FINAL AGENDA

16th Annual

SCOPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

FEBRUARY 3-6, 2025 • ROSEN SHINGLE CREEK • ORLANDO, FL

Driving Innovation in Clinical Trials & Digital Health

Discount registration by January 17

CONFERENCE PROGRAMS:

- PATIENT-CENTRIC TRIAL DESIGN & DEI
- FEASIBILITY & STUDY START-UP
- RECRUITMENT & ENGAGEMENT
- SITE ENGAGEMENT & ENABLEMENT
- BUDGETING & RESOURCES
- OUTSOURCING
- SMALL BIOPHARMA STRATEGIES
- DATA
- DECENTRALIZED & HYBRID
- DIGITAL HEALTH TECHNOLOGIES
- REAL WORLD EVIDENCE
- AI FOR CLINICAL TRIALS
- QUALITY & MONITORING
- BIOMARKERS & PRECISION MEDICINE
- CLINICAL SUPPLY & LOGISTICS
- INVESTOR CONFERENCE

FEATURED SPEAKERS:

Deirdre BeVard
SVP, R&D Strategic Operations, CSL Behring GmbH

Janice Chang
CEO, TransCelerate Biopharma, Inc.

Angela DeLuca
AVP, Global Study Operations, Amgen

Nasha Fitter
Co-Founder & CEO, FOXG1 Research Foundation

Andrew Lee
SVP & Head, Global Clinical Trial Operations, Merck & Co.

Disa Lee Choun
Head, Integrated Clinical and Operational Analytics (ICOA), J&J Innovative Medicine

April Lewis
Head, Innovative Health, Global Development, J&J Innovative Medicine

Brian Martin
Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.

Mark McClellan, MD, PhD
Dir, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

Tania Simoncelli
VP, Science in Society, Chan Zuckerberg Initiative LLC

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

Rana Lonnen
Managing Director, Capital Novartis

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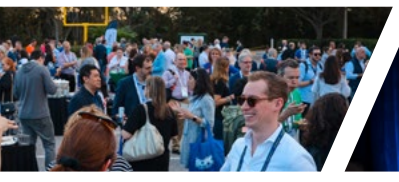
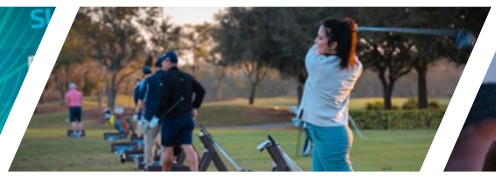
CONFERENCE PROGRAMS:

A FEW SHORTCUTS TO HELP YOU AT SCOPE:

CONFERENCE AT-A-GLANCE

CONFERENCES	MONDAY, FEBRUARY 3– WEDNESDAY, FEBRUARY 5	WEDNESDAY, FEBRUARY 5– THURSDAY, FEBRUARY 6
C1: PATIENT-CENTRIC TRIAL DESIGN & DEI	Patient Voice in Trial Design and Protocol Development	Developing and Executing Effective Diversity Plans
C2: FEASIBILITY & STUDY START-UP	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	Patient Engagement and Retention through Communities and Technology
C4: SITE ENGAGEMENT & ENABLEMENT	(NEW) 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	Partner Selection and Trial Design	Vendor Oversight & Resource Management
C8: DATA	Clinical Data Strategy and Analytics	Data Science, ML, and AI
C9: DECENTRALIZED & HYBRID	Decentralized and Hybrid Trials	DCTs and Clinical Innovation
C10: DIGITAL HEALTH TECHNOLOGIES	Digital Biomarkers and End Points in Clinical Trials	Digital Measurements Implementation at Scale
C11: REAL WORLD EVIDENCE	Accessing and Generating RWD	Leveraging RWD for Clinical Research
C12: AI FOR CLINICAL TRIALS	(NEW) Generative AI in Clinical Research	(NEW) AI for Trial Optimization
C13: QUALITY & MONITORING	Clinical Quality and Risk Management	Central and Remote Monitoring
C14: BIOMARKERS & PRECISION MEDICINE	Modernizing Lab, Biomarker & Data Management Operations	Biomarker & Biospecimen Technology & Innovation
C15: CLINICAL SUPPLY & LOGISTICS	Data Technology for End-to-End Clinical Supply Management	Clinical Supply Chain Strategies to Align Process, Products and Patients
INVESTOR CONFERENCE	**Clinical Trial Venture, Innovation & Partnering*** *(Tuesday, February 4 – Wednesday, February 5)*	
TRAINING SEMINAR	**Risk-Based Quality Management for Clinical Trials: Implementing ICH E6 R3 Requirements** *(February 6-7)*	






DAILY HIGHLIGHTS

Now more than ever, the important work of this clinical research community requires collaboration and innovation. In its 16th year of fostering these goals, SCOPE Summit 2025 will take place February 3-6, 2025, in Orlando, FL at the Rosen Shingle Creek. The programming focuses on advances and innovative solutions in all aspects of clinical trial innovation, planning, management, and operations. SCOPE 2024 attracted more than 4,000+ leaders in clinical operations and research, and all conference tracks will feature best practice case studies relevant to clinical operations experts and those new to the field.

