was transformed with a tailored generative AI approach—cutting time and effort while enhancing, not replacing, human expertise. This session will reveal tangible results and real metrics, showing how Clinical Procurement can speed market reviews, reduce operational burden, and drive smarter, faster decisions for Clinical Development teams.

9:50 Presentation to be Announced

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

AI MEETS HUMAN CONNECTION: THE FUTURE OF CLINICAL TRIAL PARTNERSHIP DYNAMICS

11:10 Chairperson's Remarks
Bertrand Le Bourgeois, CEO, PharMarketing

11:15 AI + Humans for Delivery-Ready Clinical and Financial Feasibility
Emily McInturf, Director, Feasibility, Clinical, PSI CRO AG
With the vast amounts of data and expertise accumulated in the industry and the power of AI, there's a potential to eradicate clinical trial delays and change orders. We'll demonstrate how one platform connects two worlds: financial forecasting and feasibility modeling. The methodology enables accurate feasibility data analysis, data-driven study models with their budgets, and increases the probability of hitting the operational and financial targets.

11:40 FIRESIDE CHAT: Utilizing AI and Technology to Enhance Relationships across the Clinical Trial Ecosystem
Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Keenova Therapeutics
Denise Gascard, Head of Operational Excellence and Translation Management, Sanofi
Max Ghez, Global Head, Clinical Business Development, Syneos Health
Scott Sawicki, Senior Director, Strategic Sourcing & Vendor Management, Centessa Pharmaceuticals
Through the lens of AI and digital innovation, panelists will share strategies for creating seamless trial rollouts, enhancing engagement with CROs, service providers, sites, and patients, and fostering trust that endures beyond a single study. Gain insights into how emerging technologies can accelerate collaboration, deliver measurable operational impact, and lay the foundation for sustainable, mutually beneficial relationships across all stakeholders.

12:30 pm LUNCHEON PRESENTATION: Presentation to be Announced

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

NAVIGATING CLINICAL TRIAL LOGISTICS: WHAT CLINICAL STAGE OUTSOURCING LEADERS NEED TO KNOW

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Navigating Regulatory Requirements across Multiple US Agencies for Importing Biological Materials
Sean Smith, Biological Threat Exclusion Coordinator (BTEC), Agriculture Programs and Trade Liaison, US Customs and Border Protection
CBP will provide an overview of major U.S. regulatory authorities governing biological material importations, guidelines for acceptable and unacceptable cargo descriptions, examples of non-compliant shipments of biological materials and pharmaceutical products, and provide essential resources and important contacts for support.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 Shared Learnings on Methods to Decrease Temperature Excursions
Barbara Versage, Senior Manager, Supply Chain Sourcing, Immunocore LLC
Monitoring temperature control is a vital responsibility in clinical supply, extending beyond deep-frozen storage. Even products stored at ambient conditions require monitoring to ensure they avoid freezing or overheating. This session explains how tracking at defined supply chain touchpoints enables data collection, trending, and timely intervention. By leveraging value stream checkpoints, organizations can proactively maintain product integrity, safeguarding quality while minimizing risks across distribution and storage environments.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

THINK TANK: Specimen in Transit: Untangling the Complexities of Global Transport Logistics
Brenda Yanak, Founder & Principal, Clinical Transformation Partners LLC
Where in the world is . . . . .? Have you encountered confusion or churning around supply logistics for clinical trials? Don't know where to turn? This is your opportunity to learn from industry experts in global transport logistics, sample tracking and management, along with customs clearance on a multitude of topics. Join a Think Tank facilitated small group discussion to share experiences and solutions.

10:40 Think Tank Report Outs: Listen and Learn
During the Think Tank Table discussions, we shared our experiences and working solutions for global supply logistics. Now, as a collective community, let's hear from the table facilitators as they share key discussion points and strategies and provide a wrap-up of their table's discussion. What can we take away and apply?

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

COLLABORATIVE OUTSOURCING MODELS: BALANCING COST, GOVERNANCE, AND SITE ENGAGEMENT ACROSS STAKEHOLDERS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Strengthening Sponsor-Site Partnerships in Outsourced Trials
Liza Micioni, Senior Director, Head of Clinical Operations, Tris Pharma
In fully outsourced trials, sponsor-site relationships might seem secondary—but for small and emerging biopharmas, they can be a key differentiator. Even when using a CRO or FSP model, sites still look to sponsors for clarity, support, and partnership. This session will explore why direct sponsor-site engagement still matters, how it impacts trial success, and practical ways to build trust and alignment—regardless of your outsourcing structure.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Strategic Outsourcing in Biopharma: Optimizing Vendor Partnerships, Governance, and Site Engagement
Moderator: Suzanne Vyvoda, Founder and Principal
As outsourcing continues to play a central role in clinical trial execution, biopharma leaders face increasing pressure to strike the right balance between efficiency, cost control, and stakeholder alignment. This panel will explore practical approaches to vendor selection and governance models that foster transparency, accountability, and long-term collaboration. Speakers will share strategies for engaging investigative sites as true partners, ensuring operational success while managing costs and timelines.
Panelists:
Kristin M. Ferrigno, Director of Clinical Operations, Clinical Research Site Development & Operations, Veda Clinical Trials
Tim Foley, Chief Business Officer, Scailyte
Melanie Goodwin, Director, Clinical Outsourcing, Immunocore

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 7th Annual

Building Smart Trial Foundations

Strategies for Resourcing, Capability Building, and Partner Selection

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 9th Annual

Scaling Operations with Impact

Optimizing Vendors, Data, and Strategic Value Delivery

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

AGILE CLINICAL OPERATIONS: HOW LEADERS NAVIGATE CHANGE AND DELIVER RESULTS

11:00 Chairperson's Remarks

Speaker to be Announced, Perceptive Inc

11:05 Biotech's New Reality—Market Pressures and Clinical Implications for Emerging Biopharma

Scott T. Megaffin, CEO, Adiso Therapeutics

Emerging biopharma faces tougher markets, leaner budgets, and higher expectations. In this session, Scott breaks down key economic and market trends shaping clinical operations—from funding constraints to pipeline reprioritization—and shares practical strategies to navigate these challenges, forge smart partnerships, and maintain operational excellence in an unforgiving landscape.

11:20 PANEL DISCUSSION: Thriving through Transitions—A Clinical Operations Leadership Perspective

Moderator: Valerie Reynaert, Vice President, Global Clinical Operations, Immunocore

Change is inevitable in today's biotech landscape—and for small and mid-sized companies, it often comes with higher stakes and fewer safety nets. Whether it is mergers, IPOs, co-development partnerships, or sudden portfolio pivots, these shifts can make or break a clinical development strategy. This panel will share candid insights into leading teams through uncertainty.

Panelists:
Ann-Marie Hulstine, Vice President, Clinical Operations, Alpheus Medical
Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK
Kristi Koontz, Vice President, Global Clinical Operations, Daiichi Sankyo US
Doug A. Schantz, Senior Vice President, Clinical Operations, Asklepios BioPharmaceutical, Inc.

11:55 Presentation to be Announced

12:20 pm Clinical Clarity in a Climate of Change: Key Takeaways for Leaders in Emerging Biotech

Kelly L. Smith, AD, Operations, Viracta Therapeutics, Inc.

Biotech leaders face tighter capital, rising board expectations, and complex partnerships—demanding faster, leaner execution. This session distills key strategic and operational insights, from investor-driven metrics to how M&A and IPOs impact trial continuity. We'll highlight how small and mid-sized biotechs can stay agile without sacrificing quality, while also touching on the effects of tariffs, "one BBB," and acquisition readiness on operational predictability.

12:45 Smart Growth for Small Biotech: Building the Foundation and Scaling with Impact

Shaheen Limbada, COO, Ops, WEP Clinical

Small biotech companies don't need big systems, they need smart ones – ones that are structured, hands-on, flexible, and tailored to lean teams. We will provide strategies for designing trial infrastructure and early operational foundations right from the start – so that they are that are fit-for-purpose and can evolve as your pipeline matures. We will then explore how to scale without breaking – expanding trials, territories, and partnerships – while preserving quality and capital efficiency.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

DELIVERING RESULTS: BUIDLING A SUCESSFUL CLINICAL TRIAL

3:00 Chairperson's Remarks

Sheri Lee, CEO, Principal Consultant, Premier Regulatory Consulting (PRC); Former National Program Expert, FDA

3:15 Risk-Based Monitoring as Your Early Warning System: Detecting and Addressing FDA Compliance Gaps

Sheri Lee, CEO, Principal Consultant, Premier Regulatory Consulting (PRC); Former National Program Expert, FDA

Risk-based monitoring (RBM) has evolved into a powerful compliance tool that can predict and prevent FDA inspection findings before they occur. This presentation

demonstrates how organizations can transform their RBM programs into proactive early warning systems that detect regulatory vulnerabilities in real-time. Attendees will learn how to design risk thresholds align with FDA expectations, enabling study teams to identify compliance gaps before they escalate into formal findings.

3:20 PANEL DISCUSSION: Blueprint for Growth: Core Strategies for Lean, Scalable Clinical Ops

Moderator: Robert Goldman, Global Head of Clinical Operations, Contraline, Inc.

For small to mid-size biopharma, executional fundamentals—budgeting, forecasting, team design—can determine success or failure. This panel explores practical strategies for lean, scalable clinical ops aligned with ICH/GCP E6 R3. Topics include infrastructure, vendor selection, workflows, and partnerships.

Panelists:

Allison Billups, Executive Vice President, Client Solutions, ClinLab Solutions Group

Christine Cornwell, Head of Clinical Operations US, AbelZeta

Matthew Failor, Director & Head, Clinical Operations, MAIA Biotechnology

Michael Hickey, Vice President, Clinal Operations, Processa Pharmaceuticals

3:55 AI and Human Synergy in Patient Engagement: A Blueprint for Agile Clinical Trials

Dan Brenner, CEO & Founder, Business Development, 1nHealth

The promise of AI in clinical research is only realized when guided by human insight, empathy, and adaptability. This session features 1nHealth and sponsor partners sharing a proven model from a recent Substance Use Disorder (SUD) trial that improved site efficiency, reduced screening burdens, and delivered faster, higher-quality enrollment. Learn how AI and human expertise work together to de-risk enrollment, deepen patient relationships, and make trials more agile in a competitive landscape.

4:20 Clinical Trials Winter Games: Gold-Medal Trial Execution for Small Biopharma

Chris Venezia, CEO, ProofPilot, Inc.

Jay Russak, Head of Clinical Operations, Invivyd

Without the infrastructure of big pharma, many small biopharma teams underestimate the quality and performance control they can have over their clinical trial operations. But with the right approach, even the smallest biotech can outpace key study obstacles.

In this winter games-themed panel, small biopharma leaders will compete in three events for the gold medal in trial planning, enrollment, and conduct. Like any high-performance sport, they will show how the right blueprint can give the control, precision, and speed needed to conquer today's clinical slopes.

SCALING CLINICAL OPS WITH AI, DATA, AND AGENTIC AI

4:45 Next-Gen Clinical Operations: Empowering Clinical Teams with AI Teammates

Paulius Ojeras, Vice President, Clinical Operations, Perceive Biotherapeutics

Clinical trials are entering a new era—one defined not by automation alone, but by the integration of Agentic AI. This session shares a real-world case study demonstrating how AI teammates are transforming operations from manual coordination to intelligent, self-driving systems. Attendees will gain practical insights into where Agentic AI delivers the most value, lessons learned from implementation, and key adoption challenges in this rapidly evolving space.

4:58 From Agentic AI and Data Analytics to Precision Clinical Trials

Iman Tavassoly, Associate Director of Quantitative and Systems Pharmacology, Alnylam Pharmaceuticals

Attendees will gain a clear understanding of how Agentic AI and advanced data analytics can transform clinical trials from static, protocol-driven processes into adaptive, precision-focused frameworks. They will learn practical approaches for integrating AI-driven insights into trial design, patient recruitment, and operational decision-making. The session will also highlight real-world examples, emerging best practices, and future trends that can help organizations accelerate innovation and improve patient-centric outcomes.

5:10 Sifting Through Chaos: Applying Quality by Design Approach to Data Governance

Catherine Hall, Head of GXP Quality Assurance, Security, Egnyte, Inc.

This session will describe how to establish a sustainable, quality-by-design data governance framework. The central premise is that data quality and integrity must be intentionally designed into the data lifecycle, rather than enforced through retrospective auditing. This approach requires identifying Critical Data Elements (CDEs) and understanding the data flow paths that are essential for supporting key business processes and regulatory submission goals.

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

OPTIMAL TRIAL DESIGN: MANAGING PARTNERSHIPS, CO-DEVELOPMENT, AND CRO OVERSIGHT

8:30 Chairperson's Remarks

Speaker to be Announced, Continuum Clinical LLC

8:35 Sponsored Presentation *(Opportunity Available)*

8:48 Sponsored Presentation *(Opportunity Available)*

9:00 What Happens When a Sponsor–CRO Partnership Goes Terribly *Wrong* (but Actually *RIGHT*)?

Theresa R. Devins, PhD, Vice President, Clinical Ooperations, Cognition Therapeutics, Inc.

Clinical trials can unravel under Sponsor–CRO misalignment, vendor issues, and unexpected disruptions. In this fireside chat, hear how one Alzheimer's trial overcame early setbacks through new leadership, patient focus, and a recommitment to partnership. Learn practical lessons on rebuilding trust, fostering

transparency, and driving accountability to transform strained relationships into high-functioning collaborations that achieve critical milestones.

Interviewed By:
Krista Armstrong, PhD, Senior Vice President & Head of Neurosciences, Medical & Clinical Development, Premier Research

9:25 PANEL DISCUSSION: Selecting the Right CRO and Optimizing Bid-Defense Strategy
Moderator: Manny Lazaro, Senior Vice President, Clinical Development Operations, Kailera Therapeutics
Selecting the Right CRO and Optimizing Bid-Defense Strategy
Panelists:
Krista Armstrong, PhD, Senior Vice President & Head of Neurosciences, Medical & Clinical Development, Premier Research
Theresa R. Devins, PhD, Vice President, Clinical Ooperations, Cognition Therapeutics, Inc.
Hope Meely, Vice President Clinical Operations, Halda Therapeutics
Millie A. Shultz, Global Head of Clinical Operations, Galderma

9:50 Presentation to be Announced

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*
Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

BUILD VS BUY, OR THE HYBRID APPROACHES FOR SMALL OPS TEAMS

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 Presentation to be Announced

11:27 Making Trials Happen: From Scientific Vision to First Patient-In
Albert Gianchetti, President & CEO, XyloCor Therapeutics, Inc.
Jennifer Boscia, Chief Financial Officer, BioBridges
Early-stage biotechs are challenged to transform scientific concepts into fully activated clinical studies with lean teams and limited operational infrastructure. This session will share practical strategies for achieving study readiness, identifying when and how to bring in external expertise, and leveraging program management to maintain momentum through study start-up and beyond. Drawing on lessons learned across two XyloCor studies and start-up activities at Nuevocor, we will discuss how creating and balancing the right structure, planning, and resourcing can accelerate the path from discovery to first patient-in.

11:40 The Hybrid Advantage: Building Small Ops Teams That Deliver
Randy Brown, Vice President, Clinical Operations, Altimmune, Inc.
The hybrid approach might be right for you! As a small biopharma/biotech we might be enticed to hand off all of the work to an outsourcing partner, but I encourage you to think differently. Can you, with compliance in mind, take on this work internally? You can build an operational team that can—and will—deliver. I will share three or four success stories over the last 10 years.

12:05 pm PANEL DISCUSSION: Agile Trials, Smarter Data: Strategies for Lean Biopharma Success from Informatic Experts
Moderator: Lorenzo Balsamo, Director, Clinical Informatics & Innovation, Tango Therapeutics
Small biopharma teams must run faster, leaner trials while managing complex data and limited resources. This session offers practical strategies for agile trial design, smart vendor management, and using AI to support forecasting, site selection, and execution. We'll also explore how to streamline data flow across systems, reduce inefficiencies, and make informed build-vs.-buy decisions—helping clinical leaders stay competitive, compliant, and trial-ready.
Panelists:
Stacey Arrambide, Senior Vice President, Functional Service Solutions, Advanced Clinical
Tina Henderson, Head of Life Sciences Consulting, Just in Time GCP
Derek Lawrence, Portfolio Strategy & Transformation Lead, Product, Saama
Iman Tavassoly, Associate Director of Quantitative and Systems Pharmacology, Alnylam Pharmaceuticals

12:30 LUNCHEON PRESENTATION: Empowering Success in Small Pharma/Biotech: Leveraging People & Process for Optimal Results
Meghan Patterson, Principal Consultant, Strategic Solutions, Consulting, ProductLife Group
Lyn Agostinelli, Principal Consultant, Clinical Operations, Consulting, ProductLife Group
This session will provide insights on how aligning people and process drives innovation and sustainable growth. Learn how to strategically integrate human capital with process optimization, a cornerstone for success. Through real-world examples and best practices, learn how to effectively harness the potential of teams—promoting a culture of collaboration and continuous improvement. We will focus on process-driven strategies that streamline operations and proactive quality principles that accelerate time-to-market without compromising compliance.

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the

spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced propharma

8:25 Transition to Sessions

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Navigating Regulatory Requirements across Multiple US Agencies for Importing Biological Materials
Sean Smith, Biological Threat Exclusion Coordinator (BTEC), Agriculture Programs and Trade Liaison, US Customs and Border Protection
CBP will provide an overview of major U.S. regulatory authorities governing biological material importations, guidelines for acceptable and unacceptable cargo descriptions, examples of non-compliant shipments of biological materials and pharmaceutical products, and provide essential resources and important contacts for support.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 Shared Learnings on Methods to Decrease Temperature Excursions
Barbara Versage, Senior Manager, Supply Chain Sourcing, Immunocore LLC
Monitoring temperature control is a vital responsibility in clinical supply, extending beyond deep-frozen storage. Even products stored at ambient conditions require monitoring to ensure they avoid freezing or overheating. This session explains how tracking at defined supply chain touchpoints enables data collection, trending, and timely intervention. By leveraging value stream checkpoints, organizations can proactively maintain product integrity, safeguarding quality while minimizing risks across distribution and storage environments.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

THINK TANK: Specimen in Transit: Untangling the Complexities of Global Transport Logistics
Brenda Yanak, Founder & Principal, Clinical Transformation Partners LLC
Where in the world is . . . . .? Have you encountered confusion or churning around supply logistics for clinical trials? Don't know where to turn? This is your opportunity to learn from industry experts in global transport logistics, sample tracking and management, along with customs clearance on a multitude of topics. Join a Think Tank facilitated small group discussion to share experiences and solutions.

10:40 Think Tank Report Outs: Listen and Learn
During the Think Tank Table discussions, we shared our experiences and working solutions for global supply logistics. Now, as a collective community, let's hear from the table facilitators as they share key discussion points and strategies and provide a wrap-up of their table's discussion. What can we take away and apply?

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

COLLABORATIVE OUTSOURCING MODELS: BALANCING COST, GOVERNANCE, AND SITE ENGAGEMENT ACROSS STAKEHOLDERS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Strengthening Sponsor-Site Partnerships in Outsourced Trials
Liza Micioni, Senior Director, Head of Clinical Operations, Tris Pharma
In fully outsourced trials, sponsor-site relationships might seem secondary—but for small and emerging biopharmas, they can be a key differentiator. Even when using a CRO or FSP model, sites still look to sponsors for clarity, support, and partnership. This session will explore why direct sponsor-site engagement still matters, how it impacts trial success, and practical ways to build trust and alignment—regardless of your outsourcing structure.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Strategic Outsourcing in Biopharma: Optimizing Vendor Partnerships, Governance, and Site Engagement
Moderator: Suzanne Vyvoda, Founder and Principal
As outsourcing continues to play a central role in clinical trial execution, biopharma leaders face increasing pressure to strike the right balance between efficiency, cost control, and stakeholder alignment. This panel will explore practical approaches to vendor selection and governance models that foster transparency, accountability, and long-term collaboration. Speakers will share strategies for engaging investigative sites as true partners, ensuring operational success while managing costs and timelines.
Panelists:
Kristin M. Ferrigno, Director of Clinical Operations, Clinical Research Site Development & Operations, Veda Clinical Trials
Tim Foley, Chief Business Officer, Scailyte
Melanie Goodwin, Director, Clinical Outsourcing, Immunocore

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

"This was my first SCOPE US and I enjoyed it very much – it was great to meet so many new people, connect names to faces and have thought-provoking discussions."

– Director Clinical Informatics & Innovation, Tango Therapeutics

Cambridge Healthtech Institute's 18th Annual

Clinical Data Strategy

Optimizing Data Collection, Management, and Integration

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 9th Annual

Integrating AI into Clinical Data and Analytics

Unlocking Data Potential with AI

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come…just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

RETHINKING DATA MANAGEMENT

11:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:05 Making a Unified Data-Management Platform a Reality

John Finn, Executive Director and Inflammation & Immunology-RAE TA Lead, Clinical Data Scientist, Pfizer Inc.
Rajat Nanda, Global Head, Senior Director, Data Management Reporting & Analytics, Pfizer Inc.
Ralph Russo, Executive Director, Global Head, Clinical Data Collection Strategies, Pfizer Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

This session will explore Pfizer's journey to create an end-to-end data management, reporting, and analytics platform to support clinical trials with real-time access to data. Hear how co-developing a new solution solved for true simplified EDC build, direct data capture, non-CRF data streamlined acquisition, tiered query management, dynamic SDV to support study RBM, advanced reporting and analytics, and SAE reporting automation eCRF capture and flow to safety systems.

11:55 Presentation to be Announced

12:07 pm State of the Clinical Trial Landscape—Key Trends and Expectations for 2026

John Rose, Senior Vice President, Healthcare, GlobalData Plc

Decode Trial Growth: Understand which types of clinical trials truly increased in 2025, factoring in reporting lags, start-date shifts, and withdrawn studies. Understand the true market size. Know Where to Focus: Get clarity on growth by therapy, modality, geography, and sponsor type to align your focus and competitive advantage with the clinical research market shift. Spot Signals Early: Learn how hirings, patents, and other data reveal opportunity before it's reported in clinical trial registries and products. Prepare for Q2 and Beyond: Access forecasts for Q2 2026 and beyond to align sales, competitive intelligence, capacity, and strategy.

12:20 Dataverse Unleashed: Empowering Global Therapeutics with AI-Ready Data

Gian Prakash, Director, Data & Analytics, Information Research, AbbVie, Inc.

Discover the transformative power of Dataverse, an integrated platform designed to revolutionize AI applications in global therapeutics through AI-ready data. This presentation will highlight real-world use cases where Dataverse effectively bridges the gap between proof of concept and large-scale AI use-case implementation, enabling innovative therapeutic strategies and enhancing patient outcomes globally with robust and actionable AI-ready datasets.

12:45 Innovative Models for Aligning Incentives for Clinical Trials in the Age of AI

Ariel Katz, CEO & Co Founder, H1

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

DATA SHARING AND PRODUCT-CENTRIC DATA GOVERNANCE

3:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

3:05 Strategic Data Sharing: Unlocking Clinical Insights through Secure Collaboration

Medha Patel, Clinical Design Analytics Director, Amgen

Despite significant investment in clinical research, insights often remain siloed due to limited data access and fragmented efforts. This session explores how secure, de-identified data sharing can transform isolated studies into collective scientific progress, especially in rare and high-risk diseases. Amgen will share real-world applications and regulatory experiences, illustrating how privacy-protective collaboration and synthetic data innovation can accelerate trials, reduce duplication, and ethically maximize the value of historical data.

3:30 Beyond Seeing to Chatting with Our Portfolio: Accelerating Clinical Decision-Making with Performance Central

Jacqueline Habib, Senior Director, Drug Development Portfolio Management Insights, Bristol Myers Squibb

Leyla Rich, Senior Director, R&D Portfolio Operations, R&D Business Insights & Technology, Bristol Myers Squibb Co.

Discover how Performance Central and its embedded IRIS chatbot are revolutionizing R&D portfolio operations at BMS. This enterprise platform gives teams instant, conversational access to data on over 250 projects and 300 active studies—empowering faster, smarter decisions. We'll share lessons learned from centralizing data and harmonizing metrics, highlight our 'chat with' rollout and user feedback, and reveal future milestones for scaling conversational AI across global clinical portfolios.

3:55 Presentation to be Announced

4:20 Elevating Clinical Data Management: Using Next-Gen AI and Automation to Streamline Data Collection & Review Processes

Speaker to be Announced, Deloitte

In this presentation, we explore how AI and Automation plays a key role in streamlining clinical data management processes, focusing on data aggregation from multiple sources, improving data review, medical monitoring processes, and query management. We will also talk about how a strong data foundation is essential to enabling these capabilities at scale. By the end, you will see how these innovations can lead to more efficient, reliable, compliant, and scalable clinical data workflows.

4:45 Powering Clinical-Study Innovation through Low-Code Platforms and Product-Centric Governance

Keith A. Wilson, Associate Director, Product Management, Global Development IT, Regeneron Pharmaceuticals, Inc.

Regeneron's GD-IT Enabling Technologies team established a Power Platform Center of Excellence and adopted a product-centric delivery model to streamline data capture and oversight for clinical trial operations. Strategic investments in premium licensing enabled scalable, compliant solutions to centralize study tracking and integrate with enterprise systems to support protocol development and milestone management.

5:10 Redefining Clinical Operations: The Power of Integrated Agentic AI Platform in Action

Sowmya Ballakur, Vice President, Product, Oracle Health & Life Sciences

Jason Rizzo, Group Vice President, Oracle

Clinical development is often slowed by fragmented systems and inefficiencies in patient recruitment, site selection, trial optimization, and continuous monitoring. We present an AI-enabled life sciences solution that integrates diverse data sources to streamline operations. By leveraging predictive and reasoning models, automated insights, and real-time performance tracking, it enhances recruitment, optimizes site selection, and proactively monitors trials, resulting in faster timelines, improved compliance and ultimately bringing new therapies to patients more quickly and safely.

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

AI FOR DATA MANAGEMENT

8:30 Chairperson's Remarks

Anthony Mikulaschek, Vice President, Patient Commercial Strategy, IQVIA Technologies

8:35 How Causal AI, Powered by Data, Is Revolutionizing ClinOps: Optimized Site Selection and Real-Time Dashboards

Raviv Pryluk, CEO, PhaseV Trials Ltd.

PhaseV ClinOps Platform brings precision to site selection by integrating multi-modal patient- and site-level data with causal AI, enhancing diversity and boosting efficiency. Real-time dashboards provide continuous oversight of recruitment, adherence, and site performance, while predictive "what-if" analytics enable proactive decisions, reduce risk, and support adaptive trial execution from day one.