Day 1 — MONDAY FEBRUARY 3

AM

- Welcome to Florida!
- SCOPE's 4th Annual Masters of Clinical Research Golf Tournament
- Golf Luncheon
- User Group Meetings

PM

- Monday Kickoff Plenary Keynote
- 9th Annual Participant Engagement Award
- SCOPE's Kickoff Reception

Day 2 — TUESDAY FEBRUARY 4

AM

- SCOPE's 5K Rise and Shine Fun Run!
- Morning Coffee
  Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and delicious treats, courtesy of our sponsors
- Tuesday Morning Opening Keynotes
- Grand Opening Coffee & Refreshment Break in the Exhibit Hall
- Conference Tracks (1-15)
- 1-on-1 Networking

PM

- Sponsored Networking Luncheon
- Networking Coffee & Dessert Break in the Exhibit Hall
- Conference Tracks (1-15)
- Welcome Reception in the Exhibit Hall
- SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle
- Clinical Trial Start-Up Pitch Contest
- Clinical Trial Venture, Innovation & Partnering

Day 3 — WEDNESDAY FEBRUARY 5

AM

- Breakfast Presentations
- Conference Tracks (1-15)
- Coffee Break in the Exhibit Hall
- 1-on-1 Networking
- Clinical Trial Venture, Innovation & Partnering

PM

- Sponsored Networking Luncheon
- Networking Coffee & Dessert Break in the Exhibit Hall
- Conference Tracks (1-15)
- SCOPE Site Innovation Awards
- Wednesday Afternoon Plenary Keynotes
- SCOPE Best of Show Awards
- Booth Crawl & Refreshment Break in the Exhibit Hall *(Last Chance for Exhibit Viewing)*
- SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle
- 1-on-1 Networking
- Clinical Trial Venture, Innovation & Partnering

Day 4 — THURSDAY FEBRUARY 6

AM

- Breakfast Presentation
- Conference Tracks (1-15)
- 1-on-1 Networking

PM

- SCOPE Send-Off Luncheon Presentations
- User Group Meetings
- TRAINING SEMINAR: Risk-Based Quality Management for Clinical Trials: Implementing ICH E6 R3 Requirements *(February 6-7)*

CALCULATE. ACCOMMODATE. **INNOVATE.**

Clinical trials, digital health, and clinical research are essential for **advancing medical knowledge, improving patient care, and developing new treatments and therapies for the patients** who need them. Execution of this vital work requires **collaboration, innovation, and strategic decision-making**. Now in its **16th year** of fostering these joint efforts to be inclusive of all stakeholders, SCOPE Summit 2025 will take place February 3-6, 2025, in Orlando, FL, at the Rosen Shingle Creek. 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 9th annual Participant Engagement Awards, the 2nd annual Site Innovation Award, special cross-department panels, multiple receptions, the 4th annual Master of Clinical Research **golf tournament**, and a morning Fun Run. SCOPE keeps gaining momentum (**14% YoY Growth** last year alone!). At the request of our attendees, we have **extended the coverage in 2025** on Patient-Centric Trial Design, Site Engagement, Recruitment, Generative AI, Small Biopharma Strategies, 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 **4,000 attendees and 1,200 different organizations from 30 countries**, in clinical operations, innovation, and digital health, and we want you and your company to join the community!

IN 2024...

- **4,000+ Participants**
- **75%+ of Delegates Titled as Decision-Makers**
- **240 Industry-Leading Sponsors/Exhibitors**

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.

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2024 ATTENDEE DEMOGRAPHICS

- 25% CRO
- 22% Biotech
- 17% Services
- 16% Healthcare
- 13% Pharma
- 5% Financial
- 1% Academic
- 1% Societies

- 58% Executive
- 24% Sales & Marketing
- 10% Manager
- 8% Scientist

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PLENARY KEYNOTE PRESENTATIONS

MONDAY, FEBRUARY 3, 2025

MONDAY MORNING GOLF TOURNAMENT

8:00 am SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for Golf.*

9:00 am Registration Open

PRE-CONFERENCE WORKSHOPS AND USER GROUPS: IN-PERSON ONLY

Co-locate your User Group, Workshop, or even your company's Annual Meeting with SCOPE Summit: www.scopesummit.com/scope-user-group-meetings

1:00 – 1:45 pm WORKSHOP: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 4:00 pm WORKSHOP: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:

Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)

Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry to get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees.

Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.

1:00 – 4:00 pm WORKSHOP: Efficient Importation of Biological Materials into the U.S.

SPEAKERS:

Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection

Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 pm Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco

3:58 pm Chairperson's Introduction

Speaker to be Announced, Parexel

4:00 pm KEYNOTE PRESENTATION: Fast Forward to 2035: What Success Could Look Like in Converging Clinical Research and Care...And How to Get There


Janice Chang, CEO, TransCelerate Biopharma, Inc.

Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; former Commissioner, FDA

On this stage in 2024, we spoke about our mission to converge clinical research and clinical care for the benefit of patients worldwide. We envision a world in which patients participate in research at the point of care as seamlessly as possible. And although we've set our vision, and organized the work we are undertaking accordingly, the real fruits of those efforts will not be seen in the short term. We will use this session to talk about where we hope we will be by 2035. What might we reasonably achieve? What does success look like? And what will it take to get there? This session is designed to help us all to raise our gaze beyond the near-term and find inspiration in the future possibilities.

4:25 pm Tips for Getting the Most Out of SCOPE

Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI); 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida!

https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 pm Chairperson's Introduction

Speaker to be Announced, Endpoint

4:35 pm INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?






PANEL MODERATORS:

Bridget Kotelly, Senior Conference Director, Cambridge Healthtech Institute

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

Whether at an industry event, a focus group, or another venue, we've all heard "real" patients share stories of their conditions, treatment journeys, and lives. But how accurate is what you've heard? Are the patients who speak on the podium or in a focus group truly representative of the majority of patients, or do they represent just a small sample? Our panel of patient engagement experts from some of the country's leading patient advocacy groups and other representative organizations will give the story of what it's like for most patients

PLENARY KEYNOTE PRESENTATIONS

to live with illness, including rare and chronic diseases. Join us and learn about the true challenges of disease burden, unmet needs, treatment progression, the challenges–and rewards–of clinical trials, and more.

PANELISTS:

Emily McCormack, Social Media Director, New York Blood Center
Quynh Tran, MPH, Director of Patient Activation, Cystic Fibrosis Foundation
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Brett Kleger, CEO, Inspire
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute

5:05 pm SCOPE's 9th Annual Participant Engagement Awards Introduction: Industry Mandate and Collaboration for Expanding Access to Clinical Trials *(Sponsorship Opportunity Available)*

5:10 pm SCOPE's 9th Annual Participant Engagement Awards

PANEL MODERATORS:

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

Now in its 9th 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 2025 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:

Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, CEO, Action from Data
Gretchen Goller, Senior Director, Head of Patient Recruitment, Clinical Development Operations, Seagen
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Patient Advocacy Ambassador, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception *(Sponsorship Opportunities Available)*

Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! Meet your old friends, make some new ones, and soak up the Florida vibes and another amazing SCOPE conference experience.

7:00 pm Close of Day

TUESDAY, FEBRUARY 4, 2025

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

Join SCOPE's Coordinators on Tuesday, February 4 for our Fun Run! This is an informal event, and ALL abilities are welcome. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Details will be shared closer to the event...remember to pack your sneakers.

7:30 am Registration Open

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

Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

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

**Must be present to win.*

8:30 am Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards

Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco

8:40 am Chairperson's Plenary Keynote Introduction

Speaker to be Announced, ZS

8:42 am KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

This talk focuses broadly on Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing promising science, prioritizing key opportunities, and adapting to a changing landscape. More specifically, how has Merck decided to optimize clinical trial operations, and the relationships between product development teams, clinical sub-teams, and clinical trial teams? What are key considerations for clinical trial planning, site selection, and protocol design? And, what and why did Merck keep many core capabilities "in-house"?

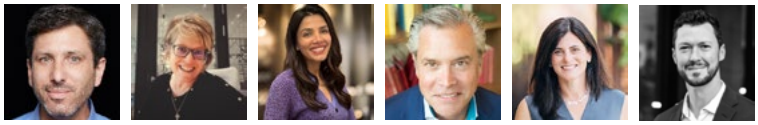
9:10 am THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying?

(Special LIVE Episode with Studio Audience)

SCOPE's Gameshow Host: Brett Kleger, a man whose dream was to be a wedding singer or gameshow host
Brett Kleger, CEO, Inspire
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

In today's episode of "The Clinical Trial Dating Game" we have our pharma industry bachelor looking for a volunteer for his trial. He must question and choose from among three patients, who are hidden from view. He has access to all of their data, but there is more to this person than data, so how will he know what questions to ask? How will he avoid bias? How will he recruit on time? Knowing how important patient centricity is to the clinical research industry and with so much on the line, will our bachelor land a date? What could go wrong?

9:20 am KEYNOTE PANEL DISCUSSION: How Patients Can—And Must—Disrupt Traditional Pharma Clinical Trials



PANEL MODERATOR:

PLENARY KEYNOTE PRESENTATIONS

Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

Should biopharma companies be the only "sponsors" for clinical trials of new medicines? Does the current model limit opportunities for unmet needs in small populations or leveraging repurposed drugs? This panel will gather leaders demonstrating ways that patient-led non-profit organizations are challenging assumptions and taking a leadership position in medicine development. No longer can we think of patients as a guest at pharma's table -- is the next transformation in medicine development going to be entirely patient-led?