9:00 Human+AI Driven Data Review Plan: A Black Hole Experiment

Sanjay Bhardwaj, Executive Director, Head of Clinical Data Technologies, AbbVie, Inc.

Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.

As clinical research steadily advances adoption of AI-driven anomaly detection for clinical data, its clear that AI remains only one component of a comprehensive data review strategy. This session introduces a framework for developing an integrated clinical data review plan where inputs from both human experts and AI systems are combined. Attendees will gain guidance on creating data review plans that harness the strengths of AI models and human expertise.

9:20 Next-Generation Analytics for Feasibility Leveraging AI Agents for on-Demand Insights

Ray Zhong, PhD, Associate Director, Data Technologies & Analytics Solutions, Data & Analytics, Otsuka America Pharmaceuticals, Inc.

Traditional approaches to feasibility analytics tools focus on the creation of rigid dashboards fit for purpose to specific metrics. In this work, we aim to change the way that study teams interact with analytics and insights for protocol feasibility and site-profiling analytics by enabling an AI-driven user interaction that focuses on generating targeted insights based on the specific user's intent and preferences.

9:35 Leveraging a Data-Mesh Framework in Clinical Trials

John Jones, Senior Vice President, Head Life Sciences Consulting, Entitech Solutions, a TANDYM Company

Vishal Janani, Dir of Digital Clinical Operations, Digital Clinical Operations, BeOne Medicines USA Inc

Beenu Kapoor, Exec Dir, Digital Clinical Operations, BeOne Medicines USA Inc
Data mesh, a decentralized architectural framework that enables domain teams to own and govern their data while facilitating cross-domain analysis, addresses the unique challenges of clinical trial operations by democratizing access to trial data while maintaining strict regulatory compliance and patient privacy standards. Data mesh, a decentralized architectural framework that enables domain teams to own and govern their data while facilitating cross-domain analysis, addresses the unique challenges of clinical trial operations by democratizing access to trial data while maintaining strict regulatory compliance and patient privacy standards.

9:50 How to Build an AI Study-Simplification System
Barrie Nelson, President, Nurocor
Henry Wei, Executive Director & Head, Development Innovation, Regeneron Pharmaceuticals, Inc.
Gillian Mac Lochlainn, Associate Director Development Innovation, Regeneron Pharmaceuticals, Inc.
Angelo Tran, Manager, AI Products, Nurocor
In today's rapidly evolving landscape, digitalization is more than just going paperless—it's about transforming the way we operate, connect, and deliver value. At the heart of this transformation is Artificial Intelligence (AI), a powerful force driving automation, insight, and innovation. As we digitalize our workflows, data, and services, we unlock the potential for AI to enhance decision-making, streamline operations, and personalize experiences at scale. Together, digitalization provides the foundation and AI delivers the intelligence—enabling smarter systems, more agile organizations, and deeper customer engagement. By embracing both, we're not just adopting new technologies—we're building a future where efficiency, creativity, and data-driven efficiencies go hand-in-hand.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*
Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 Presentation to be Announced

11:40 Leveraging a Data-Mesh Framework in Clinical Trials
Vishal Janani, Director, Digital Clinical Operations, BeOne Medicines
Beenu Kapoor, Executive Director, Global Clinical Operations, BeOne Medicines USA Inc.
Data mesh, a decentralized architectural framework that enables domain teams to own and govern their data while facilitating cross-domain analysis, addresses the unique challenges of clinical-trial operations by democratizing access to trial data while maintaining strict regulatory compliance and patient-privacy standards.

NEXT-GENERATION DATA-CAPTURE TECHNOLOGIES

12:05 pm PANEL DISCUSSION: The Great Data-Capture Debate: EHR, eSource, and Traditional Approaches
Moderator: Doug Bain, Consulting Partner, Clinflo
In an era of digital transformation, the question remains: What is the best way to capture clinical trial data? This interactive session brings together two expert panels for a dynamic and thought-provoking discussion. First, a vendor panel will represent distinct approaches to data capture. Then, a sponsor panel comprised of experienced industry professionals will respond. Ultimately, this panel will illuminate what truly matters from an operational and strategic perspective.
Panelists:
Derk Arts, Founder & CEO, Castor
Drew Garty, CTO, Clinical Data, Veeva Systems
Siggi Kloos, Senior Vice President, R&D Digital, Data, & Informatics, BioNTech US
Michael Wenger, Chief Innovation Officer, CRIO

12:30 The Hidden Cost of Misaligned Protocols—and How to Fix It
Tracy Ohrt, Director, Clinical Operations, Clinical Research Solutions, Optum
Eighty percent of clinical trials fail to meet enrollment targets, often due to misaligned eligibility criteria and protocol design that doesn't reflect real-world clinical practice. By leveraging real-world data (RWD) during protocol development—especially when defining inclusion and exclusion criteria—sponsors can reduce costly amendments, improve recruitment efficiency, increase patient diversity and increase the likelihood of meeting their target enrollment.
This is the critical moment—before trial initiation—when thoughtful design can make or break a study. A holistic review involving clinical stakeholders ensures criteria are interpretable within EHR systems and aligned with how care is actually delivered. Understanding how diagnoses are documented, labs are ordered, and procedures are performed helps sponsors create protocols that sites can easily interpret, execute effectively, and ultimately improving trial outcomes.

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)*. **Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

DIGITAL DATA FLOW & DATA SCIENCE TRANSFORMATION

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Yes, You Can (Digitalize That): Streamlining Study Design through Protocol Digitalization
William Illis, Global Head, Collaboration & Technology Strategy Clinical Development, Novartis Pharmaceuticals
Donald Jennings, Senior Director, Digital Trial Foundations and Patient Engagement, Eli Lilly and Company
Too often, clinical trial protocols are held together by a patchwork of disconnected platforms and manual workarounds, a system built on repeated data entry, mismatched formats, and limited data consistency. It's inefficient, error-prone, and a major barrier to accelerating study start-up. This session will explore how biopharmaceutical companies are changing that by digitalizing protocol design and authoring using an open-source, vendor-agnostic data model to inform better study design.

9:00 Presentation to be Announced

9:25 PANEL DISCUSSION: How to Navigate the Data-Science Transformation
Moderator: Valerie Balosso, Director, Data Management, Infectious Diseases, GSK
With the introduction of AI in Data Management and its significant impact on efficiency and decision-making, traditional Data Management must evolve toward a more analytics-driven, risk-based approach. This panel will explore the transformative shift from traditional Data Management to Clinical Data Science, highlighting the necessity to use centralized statistical monitoring, the importance of change management, workforce upskilling, and fostering collaboration to ensure the seamless integration of innovative methodologies.
Panelists:
Lynne Cesario, Executive Director, Global Lead Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Miguel Lemaire, PhD, Associate Director, Oversight Data Management, GSK
Shawntel Swannack, Regional Director (Americas), Analytical Monitoring, Data Management & Central Monitoring, Integrated Data Analytics & Reporting (IDAR), Johnson & Johnson

9:50 Harnessing Gen AI for Clinical Development
Scott Chetham, CEO & Co Founder, Faro
AI agents are moving from hype to reality in clinical development, but success requires far more than building a model. In this session, Faro's CEO will share real examples of how multiple Top 5 and Top 10 biopharma companies have moved beyond pilots to deploy AI agents that automate complex scientific, operational and regulatory functions, structure scientific intent into operational data, and accelerate core development workflows. We will break down the transformation required across four critical dimensions: organizational change management, technical and data readiness, regulatory expectations for transparency and traceability, and the security and compliance foundations needed to operate safely in a regulated environment. Attendees will leave with a clear blueprint for responsibly implementing AI agents at scale and the lessons learned from teams that are already succeeding.

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

Humans, Meet Your Co-Panelists: AI Takes the Mic in Clinical Trials
Munther H. Baara, Vice President, Product Strategy & Innovation, EDETEK, Inc.
Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Everyone's talking about AI—but what happens when AI joins the conversation? In this first-of-its-kind format, humans share the stage with agentic AI bots trained on real-world clinical-trial roles. Alongside seasoned industry experts, they'll unpack how AI is not just accelerating decisions, but reimagining the very fabric of clinical development. Whether you leave inspired or unnerved, you won't forget this session anytime soon.

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

AI-DRIVEN ANALYTICS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Building a Transformative, AI-Driven Analytics Capability for Clinical Trial Insights
Omkar Dasari, Senior Technical Product Manager, Data & Analytics, Amgen
James Vernille, PhD, Director, Clinical Systems & Analytical Reporting, Global Development Operations, Amgen, Inc.
At Amgen, we are transforming our analytics ecosystem with AI-driven tools that enable near real-time, self-service insights for global development stakeholders. Our next-generation analytics engine features a rebuilt metrics platform, centralized data governance, and a streamlined dashboard landscape leveraging Power BI with Co-Pilot and custom AI interfaces. By implementing AI/ML bots and natural language queries, we are shifting from static reporting to a dynamic, AI-driven experience.

12:00 pm From Proven Results to Product Vision: Advancing Clinical Trial Data Exchange with IgniteData Archer
Joe Lengfellner, IgniteData
Clinical trial data exchange has long limited the pace of innovation in research. This session explores how IgniteData Archer is redefining what's possible, drawing on proven results from live trials at Memorial Sloan Kettering Cancer Center. Presented by Joe Langfellner, IgniteData's Chief Product Officer, the talk connects real-world impact to a forward-looking product vision—explaining why Archer's success led him to join IgniteData and how he and the team are shaping the future of clinical trial data exchange.

12:13 Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Transforming Clinical Data Analytics with Agentic GenAI
Moderator: Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson
This panel explores how Agentic Generative AI (GenAI) is reshaping clinical data analytics by enabling autonomous and adaptive systems that streamline data processing, uncover complex patterns, and generate actionable insights. The discussion will address the opportunities and risks of integrating Agentic and Applied GenAI into regulated clinical research environments, highlighting their potential to drive innovation while maintaining data integrity and patient safety.
Panelists:
Bhargava Reddy, PhD, Senior Director, Advanced Insights and Solutions, Janssen
Richard Young, Chief Strategy Officer, CluePoints

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

ADVANCING TRIAL DELIVERY

Cambridge Healthtech Institute's 3rd Annual

Enhancing Point-of-Care Research: Solutions & Partnerships

Transforming DCTs to Expand Trial Access and Improve Patient and Site Experience

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 15th Annual

eClinical Evolution

Expanding Winning Digital Solutions and Practices

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

POC TRIAL STRATEGIES: ADAPTING DCT APPROACHES

11:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:05 Enabling Research at the Point-of-Care: What Will It Take to Get Patients, Providers, Regulators, and Life Science Companies to Collaborate?

Kevin Bugin, PhD, Head, Regulatory Policy and Intelligence, Amgen
Robert DiCicco, Vice President, Portfolio Management, TransCelerate BioPharma, Inc.

If we're going to improve patient outcomes, then we must collaborate differently. The groundwork is laid: individual organizations, consortia, and government agencies are all intent on making research at the point of care a reality by generating high-quality data that supports regulatory decision-making, informs practice guidelines, and improves outcomes. This session will review efforts to date and explain why the time is now to collaborate in this space.

11:20 Beyond Dispensing Medications: How Retail Pharmacy Is Improving Access to Clinical Trials

John Campbell, Head of Decentralized Trials, Walgreens Co.

Bringing clinical research into nontraditional sites like community pharmacies has improved, among many other things, clinical trial conduct through expanded collaboration with trusted care partners like pharmacists. As the pharmacy profession continues to evolve, hear from a Walgreens pharmacist supporting clinical research and a site manager on their experiences bringing this novel approach to clinical trials to community pharmacies.

11:35 Rethinking Pharma Research in a Changing Landscape: How DCT and Hybrid Models + Dynamic Blended Data Can Reduce Cost and Improve Access

Adam Mariano, President and General Manager, LexisNexis Risk Solutions
Damion Nero, PhD, Global Head of Statistics for HEOR/HTA, Daiichi Sankyo, Inc.

Today's complex web of intermediaries can inflate drug costs, while unrepresentative patient datasets continue to exclude diverse populations from clinical trials. These challenges make traditional models unsustainable. This session explores how direct-to-consumer and hybrid strategies—powered by community partnerships and real-world data that reflects all populations and accounts for social drivers of health—can help reduce costs, accelerate research, and expand equitable access to therapies in an evolving policy landscape.

11:55 Site and Patient Realities: New Data and What It Means for Technology's Role

Speaker to be Announced, Suvoda LLC

With the increasing complexity of clinical trials, we are seeing a heightened responsibility and burden placed on both patients and sites. In this session, we will share insights from the industry's most critical stakeholders—patients and clinical sites—shared in the 2025 CISCRP Perceptions & Insights Study and captured from Suvoda's Site Advisory Board. The consensus? There is a growing need for streamlining and flexibility. In an industry where technology can be overwhelming, we will discuss how unified solutions can bring patients and sites together—reducing workload, enabling greater visibility, and ultimately delivering a smoother clinical trial journey.

12:20 pm PANEL DISCUSSION: From Access to Outcomes: Insights on Decentralized Trials and DTP Shipments

Moderator: Joan Chambers, Senior Consultant, Tufts Center for the Study of Drug Development

Decentralized clinical trial solutions, including remote and virtual approaches, have been available for more than 15 years, with adoption peaking during COVID-19. In this presentation, empirical insights and data will be shared showing that patients and sites are highly receptive to direct-to-patient shipment of investigational treatments. The session will also highlight how the flexibility, access, and convenience of DCT solutions can improve patient recruitment, retention, and overall clinical-trial performance.

Panelists:

Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Shelly Barnes, Global Clinical Innovations and Digital Lead, UCB
Sandeep Bhat, Digital Engagement and Implementation Lead, and Imaging Scientist, Clinical Operations Platforms and Innovation, R&D, Global Clinical Operations, GSK
Maria P Ladd, Co-Founder, Clinical Research Site Collective

12:45 Presentation to be Announced

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

NEXT-GENERATION TRIAL MODELS: THE NOVARTIS STORY

3:00 Chairperson's Remarks

Jeff Huntsman, Chief Commercial Officer, EmVenio

3:05 Evolving Clinical Trial Teams for High Performance with a Center of Excellence

Carrie BenSaid, Head, Clinical Trial Team Center of Excellence, Novartis Pharma AG

Clinical Trial Teams (CTTs) drive fast, high-quality, patient-centric research. A CTT Center of Excellence (CoE) empowers global teams through innovation, operational excellence, and AI-driven solutions. This scalable, cross-functional model enhances collaboration, ensures consistency, and elevates compliance and outcomes across programs—transforming clinical delivery through science and synergy.

3:25 Precision Operational Excellence by Trial Type: Elevating Clinical Execution

Matthieu Ruffin, Head Study Leadership, SSO GCO Development, Novartis

Operational Excellence empowers clinical teams to upgrade, innovate, and streamline trial execution. Each trial type—Phase 3 registration, rare disease, pediatric—operates within a unique ecosystem. A precision operational model aligns strategy with execution, enhancing efficiency and data quality. This tailored approach enables scalable excellence, ensuring every trial benefits from optimized operations and accelerated outcomes.

3:40 Scaling Patient- and Site-Centered Operational Innovations: The Novartis Operating Model for Sustainable Success

Scott Askin, Portfolio Innovation Director, Program Strategy & Planning, Global Clinical Operations, Novartis Pharma AG

Heidi Pereira, Vendor Program Strategy Director, Novartis

How does a novel operational innovation become a model application? This session explores how Novartis's Clinical Operations Innovation and Vendor Partnership teams drive scalable innovation in clinical trials. Hear how a structured operating model and cross-functional collaboration align innovations with business needs and transition pilots into routine practice. We'll also share how we assess the innovation landscape, identify opportunities, and ensure sustainable value through effective vendor engagement and governance.

MASTERING ECOA AND HOME HEALTH SERVICES

3:55 The Scientific Risks of Commoditizing eCOA

Melissa Mooney, Director, Patient Solutions Engineering, Solution Engineering, IQVIA

Lindsay Hughes, Principal, Patient Centered Solutions, IQVIA

As eCOA adoption grows, scalable off-the-shelf solutions risk eroding scientific rigor. In this presentation, IQVIA experts Lindsay Hughes and Melissa Mooney will explore how commoditization threatens eCOA's foundational principles and how to preserve integrity. Topics explored include: The behavioral science roots of eCOA, the impact of rapid tech growth, risks of misaligned implementations, and strategies to bridge science and technology.

4:20 ET at Home: Light Years from the Clinic—Designing Decentralized Trials That Meet Patients Where They Are

Jeff Huntsman, Chief Commercial Officer, EmVenio

Megan Sniecinski, Chief Business Officer, Praxis Precision Medicines

Join us for a deep dive into the design and execution of a fully decentralized Phase 3 trial for Ulixacaltamide, an investigational therapy for essential tremor. This session will explore how Praxis Precision Medicines leveraged patient-centric solutions to support trial participation entirely from home. This case study illustrates how decentralized trial models can drive both operational efficiency and meaningful patient impact. The discussion will highlight trial-design considerations, engagement strategies, and operational learnings, with broader relevance for community-based approaches in neurology research.

ACCELERATING CLINICAL TRIALS THROUGH INDUSTRY ALIGNMENT

4:45 PANEL DISCUSSION: Transforming Protocol Digitalization to Streamline Clinical Trials

Moderator: Viral Vyas, Director, IT, Global Clinical Development, Bristol Myers Squibb

Industry alignment is fundamental to innovation and change. Regeneron, BMS, IQVIA and Nurocor have come together to demonstrate how we can do more together for utilizing protocol and SOE digitization to dramatically streamline clinical trial setup process and increase quality. Together, we are transforming protocol digitization creating a centralized source of truth for the sample journey that eliminates manual data-entry, automates lab setup and reduces sample reconciliation for clinical trials.

Panelists:

Jolene Hill, Vice President, Solutions Consulting, Nurocor, Inc.

Michel Tarabocchia, Director, Precision Medicine Operations, Clinical Genetic Medicines and Experimental Sciences, Regeneron Pharmaceuticals, Inc.

Alexander Watt, Vice President, Head, Global Client Partnerships, IQVIA

5:10 Presentation to be Announced

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

NEXT-GENERATION PARTNERSHIPS WITH HEALTHCARE SYSTEMS AND HCPs

8:30 Chairperson's Remarks
Jeff Kozloff, Board Member: ProofPilot, VersaTrial, Lokavant, Signallamp Health

8:35 Imaging Without Friction: The Missing Link in Faster, More Accurate Trial Delivery
Patrick McNamara, Chief Commercial Officer, Yunu Inc
Clinical trial imaging is a main source of operational frustration - creating delays, deviations, and rework. Drawing on real-world data, this session examines key failure points in trial imaging and their measurable impact on trial outcomes. Patrick McNamara, COO of Yunu, discusses how standardization, real-time oversight, and earlier quality intervention have reduced repeat imaging, shortened cycle times, improved data accuracy, and accelerated trial delivery while reducing operational burden.

8:48 Sponsored Presentation *(Opportunity Available)*

9:00 Local Roots, Global Reach: Redefining Decentralized Clinical Research in APAC through the Local Care Model
Rachel Soon, Director, Janssen Clinical Innovation
DCT has largely been shaped by Western healthcare systems—but what does decentralization look like in a region as diverse and infrastructure-variable as Asia-Pacific? In partnership with Clinical Research Malaysia, we co-developed a framework that integrates local clinics, labs, and community providers into the research pathway. This model holds promise for transforming access to research in emerging markets and advancing global health equity.

9:10 PANEL DISCUSSION: Oncology Trials in the Community: The Rise of a Decentralized Ecosystem
Moderator: Dawn Sauro, President, DS Clinical Consulting
The future of oncology research is being reshaped from the ground up. Once centered in academic medical centers, oncology trials are moving into community settings, driven by the need for broader access, greater diversity, and patient-centric care. This panel explores the ecosystem forming around community-based oncology research—including the roles of trial networks, navigators, pharma, and health systems—and how each contributes to expanding access without compromising quality.
Panelists:
Philip Butera, Regional Assistant Vice President, Clinical Trials, Wake Forest Baptist Comprehensive Cancer Center, Atrium Health
Renee Smith, Head, Early Development Oncology Capabilities & Alliances, Johnson & Johnson
Kent Thoelke, CEO, Paradigm Health, Inc.

9:30 PANEL DISCUSSION: From Matching to Business Models: Redefining Provider Engagement in Clinical Research
Moderator: Antonios Clapsis, Aspen Institute
By examining novel frameworks and innovative engagement paradigms, we will highlight how strategic partnerships and aligned incentives can enhance participation, streamline processes, and accelerate the delivery of clinical trials. Attendees will gain insights into practical methodologies for shifting from transactional provider matching to sustainable, value-driven collaborations that underpin the future of clinical research.
Panelists:
Mimi Fenton, CEO, Cedar Health Research
Tim Joy, Global Development Transformation, Amgen
Gregory Licholai, Chief Strategy Officer, Syneos
Matt Ullum, Lifepoint

9:50 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*
Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

NEXT-GENERATION PARTNERSHIPS WITH HEALTHCARE SYSTEMS AND HCPs (CONT.)

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 Presentation to be Announced

11:40 PANEL DISCUSSION: Expanding Research Participation through Local HCPs: Perceptions and Initial Strategies
Moderator: Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
This session will share HCP perceptions about participating in clinical research as non-investigators. We will address the challenges and opportunities for HCPs to participate in clinical trials, aligned to the FDA guidance on decentralized clinical trials (DCTs) as well as point-of-care trials. We will share some initial strategies to include HCPs in trial conduct.
Panelists:
Shelly Barnes, Global Clinical Innovations and Digital Lead, UCB
Erica Jacobsen, Senior Director, Qualitative Team Lead, Konovo
Rebecca Kottschade, Administrator, Research Operations, Mayo Clinic
Brittany Niland, Senior Director, CTF Community Based Research, Eli Lilly & Co.

12:05 pm PANEL DISCUSSION: Where Roads Are Long and Access Is Limited: Rural Connections to Research in Action, Expanding Clinical Research Participation through Partnerships, Rural Infrastructure, and Decentralized Solutions
Moderator: Dixie D. Thompson, Director, Research & Science, University of Utah CTSI & the Trial Innovation Network, Vanderbilt
Rural Connections to Research (Utah RCR) has established a six-state phlebotomy network of contracted sites and ready access to virtual engagement tools. SCOPE attendees will discover how trust, tailored access to rural community health infrastructure, and technology can enhance rural representation in clinical trials. A panel of RCR partners will share real-world lessons, scalable strategies, and tools that enable study teams and partners to bring research closer to home.
Panelists:
Elizabeth Dam, PhD, Clinical Trial Liaison, West, AstraZeneca
Jake Krong, Research Director, Canyons and Desert Regions, Office of Research, Intermountain Health
Stacey Peterson, Research Manager, Clinical & Translational Science Institute, University of Utah

12:30 Sponsored Presentation *(Opportunity Available)*

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

ECLINICAL EVOLUTION

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Overview of Empirical Evidence Measuring Investigative Site Usage and Experience with DCT Components

Roula Krayem, MS, Senior Research Analyst, Tufts Center for the Study of Drug Development (CSDD), Tufts University

The Tufts CSDD team has compiled recently published empirical evidence on investigative site use and experience with decentralized clinical-trial components including their impact on clinical-trial cycle times and enrollment performance. Quantitative data has been gathered and aggregated across several primary areas including technology adoption, workforce changes, IT infrastructure, and patient and staff satisfaction. This session will review evidence across these domains and summarize key takeaways and their implications.

8:50 Assessing Investigative-Site Experiences and Perceptions of the Use of Digital Tools

Ruby Madison Ford, MPH, Research Analyst, Tufts Center for Study Drug Development

This study examines the value of decentralized clinical trial (DCT) and digital solutions across global investigative sites. Findings show sites are independently investing in DCTs, signaling a need for sponsors to adapt partnership strategies. The research assesses current and emerging solutions for their ability to deliver richer insights, faster data access, improved patient participation, system integration, and enhanced data quality and integrity.

9:00 The DHT Tubestop: Creating a Playbook to Optimize DHT Use in Trials

Moulik Shah, Senior Vice President, Product, Data, and PMO Lead, Advanced Clinical
Lauren Tobe, Director, Regulatory Policy and Strategy, Eli Lilly

This initiative team developed a comprehensive digital toolkit (DHT Tubestop) that streamlines the integration and implementation of digital health technologies in clinical trials, enabling optimized trial design, improved data-collection modalities, enhanced patient engagement, and more efficient trial operations while ensuring compliance with regulatory requirements and data-security standards.

9:25 AI Agent-Driven Approach to Informed Consent

Aparna Swaminathan, MD, Assistant Professor, Medicine, Duke University

Current methods for informed consent are inadequate, requiring substantial staff availability and using lengthy, non-informative documents, leading to poor understanding and engagement. Advances in technology, particularly generative AI, can drive the transformation of consent processes. We have developed and evaluated an AI-agent-driven consent process for informed consent, which has the potential to enhance transparency, understanding, and accessibility to clinical trials.

9:50 Beyond the Data Silo: Paving the Way for Future Digital Health Foundation Models with Scalable Cloud Infrastructure

Bahador Marzban, PhD, Senior Digital Health Data Engineer, Innovative Medicine R&D, Johnson & Johnson

We present a pipeline that converts population-scale biosensor-based actigraphy and PPG data into training datasets for multimodal digital health foundation models. We implement a two-stage design: preprocessing and chunking the time series into binned window sizes using scalable EKS clusters, followed by distributed multi-GPU transformer training with a GPU-aware DataLoader and a time-series database to reduce I/O contention, sustain higher GPU utilization, and enable fast metadata-driven retrieval across multi-terabyte storage.

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

IN-PERSON ONLY WORKING GROUPS: Bringing Digital Health Measures to Life in Clinical Development

Kai Langel, CEO, DEEP Measures

Dive into the full journey of integrating digital health measures into clinical programs through immersive storytelling, gamified panels, and live audience participation. Gain practical insights from industry experts, engage in decision-driven simulations, and collaborate in a dynamic, hands-on environment. Whether you're a strategist or innovator, this session offers a fun, educational experience packed with actionable knowledge.

11:00 Networking Coffee Break

Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

DIGITAL INNOVATION IN TRIALS AND BEYOND

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 PANEL DISCUSSION: The Past as Prologue: What AI Innovators of Today Can Learn from DHT Innovators of the Past

Moderator: Rachel Chasse, Associate Director, Digital Science, AbbVie

Today's hottest innovation topic is AI, which the field is working hard to understand and build safe and effective solutions. It wasn't too long ago when the hottest innovation trend was DHTs and some innovators may be feeling a sense of déjà vu. In this session, we will share lessons learned for the 'new' field of AI from the 'less new' field of DHTs.