PANELISTS:

Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Tania Simoncelli, Vice President, Science in Society, Chan Zuckerberg Initiative
Grant Mitchell, MD, Co-Founder & CEO, Every Cure

9:50 am Grand Opening Coffee & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)* **Best of Show Voting Opens**

Join us for the Grand Opening Networking Coffee Break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their latest and greatest innovations and products...Voting opens for our Best of Show Awards so don't forget to vote.

WEDNESDAY, FEBRUARY 5, 2025

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GEN AI FOR TRIALS

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

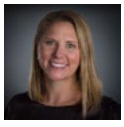
SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one Break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

2:30 pm SCOPE Around the World, Faces from the Community

Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco
Marina Filshtinsky, MD, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco

2:35 pm Chairperson's Introduction

Brad Stefanovic, Head, Clinical Innovation, Pro-ficiency, a Simulations Plus Company



2:37 pm KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation explores strategies for fostering innovation within a large pharmaceutical organization by focusing on four key areas: developing a clear mandate and compelling vision to guide innovation efforts; designing and engineering an infrastructure that supports creativity and collaboration; building a high-performance, diverse team empowered to drive innovation; and seeking opportunities for true patient-centricity and sponsor-agnostic innovation. By aligning these elements, the organization can create a sustainable innovation ecosystem that prioritizes patient outcomes and drives transformative breakthroughs in healthcare.

3:00 pm KEYNOTE PRESENTATION: How Can Sponsors Leverage Increasing Technology Capabilities with Quality

Angela DeLuca, Assistant Vice President, Global Study Operations

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 pm SCOPE Award Winners & Announcements *(Sponsorship Opportunity Available)*

Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco

3:25 pm Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 pm KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

PANEL MODERATOR:

Disa Lee Choun, Head, Integrated Clinical and Operational Analytics (ICOA), J&J Innovative Medicine

Gen AI, a ground-breaking approach that seamlessly merges artificial intelligence into our daily lives, holds immense potential for transforming the pharmaceutical and healthcare industries. This paradigm shift not only demands a thorough understanding of the ethical implications, potential biases, and social consequences of AI systems but also requires a steadfast focus on creating tangible value that benefits individuals and society at large. By harnessing advanced AI technologies, Gen AI can pave the way for unparalleled breakthroughs, elevating patient care, enabling personalized medicine, streamlining processes, and revolutionizing the way we approach healthcare as a whole. Join the debate on the real value-based use cases and explore the endless possibilities that Gen AI brings to the table.

PANELISTS:

James Gallagher, Senior Director, Innovative Health, J&J Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 pm Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall Break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 pm Close of Day

Cambridge Healthtech Institute's 2nd Annual

Patient-Centric Trial Design and Protocol Development

Innovative Protocol Design Techniques to Incorporate Patient Voice and Improve Trial Operations

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 2nd Annual

Developing and Executing Effective Diversity Plans

Tools and Strategies to Improve Diversity and Achieve Enrollment Goals

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.
**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.
Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace
Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials
INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche
While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.
INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)
U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing
INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP
This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There
Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA
In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall (Sponsorships Available) Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their latest and

greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

PATIENT VOICE IN PROTOCOL DESIGN

11:00 Chairperson's Remarks

Cheryl Byers, Sr VP Consulting, Advarra

11:05 Can You Hear Me Now? Amplifying the Patient Voice in Trial Design

Peter Schaeffer, Digital & Process Optimization Leader, Digital Analytics & Performance, GSK

Gain a clear distillation of not only why amplifying the patient voice is worthwhile but how to do it at a practical level. Our goal is to leave session participants energized and equipped with the confidence and tools to turn up the volume on patient voices in designing trials. We will focus on sharing freely available solutions that can support effective partnership and decision-making between patients and participants.

11:35 Challenges of Including Patient Voice in EU CTR Materials

Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals

Kailey Walsh, Manager, Clinical Operations, Alnylam Pharmaceuticals

EU CTR is making strides in creating harmonization, improving transparency, and increasing the use of patient lay language in materials for participants and their care partners. However, the EU CTR also brings challenges with timelines and getting the global patient voice incorporated in clinical trial materials. This session will explore challenges and impactful solutions for bringing the patient voice into EU CTR patient recruitment materials.

12:05 pm Harnessing Generative AI for Enhanced Protocol Planning: Empowering the Site and Patient Voice

Erin Reynolds, Associate Director, Clinical Trial Diversity & Inclusion, AbbVie

Sasha Tyndale, Director, Diversity & Patient Inclusion, AbbVie

By harnessing Generative AI, AbbVie aims to enhance the protocol planning process by leveraging the power of artificial intelligence to synthesize unstructured data gathered from the insights and perspectives of both sites and patients. This approach elevates the site and patient voice, ensuring that their needs, preferences, and experiences are considered in the development of clinical trial protocols.

12:35 Assumptions Are the Root of All Mistakes: Designing Engaging Studies Whilst Avoiding the "Unicorn" Protocol Design

Melissa Harris, Global Head, Patient Recruitment & Engagement, Fortrea

Assumptions in trial design impacts everything. Headways been made with patient-centric design philosophy but ultimately its sites who must execute the study. Listening to and incorporating input from sites and patients concurrently drives new treatments to the right patients, faster. A duel-centric approach is a potent model for achieving efficiency whilst meeting demands of sponsors and patients, beyond simply listening for intelligent, and compassionate protocol measures.

1:05 PANEL DISCUSSION: Harnessing Data to Devise Patient-Centric Trials

Moderator: Speaker to be Announced, PPD Part of Thermo Fisher Scientific

Clinical trials face significant challenges, with 80% encountering enrollment difficulties and up to 30% of participants withdrawing. By prioritizing patient needs and experiences at every stage—from design to retention—these challenges can be mitigated through strategic use of technology and data. Join our expert panel to explore patient-first models that leverage enhanced data collection, AI insights, and patient-friendly structures, making trials more efficient, accessible, and effective. Discover insights from using services and tools like FSP Feasibility, Integrated Trial Optimization, and Study Gage, designed to optimize trials with a focus on the patient. This session will demonstrate how by applying the right data strategies, one can design truly patient-centered trial experience.

Panelists:

Speaker to be Announced, PPD Part of Thermo Fisher Scientific

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

EMBEDDING INCLUSIVE DESIGN INTO GLOBAL DEVELOPMENT

3:20 Chairperson's Remarks

Speaker to be Announced, ObjectiveHealth

3:25 Diversity Action Plans: Perspectives from CDER—OCE-FDA

Tamy Kim, Director for Regulatory Affairs and Policy, Oncology Center for Excellence (OCE), FDA

The FDA's Diversity Action Plan guidance sets expectations for advancing diversity in clinical trial populations so that clinical trial data are representative to the U.S. population. In this session, get insights into the agency's expectations, and discuss strategies for meeting these standards. Attendees will gain a deeper understanding of how to align their trials with regulatory guidance to ensure representativeness in clinical research.

3:55 PANEL DISCUSSION: Diversity Action Planning: From Study Design to Site Execution

Moderator: Magnus Franzen, Partner, Wavestone

Learn how to embed inclusive design and planning capabilities in global clinical development to increase the likelihood of success at sites. Understand what sites really need from global sponsors to increase the number of underrepresented participants in their studies. Hear about the mechanics of enrollment monitoring between global, US site engagement and site teams to drive continuous improvements.

Panelists:

Jodie Allen, PhD, Senior Director, Clinical Trial Diversity, AstraZeneca

Allison Guy, Senior Regulatory Affairs Director, AstraZeneca

Paris Johnson, Senior Associate Director Site Engagement—Diversity, AstraZeneca

4:25 Optimizing Usability is Optimizing Data Quality—Elevating CNS Endpoint Data through Patient and Site-Centric Solutions

Holly Robertson, PhD, Head of Advisory Services, Professional Services, Medidata, a Dassault Systemes Co.

Karin Wallace, Associate Vice President, Client Solutions & Strategic Accounts, Cogstate

CNS trials present unique challenges for patients and study staff, including raters, due to complicated diagnostic criteria often involving subjective reporting and clinical judgment. These factors can lead to variability in outcomes, prompting the need for additional safeguards to ensure reliable endpoint data. However, such measures can introduce operational burdens that impact the patient and site experience, potentially negatively affecting patient enrollment, study timelines, and the ultimate success of the trial. In this session, we will explore a tech-enabled, science-driven approach to eCOA design and delivery that addresses the complexities inherent in CNS clinical trials, resulting in improved operational efficiency. Learn how this joint approach optimizes solution usability to achieve high-quality endpoint data for clinical trials and an improved experience for patients and sites.

4:55 Protocol Simplification Championship: Where Innovation Meets Simplification, Collaboration, and Recognition

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

In this session, BMS shares its Protocol Simplification Championship (PSC) designed to encourage protocol simplification through an innovative competition and recognition program. Research has shown competition can spur creativity and motivate teams. Further, recognition programs contribute to a sense of purpose and fulfillment among employees. PSC is built upon these principles and represents a novel, unique approach to simplifying protocols, allowing collaboration, celebrating innovation, and building a culture of recognition.

5:25 AI-Powered Patient Recruitment & RWD

Wout Brusselaers, CEO, Deep 6 AI

In this presentation, learn how AI can be applied to both structured and unstructured clinical data in order to access real-time data from an ecosystem of health systems across the country, query sites' EMR data for precision patient matching, and collaborate with IRB-approved site researchers via a shared platform.