Panelists:
Brinnae Bent, PhD, Faculty Director, Duke TRUST Lab, Duke University
Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Jie Shen, PhD, Research Fellow, Digital Science, AbbVie, Inc.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Digital Accessibility in Pharma & Healthcare

Moderator: Stephen Framil, Corporate Global Head Accessibility, Office of Corporate Accessibility, Merck & Co., Inc.

This panel explores how digital biomarkers and technologies in trials should be designed for real-world use, ensuring they can be seamlessly integrated into everyday patient care beyond the research setting. Emphasizing practicality and scalability, it highlights the importance of lasting digital solutions in healthcare.

Panelists:
Andy Burstein, CEO, AccessiblePharmacy
Monica Goel, Founder, Unified Accessibility

12:50 **Transition to Lunch**

12:55 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 **SCOPE Summit 2026 Adjourns**

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 **POST-CONFERENCE TRAINING SEMINARS***

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

DIGITAL MEASURES IN CLINICAL TRIALS

Cambridge Healthtech Institute's 9th Annual

Digital Endpoints and Biomarkers

Integrating Digital Measures and Biomarkers into Trial Protocols and Regulatory Pathways

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 15th Annual

Digital Measures across Studies and Labels

Scaling Digital Assessments for Cross-Trial Utility and Drug Labeling

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

SCALING DIGITAL INNOVATION

11:00 Chairperson's Remarks

Nikki Dardes, Senior Vice President, Global Partnerships, Sales & Marketing, YPrime

11:05 Scaling Innovation across the Enterprise: AbbVie's DHT Task Force

Rachel Chasse, Associate Director, Digital Science, AbbVie
Katie Chowdhury, Global Head, Digital Health Technology Devices and Specialty Products, Regulatory Affairs, AbbVie

AbbVie set the ambitious task to simultaneously integrate DHT processes into existing policies. Learn how AbbVie's DHT Task Force developed unified processes to scale innovation across the enterprise.

11:30 Driving Innovation: Integrating AI into Merck's Clinical Digital Strategy

Mei Hong, Director, Business and Information Architecture, Merck Research Laboratories, Merck & Co.

AI technologies are advancing at an unprecedented pace. To fully harness their potential in clinical development, we are implementing a holistic digital strategy that seamlessly integrates generative AI and machine learning into the end-to-end clinical trial data flow. This unified clinical platform enhances operational efficiency, reduces manual intervention, and speeds up data-driven decision-making, unlocking significant business value in the complex, highly regulated clinical-development landscape.

11:55 TrialLens: Democratizing Clinical Trial Data through AI-Powered Analytics and Natural Language Querying

Mike Kantartjis, Senior Applied AI Scientist, Outcome Science, Clinical Ink

Clinical trial data silos create inefficiencies: lengthy dashboard builds, change orders, user retraining, and fragmented insights. TrialLens solves this by unifying connected devices, operational data, and eSource into one AI-powered platform. Whether you're a PI checking patient compliance, a Site Monitor identifying training gaps, or a Sponsor tracking financials, TrialLens meets users where they are. Built on Amazon Q, it enables conversational analytics—ask a question, refine it, drill deeper—with context that persists across queries.

12:20 pm Continuous AI-Enabled Cough Monitoring: Turning Everyday Symptoms into Objective Clinical-Trial Evidence

Julia Gómez Camblor, Senior Product Manager, AI & Digital Health, Computational Sciences Center of Excellence (CS-CoE), Genentech, Inc.

This talk will share Genentech's first end-to-end experience operationalizing a digital cough endpoint in an interventional clinical trial. We will share results from a Phase 2a chronic-cough trial (NCT05660850) that deployed a novel AI-enabled cough monitor alongside the current gold standard. We will present key scientific and operational learnings from continuous, 24/7 monitoring over weeks compared to the traditional single-day snapshots.

12:45 Presentation to be Announced

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

DIGITAL MEASURES IN VARIOUS TAs: ONCOLOGY, NEUROSCIENCE, GI, DERMATOLOGY

3:00 Chairperson's Remarks

Jason Attanucci, Chief Commercial Officer, Life Sciences, Image Analysis Group

3:05 Continuous Wearable Sensing for Bowel Movements

Shuai Steve Xu, Assistant Professor of Dermatology & Medical Director, Querrey Simpson Institute for Bioelectronics, Northwestern Memorial Hospital

In this presentation, we will discuss advances in wearable monitoring for bowel movements and bowel habits. This area is relevant as digital endpoints for GI conditions such as inflammatory bowel disease.

3:17 At-Home Evaluation of DHTs for Measuring Nocturnal Scratching in Atopic Dermatitis

Stefan Avey, PhD, Senior Principal Scientist, Data Science & Digital Health, Johnson & Johnson

This presentation will showcase the analytical validation of two DHTs: the GENEActiv wrist band with Philips sleep-and-scratch algorithms and the Emerald radio-frequency touchless sensor to measure nocturnal scratching in adults with AD.

3:30 PANEL DISCUSSION: Digital Surveillance of Toxicity in Oncology Trials: Remote Toxicity and Function Tracking

Moderator: Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)

Performance status and treatment-related toxicity are cornerstone endpoints in oncology trials, yet traditional assessments rely on intermittent, subjective site reporting. This session explains how wearable sensors and activity trackers are used to derive real-time, objective proxies for performance status alongside digital capture of toxicity through ePROs. Discover how to leverage wearable and remote reporting data to support safety-signal detection, reduce site burden, and align with regulatory expectations.

Panelists:

F. Isik Karahanoglu, PhD, Director, Quantitative Sciences, Digital Sciences & Translational Imaging, Pfizer Inc.

Joanna Kemp, Senior Director, Digital Health Strategy Lead, Oncology, GSK

Mark Matson, Managing Partner, Patient Cloud, Medidata

Jay Trudeau, PhD, Senior Director, Clinical Outcome Assessment (COA) Scientist, Eli Lilly & Co.

3:55 Breaking Localization Barriers for a Faster Global Go-Live

Jonathan Norman, Director, Localization & Scale Management, Linguistic Validation & eCOA SME, YPrime

Launching a clinical trial globally requires navigating complex localization and regulatory requirements, often leading to delays that limit patient access in key regions. In this session, Jonathan Norman, Director, Localization & Scale Management at YPrime will share new strategies to enable a faster, higher-quality global go-live by combining process optimization with AI-assisted localization. He'll highlight a case study where a sponsor added an Indic language mid-study and went live on the same timeline as major European markets—reducing what is typically weeks of work to days, or less. Discover actionable insights to increase inclusivity in multinational study launches, through AI innovations in eCOA deployments.

4:20 Presentation to be Announced

4:45 PANEL DISCUSSION: Bridging the Measurement Gap: Standardizing Objective Digital Measures in Mental Health

Moderator: Erin Walsh, Associate Director, Digital Science Strategy, AbbVie

One in eight people globally lives with a mental health disorder, yet progress in treatment and care remains slow. The development of standardized, sensor-based digital measures provides a powerful opportunity to bring objectivity, scalability, and patient relevance. By focusing on cross-cutting symptoms, a core set of digital measures can unify assessment across conditions, reduce trial failure, accelerate R&D innovation, and reshape trials from high-risk endeavors to high-impact opportunities.

Panelists:

Sean Mitchell, Director Clinical Development, Neurocrine Biosciences Inc.

Javi Oyarzun, PhD, Digital Biomarker Innovation Clinical Lead, Sanofi

Shuai Steve Xu, Assistant Professor of Dermatology & Medical Director, Querrey Simpson Institute for Bioelectronics, Northwestern Memorial Hospital

5:10 Sponsored Presentation *(Opportunity Available)*

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

AI AND DATA FLOW INNOVATION TO ADVANCE DHT IN CLINICAL TRIALS

8:30 Chairperson's Remarks

Todd Rudo, MD, Executive Vice President, CMO, Clario

8:35 Built for Trust: Responsibly Uniting Agentic and Generative AI to Optimize Data Quality and Interpretation of Clinical Outcomes Assessments

Todd Rudo, MD, Executive Vice President, CMO, Clario

Alex Boudreau, Director, AI, Clario

The crossroads of data integrity, data consistency, and accurate interpretation are ripe for the application of both agentic and generative AI. Developing and operationalize such tools requires recognition of potential risks and adherence to a responsible-use framework specifically designed for the clinical trial paradigm. A case-study-based approach will be taken, with real-world examples, demonstrating how novel applications of AI can enhance clinical outcomes assessments, delivering results sponsors and regulators can trust.

9:00 PANEL DISCUSSION: AI-Powered Digital Measures for Clinical Trials

Moderator: Marissa Dockendorf, Executive Director, Head of Digital Clinical Measures, Merck & Co., Inc.

Panelists:

Stefan Avey, PhD, Senior Principal Scientist, Data Science & Digital Health, Johnson & Johnson

Julia Gómez Camblor, Senior Product Manager, AI & Digital Health, Computational Sciences Center of Excellence (CS-CoE), Genentech, Inc.

Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.

9:25 Operationalizing a Generalizable App Platform to Streamline Data Collection Across Clinical Trial Phases

Venky Iyer, Director, Data Strategy & Enablement, Pfizer Inc.

Sheraz Khan, PhD, Director, Operational AI & Data Sciences, Pfizer Inc.

The integration of Digital Health Technologies (DHTs), including mobile and wearable sensors, enables the collection of rich, real-world data in clinical trials. To address operational inefficiencies, we have strategically pivoted to a unified, Generalizable Application Platform. This presentation details the development and operationalization of this platform, designed to streamline the acquisition of

diverse datasets, such as Patient-Reported Outcomes (PROs), voice recordings, and inertial sensor data, within a single infrastructure.

9:50 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

DIGITAL-ENDPOINT SELECTION ACROSS VARIOUS STUDIES & TAs

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 From Tool to Teammate—Unlocking the Power of AI Agents

Andrew Mackinnon, Executive General Manager, Customer Value, Medable, Inc.

We'll cover three main objectives in this talk: Unlock Innovation: Discover how to overcome the initial hurdle of implementing AI, using intelligent agents to unlock new levels of efficiency and innovation in clinical development; Supercharge Your Team: Learn how to augment human effort and automate routine tasks with intelligent agents, enabling your teams to focus on high-value activities where their expertise is needed most; Explore Practical Use Cases: Gain a clear understanding of low-risk, high-impact scenarios for intelligent agents, with actionable examples including protocol automation, translations, and site monitoring.

11:40 Endpoint Selection in Mobility and Activity: Statistical Sensitivity and Patient Relevance

Jay Trudeau, PhD, Senior Director, Clinical Outcome Assessment (COA) Scientist, Eli Lilly & Co.

This talk examines the process of selecting endpoints for mobility and activity in clinical studies. It emphasizes balancing statistical sensitivity with patient relevance to ensure meaningful outcomes.

12:05 pm Validating a Novel Digital Endpoint for Cancer Cachexia

F. Isik Karahanoglu, PhD, Director, Quantitative Sciences, Digital Sciences & Translational Imaging, Pfizer Inc.

This work explores how digital health technologies and novel digital endpoints can objectively measure physical activity and functional changes in cancer patients and cancer patients with cachexia. The findings support the use of these digital measures in clinical trials, providing more patient-centric assessments of treatment effectiveness in cancer cachexia.

12:30 Talk Title to be Announced

Christer Nilsson, CEO, Replior AB

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

ECLINICAL EVOLUTION

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Overview of Empirical Evidence Measuring Investigative Site Usage and Experience with DCT Components

Roula Krayem, MS, Senior Research Analyst, Tufts Center for the Study of Drug Development (CSDD), Tufts University

The Tufts CSDD team has compiled recently published empirical evidence on investigative site use and experience with decentralized clinical-trial components including their impact on clinical-trial cycle times and enrollment performance. Quantitative data has been gathered and aggregated across several primary areas including technology adoption, workforce changes, IT infrastructure, and patient and staff satisfaction. This session will review evidence across these domains and summarize key takeaways and their implications.

8:50 Assessing Investigative-Site Experiences and Perceptions of the Use of Digital Tools

Ruby Madison Ford, MPH, Research Analyst, Tufts Center for Study Drug Development

This study examines the value of decentralized clinical trial (DCT) and digital solutions across global investigative sites. Findings show sites are independently investing in DCTs, signaling a need for sponsors to adapt partnership strategies. The research assesses current and emerging solutions for their ability to deliver richer insights, faster data access, improved patient participation, system integration, and enhanced data quality and integrity.

9:00 The DHT Tubestop: Creating a Playbook to Optimize DHT Use in Trials

Moulik Shah, Senior Vice President, Product, Data, and PMO Lead, Advanced Clinical
Lauren Tobe, Director, Regulatory Policy and Strategy, Eli Lilly

This initiative team developed a comprehensive digital toolkit (DHT Tubestop) that streamlines the integration and implementation of digital health technologies in clinical trials, enabling optimized trial design, improved data-collection modalities, enhanced patient engagement, and more efficient trial operations while ensuring compliance with regulatory requirements and data-security standards.

9:25 AI Agent-Driven Approach to Informed Consent

Aparna Swaminathan, MD, Assistant Professor, Medicine, Duke University

Current methods for informed consent are inadequate, requiring substantial staff availability and using lengthy, non-informative documents, leading to poor understanding and engagement. Advances in technology, particularly generative AI, can drive the transformation of consent processes. We have developed and evaluated an AI-agent-driven consent process for informed consent, which has the potential to enhance transparency, understanding, and accessibility to clinical trials.

9:50 Beyond the Data Silo: Paving the Way for Future Digital Health Foundation Models with Scalable Cloud Infrastructure

Bahador Marzban, PhD, Senior Digital Health Data Engineer, Innovative Medicine R&D, Johnson & Johnson

We present a pipeline that converts population-scale biosensor-based actigraphy and PPG data into training datasets for multimodal digital health foundation models. We implement a two-stage design: preprocessing and chunking the time series into binned window sizes using scalable EKS clusters, followed by distributed multi-GPU transformer training with a GPU-aware DataLoader and a time-series database to reduce I/O contention, sustain higher GPU utilization, and enable fast metadata-driven retrieval across multi-terabyte storage.

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

IN-PERSON ONLY WORKING GROUPS: Bringing Digital Health Measures to Life in Clinical Development

Kai Langel, CEO, DEEP Measures

Dive into the full journey of integrating digital health measures into clinical programs through immersive storytelling, gamified panels, and live audience participation. Gain practical insights from industry experts, engage in decision-driven simulations, and collaborate in a dynamic, hands-on environment. Whether you're a strategist or innovator, this session offers a fun, educational experience packed with actionable knowledge.

11:00 Networking Coffee Break

Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

DIGITAL INNOVATION IN TRIALS AND BEYOND

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 PANEL DISCUSSION: The Past as Prologue: What AI Innovators of Today Can Learn from DHT Innovators of the Past

Moderator: Rachel Chasse, Associate Director, Digital Science, AbbVie

Today's hottest innovation topic is AI, which the field is working hard to understand and build safe and effective solutions. It wasn't too long ago when the hottest innovation trend was DHTs and some innovators may be feeling a sense of déjà vu. In this session, we will share lessons learned for the 'new' field of AI from the 'less new' field of DHTs.

Panelists:
Brinnae Bent, PhD, Faculty Director, Duke TRUST Lab, Duke University
Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Jie Shen, PhD, Research Fellow, Digital Science, AbbVie, Inc.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Digital Accessibility in Pharma & Healthcare

Moderator: Stephen Framil, Corporate Global Head Accessibility, Office of Corporate Accessibility, Merck & Co., Inc.

This panel explores how digital biomarkers and technologies in trials should be designed for real-world use, ensuring they can be seamlessly integrated into everyday patient care beyond the research setting. Emphasizing practicality and scalability, it highlights the importance of lasting digital solutions in healthcare.

Panelists:
Andy Burstein, CEO, AccessiblePharmacy
Monica Goel, Founder, Unified Accessibility

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm

TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm

TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

"I really enjoyed SCOPE over the years. I have attended four times so far. The topics are innovative and cutting edge and it is cross functional."

– Senior Director and Head of Statistical Innovation Statistical Sciences and Analytics Data and Statistical Sciences, Abbvie

Cambridge Healthtech Institute's 15th Annual

Accessing and Generating RWD

Infrastructure and Strategies to Source and Produce High-Quality RWD

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 11th Annual

Leveraging RWD for Clinical Research

Translating Real-World Data into Actionable Clinical Insights

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come…just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

RWD AND RWE IN CLINICAL TRIALS: POWERED BY AI

11:00 Chairperson's Remarks

Brett Kleger, CEO, Inspire

11:05 Fit-for-Purpose RWD

Thomas Dougherty, Real World Data Strategy Lead, Novo Nordisk

Stakeholders of RWE (including regulatory agencies, HTAs, payors, providers, patients) are increasing their expectations on the rigor we put into generating meaningful evidence from RWD. Therefore, we need to increase our efforts around demonstrating the data we select are truly fit for the "purposes" of the evidence we are generating.

11:25 Emerging Themes in the Use of AI/ML in Causal Inference Based on RWD

Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.

The increasing availability of RWD has broadened the applications for causal inference in biomedical research. AI and ML methods are increasingly adopted in these areas. Current research topics include deep learning and ensemble methods for confounding adjustment; combining heterogeneous RWD sources; developing interpretable ML techniques for causal analysis; and using AI-driven simulations to evaluate causal assumptions. The presentation will examine multidisciplinary collaboration among industry, academia, and regulatory agencies.

11:40 Modernizing Clinical Development with AI and Real-World Data: From Proof of Concept to Scaled Impact

Sidharth (Sid) Jain, Senior Vice President, Clinical Development & Data Science, Recursion

The conversation on AI in clinical trials has moved beyond "what's possible" to "what's working and what's scalable." Drawing from real-world experience deploying AI in trial design, site selection, and patient-cohort optimization, this session will highlight practical lessons learned—from overcoming regulatory and organizational hurdles to building the right cross-functional teams—and what it takes to move from isolated pilots to meaningful adoption across clinical development.

11:55 Efficient, Effective, Effortless

Ria Westergaard, Head of Product Strategy and Innovation, Clinical Trial and RWE Solutions, Evernorth Health Services

Evernorth Health Services presents a case study on improving clinical trial recruitment using real-world evidence and its integrated solutions. By identifying the right patients for the right trial, Evernorth achieved higher recruitment rates and accelerated timelines. This session highlights how data-driven insights and strategic tools can optimize trial efficiency and patient targeting, offering valuable lessons for sponsors and clinical operations leaders.

12:20 pm PANEL DISCUSSION: The Use of Real-World Data and Evidence in Clinical Trials: Industry Use Cases

Moderator: Mary Jo Lamberti, PhD, Director and Research Associate Professor, Tufts Center for the Study of Drug Development (CSDD)

Tufts CSDD and sponsors will discuss the adoption of RWE in trials across therapeutic areas based on use cases. Areas addressed will include sources of data and applications, as well as foci of clinical-trial activities for usage of RWD/RWE. In addition, key approaches that are being leveraged across pharma companies, organizational resources available to support RWD/RWE initiatives, and challenges and opportunities will be discussed.

Panelists:

Alex Asiimwe, PhD, Head of Evidence Generation, Innovation and Partnerships, Gilead Sciences
Emily Carter, Director, Trial Execution Data Science & Analytics, Data Science & Statistics, AbbVie, Inc.
Ashley Daigneau, Head of Clinical Trials, Commercial, Verana Health

12:45 Presentation to be Announced

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

AI-POWERED RWD ADVANCES (CONT.)

3:00 Chairperson's Remarks

Nicole Keidel, Senior Advisor, Growth & Strategic Partnerships, Intelligence Solutions, Evernorth Health Services

3:05 Implementing AI to Accelerate the Next Era of RWD/RWE

Aaron W. Kamauu, MD, MS, MPH, CEO, Navidence LLC
Vladimir Turzhitsky, PhD, Director, Data Science and Outcomes Research, Merck & Co.
Real-world data is vast and expanding, but fragmented. By applying AI techniques, we can bridge gaps, reduce complexity, and create actionable real-world evidence more efficiently. Drawing on a pharmaceutical RWD/RWE program, this talk covers implementation of AI tools across key workflows: programming assistants (SQL, R/SAS/Python), protocol and report authoring, and systematic literature review. The session also describes the design of fit-for-purpose knowledge bases to ground LLMs in organizational standards.

MEANINGFUL PARTNERSHIPS WITH RWD-OWNING ORGANIZATIONS

3:25 The Future of Clinical Research: Innovative Study Designs through Pharma-Provider Partnerships by Integrating Real-World Data (RWD) Collection in Randomized Clinical Trials (RCTs)

Chris Blanchette, PhD, Vice President, Clinical Data Science and Evidence, NNI, Novo Nordisk AS
Novo Nordisk is building cross-country collaborations with healthcare providers to maximize the value of real-world data. This session will highlight case studies from the US, UK, Denmark, and Sweden, showing how Pharma–HCP partnerships advance evidence generation, enable broader patient insights, and address practical challenges in governance, data access, and alignment, delivering scalable models for global research.

3:40 Stronger Together: Pharma-Healthcare Provider Collaborations Advancing Vaccine Research and Protecting Vulnerable Populations

Sylvia M. Taylor, PhD, Executive Director, Head, Real-World Evidence & Health Outcomes, Vaccines, GSK
GSK has developed innovative collaborations with healthcare providers in the US and UK to unlock the value of real-world data. This session will share case studies demonstrating how Pharma–HCP partnerships enhance evidence generation, streamline data access, and address key challenges—highlighting lessons learned, mutual benefits, and emerging solutions for advancing research beyond traditional trials.

3:55 Presentation to be Announced

4:20 Talk Title to be Announced

Brett Huselton, Senior Vice President, Partnership, Innovation & Strategic Solutions, Marketing, UBC

4:45 PANEL DISCUSSION: Advancing Clinical Research through Pharma–Healthcare Provider Collaborations: RWD + RCT Innovations for Better Evidence

Moderator: Aaron W. Kamauu, MD, MS, MPH, CEO, Navidence LLC
As life science companies increase their use of real-world data, access to RWD has also increased in both quantity and complexity. Healthcare provider systems manage a robust source of RWD via their electronic health records and practice management systems. This session will share examples of real studies where Pharma–HCP collaborations were essential for effective evidence generation.
Panelists:
Chris Blanchette, PhD, Vice President, Clinical Data Science and Evidence, NNI, Novo Nordisk AS
Richard Nelson, Professor, Department of Internal Medicine, Co-Director, Health Economics Core, Clinical and Translational Science Institute, University of Utah
Sylvia M. Taylor, PhD, Executive Director, Head, Real-World Evidence & Health Outcomes, Vaccines, GSK

5:10 Bridging Real-World Evidence Gaps: The Role of Literature-Derived RWE in Rare or Complex Indications

Mark Kiel, PhD, Co-Founder & CSO, Science, Genomenon
The biomedical literature reflects decades of global clinical practice and millions of patient records, with deep characterization of demographics, clinical features, biomarkers, and genetics. Especially for rare or complex indications, where traditional sources of RWE may lack coverage or sufficient detail, this evidence can fill critical gaps. We reveal how literature-derived RWE can complement other sources and optimize natural history studies, trial design, and label expansion strategies.

5:23 Presentation to be Announced

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell
Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health
Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health
As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.
Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

STRIVING TOWARDS REGULATORY-GRADE RWD

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Presentation to be Announced

9:00 Redefining Research: Real-World Evidence at the Pharmacy Counter

Scott Chavers, PhD, Senior Director, Epidemiology, Real-World Evidence Clinical Trials, Walgreens Co.
Krisha Patel, MPH, Lead Epidemiologist, RWE Clinical Trials, Walgreens
As patients seek deeper engagement with healthcare, RWE is reshaping how data informs drug development and patient experience. Since June 2022, Walgreens Clinical Trials has led innovation by using pharmacy-rooted registries to drive evidence generation and patient recruitment. This has enabled solutions like in-pharmacy biospecimen collection and helped address key research challenges through its extensive pharmacy network.

9:25 From Tabletop to Trial: Collaborative Solutions for Real-World Pragmatic Studies

Meghana Chalasani, Associate Director for Clinical Trial Innovation, Office of New Drugs, FDA CDER

Zhanna Jumadilova, MD, Biopharmaceutical Physician Executive, Pragmatic Clinical Trials, R&D, Pfizer
Stacy Tegan, Program Director, TransCelerate Biopharma, Inc.
The use of pragmatic elements in clinical trials has been a popular topic of conversation, but also a source of great hesitation. While these options create opportunities, they also present challenges around sponsor oversight and selective safety data reporting. To address these challenges, TransCelerate, in collaboration with FDA's CDER Center for Clinical Trial Innovation, conducted tabletop exercises to test trial designs under real-world conditions.

9:50 Claims Data, Patient-Reported Experiences and Data Portability can Improve Care, Chronic Conditions and Clinical Trials
Speaker to be Announced, LexisNexis Risk Solutions
Healthcare is drowning in data but starving for insights. While the potential of AI is encouraging, its impact will ultimately be limited unless we solve for data fragmentation. Join leaders from LexisNexis Risk Solutions and StuffThatWorks to discuss how data portability can unlock the true promise of AI. As an example, they'll highlight how combining claims data and patient experiences can lead to smarter clinical trials that accelerate drug development, cut costs and improve outcomes.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*
Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

RWD-POWERED DECISION-MAKING

11:10 Chairperson's Remarks
Speaker to be Announced, Keiji AI

11:15 Reimagining Clinical Research with Connected RWE Data Streams
Myla Maloney, Chief Growth Officer, Premier Applied Sciences, Premier, Inc.
As clinical research rapidly evolves, the ability to link and activate real-world data has become a critical differentiator. In this session, researchers from leading health systems join Premier Applied Sciences to share how they are connecting rich patient data streams across care settings to transform trial design, execution, and outcomes research. Learn how integrated evidence infrastructures are breaking down barriers, accelerating timelines, and driving more inclusive, patient-centered research.

11:40 Innovative Approaches to Real-World Evidence/Data Proficiency through Case-Based Learning
Hayden Bosworth, PhD, Vice Chair and Professor, Population Health Science, Duke University
This session presents a proven case-based training approach to build internal capacity and literacy in real-world evidence (RWE) generation and interpretation. Using pragmatic case studies covering patient-reported outcomes, comparative effectiveness, registries, and post-marketing surveillance, this scalable model equips attendees with foundational and intermediate RWE skills. Designed for cross-functional teams, the session will foster collaboration and better decision-making using RWD across the product lifecycle.