5:40 What Women Want: Actionable Insights to Grow Enrollment for Your Next Trial from Research with Over 3,500 Diverse Women

Megan Preovolos, Director, Patient Recruitment, Bus Dev, Everyday Health Group

Give us 15 minutes, and we'll give you 3,500 patient voices. The Everyday Health Group Pregnancy & Parenting team reveals highlights from their new study on what attracts women to join clinical trials and what keeps them engaged. The

study includes insights from women 18 - 45, with more than 40% identifying as women of color. Learn why Gen Z is so unique, how to craft nuanced messaging that improves recruitment and the unique concerns and preferences of key cohorts.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

THE FUTURE OF PROTOCOL DESIGN: DIGITALIZATION AND SIMPLIFICATION

8:50 Chairperson's Remarks

Christopher Riley, Director, Strategic Insights, Solutions, H1

8:55 Going with the (Digital Data) Flow: Reduce Time & Effort on Study Start-Up

Donald Jennings, Senior Advisor of Systems, Tech@Lilly Clinical Design and Operations, Eli Lilly and Company

Clinical study start-up involves tedious manual processes, hindering efficiency and innovation. The Digital Data Flow (DDF) initiative aims to automate these processes, replacing manual asset creation with a dynamic, digital approach. This session will explore how the Unified Study Definitions Model, developed by CDISC and TransCelerate, enables this transformation, helping to digitize protocols and enhance the downstream benefits, ultimately speeding up study start-up and delivering new medicines faster.

9:15 This, Not That: Data Collection, Optimized

Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck

This session provides an update on a collaborative research study looking at optimizing the collection of non-core and extraneous clinical research data collection practices, with the aim to reduce patient and site burden. The session will explore considerations that helped define the study methodology and initial study findings from a sample of protocols. Speakers will also discuss implications of early study findings and potential strategies to optimize protocol data collection.

9:35 Designing and Operationalizing Double-Blind RCTs with Sham Controls in Digital Therapeutics

Gazal Vakili, Director, Digital Health Innovation, Sumitomo Pharma

This presentation delves into the design and operationalization of double-blind randomized controlled trials (RCTs) featuring sham controls within the realm of digital therapeutics. By exploring best practices for trial design, participant engagement, and data integrity, we will discuss the critical elements that ensure robust and reliable outcomes. Attendees will gain insights into the challenges and innovative solutions in conducting RCTs in digital health, paving the way for evidence-based therapeutic interventions.

9:55 Putting Patients at the Heart of Research: Transforming Trials through Inclusive Design

Akiko Shimamura, Senior Vice President, Trial Design & Optimization, TriNetX, LLC

As industry leaders and healthcare organizations seek to enhance the relevance and impact of their research, they face the dual challenge of designing studies that are scientifically rigorous and genuinely representative.
Explore how inclusive trial design empowers diverse patient populations and advances research outcomes. Akiko Shimamura, SVP of Trial Design & Optimization at TriNetX, shares strategies to integrate patient perspectives into protocol design, overcoming barriers to patient participation, and leveraging real-world data to enhance inclusivity in trial cohorts. Learn actionable frameworks for equitable, technology-driven, patient-centric research that enhances the relevance and impact of clinical studies, putting the patient at the heart of every study.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

DRIVING THE CHARGE: DIVERSITY LEADERS SHARE HOW THEY ARE CHAMPIONING THE IMPERATIVE OF INCLUSIVE TRIALS

11:20 Chairperson's Remarks

Natasha Massias, Solutions Architecture Director, Datacubed Health

11:25 PANEL DISCUSSION: Diversity in Clinical Trials: The Homework and the Homeruns

Moderator: Bianca Green, Lead, Diversity & Inclusion in Clinical Trials, Takeda

Join a panel of industry leaders who are spearheading initiatives to break down barriers in recruiting racially, ethnically, and socioeconomically diverse populations. Hear case study examples of initiatives they have implemented—

learn what has worked and gain lessons from what has not. Engage in open discussions, exchange innovative ideas, and collaborate with peers to develop actionable steps that advance Diversity, Equity, and Inclusion in clinical trials.

Panelists:

Monique Adams, PhD, MS, Executive Director, Global Head Diversity & Inclusion in Clinical Trials, Sanofi

Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck

Marie Emms, Head, Patient Engagement and Recruitment, Global Development Operations, Bristol Myers Squibb

Neha Shah Londono, Director, Global Clinical Trial Diversity, Equity, and Inclusion, Pfizer

Michel Reid, Senior Director & Head, Global Demographics & Diversity, GSK

LaShell Robinson, MS, Senior Director Diversity, Equity & Inclusion in Clinical Research, Takeda

Kate Wilson, Head of Clinical Trial Diversity, Global Clinical Operations, Biogen

12:25 pm Leave Nothing to Chance: A Strategic Guide to Inclusive Clinical Trial Enrollment

Neil Weisman, President, Continuum Clinical

Many organizations have yet to implement a corporate DEI strategy that effectively informs Clin Ops on how to approach developing a Diversity Action Plan. This session will provide practical strategies for those who do not have an established DEI framework and are charged with improving engagement and enrollment of trial participants in underrepresented communities. You'll leave with actionable insights to drive meaningful, inclusive progress in clinical research.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

DIVERSITY ACTION PLANS: EXPECTATION, DEVELOPMENT, IMPLEMENTATION, AND FEEDBACK

8:20 Chairperson's Remarks Chairperson's Remarks

Speaker to be Announced, PPD Part of Thermo Fisher Scientific

8:25 PANEL DISCUSSION: Actionable Strategies to Promote Diversity in Clinical Research Participation

Moderator: Katie Shaw, Senior Director Patient Recruitment & Enablement, Global Patient and Site Services, IQVIA

This topic gets a lot of airtime; rightfully so. But airtime doesn't equal progress. Progress comes most quickly when we exchange learnings freely. This panel will share findings based on efforts in diversifying clinical research participation, including insights from TransCelerate sponsor interviews. The goal? To help us all make more progress more quickly in diversifying clinical research participation.

Panelists:

Brittany Gerald-Lewis, Associate Director, Clinical Trial Health Equity, Moderna, Inc.

Neha Shah Londono, Director, Global Clinical Trial Diversity, Equity, and Inclusion, Pfizer

Casey Orvin, CCO, Alcanza Clinical Research

9:10 Incorporating real time patient insights at scale and speed to inform trial strategy at a Portfolio scale: An AbbVie and HealthMatch case study.

Speaker to be Announced, HealthMatch

Incorporating the patient 'voice' into drug development has well established benefits. This presentation will address how AbbVie is harnessing rapid, real-time patient insights to help inform their clinical trial design process. The speakers will touch on the importance of scale and timing when incorporating patient insights and the power of a portfolio wide strategy.

9:40 Supplementing Patient Burden Assessments with Patient-Centric Learnings to Drive Operational Excellence

Eduardas Valaitis, Managing Director, Pharma R&D Analytics, PwC

Meenakshi Sinha, Pharmaceutical and Life Sciences, PwC

Ellen Lau, Senior Product Director, Clinical Design & Patient Engagement, GSK

Incorporating patient perspective into protocol design is vital for patient-centric trials. We will describe an automated patient burden assessment framework that we use to quantify patient burden in trials. However, specific patient populations experience burden differently. We will discuss approaches for incorporating such differences and recommend mitigation strategies aimed at reducing the negative impacts on patient experience and operational outcomes.

10:10 Being Intentional About Diversity in Clinical Trials: Real-World Results

Tamara Oyejide, Senior Director of Patient Recruitment, Apnimed

You've heard the reasons as to why diversity in clinical trials is so important. You may have even received "tips and tricks" to increase diversity in your own clinical trials. In this session we invite you to sit back, relax, and listen to real-world examples of how two Phase 3 clinical trials met or exceeded the CDC national averages while recruiting key patient populations. Listen, Learn, and Execute!

10:40 PANEL DISCUSSION: Challenges of Diversity Data in Clinical Trials: Bridging Gaps for Inclusive Research

Moderator: Michel Reid, Senior Director & Head, Global Demographics & Diversity, GSK

Diversity in clinical trial data is crucial, yet cultural differences in health behaviors, communication styles, and varying values on research participation create barriers. Historical data lacks representation, and limited infrastructure in certain regions further hinders inclusivity. Without diverse participation, we risk missing important insights and correlations. Expanding access and investing in outreach to diverse populations are essential steps to bridging these gaps for more inclusive and accurate research outcomes.

Panelists:

Claire Riches, Vice President, Clinical Solutions, Citeline

Sema Sgaier, CEO & Co Founder, Surgo Health

Samantha Shaw, Director, Product Management, TriNetX

Rita Yankyera, Assistant Medical Director, Elligo Health Research

11:10 Networking Coffee Break

INTEGRATING CLINICAL RESEARCH INTO CLINICAL CARE

11:50 Chairperson's Remarks

Speaker to be Announced, HealthMatch

11:55 Taking Research to the People: Decentralized Trials, Leveraging Technology to Enable Community-Based Approaches

Amy Yarker, Senior Business Development Manager, Life Sciences Partnership & Growth, NIHR Clinical Research Network

This session will explore the transformative power of decentralized clinical trials, taking research beyond traditional hospital clinics to reach participants in social care settings and underserved communities. Discover how cutting-edge technology and innovating methods are breaking down barriers, improving accessibility, and generating valuable real-world evidence. From mobile research units to patients' homes, learn how decentralized trials are bringing research directly to people.