12:00 pm The Use of Negative Controls to Inform Regulatory Decision-Making
Yun Lu, PhD, Deputy Division Director, CBER/OBPV/DABRA, FDA
Real-world evidence (RWE) has been increasingly used to answer scientific and regulatory questions. The Prescription Drug User Fee Act (PDUFA) VII for fiscal years 2023-27 mandated the U.S. Food and Drug Administration (FDA) to develop negative-control methodology to support causal inference when RWE are used for studying safety and effectiveness. In this talk, we review the current landscape and use cases of using negative controls to inform regulatory decision-making.

12:15 Negative Control for Real-World Evidence: Methods and Best Practices
Hongwei Wang, PhD, Senior Research Fellow, Medical Affairs & Health Technology Assessment Statistics, AbbVie, Inc.
Unmeasured confounding is a major threat to the validity of real-world evidence. Methods via negative control have been proposed to detect and, more importantly, adjust for unmeasured confounders. In this talk, we review the latest methodology development, including their advantages, limitations, and recommend best practices in leveraging negative control during the design and analysis of real-world studies.

12:30 Accelerating Clinical Trial Design and Execution with Complete Real-World Data
Ryan Ahern, CMO & Co-Founder, Truveta
Traditional trials are slow, costly, and face persistent recruitment challenges. This session will explore how life sciences organizations are modernizing study design and execution using Truveta's complete, daily updated, and trusted real-world data. Learn how longitudinal linkage across EHR, claims, mortality, and SDOH enables faster recruitment, smarter feasibility modeling, and long-term evidence generation to reduce trial time, cost, and complexity.

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success *{nc}*




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

RWD MEETS RCTs

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Not All Real-World Data Is Created Equal: Why Source Matters
Shawn Murphy, MD, PhD, Chief Research Information Officer, Mass General Brigham
As real-world evidence becomes central to clinical and regulatory strategies, too much reliance remains on fragmented, decontextualized data. This session will share how Academic Medical Centers (AMCs), through integrated research platforms like MGB HIRO, provide traceable, audit-ready, clinically rich data at the point of care. Attendees will learn why AMCs are essential partners in generating credible evidence—and how to unlock speed, quality, and trust across the R&D lifecycle.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 RWD Trial Calibration and ECA
Dorothee B. Bartels, PhD, Strategist, Global Real World Evidence and (Gen)AI in Healthcare
This presentation discusses the calibration of real-world data (RWD) trials and the application of External Control Arms (ECA). It highlights methods to improve trial accuracy, reduce costs, and enhance regulatory acceptance by effectively integrating RWD and ECA for robust clinical evidence.

9:37 Benchmarking Real-World Evidence for Expanding Indications
Nils Kruger, Physician Scientist, Cardiovascular Medicine, Technischen Universitat Munchen (TUM); Instructor, Pharmacoepidemiology and Pharmacoeconomics, Harvard Medical School, Brigham and Women's Hospital
RCTs provide critical evidence of the efficacy of medications but often leave questions unanswered about their effectiveness in diverse patient populations not included in trials or different outcomes. While additional trials answering these questions would be preferred, they may not be available for various reasons or will only become available with delay. In such cases, RWE can offer timely, cost-effective insights.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

ROUNDTABLE DISCUSSION: AI-Powered COA Translation: Transforming Global Clinical Trials
Joseph Im, Head of Digital Health Technolgies Operations, Regeneron Pharmaceuticals, Inc.
Discuss how AI can transform the world of COA translations.
- What are the most effective AI technologies in translations?
- AI vs. Human translator—competitive or complementary?
- What quality risks should we consider and how can we mitigate them?
- Regulatory or legal considerations
- What can we do as an industry to optimize AI translations for COA?

ROUNDTABLE DISCUSSION: AI-powered Advances in RWD
Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.

ROUNDTABLE DISCUSSION: The Use of Real-World Data and Evidence in Clinical Trials
Emily Carter, Director, Trial Execution Data Science & Analytics, Data Science & Statistics, AbbVie, Inc.

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

AI-DRIVEN ANALYTICS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Building a Transformative, AI-Driven Analytics Capability for Clinical Trial Insights
Omkar Dasari, Senior Technical Product Manager, Data & Analytics, Amgen
James Vernille, PhD, Director, Clinical Systems & Analytical Reporting, Global Development Operations, Amgen, Inc.
At Amgen, we are transforming our analytics ecosystem with AI-driven tools that enable near real-time, self-service insights for global development stakeholders. Our next-generation analytics engine features a rebuilt metrics platform, centralized data governance, and a streamlined dashboard landscape leveraging Power BI with Co-Pilot and custom AI interfaces. By implementing AI/ML bots and natural language queries, we are shifting from static reporting to a dynamic, AI-driven experience.

12:00 pm From Proven Results to Product Vision: Advancing Clinical Trial Data Exchange with IgniteData Archer
Joe Lengfellner, IgniteData
Clinical trial data exchange has long limited the pace of innovation in research. This session explores how IgniteData Archer is redefining what's possible, drawing on proven results from live trials at Memorial Sloan Kettering Cancer Center. Presented by Joe Langfellner, IgniteData's Chief Product Officer, the talk connects real-world impact to a forward-looking product vision—explaining why Archer's success led him to join IgniteData and how he and the team are shaping the future of clinical trial data exchange.

12:13 Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Transforming Clinical Data Analytics with Agentic GenAI
Moderator: Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson
This panel explores how Agentic Generative AI (GenAI) is reshaping clinical data analytics by enabling autonomous and adaptive systems that streamline data processing, uncover complex patterns, and generate actionable insights. The discussion will address the opportunities and risks of integrating Agentic and Applied GenAI into regulated clinical research environments, highlighting their potential to drive innovation while maintaining data integrity and patient safety.
Panelists:
Bhargava Reddy, PhD, Senior Director, Advanced Insights and Solutions, Janssen
Richard Young, Chief Strategy Officer, CluePoints

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* or Enjoy Lunch on Your Own

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 2nd Annual

Agentic AI in Clinical Research

Exploring Use Cases and Implementation of GenAI in Trials

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 2nd Annual

AI for Trial Optimization

Applying AI to Accelerate and Improve Clinical Development

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

AI IN CLINICAL DEVELOPMENT: DRIVING EFFICIENCIES OR ENABLING TRANSFORMATION?

11:00 Chairperson's Remarks

Speaker to be Announced, PPD Part of Thermo Fisher Scientific

11:05 PANEL DISCUSSION: AI in Clinical Development: Driving Efficiencies vs. Enabling Transformation

Moderator: Craig Serra, Executive Data Management and Clinical Systems Leader, Amgen

This panel explores the role of AI in clinical development, discussing whether AI primarily drives efficiency or enables a complete transformation. Experts examine how AI speeds up data analysis, reduces costs, and improves decision-making. The panel also considers the potential for AI to fundamentally change clinical-research practices without dropping any balls.

Panelists:
Jeanine Bortel, Vice President, Head, AI Portfolio, Development, Pfizer Inc.
Jason Raines, Vice President, Clinical Data and Insights, AstraZeneca

11:30 PANEL DISCUSSION: Fit-for-Purpose AI Applications in Clinical Trials

Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine

This panel will explore practical AI applications in clinical trials, linking each use case to measurable outcomes like time savings and ROI. Featuring an esteemed group of industry experts, the talk will combine case studies with an open discussion on implementation and impact.

Panelists:
Amy Chowansky, Senior Director, AI Strategy Lead, Pfizer Inc.
Nareen Katta, Head of Data Science & Analytics, AbbVie, Inc.
Henry Wei, MD, Executive Director, Development Innovation, Regeneron

11:55 Talk Title to be Announced

Prasanna Rao, Chief Products and Innovation Officer, Executive, Saama

12:20 pm Building a Unified Clinical Intelligence Ecosystem Using Graph (Magellan)

Bryan Feldman, Senior Director, Business Technology for Clinical Development, Regulatory Affairs, and R&D QA, AbbVie
Ankit Singh, MS, Senior AI Scientist, IR – Global Therapeutic Platforms, AbbVie, Inc.

Project Magellan is an initiative by AbbVie's BTS-IR Global Therapeutics Platform organization with potential to support a variety of AI-centric use cases in research and development by digitizing clinical documents and creating an integrated graph-based environment. Built on modern graph technology and leveraging the integrated data platform, Magellan uses Agents to extract and integrate clinical documents that enable extensive data exploration.

12:45 LUNCHEON PRESENTATION: Beyond Automation: Agentic AI and the Future of Clinical Trial Design and Execution

Speaker to be Announced, PPD Part of Thermo Fisher Scientific

We are entering the era of agentic AI—systems capable not just of analysis, but autonomous reasoning and adaptive decision-making. This session examines how agentic AI can reshape trial design, site selection, patient recruitment, and monitoring. It explores real-world pilots and governance frameworks that ensure safety, transparency, and human oversight, while unlocking efficiency and innovation.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

IMPLEMENTATION CHALLENGES AND FRAMEWORKS

3:00 Chairperson's Remarks

Siddhartha Bhattacharya, Partner & Life Sciences AI Leader, AI Pharma & Life Sciences, PwC

3:05 Building a Robust Data Foundation for AI Transformation

Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
A strong, well-structured data foundation is critical for successful AI transformation in clinical research. This talk will explore strategies for consolidating, standardizing, and governing clinical trial data to enable advanced analytics, predictive modeling, and AI-driven insights. Attendees will learn practical approaches to preparing data ecosystems that support scalable, compliant, and impactful AI applications.

3:30 AI in Clinical Development: Shaping the Regulatory Environment to Enable Transformative Innovation
Kevin Bugin, PhD, Head, Regulatory Policy and Intelligence, Amgen
Anindita Saha, Associate Director, Data Science and Artificial Intelligence Policy, FDA CDER
This session will explore how emerging AI applications in clinical development—from operational optimization to patient identification—are challenging and advancing current regulatory paradigms. Presenters will share real-world use cases, such as Amgen's ATOMIC initiative, and examine evolving regulator perspectives (including EMA and FDA) and regulatory considerations. Attendees will gain insights into strategic considerations for external engagement, regulatory policy implications, and frameworks needed to responsibly scale AI-enabled innovation in drug development.

3:55 Designing with Foresight: Turning Operational Data into Protocol Performance ADVARRA
Ian Bailey, Managing Director, AI & Data Science, Advarra
Jamie Bendrick-Peart, Sr Dir Innovation & Strategic Projects, SMM Oncology, Novartis Pharmaceuticals Corp
What if we could validate study assumptions before the first site is activated? This discussion dives into how combining AI with operational datasets enables sponsors to evaluate design hypotheses, identify amendment risks early, and optimize trial execution. Hear from industry leaders on how data-driven insights are reshaping protocol development and improving decision-making across the clinical lifecycle.

4:20 Presentation to be Announced parexel

4:45 PANEL DISCUSSION: Agentic AI: Unlocking Business Value Amid Compliance and Intellectual Property Concerns
Moderator: Syed W. Haider, PhD, Global Head, Senior Director, eClinical Business Intelligent Automation and Life Data Sciences, Merck
Agentic AI introduces significant privacy and legal concerns. Legal teams are wary of using proprietary data to train third-party AI tools. Business functions are eager to adopt AI solutions rapidly to realize their benefits. Data science teams must balance customer demands with regulatory and compliance requirements.
Panelists:
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Srivatsan Nagaraja, Founder, Vidya Seva
Angela Radcliffe, DTRA Member & Founder, How Mighty We Ventures

5:10 Presentation to be Announced CITELINE a norstella company

5:22 Rethinking Participant Adherence: What AI Can Reveal before Compliance Drops curebase
Storm Stillman, CEO, Curebase
If you care about having higher compliance in your studies, lower withdrawal, and better visibility, then this is the talk for you. One of the biggest challenges in clinical research is keeping participants engaged and ensuring that data isn't missing. Despite all of the tech out there, we know so many of you are still dealing with things like missed diary entries, late or low-quality data, lack of understanding of prioritization for risks, and endless manual follow-ups.
Storm will talk about solutions. AI can predict non-compliance before it happens and can even priority-rank the most high-risk participants for triage to manual follow-up or follow-up by AI voice agents. The talk goes through all of this and more.

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants CISCRP
Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials SUBJECTwell
Tobias Kruse, PhD, Managing Director, Europe, SubjectWell
Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment gcihealth
Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health
Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health
As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)
MODERATOR:
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.
Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

AI TO ACCELERATE CLINICAL DEVELOPMENT

8:30 Chairperson's Remarks
Jeanette Towles, President & CEO, Ops, Synterex

8:35 Presentation to be Announced CluePoints

9:00 Clinical Control Tower—A View on Melding AI Predictive Features with Operational Overview
Francis Kendall, Head of Statistical Programming, Digital and Data Sciences, Biogen
The Clinical Control Tower integrates operational oversight with AI-driven predictive insights to enhance trial management. This talk will explore how predictive features can be combined with real-time operational data to anticipate risks, optimize site performance, and support decision-making, offering a practical perspective on leveraging AI while maintaining a comprehensive view of trial operations.

9:15 Clinical Trial Compliance through Autonomous Agents
Sujan Gowda, Senior Manager, Engineering, Global Clinical Development, Bristol Myers Squibb
Shuba Simha, Senior Director, Head, Engineering & Operations, Bristol Myers Squibb Co
We developed an intelligent automation tool that transformed manual protocol assessment to autonomous assessment through agents. This application analyzes approved Protocol Amendments and compares them with ClinicalTrials.gov listing to identify the changes. The solution leverages 7 Specialized AI Agents and integrates with Authoring system, clinicaltrials.gov and Clinical Trials Registration & Results system to facilitate efficient data extraction, comparison and updates.

9:35 Transforming Clinical-Development Decision-Making with AI/ML and Clinical Statistical Modeling

Zhaoling Meng, PhD, Associate Vice President & Global Head, Clinical Modeling & Evidence Integration, Sanofi

AI/ML and clinical predictive modeling play increasingly vital roles in drug development by enabling more robust decision-making by integrating evidence from various data sources. This talk explores the transformative impact of these innovations using applications in clinical-trial planning, patient enrollment, and decision-making. By harnessing AI/ML and clinical predictive modeling, clinical development becomes more efficient, data-driven, and adaptive, ultimately enhancing the success of new therapies.

9:50 Agentic Clinical Trials in the Era of Commoditized Intelligence: A Case Study of an Agentic AI Platform Implementation across Six Clinical Trial Functions

Moulik Shah, CEO, Maxis AI
Susan Bornstein, MPH, Agentic AI Advisor, Maxis AI; Principal, SMB Consulting & Board Advisory

Summary: The commoditization of intelligence is inevitable. Organizations that strategically apply frameworks like Verifier's Law and The Jagged Edge will thrive, transforming their business model from labor arbitrage to technology-enabled strategic partnership. This case study demonstrates that by automating the verifiable and empowering human oversight for the complex, CROs can reverse the effects of Eroom's Law, achieve significant competitive differentiation, and create a future where human skills are amplified, not replaced. The key to success is not merely adopting AI but architecting a collaborative ecosystem where human and machine intelligence work in a state of productive asymmetry.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

FIT-FOR-PURPOSE SOLUTIONS

11:10 Chairperson's Remarks

Jamuna Thimmarayappa, Dir Product Mgmt, Product Mgmt, Oracle Corp

11:15 Talk Title to be Announced

Arnab Roy, Assoc Principal, R&D, ZS Associates
Rajiv Harpalani, Associate Director, BTS Dataverse, AbbVie
Sunanda Teeparti, Associate Director, Data Engineering & Analytics, AbbVie

11:40 Accelerating CRF and Edit Check Generation Using an Agentic AI Framework

Jeremy Zhang, PhD, Senior Director, Data Science, Data & Analytics, Otsuka America Pharmaceuticals, Inc.

Case report forms (CRFs) and edit checks are critical components of database build during study start. In this implementation of agentic AI frameworks, we demonstrate how generative AI can be used to significantly accelerate the creation of CRFs and edit checks and decrease study startup timelines.

11:58 AI for Enhanced Patient Matching and Community-Based Trial Monitoring and Engagement

Ramita Tandon, Chief Clinical Trials Officer, Walgreens

AI is transforming the way clinical trials are designed, conducted, and analyzed. This session will explore the various applications of AI in clinical trials and their potential to accelerate innovation in research, optimize outcomes, and reduce costs. Walgreens Clinical Trials can discuss its approach of "trust and verify" to ensure the AI results are accurate and free of bias.

12:15 pm From Manual to Intelligent: The Role of AI in Modernizing Trial Activation

Karen Hartman, Vice Chair, Research Administration, Mayo Clinic

This presentation provides an overview of artificial intelligence (AI) and its potential to transform clinical trial activation. Practical examples of AI tools currently in use will be shared, highlighting how they streamline workflows, automate routine tasks, and reduce administrative burden. We'll explore the broader implications of AI adoption, including its impact on teams, costs, and regulatory considerations.

12:30 The Next Era of eCOA: How AI Can Power Efficient, Streamlined eCOA Implementation

Paul O'Donohoe, Senior Director, eCOA Product and Science, Medidata, a Dassault Systemes Co.

With AI entering the landscape of clinical research, new opportunities are taking shape for transforming the eCOA experience for patients, sites, and sponsors. This session will share learnings from how AI is being leveraged today for smarter and more efficient end-to-end eCOA study builds, reducing the timeline to go-live, and the transformative possibilities on the horizon for technology-driven data capture.

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

DATA AND TECHNOLOGY FOUNDATION

8:30 Citizen AI: Enabling Broader Adoption of AI/ML Using Low-Cost Solutions

Randy Santiano, Associate Director, Delivery & Performance Analytics, Data & Analytics, Eli Lilly & Co.

At Eli Lilly, we implemented a structure using MS Fabric to develop, deploy, and maintain environments that allow several business units to utilize machine learning (ML) and large language model (LLM) system. This has been important to bridge the trust gap between the exponential growth of AI/ML offerings and the social adoption of new technologies.

8:30 Chairperson's Remarks

Speaker to be Announced, Todata Analytics

8:55 Leveraging AI to Automate the Clinical Trial Design and Execution

Matthew Markman, Manager, Advisory, PwC
Joe Ricks, PwC

9:20 Why Robust Standards Are Critical to Leveraging AI to Accelerate Clinical Research

Chris Decker, President & CEO, CDISC

AI has rapidly emerged as a transformative force in clinical research. However, the effectiveness and reliability of AI systems are fundamentally dependent on the quality and interoperability of the underlying data. Without unified data standards, AI applications may yield biased, irreproducible, or clinically irrelevant results. Therefore, the adoption and enforcement of rigorous data standards are pivotal for maximizing the benefits of AI and ensuring its responsible use in clinical research.

9:35 Evaluating Generative AI Output: Toward Robust Assessment with Human and Automated Methods

Rogier Landman, PhD, Associate Director, Digital Medicine Data Science, Pfizer Inc.

The rapid adoption of generative AI in clinical research necessitates rigorous evaluation to ensure outputs meet professional standards. We propose a structured framework comprising three foundational pillars: Accuracy (factual correctness, completeness, and source attribution), Quality (natural language use, writing style, consistency, and avoidance of repetition), and Reasoning (causal inference and contextual understanding). To achieve comprehensive evaluation, we advocate a combined approach leveraging both human expertise and automated measures.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation.

After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

Humans, Meet Your Co-Panelists: AI Takes the Mic in Clinical Trials

Munther H. Baara, Vice President, Product Strategy & Innovation, EDETEK, Inc.
Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

Everyone's talking about AI—but what happens when AI joins the conversation? In this first-of-its-kind format, humans share the stage with agentic AI bots trained on real-world clinical-trial roles. Alongside seasoned industry experts, they'll unpack how AI is not just accelerating decisions, but reimagining the very fabric of clinical development. Whether you leave inspired or unnerved, you won't forget this session anytime soon.

11:00 Networking Coffee Break

Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

AI-DRIVEN ANALYTICS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Building a Transformative, AI-Driven Analytics Capability for Clinical Trial Insights

Omkar Dasari, Senior Technical Product Manager, Data & Analytics, Amgen
James Vernille, PhD, Director, Clinical Systems & Analytical Reporting, Global Development Operations, Amgen, Inc.

At Amgen, we are transforming our analytics ecosystem with AI-driven tools that enable near real-time, self-service insights for global development stakeholders. Our next-generation analytics engine features a rebuilt metrics platform, centralized data governance, and a streamlined dashboard landscape leveraging Power BI with Co-Pilot and custom AI interfaces. By implementing AI/ML bots and natural language queries, we are shifting from static reporting to a dynamic, AI-driven experience.

12:00 pm From Proven Results to Product Vision: Advancing Clinical Trial Data Exchange with IgniteData Archer

Joe Lengfellner, IgniteData

Clinical trial data exchange has long limited the pace of innovation in research. This session explores how IgniteData Archer is redefining what's possible, drawing on proven results from live trials at Memorial Sloan Kettering Cancer Center. Presented by Joe Langfellner, IgniteData's Chief Product Officer, the talk connects real-world impact to a forward-looking product vision—explaining why Archer's success led him to join IgniteData and how he and the team are shaping the future of clinical trial data exchange.

12:13 Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Transforming Clinical Data Analytics with Agentic GenAI

Moderator: Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson

This panel explores how Agentic Generative AI (GenAI) is reshaping clinical data analytics by enabling autonomous and adaptive systems that streamline data processing, uncover complex patterns, and generate actionable insights. The discussion will address the opportunities and risks of integrating Agentic and Applied GenAI into regulated clinical research environments, highlighting their potential to drive innovation while maintaining data integrity and patient safety.

Panelists:
Bhargava Reddy, PhD, Senior Director, Advanced Insights and Solutions, Janssen
Richard Young, Chief Strategy Officer, CluePoints

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm

TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm

TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications

** In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 12th Annual

Risk-Based Quality Management

Navigating Risk with High-Level Strategy and Best Practices

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 12th Annual

Central Monitoring and Signal Detection

Unlocking Study Insights through Central Monitoring and Data-Driven Analytics

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

FOSTERING A QUALITY CULTURE

11:00 Chairperson's Remarks

Jonathan Rowe, Principal, ZS

11:05 Quality in the Time of AI: Elevating Quality Culture amid Technological Change

Rich Bowling, PD Quality Excellence Digital Team Lead, Genentech
Jennifer Hebert, Principal Quality Lead, Quality Assurance Programs, Roche/Genentech
Mandy White, Senior Quality Lead, Genentech

This session addresses how the integration of AI is reshaping the quality landscape for organizations seeking to leverage the latest advances to reap efficiencies in quality professionals' work. We'll explore challenges like data quality, bias, transparency, and balancing technology with human oversight, alongside validating AI outputs and preserving human judgment. Attendees will gain actionable strategies, learn how to start effectively, and navigate talent and culture questions as AI adoption expands.

11:25 Why Some Risk Assessments Work—And Others Don't

Kristin Stallcup, MS, Director, RBQM Operations, Takeda

We agree that risk assessment is foundational to the clinical trials—but let's be honest, not all risk assessments feel meaningful. Some fall flat, while others unlock the power of cross-functional insight. This PHUSE working group came together to understand why, and to share practical ways to make every risk assessment consistently effective—including how AI can help us get there.

11:40 Embedding RBQM Principles to Transform Clinical Trials: The Novartis Journey

Aurelie Dequelson, Head Risk Surveillance, Development, Novartis
Mathias Milici, PhD, Head of Central Monitoring, Novartis

At Novartis, RBQM QbD has proven its value through a successful pilot, demonstrating measurable benefits with the Risk Surveillance lead as an enabler. Central Monitoring marks the next phase of the RBQM journey. Novartis is shifting study teams' mindsets toward risk- and data-driven practices. This is the story of transformation from pilot to scale-up, with a quality mindset at the core and RBQM principles as the foundation for sustainable excellence.

11:55 Talk Title to be Announced

Vera Pomerantseva, Director, Product Management, eClinical Solutions

12:20 pm PANEL DISCUSSION: Cross-Functional RBQM: Streamlining Site Engagement and Integrated Data Review

Moderator: Shawntel Swannack, Regional Director (Americas), Analytical Monitoring, Data Management & Central Monitoring, Integrated Data Analytics & Reporting (IDAR), Johnson & Johnson

Risk-Based Quality Management is reshaping how sponsors interact with study sites, emphasizing strategic, targeted engagement that minimizes unnecessary queries. As data visualization and technology expand, cross-functional collaboration between safety, quality, and medical teams becomes essential. This panel will explore integrated data review strategies, leadership coordination, and approaches to reduce duplication while ensuring study quality.

Panelists:

Valerie Balosso, Director, Data Management, Infectious Diseases, GSK
Kristi Koontz, Vice President, Global Clinical Operations, Daiichi Sankyo US

12:45 Talk Title to be Announced

Duncan Hall, CEO & Founder, TRI

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

2:10 Special Book Signing Risk-Based Quality Management: The Ultimate Clinical Researcher's Guide Authors: Artem Andrianov (PhD), Johann Proeve (PhD)

Location: Booth #615

DIGITAL DISRUPTION AND INNOVATION IN RBQM

3:00 Chairperson's Remarks

Speaker to be Announced, Premier Research

3:05 Digital Disruption: Transforming Inspection Readiness and Quality in Clinical Trials

Kevin Richards, Senior Director, Clinical Quality, AstraZeneca

Digital transformation is revolutionizing inspection readiness in clinical trials. By implementing automated study storyboards and inspection readiness solutions for study teams, organizations can provide real-time, comprehensive overviews of trial data, ensuring consistency and transparency. This approach streamlines preparation for audits and inspections, reduces manual errors, and enables proactive quality management.

3:25 Integrating Data Science at-Scale: Lessons Learned in RBQM and Anomaly Detection for Clinical Operations

Numan Karim, MS, Associate Director, Data Science & Analytics, AbbVie, Inc.

AbbVie's in-house Risk-Based Quality Management (RBQM) platform not only brings advanced risk and anomaly-detection capabilities but also represents a significant change management initiative. Building on last year, this talk will explore how our technology streamlines risk detection and management, while scaling a complex technological solution alongside managing organizational change. Key topics include challenges, lessons learned, derived benefits, and showcasing how RBQM integrates seamlessly into our operational fabric.

3:40 Turning Signals into Strategy: Data-Driven RBQM to Optimize Monitoring at Site, Study, and Portfolio Levels

Łukasz Bojarski, Executive Director, Centralized Monitoring & Risk Based Quality Management, AstraZeneca

This presentation demonstrates how data-driven RBQM transforms oversight from reactive review to proactive, scalable risk management. Examples will illustrate how insights translate into right-sized monitoring plans, more robust signal detection, and consistent quality improvements across the portfolio and enterprise.

3:55 Presentation to be Announced

4:20 The Rise of the Central Monitor 3.0: Are You Ready?

Olgica Klindworth, Vice President, Clinical Data Studio, R&D, Medidata, Dassault Systemes

Jenn Krohn, Associate Director RBQM & Clinical Operations, RBQM & Clinical Operations, Gilead Sciences, Inc.

Sarah Gill, Senior Director, RBQM Solutions, Caidya

Swantel Swannack, Regional Director, Analytical Monitoring & Data Quality Assurance, Johnson & Johnson Innovative Medicine

What is the role of the central monitor of the future? Today they face growing challenges—fragmented data and tools, manual processes, and internal change management obstacles . This panel explores the rise of the Central Monitor 2.0 - how automation, AI, and ICH E6 R3 driven RBQM evolution is transforming centralized monitoring. Discussion includes the need for a centralized 'quality command center', better unification of monitoring as a holistic concept, and the evolving skill set for future central and onsite monitors.

4:45 PANEL DISCUSSION: From Guidelines to Game-Changer: What Will It Take to Implement RBQM with Agentic AI?

Moderator: Nechama Katan, Chief Wizard, Wicked Problem Wizards

ICH E6(R3) calls for a risk-based approach to trial oversight, ensuring that measures are proportionate to the risks and to the importance of the data collected. Agentic AI offers continuous monitoring, dynamic risk assessment, and proportionate intervention at scale. But what would it take to implement such systems? Expect a lively discussion that goes beyond hype, drawing on expertise to map a realistic path from concept to compliant, value-adding deployment.

Panelists:

Bo Maach-Moller, Vice President, Risk Based Quality Management and Central Monitoring, Novo Nordisk AS

5:10 Closing the Last-Mile Adoption Gap to Achieve Clinical Trial Excellence

Speaker to be Announced, Whatfix

Even the best-designed SOPs fall short when clinical teams struggle to use the digital systems that support trial execution. Across global studies, everyday usability challenges within Clinical Trial Management Systems (CTMS) and Electronic Trial Master File (eTMF) systems often lead to inconsistent execution, avoidable deviations, and increased monitoring burden. This session explores how to solve for the "last-mile adoption gap" and address the disconnect between documented processes and how users actually navigate complex clinical technologies hence, improving clinical quality, compliance, and operational efficiency.

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link**: https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

CROSS-FUNCTIONAL COLLABORATION

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Sponsored Presentation *(Opportunity Available)*

9:00 RBQM Leads—Orchestrating Methodology Adoption & Change Management

Danilo Branco, Associate Director, Risk Based Quality Management Lead, BeOne Medicines

Creating the cross-functional engagement required for successful RBQM adoption at study level is a known bottleneck in the process. Build rapport with study teams while adding value is critical to achieve it...and requires a specific skillset. In this presentation, let's explore the importance of the RBQM lead role in the QbD approach, meaningful risk control, and, ultimately, nutrition of a risk-based organizational culture.

9:20 Integrated Quality and Risk Management Approach—Driving Proportionality into Processes

Bo Maach-Moller, Vice President, Risk Based Quality Management and Central Monitoring, Novo Nordisk AS

How a business case for scaling up fosters interpretation and strategic implementation of GCP E6 R3 principles to redesign processes and business systems as an integrated quality and risk management approach.

9:40 Characterizing the Transition from Legacy, Onsite Monitoring to Centralized and Risk-Based Approaches

Hana Do, Research Analyst, Tufts Center for the Study of Drug Development (CSDD)

This session presents the results of a new Tufts CSDD study looking at how companies have made, or are making, the transition from traditional, high frequency onsite monitoring to centralized, remote and risk-based approaches. Qualitative and quantitative data will be reviewed showing how organizations are modifying their monitoring approaches and practices, and the impact of centralized approaches on CRA-site relationship quality and effectiveness.

9:50 From Black Box to Glass House: Observations and Lessons from the FDA's CRL Transparency on Investigators, Sites, and Sponsors

Speaker to be Announced, Sabai Global

This session examines newly released FDA Complete Response Letter data to uncover quality and operational compliance issues involving sites, investigators, and vendors. By analyzing emerging trends and common contributors to CRLs, the presentation offers practical strategies to reduce compliance risk, strengthen oversight, and improve safety, data integrity, and regulatory submissions across clinical research.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

RISK-BASED DATA MANAGEMENT AND CENTRALIZED MONITORING

11:10 Chairperson's Remarks

Johann Proeve, CSO, Cyntegrity Germany GmbH

11:15 Intelligent Technology: Fueling Human Compulsion for Quality

Clare Campbell-Cooper, Global Head, Digital Health and Innovation, Fortrea

Data quality and integrity remain non-negotiable in clinical research. While innovative technologies are advancing to enhance compliance and quality, our industry continues to rely heavily on people. The adoption of new processes and workflows often faces delays due to slow uptake. This session explores how the convergence of technology and behavioral science can drive the creation of workflows that are resilient, efficient, and future-ready. Learning objectives include discussing the challenges facing adoption of innovation by interested parties and how this is changing over time, understand fundamental concepts unpinning compliance human nature, and seeing examples of where technology insights promote quality and the desire to improve.

11:40 Applying Acceptable Ranges: QTLs for Early-Phase and Safety/Exposure-Focused Clinical Trials

Kristin Stallcup, MS, Director, RBQM Operations, Takeda
Hui Yang, PhD, Director, Statistics Team Lead, Takeda

The ICH E6(R3) concept of "acceptable ranges" broadens the use of Quality Tolerance Limits (QTLs), including for early phase studies and those with safety/exposure endpoints. But applying QTLs in these settings requires a different approach. This session shares practical tips and considerations for implementing QTLs in safety/exposure-focused, early-phase studies—and why building a consistent framework across all trials can benefit the broader portfolio.

12:00 pm New Approaches for Risk-Based Data Management and Central Monitoring in Oncology

Jacqueline Cousart, Central Monitoring Manager, Data Management Central Monitoring, Johnson & Johnson

This presentation will focus on how risk-based data management methodology has been introduced with consistency across several trials within an oncology program. Key topics of discussion will include how study teams identified critical data for endpoints early in protocol discussions, the importance of cross-functional collaboration (Central Monitoring, Data Management, Stats, Clinical, etc.), and improvements to monitoring strategies to increase efficiencies.

12:15 RBQM Insights on Asset-Level Integration

Cilla Mistry, Associate Director, RbQM & Central Monitoring, GSK

As Risk-Based Quality Management (RBQM) matures, organizations are expanding its impact beyond individual studies. This session explores how RBQM principles can be strategically integrated at the asset level to drive portfolio-wide insights, optimize oversight, and align with broader business objectives. Learn how to leverage cross-study data, enhance decision-making, and elevate quality management from a study-centric function to an enterprise-wide value driver.

12:30 Presentation to be Announced

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced propharma

8:25 Transition to Sessions

BALANCING ONSITE MONITORING WITH CENTRALIZED APPROACHES

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 PANEL DISCUSSION: Swipe Right for Quality: Good Idea or Nope?
Moderator: Leslie Sam, President, Leslie Sam & Associates LLC
In this interactive panel, vote on whether trial management and technology strategies are brilliant or broken. Through a series of "swipe right or nope" prompts, we'll explore what resonates with experienced research and quality professionals. Panelists from pharma, biotech, and tech will weigh in after each vote to unpack pros, risks, and impacts. You'll leave with a sharper sense of how to evaluate innovation for feasibility, compliance, and quality outcomes.
Panelists:
Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK
Michael Torok, PhD, Vice President, Global Head, Quality Assurance Programs, Roche

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 PANEL DISCUSSION: Maximizing Efficiency: The Delicate Dance between Central Monitoring and Onsite Activities
Moderator: Randall Holzberger, MS, Director of RBQM Risk Management, Biostatistics & Data Management, Daiichi Sankyo
According to E6 R3 Section 3.11.4, "Monitoring may include site monitoring (performed onsite and/or remotely) and centralized monitoring, depending on the monitoring strategy and the design of the clinical trial." Many companies struggle with the relationship between centralized and onsite monitoring activities. How can we as an industry increase our efficiency by balancing central/onsite monitoring activities while maintaining or increasing the overall quality?
Panelists:
Danilo Branco, Associate Director, Risk Based Quality Management Lead, BeOne Medicines
Taryn Haffner, Associate Director Clinical Operations, Genmab AS
Anne Smith, Director, Central Monitoring, Regeneron Pharmaceuticals, Inc.
Gosia Szczodrak, Associate Director, Clinical Operations, Gilead

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

IN-PERSON ONLY WORKING GROUP: From ALCOA to Action: Achieving Fit-for-Purpose, Risk-Proportionate Clinical Data Under ICH E6(R3)
Deborah A. Guattery, GCP Quality Expert, Chase The Sky For Quality LLC
Nechama Katan, Chief Wizard, Wicked Problem Wizards
According to ICH E6(R3) principles, every element of trial design, oversight, and execution can—and should—be risk-based. But making that shift is more than checking the ALCOA boxes. It's about building data systems and processes that are fit-for-purpose, so risk triggers proportional, timely, and effective responses.

In this working session, we'll explore challenges, identify capability gaps, and design practical solutions for implementing proportionate, risk-based quality management.

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

AI-DRIVEN ANALYTICS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Building a Transformative, AI-Driven Analytics Capability for Clinical Trial Insights
Omkar Dasari, Senior Technical Product Manager, Data & Analytics, Amgen
James Vernille, PhD, Director, Clinical Systems & Analytical Reporting, Global Development Operations, Amgen, Inc.
At Amgen, we are transforming our analytics ecosystem with AI-driven tools that enable near real-time, self-service insights for global development stakeholders. Our next-generation analytics engine features a rebuilt metrics platform, centralized data governance, and a streamlined dashboard landscape leveraging Power BI with Co-Pilot and custom AI interfaces. By implementing AI/ML bots and natural language queries, we are shifting from static reporting to a dynamic, AI-driven experience.

12:00 pm From Proven Results to Product Vision: Advancing Clinical Trial Data Exchange with IgniteData Archer IgniteData
Joe Lengfellner, IgniteData
Clinical trial data exchange has long limited the pace of innovation in research. This session explores how IgniteData Archer is redefining what's possible, drawing on proven results from live trials at Memorial Sloan Kettering Cancer Center. Presented by Joe Langfellner, IgniteData's Chief Product Officer, the talk connects real-world impact to a forward-looking product vision—explaining why Archer's success led him to join IgniteData and how he and the team are shaping the future of clinical trial data exchange.

12:13 Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Transforming Clinical Data Analytics with Agentic GenAI
Moderator: Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson
This panel explores how Agentic Generative AI (GenAI) is reshaping clinical data analytics by enabling autonomous and adaptive systems that streamline data processing, uncover complex patterns, and generate actionable insights. The discussion will address the opportunities and risks of integrating Agentic and Applied GenAI into regulated clinical research environments, highlighting their potential to drive innovation while maintaining data integrity and patient safety.
Panelists:
Bhargava Reddy, PhD, Senior Director, Advanced Insights and Solutions, Janssen
Richard Young, Chief Strategy Officer, CluePoints

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's Inaugural

Innovation and Operational Excellence in Drug Safety

Driving Proactive Pharmacovigilance throughout the Development Lifecycle

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's Inaugural

Central Monitoring and Signal Detection

Unlocking Study Insights through Central Monitoring and Data-Driven Analytics

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

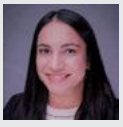
4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards





Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants (IN-PERSON ONLY)

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

THE INTERSECTION OF PHARMACOVIGILANCE, SAFETY, AND CLINOPs

11:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:05 Pharmacovigilance: Ensuring and Advancing Patient Safety through Cross-Functional Collaboration

Ankit Lodaya, Senior Director, Pharmacovigilance

The successful execution of a clinical trial relies on the expertise and collaboration of every team member involved. This session will focus on the pharmacovigilance team and its pivotal role within clinical research. We will go over how effective cross-functional collaboration contributes to monitoring and ensuring patient safety. In the latter portion, a panel discussion will feature experts from clinical research-related disciplines to share insights from their professional experiences.

11:30 PANEL DISCUSSION: Pharmacovigilance: Ensuring and Advancing Patient Safety through Cross-Functional Collaboration

Moderator: Ankit Lodaya, Senior Director, Pharmacovigilance

This panel discussion will bring together experts across clinical research functions to discuss how cross-functional collaboration strengthens patient safety. Panelists will share practical insights from their disciplines, highlight strategies for integrated safety oversight, and explore how collaborative approaches enhance the quality and success of clinical trials.

Panelists:
Niki Witthuhn, Senior Director, Pharmacovigilance Operations, bluebird bio
Laura Rossetti, Director, Clinical Operations, Taysha Gene Therapies
Sanjeev Kommera, Director, Statistical Programming, bluebird bio
Gerald Downey, Statistical Scientist, Gene Therapy, Rare Diseases, RWD/RWE, Market Access

11:55 Sponsored Presentation *(Opportunity Available)*

12:20 pm Structured Benefit-Risk as a Lifecycle Activity

Michael Forstner-Dambenois, CSO, MedGenie AG

The focus of BR assessments is shifting from a peri- and post-approval activity to early in clinical development, aiming to establish a lifecycle framework for the continuous assessment and optimization of a product's BR profile as early as first-in-human. In this presentation we are looking at opportunities at various lifecycle stages and at important considerations for successfully performing and communicating BR assessments.

12:45 Sponsored Presentation *(Opportunity Available)*

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

2:10 Special Book Signing Risk-Based Quality Management: The Ultimate Clinical Researcher's Guide Authors: Artem Andrianov (PhD), Johann Proeve (PhD)

Location: Booth #615

MODERNIZING SAFETY DATA PREDICTION AND SURVEILLANCE

3:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

3:05 Safety Gateway Enablement Takes Two to Tango

Kimberly Rivera, Senior Director, Senior Group Lead, Clinical Data and Information Sciences, Pfizer Inc.

Safety integration projects require strong collaboration with technology vendors & internal company lines. Designing user requirements requires mutual understanding of each other's differences in business processes/regulations with the goal of improving the overall user experience. Team sharply focused on improvements including enabling data capture to push/trigger delivery of safety data cases for required PV reporting, elimination of SAE reconciliation, & automation of case delivery to Safety to avoid late reporting.

3:25 The Where and How of AE Prediction Using Machine-Learning Methods

Francesca Kolitsopoulos, Senior Director, RWE Pharmacoepidemiology and Safety Head, Oncology, Gilead Sciences Inc
Machine learning (ML) is increasingly being used to predict specific adverse events (AEs) using real-world data (RWD), such as electronic health record (EHR) and insurance claims. In this session, you will learn how AE prediction using ML can help optimize clinical trial design, improve patient recruitment and pinpoint at-risk clinical sites needing more oversight, ultimately leading to faster, more successful trials.

3:40 Modernizing Patient Safety Data Surveillance and Analysis
Numan Karim, MS, Associate Director, Data Science & Analytics, AbbVie, Inc.
AbbVie modernized patient safety surveillance by replacing static, delayed reports with an interactive, self-service analytics platform. This approach enabled real-time engagement with safety data, streamlined regulatory reporting, and improved overall monitoring during study conduct. The talk will share lessons from building a scalable solution and ongoing challenges in predictive signal detection.

3:55 Presentation to be Announced

4:08 Sponsored Presentation *(Opportunity Available)*

4:45 Facilitating Pharmacokinetics Reporting with Generative AI
John Samuelsson, PhD, Senior Data Scientist, Artificial Intelligence & Machine Learning Quantitative & Digital Sciences, Pfizer Inc.
This session will showcase how Pfizer developed an internal genAI copilot to streamline the authoring of Pharmacokinetics (PK) sections in Clinical Study Reports (CSRs). By leveraging content from the Study Protocol and TLFs, the tool can generate a high-quality draft. In blinded evaluations, the AI-generated drafts scored 80–90% compared to finalized human-authored reports, demonstrating the potential of genAI to accelerate CSR development without compromising scientific rigor.

5:10 Sponsored Presentation *(Opportunity Available)*

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants
Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials
Tobias Kruse, PhD, Managing Director, Europe, SubjectWell
Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment
Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health
Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health
As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)
MODERATOR:
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.
Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

APPLYING SAFETY RISK ASSESSMENTS TO RCTs

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Sponsored Presentation *(Opportunity Available)*

9:00 Risk Management in Gene Therapy
Asif Mahmood, MD, Vice President, Head, Medical Safety & Pharmacovigilance, Asklepios Biopharmaceutical, Inc.
Gene therapy presents unique safety challenges, requiring risk management across three dimensions: the investigational product itself, its delivery to target organs, and the delivery device. This talk will examine strategies to address these complexities and ensure patient safety in the rapidly advancing field of gene therapy.

9:25 Problems with Serious Adverse Events Assessment in Clinical Trials
Gerald Klein, MD, Principal, MedSurgPI
This important aspect of clinical trial safety is often performed inadequately by the investigational sites and can affect the success or failure of a product's development. A methodology to improve the quality and reliability of this process is discussed.

9:50 Retention by Design: Reimagining Long-Term Follow-Up to Live Up to Its Name
Dan Drozd, Chief Medical Officer, PicnicHealth
Long-term follow-up (LTFU) is central to safety and pharmacovigilance. Yet 15 years of visits are unsustainable for patients, resulting in attrition that weakens signal detection, jeopardizes regulatory commitments, and leaves long-term benefit–risk unanswered.
This panel brings together a patient advocate, regulator, and clinical researchers to reimagine LTFU through a "retention by design" lens. Discussions will center around designing LTFU studies from the outset around pharmacovigilance objectives and patients' lives.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*
Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

RISK-BASED DATA MANAGEMENT AND CENTRALIZED MONITORING

11:10 Chairperson's Remarks
Johann Proeve, CSO, Cyntegrity Germany GmbH

11:15 Intelligent Technology: Fueling Human Compulsion for Quality
Clare Campbell-Cooper, Global Head, Digital Health and Innovation, Fortrea
Data quality and integrity remain non-negotiable in clinical research. While innovative technologies are advancing to enhance compliance and quality, our industry continues to rely heavily on people. The adoption of new processes and workflows often faces delays due to slow uptake. This session explores how the convergence of technology and behavioral science can drive the creation of workflows that are resilient, efficient, and future-ready. Learning objectives include discussing the challenges facing adoption of innovation by interested parties and how this is changing over time, understand fundamental concepts unpinning compliance human nature, and seeing examples of where technology insights promote quality and the desire to improve.

11:40 Applying Acceptable Ranges: QTLs for Early-Phase and Safety/Exposure-Focused Clinical Trials
Kristin Stallcup, MS, Director, RBQM Operations, Takeda

Hui Yang, PhD, Director, Statistics Team Lead, Takeda
The ICH E6(R3) concept of "acceptable ranges" broadens the use of Quality Tolerance Limits (QTLs), including for early phase studies and those with safety/exposure endpoints. But applying QTLs in these settings requires a different approach. This session shares practical tips and considerations for implementing QTLs in safety/exposure-focused, early-phase studies—and why building a consistent framework across all trials can benefit the broader portfolio.

12:00 pm New Approaches for Risk-Based Data Management and Central Monitoring in Oncology
Jacqueline Cousart, Central Monitoring Manager, Data Management Central Monitoring, Johnson & Johnson
This presentation will focus on how risk-based data management methodology has been introduced with consistency across several trials within an oncology program. Key topics of discussion will include how study teams identified critical data for endpoints early in protocol discussions, the importance of cross-functional collaboration (Central Monitoring, Data Management, Stats, Clinical, etc.), and improvements to monitoring strategies to increase efficiencies.

12:15 RBQM Insights on Asset-Level Integration
Cilla Mistry, Associate Director, RbQM & Central Monitoring, GSK
As Risk-Based Quality Management (RBQM) matures, organizations are expanding its impact beyond individual studies. This session explores how RBQM principles can be strategically integrated at the asset level to drive portfolio-wide insights, optimize oversight, and align with broader business objectives. Learn how to leverage cross-study data, enhance decision-making, and elevate quality management from a study-centric function to an enterprise-wide value driver.

12:30 Presentation to be Announced

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

BALANCING ONSITE MONITORING WITH CENTRALIZED APPROACHES

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 PANEL DISCUSSION: Swipe Right for Quality: Good Idea or Nope?
Moderator: Leslie Sam, President, Leslie Sam & Associates LLC
In this interactive panel, vote on whether trial management and technology strategies are brilliant or broken. Through a series of "swipe right or nope" prompts, we'll explore what resonates with experienced research and quality professionals. Panelists from pharma, biotech, and tech will weigh in after each vote to unpack pros, risks, and impacts. You'll leave with a sharper sense of how to evaluate innovation for feasibility, compliance, and quality outcomes.
Panelists:
Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK
Michael Torok, PhD, Vice President, Global Head, Quality Assurance Programs, Roche

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 PANEL DISCUSSION: Maximizing Efficiency: The Delicate Dance between Central Monitoring and Onsite Activities
Moderator: Randall Holzberger, MS, Director of RBQM Risk Management, Biostatistics & Data Management, Daiichi Sankyo
According to E6 R3 Section 3.11.4, "Monitoring may include site monitoring (performed onsite and/or remotely) and centralized monitoring, depending on the monitoring strategy and the design of the clinical trial." Many companies struggle with the relationship between centralized and onsite monitoring activities. How can we as an industry increase our efficiency by balancing central/onsite monitoring activities while maintaining or increasing the overall quality?
Panelists:
Danilo Branco, Associate Director, Risk Based Quality Management Lead, BeOne Medicines
Taryn Haffner, Associate Director Clinical Operations, Genmab AS
Anne Smith, Director, Central Monitoring, Regeneron Pharmaceuticals, Inc.

Gosia Szczodrak, Associate Director, Clinical Operations, Gilead

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

IN-PERSON ONLY WORKING GROUP: From ALCOA to Action: Achieving Fit-for-Purpose, Risk-Proportionate Clinical Data Under ICH E6(R3)

Deborah A. Guattery, GCP Quality Expert, Chase The Sky For Quality LLC
Nechama Katan, Chief Wizard, Wicked Problem Wizards

According to ICH E6(R3) principles, every element of trial design, oversight, and execution can—and should—be risk-based. But making that shift is more than checking the ALCOA boxes. It's about building data systems and processes that are fit-for-purpose, so risk triggers proportional, timely, and effective responses. In this working session, we'll explore challenges, identify capability gaps, and design practical solutions for implementing proportionate, risk-based quality management.

11:00 Networking Coffee Break

Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

AI-DRIVEN ANALYTICS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Building a Transformative, AI-Driven Analytics Capability for Clinical Trial Insights

Omkar Dasari, Senior Technical Product Manager, Data & Analytics, Amgen
James Vernille, PhD, Director, Clinical Systems & Analytical Reporting, Global Development Operations, Amgen, Inc.

At Amgen, we are transforming our analytics ecosystem with AI-driven tools that enable near real-time, self-service insights for global development stakeholders. Our next-generation analytics engine features a rebuilt metrics platform, centralized data governance, and a streamlined dashboard landscape leveraging Power BI with Co-Pilot and custom AI interfaces. By implementing AI/ML bots and natural language queries, we are shifting from static reporting to a dynamic, AI-driven experience.

12:00 pm From Proven Results to Product Vision: Advancing Clinical Trial Data Exchange with IgniteData Archer

Joe Lengfellner, IgniteData

Clinical trial data exchange has long limited the pace of innovation in research. This session explores how IgniteData Archer is redefining what's possible, drawing on proven results from live trials at Memorial Sloan Kettering Cancer Center. Presented by Joe Langfellner, IgniteData's Chief Product Officer, the talk connects real-world impact to a forward-looking product vision—explaining why Archer's success led him to join IgniteData and how he and the team are shaping the future of clinical trial data exchange.

12:13 Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Transforming Clinical Data Analytics with Agentic GenAI

Moderator: Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson

This panel explores how Agentic Generative AI (GenAI) is reshaping clinical data analytics by enabling autonomous and adaptive systems that streamline data processing, uncover complex patterns, and generate actionable insights. The discussion will address the opportunities and risks of integrating Agentic and Applied GenAI into regulated clinical research environments, highlighting their potential to drive innovation while maintaining data integrity and patient safety.

Panelists:
Bhargava Reddy, PhD, Senior Director, Advanced Insights and Solutions, Janssen
Richard Young, Chief Strategy Officer, CluePoints

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm

TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm

TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Partnering Organizations

SCOPEsummit.com/partnering-organizations

Cambridge Healthtech Institute's 11th Annual

Modernizing Lab, Biospecimen & Data Management Operations

Biomarker-Driven Trial Design, Operational Frameworks, and Standardization Efforts

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 10th Annual

Biomarker & Biospecimen Technology & Innovation

Patient-Centric Collection, Sample Tracking, Vendor Management, and Data Considerations

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

STRATEGIC FOUNDATIONS FOR MODERN BIOSPECIMEN OPERATIONS

11:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:05 Utility of Small Language Models for Optimizing Biomarker Operations

Dmitri Mikhailov, PhD, Director & Global Head, Biomarker Coordination, Novartis Institutes for BioMedical Research, Inc.

Implementing biomarkers in clinical trials involves multiple stages, from early project strategy to study setup and CRO oversight, to data delivery and report writing. This presentation will showcase how small language models and AI tools enhance efficiencies throughout the biomarker planning process.

11:30 From Data to Decisions: Visualizing Specimen Tracking for Operational Excellence

Dharmesh Patel, Director, Biospecimen Operations, Bristol Myers Squibb Co.

We have transformed the biospecimen management system by centralizing, normalizing, and validating metadata to ensure reliable data integration and audit readiness in line with ICH E6(R3). With the integration of software, stakeholders gain dynamic, transparent visualizations, and actionable insights. Key strategies include robust system architecture, integration, and automation, driving quality, process improvement, and streamlined logistics across diverse clinical studies.

11:55 Presentation to be Announced

12:20 pm Enhancing the Efficiency and Success of Clinical Trial Biospecimens by Digitalizing Sample Management

Brooke J. Samuelian, Senior Manager, Biomarker Operations, Syndax Pharmaceuticals

As the importance of successful biospecimen readouts continues to grow, we are familiar with manual processes contributing to operational inefficiencies and error. Traditional sample management methods, such as spreadsheets, are not capable of supporting large trials and increase the risk of missed collections, lost shipments, lab queries, protocol deviations, and even patient replacement. Electronic sample management platforms have the potential to streamline specimen tracking and improve collection and analysis rates.

12:45 Operational Intelligence: AI Agents Driving Compliance and Risk Mitigation in Clinical Trials

Tobias Guennel, PhD, Co-Founder and CTO, QuartzBio

Thousands of data issues plague an average trial -- and 75% of them slip through traditional reconciliation processes, impacting timelines and operational efficiency. Learn how QuartzBio's Precision Medicine agentic framework, powered by proactive and prescriptive AI, transforms clinical operations. These AI agents track sample logistics, flag inconsistencies, and issue alerts with actionable, corrective steps, reducing issues by >80% and accelerating milestones. Teams can shift from manual oversight to strategic innovation, driving end-to-end operational excellence.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

BIOSPECIMEN MANAGEMENT TODAY: CHALLENGES AND OPPORTUNITIES

3:00 Chairperson's Remarks

Speaker to be Announced, Slope

3:05 Case Study: The Problem Statement in Biospecimen Management—What Are We Really Solving For?

Amy Ripston, Founder & President, Biospecimen Management Consortium

Biospecimen management in clinical research remains a complex landscape, strained by misaligned processes, inconsistent tools, and disparate nomenclature between sponsors, sites, labs, and other stakeholders. To truly understand what we are aiming to solve, we must clearly dissect the problem. This case study presentation walks attendees through the creation of the ecosystem-wide problem statement and details initiatives underway to solve for them.

3:30 The Hidden Complexities of Biospecimen Management at the Site

Kira Pavlik, MPH, CCRP, Associate Director, Clinical Operations, Yale Cancer Center Clinical Trials Office

3:55 Sponsored Presentation *(Opportunity Available)*

4:45 PANEL DISCUSSION: Voices from the Field: A Candid Panel on Overcoming Challenges in Biospecimen Management

Moderator: Eli Stoddard, Senior Director, Clinical Lab Sciences, Eli Lilly & Co.

This panel brings together key stakeholders for an open and candid discussion on the complex challenges of biospecimen management in clinical trials. Panelists will share insights into operational pain points, regulatory hurdles, and workflow inefficiencies that threaten sample quality, data integrity, and trial timelines. The conversation will also explore transformative opportunities to strengthen collaboration, standardization, and innovation across the biospecimen ecosystem.

Panelists:

Karina Bienfait, PhD, Executive Director, Consent, Biospecimen & Imaging Management, Bristol Myers Squibb Co.

Anna Kosenko, Associate Director, Biospecimen Operations, BioNTech US, Inc.

Kira Pavlik, MPH, CCRP, Associate Director, Clinical Operations, Yale Cancer Center Clinical Trials Office

Mark Slette, Vice President, Global Operations & Strategic Transformation, Labcorp

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

NAVIGATING CAREER PATHS IN AN EVOLVING ECOSYSTEM

8:35 PANEL DISCUSSION: Flourishing in Today's Biospecimen Landscape: Career Paths, Skills, and Strategies

Moderator: Brenda Yanak, Founder & Principal, Clinical Transformation Partners LLC

Panelists:

Deborah Shepard, PhD, Director, Group Lead—Biomarkers Clinical Data Acquisition, Pfizer Inc.

Heather Shih, PhD, MBA, Senior Director Biomarker Operations, Global Clinical Development Operations, BioNTech US, Inc.

John Smutko, Head of Specimen Management Oncology, GSK

NAVIGATING REGULATORY AND COMPLIANCE CHANGES

9:00 ICH E6(R3) Meets the Lab: Navigating Biospecimen Compliance in Clinical Trials

Edye Edens, CEO, EEDEE Law

This session offers a practical interpretation of ICH E6(R3) through the lens of biospecimen operations. Attendees will gain clarity on new regulatory expectations and how they affect collection, handling, storage, and traceability. With real-world insights and actionable compliance strategies, the presentation bridges regulatory theory with operational reality—equipping research teams to align their biospecimen practices with evolving global standards.

9:25 ICH E6(R3) Implementation: Building a Quality Framework for Specimen Management

Michael Tanen, Senior Director, Head of Laboratory Operations and Logistics, Merck

The adopted ICH E6 (R3) guideline for GCP highlights biospecimens as vital data sources impacting the reliability of trial results. It promotes proactive risk assessment, data integrity, robust documentation, and leveraging digital tools to ensure specimen quality and traceability. We will summarize key themes in the guidance and provide strategies to implement a quality framework for specimen management to minimize the risks associated with specimen collection, processing, storage, and transport.

9:50 Beyond Compliance: Why Site-Level Biospecimen Management Is Clinical Operations' Biggest Blind Spot

Speaker to be Announced, Slope

While the industry debates ICH E6(R3) interpretation, a fundamental problem persists: 70% of FDA submission data depends on biospecimens, yet disparate systems and processes that are forced upon sites create compliance vulnerabilities that no single sponsor, CRO, or lab can fix.

We'll show how the latest practices across the ecosystem cause deviations, queries, and lost samples, quantify the impact on study integrity, and demonstrate what excellence looks like when sites are set up for success.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

VENDOR PARTNERSHIPS AND OPERATIONAL EFFICIENCY

11:10 Chairperson's Remarks

Speaker to be Announced, Slope

11:15 PANEL DISCUSSION: Breaking Silos—End-to-End Biospecimen Strategies for Smarter, Scalable Clinical Operations

Moderator: Alekhya Pochiraju, Senior Product Development Lead, Clinical Operations, Genentech

As clinical trials grow in complexity, the ability to design and execute seamless end-to-end biospecimen strategies has become a critical differentiator. This panel will explore how organizations are aligning protocol simplification, clinical operations, data science, and biobanking to transform biospecimen management into a strategic asset. Panelists will discuss how integrated approaches can

optimize sample logistics, enable timely data return, and bridge traditional operational silos.
Panelists:
Mine Cicek, PhD, Biorepository Program Director, Mayo Clinic Bioservices
Anamika Sarkar, PhD, Intelligent Automation Lead, Global Development Solutions, Regeneron Pharmaceuticals, Inc.
Johanna Sy, Biosample Therapeutic Area Leader, Genentech
Michael Tanen, Senior Director, Head of Laboratory Operations and Logistics, Merck

11:40 Strategic Vendor Management in Biomarker Analysis: Aligning Quality and Efficiency
Arkady Gusev, PhD, Head, Lab Excellence & Operations in Biomarker Development, Novartis Institutes for BioMedical Research, Inc.
Pharmaceutical research and development has strategically evolved its outsourcing models which have progressed from transactional engagements to strategic, long-term partnership with CROs, ensuring flexibility, innovation, and compliance with global regulatory standards as well as Novartis internal quality standards. This presentation will explore best practices for strategic vendor management in biomarker analysis, including aligning partner capabilities with program goals, ensuring data quality and value-added CRO service propositions.

12:05 pm PANEL DISCUSSION: Talk Title to be Announced

12:05 Talk Title to be Announced

12:30 The Evolution of Biobanking: When Science and Technology Collide
Amreen Ahmed, Director of Product Management, IQVIA
Sujan Gowda, Senior Manager, Engineering, Global Clinical Development, Bristol Myers Squibb
Karl Kammerhoff, Director, Specimen Library, Systems & Logistics, Bristol Myers Squibb

12:55 Sponsored Networking Luncheon
Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**
Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design
Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG
Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.
Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology
Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.
AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.
Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**
As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*
SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

COLD CHAIN, TRANSPORT & LOGISTICS EXCELLENCE

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Navigating Regulatory Requirements across Multiple US Agencies for Importing Biological Materials
Sean Smith, Biological Threat Exclusion Coordinator (BTEC), Agriculture Programs and Trade Liaison, US Customs and Border Protection
CBP will provide an overview of major U.S. regulatory authorities governing biological material importations, guidelines for acceptable and unacceptable cargo descriptions, examples of non-compliant shipments of biological materials and pharmaceutical products, and provide essential resources and important contacts for support.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 Shared Learnings on Methods to Decrease Temperature Excursions
Barbara Versage, Senior Manager, Supply Chain Sourcing, Immunocore LLC
Monitoring temperature control is a vital responsibility in clinical supply, extending beyond deep-frozen storage. Even products stored at ambient conditions require monitoring to ensure they avoid freezing or overheating. This session explains how tracking at defined supply chain touchpoints enables data collection, trending, and timely intervention. By leveraging value stream checkpoints, organizations can proactively maintain product integrity, safeguarding quality while minimizing risks across distribution and storage environments.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*
Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

THINK TANK: Specimen in Transit: Untangling the Complexities of Global Transport Logistics
Brenda Yanak, Founder & Principal, Clinical Transformation Partners LLC
Where in the world is . . . . .? Have you encountered confusion or churning around supply logistics for clinical trials? Don't know where to turn? This is your opportunity to learn from industry experts in global transport logistics, sample tracking and management, along with customs clearance on a multitude of topics. Join a Think Tank facilitated small group discussion to share experiences and solutions.

10:40 Think Tank Report Outs: Listen and Learn
During the Think Tank Table discussions, we shared our experiences and working solutions for global supply logistics. Now, as a collective community, let's hear from the table facilitators as they share key discussion points and strategies and provide a wrap-up of their table's discussion. What can we take away and apply?

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

SITE COLLABORATION

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 CO-PRESENTATION: Site Partnerships: The Power of Collaboration for Clinical Trial Supply Management Success
Latoya Marshall, Director, Clinical Research, Neely Center for Clinical Cancer Research, Tufts Medical Center
Stephanie Russell, Senior Director, RTSM Solution Services, Medidata
This co-presentation offers a rare and valuable site-centric perspective on one of the most underrepresented yet critical aspects of clinical trials: supply management. While much of the industry dialogue focuses on sponsor or CRO-led innovations, this session flips the narrative by elevating the site's voice.

12:00 pm Waste Not, Want Not: Innovative Strategies to Minimize Specimen Kit Wastage in Clinical Trials
Margaret Suhanovsky, Associate Director & Alliance Lead, Global Development Operations, Bristol Myers Squibb Co.
Lab kit wastage can spiral, leading to increased costs, diminished site experience, and negative impacts on sustainability—necessitating prompt and strategic action. By tackling operational inefficiencies, enhancing processes collaboratively with our partners, and promoting solutions that are practical for sites to implement, we seek to achieve incremental improvements that yield long-term benefits. Discover how a holistic strategy curbs waste and turns chaos into control.

12:25 PANEL DISCUSSION: From Sites to Sponsors: Overcoming Supply Challenges Together
Moderator: Latoya Marshall, Director, Clinical Research, Neely Center for Clinical Cancer Research, Tufts Medical Center
Join us for a candid discussion on real-world obstacles sites encounter and explore solutions to improve supply chain efficiency. Gain valuable perspectives on how sponsors, CROs, and technology providers can better support sites in optimizing supply management to keep trials running smoothly. These issues directly impact patient safety, data integrity, and trial timelines, making them highly relevant to all stakeholders in the clinical ecosystem.
Panelists:
Stephanie Russell, Senior Director, RTSM Solution Services, Medidata
Kate Trigg, PhD, Clinical Research Supervisor, Internal Medicine, University of California Davis

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's 7th Annual

Communication & Digitization for End-to-End Clinical Supply Management

Controlling the Complexity of Clinical Supply Chain Forecasting and Contingency Planning

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's 7th Annual

Clinical Supply Chain Strategies to Align Process, Products and Patients

Ensuring a Safe, Stable, and Secure Supply Chain in Constantly Shifting Dynamic Clinical Trials

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:
Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca
Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

IRT/RTSM: NAVIGATING THE DIGITAL NEIGHBORHOOD

11:00 Chairperson's Remarks

Speaker to be Announced, Imperial Clinical Research Svcs

11:05 Getting RTSM Right: Why and How

Paul F. Hughes, Director, Randomization & Trial Supply Management (RTSM), J&J Innovative Medicine

Randomization and Trial Supply Management (RTSM) Systems are the most important clinical trial systems. Prove me wrong. To truly harness RTSM's value, sponsors and suppliers need to implement strategic steps that minimize risks and maximize benefits. Success hinges on getting RTSM right—and I'm here to discuss the "Hows" to make that happen.

11:18 Onboarding RTSM/IRT Vendors: The Sponsor POV

Imran Shakur, Director, IRT and Technology Lead, Clinical Supply Management, Alexion Pharmaceuticals

11:30 Taming the Chaos: Standardizing IRT/RTSM Systems across Multiple Vendors

J. Derek Thornton, Associate Director, Clinical Services & Analytical Reporting (IRT), Amgen

With over 22 different RTSM/IRT vendors available in the marketplace, standardizing system designs is a daunting but necessary challenge. This presentation explores how sponsors and vendors can identify which elements are best to standardize, align on a unified approach, and deploy standards across diverse platforms. Learn how to balance adaptability with consistency, navigate supplier differences, and evaluate the impact of standardization efforts across the industry.

11:42 RTSM 2075: Imagining the Future of Clinical Supply Chain

Barry Moore, Head, RTSM, R&D, GSK

RTSM has journeyed from IVRS to today's digital platforms, but what's next? This session explores the future of RTSM over the next 50 years, considering advances in science, technology, and culture. From adaptive trials to bioprinting, AI co-pilots to digital twins, we'll imagine how RTSM might transform the future of clinical research.

11:55 Journey to the Digital Protocol

Cara Woodruff, Director of Product Management – IRT, Clinical Technologies Patient Suite, IQVIA Technologies

The heart of a clinical trial is the protocol, from which workflows and data flows are created for and between sites, sponsors, CROs, and patients. While sponsors have been discussing and pursuing the nirvana of a digital protocol for nearly a decade, the ambition is now within reach because of the advanced automation and adaptability of agentic AI. In this panel, we'll discuss how the industry is advancing toward digital protocols and how randomization and trial supply leaders need to prepare.

12:20 pm PANEL DISCUSSION: Untangling Complexity in IRT/RTSM: Pain Points and Progress

Moderator: Paul F. Hughes, Director, Randomization & Trial Supply Management (RTSM), J&J Innovative Medicine

Join this panel of experts as they unpack the hidden challenges of IRT/RTSM—from vendor communication gaps to integration bottlenecks—and explore practical solutions for smarter, more efficient trials. Gain insights into how today's pain points can be transformed into tomorrow's progress.

Panelists:
Barry Moore, Head, RTSM, R&D, GSK
Imran Shakur, Director, IRT and Technology Lead, Clinical Supply Management, Alexion Pharmaceuticals
J. Derek Thornton, Associate Director, Clinical Services & Analytical Reporting (IRT), Amgen

12:45 Sponsored Presentation *(Opportunity Available)*

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

THE CRITICAL ROLE OF COLLABORATION AND COMMUNICATION IN CLINICAL-SUPPLIES MANAGEMENT

3:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

3:05 Participant and Site Receptivity to Direct-to-Patient (DTP) Shipments of Investigational Treatments in Clinical Trials

Maria Florez, Senior Consultant, Tufts CSDD

During this interactive session, we will discuss results from a recent study conducted by the Tufts Center for the study of Drug Development, focusing on (1) how U.S. clinical trial participants and sites perceive and experience Direct-to-Patient (DTP) shipments of investigational treatments, (2) the key benefits and challenges, and (3) actionable insights to improve patient satisfaction, site receptivity, and operational efficiency when using DTP shipments in clinical trials.

3:30 Adapting to Change: TMF and Clinical Supply Management in the ICH E6 R3 Landscape

Denise Moak, Principal Consultant, Alexander-Moak Consulting Services

This presentation addresses how we can best prepare to align our processes to the risk-based requirements explicit in ICH E6 R 3? We will dive into meaningful steps and TMF documentation that will demonstrate Sponsor oversight in a quality-first clinical supply chain.

3:55 Using RTSM to Enhance Supply Chain Agility in Complex Trial Designs

Ian Davidson, Subject Matter Expert, RTSM, Medrio

Diane Greenlaw, Director, RTSM at Medrio

This session offers a real-world view of managing supply chains under dynamic study conditions. Using a complex protocol framework, speakers will outline methods for cohort-driven dispensing, titration-related product changes, predictive supply modeling, temperature monitoring, and structured communication practices that preserve control as patient pathways and dosing patterns shift.

4:20 Sponsored Presentation *(Opportunity Available)*

4:45 Team Building in a Virtual World

Lisamarie Georgen, President, GuidedPath Consulting

In today's globalized and hybrid work environment, virtual teams have become essential to the success of Clinical Supply Operations. This presentation explores the key strategies for building and sustaining high-performing virtual teams within the clinical supplies domain. Drawing on real-world examples and industry best practices, we will examine how to foster trust, accountability, and clear communication across geographically dispersed teams.

5:10 Sponsored Presentation *(Opportunity Available)*

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

BUILDING THE SUPPLY INFRASTRUCTURE FOR CELL AND GENE THERAPIES

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Sponsored Presentation *(Opportunity Available)*

9:00 Bringing CAR T Cell Therapies to the Community

Michael Mehler, Director, Cell Therapy Operations, AstraZeneca

Bringing CAR T Cell Therapies to the Community

9:25 CO-PRESENTATION: Delivering a Nationally Supported Environment for Cell and Gene Therapy (CGT) Studies

Tracy Harman, Deputy Director of Strategic Development, National Institute for Health & Care Research (NIHR), Research Delivery Network (RDN) Coordinating Centre

Emily Merrell, Director, ATTC Network Coordination, Cell and Gene Therapy Catapult

We will outline how the ATTCs and the NIHR Research Delivery Network (RDN) are developing a robust site and sponsor support package for CGT studies. This includes providing faster and easier access to experts for advice, offering early feedback on protocols to fit the UK health pathways, supporting improved site selection through a web-based portal, enabling patient involvement in study design, and offering bespoke training programmes for research delivery staff.

9:50 Presentation to be Announced

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

FROM APPROVALS TO ACCESS: CLOSING THE CGT ADOPTION GAP

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 Sponsored Presentation *(Opportunity Available)*

11:40 Developing a Cell Therapy cGMP Program for Early Phase Trials within a Hospital Setting

Tatyana Matveeva, PhD, Director of cGMP Cell Production Operations, Neurosurgery, Massachusetts General Hospital

Neurodegenerative conditions are diseases with severe economic, personal, and healthcare expenses. Cell replacement therapies have offered a route to functional recovery, but clinical cell manufacturing frequently requires distributed production and oversight associated with substantial financial burden. The present

report will outline an in-hospital cGMP cell manufacturing facility with adjacent quality control and in direct proximity to patients, and demonstrate the challenges of developing a compliant and all-inclusive program at cost.

12:05 pm PANEL DISCUSSION: We Don't Have a Supply Problem—We Have a Demand Problem

Moderator: Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America

Despite record CGT approvals and growing pipelines, widespread adoption is hindered by manufacturing complexity, limited specialist centers, and logistical barriers. This panel will explore how the CGT community can expand infrastructure, streamline global operations, and bring advanced therapies to broader patient populations—ensuring demand translates into real-world impact.

Panelists:

Joe DePinto, Head, Cell Gene Advanced Therapies, McKesson Bioservices
Tracy Harman, Deputy Director of Strategic Development, National Institute for Health & Care Research (NIHR), Research Delivery Network (RDN) Coordinating Centre
Tatyana Matveeva, PhD, Director of cGMP Cell Production Operations, Neurosurgery, Massachusetts General Hospital
Michael Mehler, Director, Cell Therapy Operations, AstraZeneca
Kim Tedesco, Director, Gene & Cell Therapy Pharmacy Operations, Walgreens Gene & Cell Services

12:30 Sponsored Presentation *(Opportunity Available)*

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)***—Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:

Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:

Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

SUPPLY-CHAIN LOGISTICS: STREAMLINING DISTRIBUTION

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Navigating Regulatory Requirements across Multiple US Agencies for Importing Biological Materials

Sean Smith, Biological Threat Exclusion Coordinator (BTEC), Agriculture Programs and Trade Liaison, US Customs and Border Protection

CBP will provide an overview of major U.S. regulatory authorities governing biological material importations, guidelines for acceptable and unacceptable cargo descriptions, examples of non-compliant shipments of biological materials and pharmaceutical products, and provide essential resources and important contacts for support.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 Shared Learnings on Methods to Decrease Temperature Excursions

Barbara Versage, Senior Manager, Supply Chain Sourcing, Immunocore LLC

Monitoring temperature control is a vital responsibility in clinical supply, extending beyond deep-frozen storage. Even products stored at ambient conditions require monitoring to ensure they avoid freezing or overheating. This session explains how tracking at defined supply chain touchpoints enables data collection, trending, and timely intervention. By leveraging value stream checkpoints, organizations can proactively maintain product integrity, safeguarding quality while minimizing risks across distribution and storage environments.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation.
After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

THINK TANK: Specimen in Transit: Untangling the Complexities of Global Transport Logistics

Brenda Yanak, Founder & Principal, Clinical Transformation Partners LLC

Clinical Supply & Logistics

Where in the world is . . . . .? Have you encountered confusion or churning around supply logistics for clinical trials? Don't know where to turn? This is your opportunity to learn from industry experts in global transport logistics, sample tracking and management, along with customs clearance on a multitude of topics. Join a Think Tank facilitated small group discussion to share experiences and solutions.

10:40 Think Tank Report Outs: Listen and Learn
During the Think Tank Table discussions, we shared our experiences and working solutions for global supply logistics. Now, as a collective community, let's hear from the table facilitators as they share key discussion points and strategies and provide a wrap-up of their table's discussion. What can we take away and apply?

11:00 Networking Coffee Break
Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

SITE COLLABORATION: MANAGING THE COMPLEXITIES OF TRIAL SUPPLIES

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 CO-PRESENTATION: Site Partnerships: The Power of Collaboration for Clinical Trial Supply Management Success
Latoya Marshall, Director, Clinical Research, Neely Center for Clinical Cancer Research, Tufts Medical Center
Stephanie Russell, Senior Director, RTSM Solution Services, Medidata
This co-presentation offers a rare and valuable site-centric perspective on one of the most underrepresented yet critical aspects of clinical trials: supply management. While much of the industry dialogue focuses on sponsor or CRO-led innovations, this session flips the narrative by elevating the site's voice.

12:00 pm Waste Not, Want Not: Innovative Strategies to Minimize Specimen Kit Wastage in Clinical Trials
Margaret Suhanovsky, Associate Director & Alliance Lead, Global Development Operations, Bristol Myers Squibb Co.
Lab kit wastage can spiral, leading to increased costs, diminished site experience, and negative impacts on sustainability—necessitating prompt and strategic action. By tackling operational inefficiencies, enhancing processes collaboratively with our partners, and promoting solutions that are practical for sites to implement, we seek to achieve incremental improvements that yield long-term benefits. Discover how a holistic strategy curbs waste and turns chaos into control.

12:25 PANEL DISCUSSION: From Sites to Sponsors: Overcoming Supply Challenges Together
Moderator: Latoya Marshall, Director, Clinical Research, Neely Center for Clinical Cancer Research, Tufts Medical Center
Join us for a candid discussion on real-world obstacles sites encounter and explore solutions to improve supply chain efficiency. Gain valuable perspectives on how sponsors, CROs, and technology providers can better support sites in optimizing supply management to keep trials running smoothly. These issues directly impact patient safety, data integrity, and trial timelines, making them highly relevant to all stakeholders in the clinical ecosystem.
Panelists:
Stephanie Russell, Senior Director, RTSM Solution Services, Medidata
Kate Trigg, PhD, Clinical Research Supervisor, Internal Medicine, University of California Davis

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns
And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm
TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm
TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

Cambridge Healthtech Institute's Inaugural

Trial Design & Real World Evidence

Real-World Evidence Starts at Trial Design—and Ends with Market Access

FEBRUARY 2–4, 2026
All Times EST

Cambridge Healthtech Institute's Inaugural

Market Access, Pricing & Reimbursement

Where Clinical Strategy Meets Commercial Success

FEBRUARY 4–5, 2026

MONDAY, FEBRUARY 2

6:30 am Golf Check-In & Breakfast Buffet*

8:00 SCOPE's 5th Annual Masters of Clinical Research Golf Tournament* SOLD OUT (Sponsorship Opportunities Still Available)
Network on the greens at SCOPE's 5th Annual Golf Tournament! Visit the SCOPE Summit website for player and sponsorship opportunities.
9:00 Registration Open

12:00 pm Golf Lunch Buffet *(Sponsorship Opportunities Available)**

1:00 Close of the Masters of Clinical Research Golf Tournament
**Limited spots available. Separate registration and fee apply.*

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

1:00 – 1:45 pm OPEN WORKSHOP: Talk Title to be Announced
(Sponsorship Opportunity Available)

2:00 – 3:30 pm OPEN WORKSHOP: Modernizing Informed Consent: AI, Automation, and Ethics in Global Clinical Trials
INSTRUCTORS:
Kiernan Finney, Director, Compliance and Governance, Biosamples, AstraZeneca
Hilde Vanaken, Head EFGCP eConsent Initiative, European Forum for Good Clinical Practices
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

For more details on Pre-Conference Events, please visit: Workshops/User Groups

MONDAY AFTERNOON PLENARY SESSION: PATIENT PANEL, SITE INNOVATION AWARD, PARTICIPANT ENGAGEMENT AWARD

3:45 Grab Your Seat: Early-Bird Seat Golden Ticket Raffle & Prize Giveaway! *
**Must be present to win.*

3:50 Organizer's Welcome Remarks & 5th Annual Masters of Clinical Research Golf Tournament Awards and Jacket Signing
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Speaker to be Announced, PAREXEL International

4:00 FIRESIDE CHAT: Hope: The Double-Edged Sword of Patient Experience
Lindsay Guentzel, Multimedia Journalist & Patient Advocate
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA); Board Member, The Myositis Association (TMA)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation
In this fireside chat, two CAR T trial participants and a patient advocate/clinical research professional unpack the journey: find the trial, fight the insurer, cross state lines, then live the trial reality, along with your family. Careful research, long consent forms, and great care teams can still miss key things that matter. For clinical researchers, we share a clear look at what we ask—and what patients still can't see.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Visit our FAQ page! We hope this page answers some of your questions related to SCOPE. It consolidates a lot of info for speakers, attendees, and vendors into one page. We look forward to seeing you at SCOPE on February 2-5, 2026, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction: Developing Site Relationships beyond Study-Level Engagement
Elisa Cascade, Chief Growth Officer, Head of Americas, TrialScreen

4:35 SCOPE's 3rd Annual Site Innovation Awards
Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Irfan Khan, CEO, Circuit Clinical
Mara Kramer, Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Amanda Wright, Co-Founder & Senior Vice President, Healthcare Alliance, Javara

5:05 SCOPE's 10th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials
Jonathan Rowe, Principal, ZS

5:10 KEYNOTE INTERACTIVE PANEL: SCOPE's 10th Annual Participant Engagement Awards








Co-Moderators:
Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head, Innovative Patient Recruitment, Evinova, an AstraZeneca Company; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC; Co-Creator of the SCOPE Participant Engagement Award
Panelists:
Beth Brooks, Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi
Mark Evans, Managing Director, Patient Recruitment, Faze
Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Neha Shah Londono, Director, Clinical Trial Diversity and Community Engagement Lead, Pfizer Inc.
Jessica Perry, Senior Director, Trial Optimization, Kymera Therapeutics
Samantha Rogers, Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)
Brad Watts, CAR T Recipient and Patient Advocate, Emily Whitehead Foundation

5:40 SCOPE's Winter Games Opening Reception
(Sponsorship Opportunities Available)
Break out your coolest Winter Games—inspired look—no snow required! Think country flag t-shirts, Olympic colors, or your favorite team gear. While we may be in sunny Florida, let's ignite the spirit of unity, energy, and excitement—as we toast to teamwork and triumph!

7:00 Close of Day

TUESDAY, FEBRUARY 3

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am. Registration Link:** https://www.ciscrp.org/sunrise-yoga

6:30 SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*

Lace up and join SCOPE's Coordinators for the Fun Run on Tuesday, February 3! Sprint, jog, walk, or talk-your-way-through—ALL abilities are welcome. This informal event is all about getting moving together. Full details to come...just don't forget your sneakers!

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*

Fuel your morning with made-to-order coffee and sweet bites, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION

8:25 Grab Your Seat—Early Bird Seat Raffle & Prize Giveaway!* *(Sponsorship Opportunity Available)*

Don't miss your chance to win! Arrive early, grab your seat, and take part in SCOPE's Early Bird Seat Raffle & Prize Giveaway. Exciting prizes are up for grabs—must be present to win!

8:30 Welcome to SCOPE 2026—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

- SCOPE and Clinical Research News Best of Show Awards: https://www.scopesummit.com/best-of-show-awards
- SCOPE Site Innovation Award: https://www.scopesummit.com/site-innovation-award
- SCOPE Participant Engagement Award: https://www.scopesummit.com/participant-engagement-award

8:38 Chairperson's Plenary Keynote Introduction: Patient Engagement as a Guiding Principle in Research

Lisa Moneymaker, Chief Strategy Officer, Medidata

8:40 KEYNOTE PRESENTATION: Aligning Purpose, Innovation, and Operational Excellence in Clinical Development

Eliav Barr, Head, Global Clinical Development and CMO, Global Clinical Development, Merck & Co.

Pharma's mission to deliver life-changing therapies depends on its ability to innovate while staying grounded in execution. This keynote will highlight how companies are aligning purpose with investment in new clinical models and technologies. The conversation will focus on where big pharma is directing innovation strategy—and how operational alignment ensures impact for patients and the healthcare system.

9:05 SCOPE's Stretch Break & Annual T-Shirt Toss

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

Take a quick pause to stretch, recharge, and enjoy a little SCOPE tradition—our Annual T-Shirt Toss! Watch for the t-shirt slingshot sending giveaways into the audience as we add some fun to your day.

9:15 KEYNOTE PANEL DISCUSSION: From Years to Months: Is Radical Acceleration in Clinical Research Possible?



Moderator: Jeremy Goldberg, Operating Partner, Healthcare, Arsenal Capital Partners

Clinical development timelines remain a major barrier between innovation and patients. Incremental fixes won't cut it—this keynote explores bold, actionable strategies to compress timelines, rethink operations, and invest for impact. Leaders will examine how smarter funding, data integration, and operational transformation can turn years into months and drive the future of clinical research.

Panelists:

Sandeep Burugupalli, Head, Data Science & Biopharmaceuticals R&D, AstraZeneca

Jared Saul, MD, CMO, Commercial Healthcare and Life Sciences, Amazon Web Services

9:45 Grand Opening Coffee & Refreshment Break in the Exhibit Hall —Best of Show Voting Opens

Step into SCOPE's one-of-a-kind exhibit hall! With 300+ leading clinical trial technology and service companies, it's the place to discover new partners and reconnect with familiar ones. Cast your vote for SCOPE's Best of Show, recharge with coffee, snap a photo, and don't forget your comfy shoes—you'll have miles to explore!

INCORPORATING PATIENT INSIGHTS INTO TRIAL DESIGN

11:00 Chairperson's Remarks

Ariel Katz, CEO & Co Founder, H1

11:05 PANEL DISCUSSION: How to Transform an Organization from Sporadic to Systematic Patient-Centricity in Clinical Research

Moderator: Wouter Daniels, Clinical Trial Patient & Site Engagement Lead, Boehringer Ingelheim Pharma GmbH & Co KG

Many organizations embrace patient-centricity in theory—but struggle to embed it in practice. This panel explores how to move beyond one-off initiatives and build scalable, repeatable strategies that put patients at the heart of clinical research. Learn how leading teams are aligning culture, infrastructure, and partnerships to operationalize patient-centricity across the trial life cycle—and walk away with practical ideas to make it a true organizational advantage.

Panelists:

Speaker to be Announced, Surgo Health

Angela Bilkhu, Senior Global Patient Partnership Director, Sickle Cell Disease and aHUS, Roche

Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim

Sema Sgaier, Co-founder & CEO, Surgo Health

11:30 Elevating the Patient Voice in Clinical Trials: What Patients Want Us to Know

Christina Brennan, MD, MBA, Senior Vice President, Clinical Research, Northwell Health

Jesse Hoffman, Chief Business Officer, AMR Clinical

This session shares findings from a national study capturing what clinical trial participants believe is most important for sponsors, sites, and CROs to know about their experiences. Attendees will hear patient-derived insights on care, support, and respect in trials—offering actionable guidance to improve quality, engagement, and patient-centered trial design.

11:55 Future-Proofing Clinical Trials: Designing Protocols for Flexibility

Speaker to be Announced, Science 37

Modern clinical trials face growing operational, regulatory, and patient engagement complexities, making early planning essential. Early protocol development is key to building adaptability that can make the difference between a smooth pivot and a costly overhaul.

This panel explores strategies for embedding flexibility in early trial design, allowing sponsors to incorporate alternative operational models or approaches without extensive amendments. Hear from sponsors, investigators, technology, and logistics partners on how to proactively design trials that are robust and agile, setting the stage for future optionality and seamless execution.

12:20 pm PANEL DISCUSSION: From Insight to Impact: Bringing Patient Voice into Our Clinical Trials

Moderator: Tuba Bas, PhD, Senior Director, Clinical Center of Excellence, Bristol Myers Squibb Co.

This panel explores how Bristol Myers Squibb integrates patient voice and advocacy insights into clinical trial design. Experts will present a framework aligned with diversity and inclusion regulations, supported by real-world examples. Attendees will gain practical strategies for enhancing study design, improving recruitment, and advancing health equity—demonstrating how patient-informed approaches strengthen scientific rigor and drive global trial success.

Panelists:

Amy Fesmire-Baus, Global Patient Recruitment, Research & Drug Development, Global Patient Outreach, Bristol Myers Squibb

Josee Pelletier, Senior Director, Research & Drug Development, Global Patient Advocacy, Bristol Myers Squibb

Ashish Shah, Director, Clinical Science Lead, Neurosciece, Bristol Myers Squibb

12:45 Bridging the Gap: Using AI and Real-World Evidence to Optimize Clinical Trial Protocols

Tabby Khan, MD, MPH, Senior Director, Analytics, Komodo Health

As the integration of Real-World Data (RWD) accelerates across the industry, forward-thinking sponsors are moving beyond post-approval applications to utilize Real-World Evidence (RWE) at the earliest stages of clinical development. This presentation examines the evolution of RWE and its critical role in informing protocol development to create trials that are more efficient, patient-relevant, and aligned with market access requirements.

1:10 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

2:10 Networking Coffee & Dessert Break in the Exhibit Hall

Keep the conversations going in the Exhibit Hall with coffee and dessert, courtesy of SCOPE sponsors. Network with colleagues, explore new products and services, and don't forget—Best of Show Award voting is still open, so be sure to cast your vote!

AI-POWERED RWD ADVANCES (CONT.)

3:00 Chairperson's Remarks

Nicole Keidel, Senior Advisor, Growth & Strategic Partnerships, Intelligence Solutions, Evernorth Health Services

3:05 Implementing AI to Accelerate the Next Era of RWD/RWE

Aaron W. Kamauu, MD, MS, MPH, CEO, Navidence LLC

Vladimir Turzhitsky, PhD, Director, Data Science and Outcomes Research, Merck & Co.

Real-world data is vast and expanding, but fragmented. By applying AI techniques, we can bridge gaps, reduce complexity, and create actionable real-world evidence more efficiently. Drawing on a pharmaceutical RWD/RWE program, this talk covers implementation of AI tools across key workflows: programming assistants (SQL, R/SAS/Python), protocol and report authoring, and systematic literature review. The session also describes the design of fit-for-purpose knowledge bases to ground LLMs in organizational standards.

MEANINGFUL PARTNERSHIPS WITH RWD-OWNING ORGANIZATIONS

3:25 The Future of Clinical Research: Innovative Study Designs through Pharma-Provider Partnerships by Integrating Real-World Data (RWD) Collection in Randomized Clinical Trials (RCTs)

Chris Blanchette, PhD, Vice President, Clinical Data Science and Evidence, NNI, Novo Nordisk AS

Novo Nordisk is building cross-country collaborations with healthcare providers to maximize the value of real-world data. This session will highlight case studies from the US, UK, Denmark, and Sweden, showing how Pharma–HCP partnerships advance evidence generation, enable broader patient insights, and address practical challenges in governance, data access, and alignment, delivering scalable models for global research.

3:40 Stronger Together: Pharma-Healthcare Provider Collaborations Advancing Vaccine Research and Protecting Vulnerable Populations

Sylvia M. Taylor, PhD, Executive Director, Head, Real-World Evidence & Health Outcomes, Vaccines, GSK

GSK has developed innovative collaborations with healthcare providers in the US and UK to unlock the value of real-world data. This session will share case studies demonstrating how Pharma–HCP partnerships enhance evidence generation, streamline data access, and address key challenges—highlighting lessons learned, mutual benefits, and emerging solutions for advancing research beyond traditional trials.

3:55 Presentation to be Announced

4:20 Talk Title to be Announced

Brett Huselton, Senior Vice President, Partnership, Innovation & Strategic Solutions, Marketing, UBC

4:45 PANEL DISCUSSION: Advancing Clinical Research through Pharma–Healthcare Provider Collaborations: RWD + RCT Innovations for Better Evidence

Moderator: Aaron W. Kamauu, MD, MS, MPH, CEO, Navidence LLC

As life science companies increase their use of real-world data, access to RWD has also increased in both quantity and complexity. Healthcare provider systems manage a robust source of RWD via their electronic health records and practice management systems. This session will share examples of real studies where Pharma–HCP collaborations were essential for effective evidence generation.

Panelists:

Chris Blanchette, PhD, Vice President, Clinical Data Science and Evidence, NNI, Novo Nordisk AS

Richard Nelson, Professor, Department of Internal Medicine, Co-Director, Health Economics Core, Clinical and Translational Science Institute, University of Utah

Sylvia M. Taylor, PhD, Executive Director, Head, Real-World Evidence & Health Outcomes, Vaccines, GSK

5:10 Bridging Real-World Evidence Gaps: The Role of Literature-Derived RWE in Rare or Complex Indications

Mark Kiel, PhD, Co-Founder & CSO, Science, Genomenon

The biomedical literature reflects decades of global clinical practice and millions of patient records, with deep characterization of demographics, clinical features, biomarkers, and genetics. Especially for rare or complex indications, where traditional sources of RWE may lack coverage or sufficient detail, this evidence can fill critical gaps. We reveal how literature-derived RWE can complement other sources and optimize natural history studies, trial design, and label expansion strategies.

5:23 Presentation to be Announced

5:35 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wrap up the day with colleagues, friends old and new at SCOPE's Welcome Reception in the Exhibit Hall. Enjoy drinks, network with exhibitors, and enter to win fabulous raffle prizes (must be present to win). Keep the evening going with dinner at Rosen Shingle Creek's restaurants—no Orlando traffic required!

7:00 Close of Day

7:00 SCOPE Out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle

**Times subject to change. More details closer to the event.*

WEDNESDAY, FEBRUARY 4

6:00 am Sunrise Yoga: In Gratitude for Clinical Research Participants

Join us at sunrise for a restorative yoga session celebrating the invaluable contributions of clinical research participants. Led by a trained instructor, this all-levels practice will focus on mindful movement, breath, and grounding—no experience necessary. Yoga mats and towels will be provided by the hotel; just wear comfortable clothing. During this yoga session, CISCRP asks participants to join us in showing gratitude for the individuals who have participated in clinical research. Each ticket includes a complimentary breakfast and a branded CISCRP yoga towel. Proceeds from this event help support CISCRP's mission. **Yoga begins at 6:30 am.Registration Link:** https://www.ciscrp.org/sunrise-yoga

7:30 Registration Open

BREAKFAST PRESENTATIONS

8:00 BREAFAST PRESENTATION OPTION #1: Reaching the Unreachable: Proven Strategies You Can Apply to Engage Underserved Populations in Global Clinical Trials

Tobias Kruse, PhD, Managing Director, Europe, SubjectWell

Underserved populations are often excluded from clinical trials, limiting engagement, scientific validity, and real-world relevance. Traditional strategies often rely on outdated assumptions and overlook patient realities. This session reveals proven, globally scalable strategies to engage these communities through real-world data (RWD), behavioral insights, and human-centered approaches—replacing guesswork with precision to accelerate inclusive trial enrollment and shorten study timelines.

8:00 BREAKFAST PRESENTATION OPTION #2: From Elusive to Enrolled: A Case Study in Precision Recruitment

Matthew Graffeo, Managing Director, Healthcare & Digital, GCI Health

Nikki Buchmayer, SVP, Digital, Clinical Trial Recruitment, GCI Health

As the pace of innovation accelerates, scientific breakthroughs bring new hope to patients. Effectively including and supporting underrepresented populations is critical for the success of clinical trials designed to benefit these communities. GCI Health's experts will share their "secret sauce" for building meaningful engagement with niche communities along with a real-world example of its methodology in action through its work with the University of Florida's traumatic brain injury trial.

8:00 Sponsored Breakfast Presentation *(Opportunity Available)*

8:00 – 9:00 am WORKING GROUP BREAKFAST: Pharma Leadership Forum: Overcoming Geopolitical Challenges in Clinical Development (Invite Only)

MODERATOR:

Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

Global clinical development is increasingly vulnerable to geopolitical forces. Sponsors face rising risks in running global trials, requiring proactive and diversified strategies to maintain momentum and safeguard patients. A group of top clinical research leaders from biopharma companies will get together at SCOPE to exchange ideas and case studies and to explore opportunities for sponsor companies to unify their efforts. Some of the challenges to be discussed include regulatory divergence, supply chain disruptions, patients recruitment in global trials, data security & sovereignty, IP protection, and cyber threats.

8:25 Transition to Sessions

BREAKING SILOS: HOW CLINICAL OPS AND MARKET ACCESS DRIVE LAUNCH SUCCESS TOGETHER

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Sponsored Presentation *(Opportunity Available)*

9:00 From Approval to Access: Embedding Market Access into Clinical Development—Accelerated by Real-World Data and Artificial Intelligence

Mei Yang, Co-Founder, NouStarX

Regulatory approval is no longer enough—market access must be built in from the start. This session kicks off SCOPE's new Market Access, Pricing & Reimbursement track by exploring how early integration of access strategy influences study design, endpoints, and data capture. Learn how real-world data and AI are reshaping trials to be access-ready, supporting faster launches, smarter evidence generation, and better alignment with payer expectations.

9:25 PANEL DISCUSSION: Access-Ready by Design: Aligning Evidence Generation with Payer Needs

Moderator: Mei Yang, Co-Founder, NouStarX

Clinical trials must now meet both regulatory and payer needs. This panel explores how clinical, HEOR, and market access teams can align early to design trials that support global reimbursement. Panelists will share strategies for optimizing endpoints, data collection, and timelines, plus how AI and real-world data are enabling smarter, access-ready evidence generation to reduce delays and accelerate time to market—across both U.S. and global settings.

Panelists:
Laurence Djatche, Global Value Evidence and Access Lead, Sanofi
Wayne Su, Global Value Lead, Zanidatamab, Jazz Pharmaceuticals
Jon Weber, PhD, Senior Director & Market Access Lead, Cell & Gene Therapy, Bayer AG
Jie Zhang, Head, Global Pipeline Market Access, CSL

9:50 Enhancing Clinical Trial Design for Payer Relevance: Key Considerations for Market Access

Wayne Su, Global Value Lead, Zanidatamab, Jazz Pharmaceuticals

To optimize market access, clinical trials must align with payer expectations beyond regulatory requirements. This includes selecting payer-relevant comparators, ensuring trial sites in key markets, and incorporating long-term follow-up for robust outcomes. Moreover, tokenization can enable real-world data collection during and post-trial. Collecting healthcare resource use (HCRU) and implementing comprehensive patient-reported outcomes (PROs) further support the demonstration of economic and patient value.

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

11:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:15 From Clinic to Market Access: Designing Trials that Secure Global Success

Brian J. Cuffel, PhD, Vice President, Market Access & Health Economics Outcomes Research, Ambros Therapeutics

Market access success starts in the clinic, not at launch. Smart trial design can meet regulator and payer needs, while poor planning risks delays, restricted access, and costly evidence gaps. Breaking silos across clinical, medical, HEOR, and market access is essential to ensure innovation reaches patients quickly and at target prices. This session will share lessons from global launches where access and development were aligned from the start.

11:40 Embedding Market Access into Clinical Development Is a Team Sport: Sequencing of Events for Optimal Outcome

Josephine Li-McLeod, RPH, PhD, Chief Strategy Officer, Stratevi

Market access planning is an iterative process; clinical development activities should inform the access plan and vice versa. To do this successfully, market access and clinical development teams should work in an integrated fashion to ensure timing and tactics are aligned. Learn about access activities happening during clinical development, as well as practical strategies for the timely connection of stakeholder insights, clinical data, and real-world evidence to support access success.

12:05 pm Presentation to be Announced

12:30 Sponsored Presentation *(Opportunity Available)*

12:55 Sponsored Networking Luncheon

Recharge, refuel, and connect over lunch—compliments of SCOPE sponsors! Enjoy a well-deserved break, whether you prefer Florida sunshine or the cool comfort of indoor seating.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*—**Best of Show Winner to be Announced**

Recharge with coffee, dessert, and networking at SCOPE's Exhibit Hall Break! Grab a sweet treat courtesy of our sponsors, visit Game Card Sponsors to collect stickers, and connect with colleagues before the afternoon sessions. Plus, don't miss the announcement of the Best of Show winner!

WEDNESDAY PLENARY AFTERNOON SESSION

2:30 SCOPE around the World, Faces from the Community

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco
SCOPE's Producer Team (Meet the Team!)

2:40 Chairperson's Introduction: Rethinking Trial Design

Speaker to be Announced, PwC

2:42 KEYNOTE INTERACTIVE PANEL: Clinical Is Not an Island: How Med Affairs and Access Can Transform Trial Success




Moderator: Rosemary Rebuli, Global Head, Study & Site Operations, Novartis Pharma AG

Clinical operations leaders face increasing pressure to design trials that not only deliver clean data but also support downstream market success. This keynote panel explores how biopharma organizations can break down functional silos by integrating insights from medical affairs, market access, and field-facing roles like MSLs and CRAs. Panelists will discuss how early cross-functional collaboration improves protocol design, enhances site and prescriber engagement, and aligns clinical development with real-world needs.

Panelists:
Karen Correa, PhD, Vice President, Development Operations, Boehringer Ingelheim
Raza Zaheer, Medical Head, Next Gen Immunology, North America, Sanofi
Jie Zhang, Head, Global Pipeline Market Access, CSL

3:12 SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, SCOPE, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:23 Chairperson's Introduction: AI Adoption in eClinical Technology

Nagaraja Srivatsan, CEO, Endpoint Clinical, Inc.

3:25 KEYNOTE INTERACTIVE PANEL: Change Management for AI Adoption in Pharma Clinical Development Teams




Moderator: Mike Sullivan, Executive Director, Global Development Operations Business Insights & Technology, Bristol Myers Squibb Co.

AI is rapidly entering clinical development, but the real challenge isn't the technology—it's managing the people, processes, and culture shifts required for adoption. This panel will share practical lessons from pharma leaders on how to align stakeholders, upskill teams, and build trust in AI-driven tools across clinical operations. Discussion will focus on real-world strategies that move beyond theory to accelerate adoption, improve decision-making, and deliver measurable impact in drug development.

Panelists:
Chris Sinclair, PhD, Vice President, Global Therapeutic Platforms, AbbVie, Inc.
Susie Stephens, PhD, Head of Clinical Facing Technology R&D, Amgen
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

3:55 SCOPE's Closing Ceremony Booth Crawl *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

As the flame of another unforgettable SCOPE conference comes to a close, join us for our final reception, our infamous "booth crawl." Just like the Closing Ceremonies of the Games, we'll come together one last time to honor the moments of triumph, teamwork, and inspiration that made this week so special. Gather with friends, old and new, enjoy great food and drink, and celebrate the spirit of unity that connects us all. SCOPE 2026 may be ending, but the memories will last long after the torch goes out.

4:55 Close of Day

5:00 SCOPE out the Restaurants and Shops at Pointe Orlando, via Our Courtesy Shuttle* *(Sponsorship Opportunities Available)*

SCOPE out the restaurants and shops at Pointe Orlando, via our courtesy Shuttle
*Times subject to change. More details closer to the event.

THURSDAY, FEBRUARY 5

7:30 am Registration Open

BREAKFAST PRESENTATION

8:00 BREAKFAST PRESENTATION: Presentation to be Announced

8:25 Transition to Sessions

RWD MEETS RCTs

8:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:35 Not All Real-World Data Is Created Equal: Why Source Matters

Shawn Murphy, MD, PhD, Chief Research Information Officer, Mass General Brigham

As real-world evidence becomes central to clinical and regulatory strategies, too much reliance remains on fragmented, decontextualized data. This session will share how Academic Medical Centers (AMCs), through integrated research platforms like MGB HIRO, provide traceable, audit-ready, clinically rich data at the point of care. Attendees will learn why AMCs are essential partners in generating credible evidence—and how to unlock speed, quality, and trust across the R&D lifecycle.

9:00 Sponsored Presentation *(Opportunity Available)*

9:25 RWD Trial Calibration and ECA

Dorothee B. Bartels, PhD, Strategist, Global Real World Evidence and (Gen)AI in Healthcare

This presentation discusses the calibration of real-world data (RWD) trials and the application of External Control Arms (ECA). It highlights methods to improve trial accuracy, reduce costs, and enhance regulatory acceptance by effectively integrating RWD and ECA for robust clinical evidence.

9:37 Benchmarking Real-World Evidence for Expanding Indications

Nils Kruger, Physician Scientist, Cardiovascular Medicine, Technischen Universitat Munchen (TUM); Instructor, Pharmacoepidemiology and Pharmacoeconomics, Harvard Medical School, Brigham and Women's Hospital

RCTs provide critical evidence of the efficacy of medications but often leave questions unanswered about their effectiveness in diverse patient populations not included in trials or different outcomes. While additional trials answering these questions would be preferred, they may not be available for various reasons or will only become available with delay. In such cases, RWE can offer timely, cost-effective insights.

9:50 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE WORKING GROUPS (IN-PERSON ONLY)

10:15 Find your Working Group

10:20 Interactive Working Groups *(Sponsorship Opportunity Available)*

Step away from the slide decks and into the conversation.

After a full agenda of case studies, technical talks, and panels, SCOPE's Interactive Working Groups offer a unique chance to roll up your sleeves and engage. Choose the topic that interests you—whether it aligns with your expertise or challenges you to think differently. Each group will explore a distinct theme using collaborative formats like hackathons, open innovation challenges, or problem-solving sprints. The only requirement: jump in and contribute.

ROUNDTABLE DISCUSSION: AI-Powered COA Translation: Transforming Global Clinical Trials

Joseph Im, Head of Digital Health Technolgies Operations, Regeneron Pharmaceuticals, Inc.

Discuss how AI can transform the world of COA translations.

- What are the most effective AI technologies in translations?
- AI vs. Human translator—competitive or complementary?
- What quality risks should we consider and how can we mitigate them?
- Regulatory or legal considerations
- What can we do as an industry to optimize AI translations for COA?

ROUNDTABLE DISCUSSION: AI-powered Advances in RWD

Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.

ROUNDTABLE DISCUSSION: The Use of Real-World Data and Evidence in Clinical Trials

Emily Carter, Director, Trial Execution Data Science & Analytics, Data Science & Statistics, AbbVie, Inc.

11:00 Networking Coffee Break

Take a break and reconnect at SCOPE's Networking Coffee Break! Grab a cup of coffee, meet colleagues old and new, and fuel up before the next sessions. A perfect pause to spark conversations and make connections!

AI-DRIVEN ANALYTICS

11:30 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:35 Building a Transformative, AI-Driven Analytics Capability for Clinical Trial Insights

Omkar Dasari, Senior Technical Product Manager, Data & Analytics, Amgen
James Vernille, PhD, Director, Clinical Systems & Analytical Reporting, Global Development Operations, Amgen, Inc.

At Amgen, we are transforming our analytics ecosystem with AI-driven tools that enable near real-time, self-service insights for global development stakeholders. Our next-generation analytics engine features a rebuilt metrics platform, centralized data governance, and a streamlined dashboard landscape leveraging Power BI with Co-Pilot and custom AI interfaces. By implementing AI/ML bots and natural language queries, we are shifting from static reporting to a dynamic, AI-driven experience.

12:00 pm From Proven Results to Product Vision: Advancing Clinical Trial Data Exchange with IgniteData Archer

Joe Lengfellner, IgniteData

Clinical trial data exchange has long limited the pace of innovation in research. This session explores how IgniteData Archer is redefining what's possible, drawing on proven results from live trials at Memorial Sloan Kettering Cancer Center. Presented by Joe Langfellner, IgniteData's Chief Product Officer, the talk connects real-world impact to a forward-looking product vision—explaining why Archer's success led him to join IgniteData and how he and the team are shaping the future of clinical trial data exchange.

12:13 Sponsored Presentation *(Opportunity Available)*

12:25 PANEL DISCUSSION: Transforming Clinical Data Analytics with Agentic GenAI

Moderator: Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson

This panel explores how Agentic Generative AI (GenAI) is reshaping clinical data analytics by enabling autonomous and adaptive systems that streamline data processing, uncover complex patterns, and generate actionable insights. The discussion will address the opportunities and risks of integrating Agentic and Applied GenAI into regulated clinical research environments, highlighting their potential to drive innovation while maintaining data integrity and patient safety.

Panelists:
Bhargava Reddy, PhD, Senior Director, Advanced Insights and Solutions, Janssen
Richard Young, Chief Strategy Officer, CluePoints

12:50 Transition to Lunch

12:55 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 SCOPE Summit 2026 Adjourns

And that's a wrap! Thank you for joining us at SCOPE Summit 2026. We hope you leave inspired, connected, and energized for what's next in clinical trials. Safe travels, and we can't wait to see you at the next SCOPE event!

2:00 POST-CONFERENCE TRAINING SEMINARS*

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 4:00 pm

TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams
TS2: Quality and Process Improvement Techniques and Tools

THURSDAY, FEBRUARY 5, 2026 2:00 – 5:00 pm
FRIDAY, FEBRUARY 6, 2026 9:00 am – 12:00 pm

TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications* *In-Person Only, Separate registration required.*

THERAPEUTIC AREA SPOTLIGHT

Complimentary Short Courses – These are Offered IN-PERSON ONLY. RSVP Required.
Sponsored Presentation (Opportunities Available)

TA SPOTLIGHT 1: CNS and Mental Health Trials

Tuesday, February 3, 2026 | 11:00 am – 1:10 pm

Instructors:
Rachna Saralkar, MD, MS, Principal Investigator, Flourish Research
Scott Askin, Portfolio Innovation Director, Program Strategy & Planning, Global Clinical Operations, Novartis Pharma AG
Rachel McGovern, Senior Associate Director & Lead, Clinical Development Operations, Boehringer Ingelheim Pharma GmbH & Co. KG
Christine Oman, Clinical Trial Manager, MindMed
Kristen Dopf, MHS, PA-C Principal Investigator, Suburban Research Associates
Emma Rouse, Senior Patient Engagement Lead, Global Trial Optimization, Regeneron

CNS and mental health trials remain some of the most complex and challenging studies to execute. Unique patient populations, evolving diagnostic criteria, high placebo response rates, and burdensome assessments create hurdles that impact trial design, recruitment, and execution. This TA Spotlight session explores practical strategies for optimizing trial execution, from protocol design through site selection, recruitment and operations. Explore common challenges—including site selection and readiness, recruitment and retention of diverse patient populations, and the operationalization of innovative digital endpoints.

12:45 pm CLOSING Q&A: Optimizing CNS & Mental Health Trials: Practical Strategies for Success

This final session provides an open forum for audience questions and shared discussion, allowing participants to reflect on the topics covered throughout the workshop. Speakers and attendees will explore common themes, lessons learned, and remaining challenges, helping to reinforce key takeaways and highlight considerations for future study design and execution.

Rachna Saralkar, MD, MS, Principal Investigator, Flourish ResearchScott Askin, Portfolio Innovation Director, Program Strategy & Planning, Global Clinical Operations, Novartis Pharma AGRachel McGovern, Senior Associate Director & Lead, Clinical Development Operations, Boehringer Ingelheim Pharma GmbH & Co. KGChristine Oman, Clinical Trial Manager, MindMedKristen Dopf, MHS, PA-C Principal Investigator, Suburban Research AssociatesEmma Rouse, Senior Patient Engagement Lead, Global Trial Optimization, Regeneron

11:00 am CLOSING Q&A: Optimizing CNS & Mental Health Trials: Practical Strategies for Success

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TA SPOTLIGHT 2: Obesity and Metabolic Trials

Tuesday, February 3, 2026 | 3:00 – 5:35 pm

Instructors:
Laura Whitmore, Senior Director, Business Operations and Clinical Outsourcing, Kailera Therapeutics
Jennifer Jackman, PhD, MBA, Associate Director, Industry Partnerships and Strategic Programs, Duke Clinical Research Institute
Sheetal Telang, Vice President, Americas Head of Therapeutic Strategy, IQVIA
Calvin Bidner, Key Account Executive, Clinical Trials, Abbott Point of Care
Rebecca Clark, MBChB MRCGP DFSRH, Principal Investigator, Layton Medical Centre
MIchelle Hartmann, MS, CCRP, Director, South Broward Research

With a record number of obesity and metabolic trials currently underway, the demand for innovative strategies to advance clinical development has never been greater. This spotlight session explores approaches to strengthen collaborations, improve trial efficiency, and address the complexities of recruitment and retention in obesity and metabolic disease studies. Presentations will highlight emerging partnership models, novel tools such as point-of-care pre-screening to reduce costly screen failures, and best practices for aligning operational execution with scientific goals. The session concludes with an interactive panel discussion where experts from sites, sponsors, and research organizations will share practical insights on overcoming barriers and driving progress in obesity and metabolic trials.

Sponsored Presentation *(Opportunity Available)*

TA SPOTLIGHT 3: Oncology Trials

Wednesday, February 4, 2026 | 8:30 am – 12:55 pm

Instructors:
Ariel Bourla, MD, PhD, Executive Director, Head of Solid Tumor Oncology, Data Science and Digital Health, Johnson & Johnson R&D
Gaelan Ritter, Vice President, Global Head, Clinical Digital Development, Sanofi
Ramya Krishna Chunduru, Clinical Research Regulatory Supervisor, Office of Centralized Regulatory Operations, Baylor Scott & White Health
Sidharth (Sid) Jain, Senior Vice President, Clinical Development & Data Science, Recursion
Shaalan Beg, MD, Senior Advisor for Clinical Research, National Cancer Institute (NCI)
Guneet Walia, PhD, Senior Director, Data Science and Digital Health, Johnson & Johnson

With oncology remaining the most active area of clinical research worldwide, the complexity and volume of trials demand new operational, technological, partnering, and regulatory approaches. This spotlight session examines how oncology trials are evolving across diverse settings, from the growth of community-based and decentralized research models to innovations in regulatory workflows and data management. Expert presentations will showcase applications of AI, advanced digital tools, and computational pathology in driving efficiency, improving data quality, and advancing precision medicine. The program culminates with a forward-looking panel discussion on the future of oncology trial design, collaboration, and patient care

ONCOLOGY TRIALS ECOSYSTEM: COMMUNITY TRIALS AND REGULATORY APPROACHES

Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

8:30 am Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

Fuel up and connect at SCOPE's Coffee Break in the Exhibit Hall! Visit booths you haven't seen, network with colleagues and exhibitors, and cast your final vote for the Best of Show Award—make your vote count!

UNIQUE CHALLENGES AND SOLUTIONS IN ONCOLOGY TRIALS

TA SPOTLIGHT 4: Cell and Gene Therapy

Wednesday, February 4, 2026 | 8:30 am – 12:55 pm

Instructors:
Kian Talaei, Senior Consultant, Dedham Group
Magdalene Pedersen, Vice President, Global Commercial Lead, Cell Therapy Myeloma & Lymphoma, Bristol Myers Squibb Co.
Ivan M. Borrello, MD, Director, Multiple Melanoma & BMT & Cell Therapy, Tampa General Hospital
Curt Kugel, PhD, Associate Principal, Strategy Insights & Planning, ZS Associates

Bringing Cell & Gene Therapies to the Community: Cell and gene therapies can only reach their full potential when access extends beyond the centralized academic centers. This therapeutic area spotlight session highlights operational learnings from approved products and examines the logistical challenges of bringing trials and commercial treatments closer to patients, particularly in the evolving CAR T landscape. Through collaboration, streamlined workflows, and expanded site capabilities, the community can create scalable models that integrate these therapies into standard care pathways and improve patient reach & access.

Chairperson's Remarks *(Sponsorship Opportunity Available)*

Sponsored Presentation *(Opportunity Available)*

POST-CONFERENCE TRAINING SEMINARS

IN-PERSON ONLY. Separate Registration Required.

Thursday, February 5, 2026 | 2:00 – 5:00 pm
Friday, February 6, 2026 | 9:00 am – 4:00 pm

TS1: Service Provider Oversight: Practical Tools for Clinical Operations Teams

Instructor:
Maria Veleva, MD, Founder & Managing Director, Veleva Consulting Ltd.; Individual Consultant; Senior Trainer, Barnett International

Effective oversight of service providers is essential to ensure the quality, compliance, and success of clinical trials. This practical, interactive course is designed for clinical operations professionals who work closely with external vendors such as CROs, laboratories, and other service providers. Participants will explore key regulatory expectations and industry best practices for vendor oversight and gain hands-on tools to manage relationships, assess performance, and mitigate risks throughout the clinical trial lifecycle.

TS2: Quality and Process Improvement Techniques and Tools

Instructor:
Susan M. Leister, MBA, PhD, CQA, CSSBB, Vice President, Quality & Compliance, Technical Resources International, Inc.; Senior Trainer, Barnett International

Proper investigation of issues identifying the root cause is critical to the long-term success of a clinical trial. Using the correct quality tools and techniques is essential to ensure the problems are fully understood, investigated, and resolved. This interactive course is designed for quality staff and clinical staff who work seek to better understand how to select and utilize various tools to investigate risks and proactively mitigate them.

Thursday, February 5, 2026 | 2:00 – 5:00 pm
Friday, February 6, 2026 | 9:00 am – 12:00 pm

TS3: ICH E6(R3) and E8 Implementation Workshop: Understanding Key Points and Practical Applications

Instructor:
Nikki Christison, President, Clinical Resolutions, Inc.; Senior Trainer, Barnett International

This highly interactive course will provide an overview of key changes between E6(R2) and E6(R3) through the hands-on development of a protocol outline. Key elements from E6 GCP and E8 General Considerations for Clinical Trials will be addressed through application of pre-planning, development, risk management and execution throughout the life cycle of a study. Participants will apply information from E6 and E8 in practical, applicable and useful ways for every type of study design from Phase I to Phase IV, in-house or outsourced portions, as well as considerations for non-traditional study designs for collection of data. The course design takes into consideration all roles across an organization from clinical operations, regulatory, quality, project management, manufacturing, development, medical, etc. and how they must cross over and work together across a product lifecycle to ensure the protection of study subjects, the integrity of the data, the reliability of results, and the ability of the studies to meet their objectives.

CLINICAL TRIAL
VENTURE, INNOVATION & PARTNERING

Accelerating Innovation, Accessibility and Scale

February 2-3, 2026 | Rosen Shingle Creek | **Orlando, FL** | In-Person

Join us for the 4th annual exclusive gathering of senior-level investors, corporate executives, entrepreneurs, and start-up leaders from the clinical trials space.

As part of the renowned *17th Annual* **SCOPE Summit**, the *4th Annual* **Clinical Trial Venture, Innovation & Partnering Conference,** taking place February 2-3, 2026, offers a focused, executive-level platform designed for forward-thinking investors, corporate leaders, and entrepreneurs shaping the future of clinical research. This high-impact, boutique event convenes a distinguished audience of C-suite executives from investment firms, growth-stage and mature companies, large pharma, hospitals, and corporate venture arms. With a dual focus on current market dynamics and long-term forecasting, this conference delivers actionable insights into emerging investment trends, scalable innovation strategies, and the evolving landscape of clinical trial partnerships. Attendees will benefit from candid discussions, fireside chats, and curated panels led by industry pioneers, covering capital allocation strategies, innovation pipelines, regulatory tailwinds, and risk-adjusted returns. Explore the exhibit hall featuring high-growth start-ups and established players, and gain visibility into breakthrough technologies, investment-grade opportunities, and strategic collaborations that will define the clinical trial ecosystem over the next decade. Whether you're seeking to inform your investment thesis, identify acquisition targets, or shape your corporate venture strategy, this event is engineered to support long-term value creation, portfolio growth, and strategic decision-making.

Meet Our Co-Chairs

Rana Lonnen
General Partner
Science Capital

Dave Stevenson
COO & Managing Director
Merck Global Health Innovation Fund

Sunny Kumar
Partner
GSR Ventures

Learn more at SCOPEsummit.com/partnering

3rd Annual

SITE INNOVATION AWARD

Monday, February 2, 2026 | 4:35 pm

WHAT IS IT?

We are excited to announce our 3rd Annual Site Innovation Award, recognizing sites and partnerships pioneering new approaches to improve clinical trials. This is an opportunity to highlight your successes and be recognized by your peers for your dedication to advance clinical research. By sharing your actionable solutions, you will inform the broader Clinical Operations Community at SCOPE.

Our definition of innovation is inclusive of low-tech or high-tech solutions, or any site operations-related process improvements that effectively reduce site burden and improve a site's ability to advance clinical research while providing patient-centered care.

WHO IS IT FOR?

We welcome submissions from sponsors, sites, site networks, academic medical centers, CROs, and service providers who are leveraging new technologies, processes, workflows, and/or partnerships in an effort to modernize clinical trials while reducing site burden.

HOW DOES IT WORK?

All submissions will be reviewed by our panel of industry experts representing perspectives from various sides of the clinical operations ecosystem. Finalists will be selected to present their concepts in-person at SCOPE taking place February 3-6, 2025 in Orlando, Florida.

Each finalist will be given 2 minutes to present, followed by a question-and-answer session conducted by the judges. Each submission will be reviewed and rated for creativity in improving site success, reducing burden, and supporting digitalization of clinical trials. Awards will be given for 1st through 3rd place with special recognition for all presenters.

We are looking for:

- Solutions that reduce site burden and enable staff to do their best work
- Approaches that improve diversity, community engagement, and trial access
- Innovations that streamline workflows, improve data flow, or enhance activation
- Technologies or partnerships that make clinical trials easier to conduct—and easier for patients to participate in

The bottom line: if it helped a site succeed, we want to hear about it.

Deadline for submissions: October 31, 2025

EVENT HOSTS & JUDGES

Angela DeLuca
Associate Vice President, Global Study Operations, Amgen

Kimberley Kallsen
Head of Patient & Site Engagement, Global Clinical Development

Mara Kramer
Feasibility Transversal Projects Lead, Global Clinical Early Operational Strategy, Sanofi Operations, Boehringer Ingelheim

Sean Soth
Senior Vice President, Strategy and Global Business Partnerships, SCRS

Jeffrey Somerstein
Site Director, Pioneer Clinical Studies

Amanda Wright
Co-Founder & COO, Javara

Learn more at: SCOPEsummit.com/site-innovation-award

10th Annual

PARTICIPANT ENGAGEMENT AWARD

SCOPE

IN MEMORY OF JERRY MATCZAK
#BELIKEJERRY #SCOPEsummit

Monday, February 2, 2026 | 5:10 pm

WHAT IS IT?

Now in its 10th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. PEA embodies the values and personal accomplishments of Jerry Matczak, who sadly passed away soon after receiving the inaugural 2017 award. We dedicate this award to Jerry in the hope that it will serve as a reminder of his ideals and accomplishments. SCOPE's 2026 Participant Engagement Award program is brought to you by Cambridge Healthtech Institute (CHI)'s SCOPE.

HOW DOES IT WORK?

We welcome submissions from all facets of the industry, including, but not limited to: Sites, CROs, e-Patient Advisors, Agencies, Start-Ups, and Sponsors, and invite you to submit your best work in the Patient Recruitment and Retention communications field.

- Each submission will be reviewed and rated for creativity, innovation, regulatory and legal compliance, and the ability to improve access, awareness, and participation in clinical trials.
- Prior to SCOPE in February, Finalists will be invited to submit a 3-minute video showcasing their work.
- The video presentation, on-stage discussion and judging will occur LIVE in-person at SCOPE taking place February 2-5, 2026, in Orlando, Florida.

HOW TO WIN?

Your submission must truly be designed to engage potential, current, or alumni study participants and/or their influencers and show marked improvements in the status quo.

- We *are not* looking for: tip sheets, guidance documents, promotional "brochure-ware" or rewritten press releases
- We *are* looking for: submissions based in education, recruitment, awareness and beyond. This can be anything from an interactive tool to a Superbowl Television commercial. The world is your pallet … find your medium and your muse.

Deadline for submissions: October 31, 2025

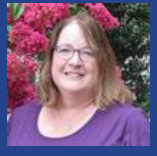
EVENT HOSTS & JUDGES

Micah Lieberman
Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

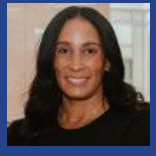
Kelly McKee
Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award

David Sall
President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award

Brad Watts
CAR-T Recipient and Patient Advocate, Emily Whitehead Foundation



Beth Brooks
Head of Patient Insights & Behavioral Sciences, Patient Informed Development & Health Value Translation, Sanofi



Jameka Hill
Senior Director, Global Head of Clinical Trial Health Equity, Moderna

Samantha Rogers
Director, Patient Engagement & Patient-Centered Innovation, Raven (RA Ventures)

Mark Evans
Managing Director, Faze

Neha Shah Londono
Director, Global Clinical Trial Diversity, Equity, and Inclusion, Pfizer Inc.

Jessica Perry
Senior Director, Trial Optimization, Kymera Therapeutics

Learn more at: SCOPEsummit.com/participant-engagement-award

SUMMIT FOR CLINICAL OPS EXECUTIVES

BEST of SHOW AWARD

Recognizing Exceptional Innovation in Technologies Used by Clinical Research Professionals

The 2025 Best of Show Awards offer exhibitors of the SCOPE Summit an exclusive opportunity to distinguish and highlight their products, ranging from an innovative application, technology, tool, or solution. The SCOPE community is invited to identify exceptional innovation in technologies used by life science professionals, voting on most impactful new products of the year.

Exhibitors are invited to enter your products via the online submission form below. Attendees are encouraged to explore the novel technologies and solutions firsthand in the exhibit hall and vote for the People's Choice Award once the conference has begun. Please note, selection is not based upon level of sponsorship or exhibit participation.

Submission Deadline: Friday, January 24, 2026

Learn more at: SCOPEsummit.com/best-of-show-awards

CONFERENCE VENUE & HOTEL

ROSEN SHINGLE CREEK

9939 Universal Boulevard
Orlando, FL 32819

Discounted Room Rate: $269 s/d

Discounted Room Rate Cut-Off Date:
January 5, 2026

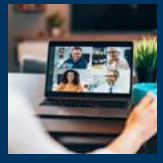
For hotel reservations please go to the Travel Page of **SCOPEsummit.com »**

Can't Make it to Florida?

Join via our Robust Virtual Platform:

- INTUITIVE INTERFACE
- LIVE CHAT
- RECORDED SESSIONS
- COMPANY BRANDING
- LIVE SESSIONS
- DOWNLOADS






2026 EVENT HIGHLIGHTS

GOLF TOURNAMENT

Sign up today for the 5th Annual Masters of Clinical Research Golf Tournament, morning Fun Run, and Yoga
Connect with your peers and colleagues at SCOPE's 5th Annual Masters of Clinical Research Golf Tournament. Opportunities are available for those who would like to golf or attend. If you would like to sponsor the event, please visit the website below.

Masters of Clinical Research
SCOPE's 5th Annual Golf Tournament

Monday, February 2, 2026 | 8:00 am

*Limited space available. Separate registration and fee required for Golf.

Interested in taking part in the 5th Annual Golf Tournament? For complete event information, including registration* details, visit SCOPEsummit.com/sponsor-exhibitor/masters-of-clinical-research

(A portion of your green fee will be donated to "CureSMA" Spinal Muscular Atrophy. The donated portion will also be matched by SCOPE Summit 2026)

Attention Pharma!

50 for 25

If you are an employee of the following TOP 50 Pharmaceutical Companies as cited by Pharmaceutical Executive you may attend this meeting at a 25% discount off the current rate.

Enter Keycode PH25 upon checkout when registering.

REGENERON, moderna, Abbott, MENARINI, Jazz Pharmaceuticals, Dr. Reddy's, SANDOZ, GRIFOLS, BAUSCH Health, IPSEN, UCB, FRESENIUS, YUNNAN BAIYAO, MITSUBISHI CHEMICAL GROUP, ORGANON, Eisai, VERTEX, SUN PHARMA, SPHBio, Pfizer, abbvie, CHUGAI, Johnson & Johnson, NOVARTIS, MERCK, Roche, Bristol-Myers Squibb, SERVIER, STADA, Otsuka, AstraZeneca, SANOFI, gsk, Takeda, GILEAD, novo nordisk, biogen idec., Incyte, Lilly, AMGEN, Boehringer Ingelheim, BAYER, VIATRIS, CSL, teva, MERCK, astellas

For More Information and Group Discounts, Please Contact:

Melissa Dolen, Account Manager
T: (+1) 781-972-5418
E: mdolen@healthtech.com

TEAM DISCOUNTS FOR SMALL BIOPHARMA

If you are coming from a **small pharma, biotech start-up, or virtual pharma** we understand conference and training budgets are tight. We want your clinical teams at SCOPE!

This applies to small clinical trial sponsor organizations with less than $1B in annual revenue.

HOST A USER GROUP, WORKSHOP, OR COMPANY MEETING

Co-locate your User Group, a Workshop, or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market to prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point!

FOR PARTNERING AND SPONSORSHIP INFORMATION:

Companies A-E

Ilana Quigley
Director, Sales
(+1) 857-636-2334
Email

Companies F-N

Katelin Fitzgerald
Sr. Manager, Business Development
(+1) 781-247-1824
Email

Companies O-V

Jon Stroup
Lead Business Development Manager
(+1) 781-972-5483
Email

Companies W-Z

Patty Rose
Vice President, Sales
(+1) 781-972-1349
Email

VENTURE, INNOVATION & PARTNERING

Brian Caine
Manager, Strategic Partnerships
(+1) 908-809-0946
Email

SPONSORSHIP & EXHIBIT OPPORTUNITIES

CHI offers comprehensive packages that can be customized to your budget and objectives. Sponsorship allows you to achieve your goals before, during, and long after the event. Packages may include presentations, exhibit space and branding, as well as the use of delegate lists. Signing on early will maximize your exposure to qualified decision-makers and drive traffic to your website in the coming months.

PRESENTATIONS — Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15 or 30-minute podium presentation on the scientific agenda, exhibit space, branding, full conference registrations, use of the event mailing list, and more.

LUNCHEON PRESENTATIONS

Opportunity includes a 30-minute podium presentation in the main session room. Lunch will be served to all delegates in attendance. A limited number of presentations are available for sponsorship, and they will sell out quickly. Sign on early to secure your talk!

USER GROUP / HOSTED WORKSHOP

Meeting room set for 20-40 people, ready with LCD projector & screen. CHI will co-market to prospective attendees and extend your users a discount to attend.

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional branding and promotional opportunities are available, including:

- Golf Tournament Sponsorships
- Conference Tote Bags
- Beverage Carts, Swag Bags, Golf Course Hole Sponsorships
- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Conference Materials Advertisement
- Padfolios and More...




For additional information, please contact:

Companies A-E

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Director, Sales
(+1) 857-636-2334
iquigley@healthtech.com

Companies F-N

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Sr. Manager, Business Development
(+1) 781-247-1824
kfitzgerald@cambridgeinnovationinstitute.com

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Lead Business Development Manager
(+1) 781-972-5483
jons@healthtech.com

Companies W-Z

Patty Rose
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VENTURE, INNOVATION & PARTNERING

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2025 ATTENDEE DEMOGRAPHICS

- 23% Biotech
- 19% Pharma
- 16% CRO
- 16% Services
- 13% Healthcare
- 9% Financial
- 3% Academic
- 1% Societies

- 57% Executive
- 24% Sales & Marketing
- 11% Manager
- 7% Scientist
- 1% Other

REGISTRATION

17th Annual SCOPE
February 2-5, 2026
Orlando, Florida
Rosen Shingle Creek

INDIVIDUAL EVENT PRICING

Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Monday, February 2 access to the following.

- *SCOPE's Fifth Annual Masters of Clinical Research Golf Tournament (separate registration required)*
- *Afternoon Pre-Con User Group Meetings & Hosted Workshops (opportunities available)*
- *Evening Kick-Off Plenary Keynote and 10th Annual Participant Engagement Awards*
- *SCOPE's Kick-Off Networking Reception*

In addition, you will receive on-demand access to all presentations for one year.

	Pharma-Biotech-Med Device Finance Company	CRO-Vendor-Tech Consultancy-Services Provider	Investor/Banker, Academic-Government-Site-Hospital
Early Bird Discount until October 24, 2025	$2,499	$2,649	$1,299
Early Registration Discount until November 14, 2025	$2,799	$2,849	$1,599
Advance Registration Discount until January 9, 2026	$3,099	$3,049	$1,699
Standard Registration after January 9, 2026 and on-site	$3,199	$3,299	$1,799

GROUP EVENT PRICING

Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Monday, February 2 access to the following.

- *SCOPE's Fifth Annual Masters of Clinical Research Golf Tournament (separate registration required)*
- *Afternoon Pre-Con User Group Meetings & Hosted Workshops (opportunities available)*
- *Evening Kick-Off Plenary Keynote and 10th Annual Participant Engagement Awards*
- *SCOPE's Kick-Off Networking Reception*

In addition, you will receive on-demand access to all presentations for one year.

Early Bird Discount until October 24, 2025	$1,799	$1,899	$899
Early Registration Discount until November 14, 2025	$1,999	$2,099	$1,099
Advance Registration Discount until January 9, 2026	$2,249	$2,199	$1,199
Standard Registration after January 9, 2026 and on-site	$2,299	$2,399	$1,299

ON-DEMAND CONFERENCE PRICING

For those who cannot attend SCOPE on February 2-5, 2026, whether in-person or virtual. After the Event, will receive access to recordings of ALL presentations. Does not include Q&A or networking sessions.

Standard Registration and Onsite	$2,399	$2,549	$1,199

POST-CONFERENCE TRAINING SEMINARS PRICING

I have registered for SCOPE and wish to also attend one of the Training Seminars	$899
I have not registered for SCOPE but wish to attend one of the Training Seminars	$1499

FLEXIBLE REGISTRATION

SEAMLESSLY SWITCH BETWEEN IN-PERSON AND/OR VIRTUAL

Select an in-person or virtual option, and you have the flexibility to switch your preferred event experience at any time leading up to the conference. Our flexible registration is designed to take the uncertainties out of these uncertain times.

Want to Register by Phone?

Contact our Registration department at (+1) 781-972-5400 or Toll-free in the US 888-999-6288.

WAYS TO SAVE!

Group Discounts are Available!

Have your colleagues or entire team attend SCOPE SUMMIT In-Person or Virtually. Purchase a full price registration here, and participants from the same organization will receive a 25% discount when registering through the **Group Registration page**.

For more information on group discounts contact Melissa Dolen at (+1) 781-972-5418.
mdolen@healthtech.com

Alumni Discount — SAVE 15%

CHI appreciates your past participation at Summit for Clinical Ops Executives (SCOPE). As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 15% off the registration rate.

Alumni, X, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.

How to Register: SCOPEsummit.com

reg@healthtech.com • P: (+1) 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **SCOPE PDFF** when registering!