12:25 pm Talk Title to be Announced

Alison Bawden, Director, Regulatory Affairs, Veristat

12:55 Integrating Community Health Solutions: A Case Study

Shelly Barnes, Global Clinical Innovations and Digital Lead, UCB

Is it feasible to develop a clinical research plan that incorporates community-based health entities into clinical research? The FDA supports this, but challenges persist, especially when community solution providers struggle with establishing a favorable cost model. Additionally, is there evidence that investigators and providers are willing to adopt this model? This UCB case study explores the advantages, disadvantages, and potential of integrating community health solutions into clinical trials.

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Rethinking Trial Design with Real-World Data

Kwame Marfo, Senior Director, Product Strategy, Clinical Development, Komodo Health

Discover how Komodo's innovative no-code solution, MapView with MapAi, is reshaping the way clinical development teams understand and address the diverse healthcare journeys of patients from different racial and ethnic backgrounds.

Komodo's presentation will explore how streamlined data insights can uncover disparities, enhance trial inclusivity, and optimize patient representation, empowering teams to design more equitable and effective clinical trials.

2:00 SCOPE Summit 2025 Adjourns

"I wanted to send you a quick message to express my gratitude and relay how much I enjoyed SCOPE. What a monumental success – you know how to rock a conference!"

– Director of Research Operations, Mary Crowley Cancer Research

Cambridge Healthtech Institute's 15th Annual

Data-Informed Feasibility and Investigator Selection

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

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 12th Annual

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

New Processes and Technologies to Streamline Study Start-Up and Operations

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.
**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.
Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace
Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials
INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche
While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.
INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)
U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing
INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP
This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There
Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA
In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

EVOLUTION OF SITE MODELS

11:00 Chairperson's Remarks

Brook White, Vice President of Marketing/Commercial Operations, Marketing, CRIO

11:05 Mapping the Evolving Global Landscape of Investigative Site Models

Joan Chambers, Senior Consultant, Tufts Center for the Study of Drug Development

Over the past decade, clinical trial models have evolved with site staff embedded in clinical care, remote sites, retail pharmacies, urgent care, and mobile units. Many part-time sites have exited, while Site Management Organizations and Site Networks have scaled. Tufts CSDD presents new research mapping these changes, providing insights into the current global site landscape, emerging structural changes, and future site management strategies.

DATA SCIENCE & ANALYTICS TO IMPROVE SITE SELECTION AND TRIAL EXECUTION

11:35 Opportunities for AI, RWD, and People to Power Trial Optimization

Desiree Abu-Odeh, PhD, MPH, Senior Scientist, Global Trial Optimization, Merck

Dana Wheeler, Associate Principal Scientist, Global Trial Optimization, Merck

Artificial intelligence (AI) and real-world data (RWD) pose exciting opportunities for streamlining and optimizing trial feasibility assessments. This presentation describes where AI and RWD fit together in trial feasibility work, need-to-know steps for clinical trial professionals using AI alongside RWD, and how we can use multiple methodologies to foster cross-functional collaboration to innovate and enhance trial feasibility.

12:05 pm Adopting Predictive Methods to Drive Geostrategy, Site Selection, and Timelines

Andrew Coates, Feasibility Director, AbbVie

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.

12:35 Streamlining Clinical Trials with AI-Powered Insights: An End-to-End Approach to Design, Planning, and Execution

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

Kelly Hoang, Associate Director, Data Scientist, Gilead

When designing and planning trials, study teams often struggle with fragmented systems where data analytics are isolated, making it difficult to effectively apply insights to key decisions. Medidata is redefining study planning by delivering an integrated, end-to-end trial management ecosystem that leverages real-time data and AI to streamline decisions, from protocol optimization and feasibility assessments to live forecasting. This session will explore how a connected platform can minimize inefficiencies and empower smarter decision-making by study teams.

1:05 Streamlining Site Feasibility: Unlocking Data for Faster Clinical Trials

Steven Martin, Vice President, Product Management and Strategy, WCG

Cristin MacDonald, PhD, Vice President, Client Delivery, WCG

Amy Froment, Senior Director & Head, Global Trial Optimization, Regeneron Pharmaceuticals

Study start-up is a process commonly prone to delays due to the involvement of multiple stakeholders, systems, and decisions. One decision that can greatly impact the success of a study is determining which sites to partner with. Unfortunately, this process is broken. In this session, we'll discuss a new approach to site feasibility, which unlocks data and insights for more precise sites matched to a study, reduces burden, and creates faster response times from potential sites.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

INCORPORATING DIVERSITY INTO FEASIBILITY PROCESSES AND FRAMEWORKS

3:20 Chairperson's Remarks

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

3:25 Expanding Horizons: Site Selection Strategies and Training for Diverse Enrollment Success

Marland May, Associate Director, Clinical Trial Diversity & Inclusion, AbbVie

Erin Reynolds, Associate Director, Clinical Trial Diversity & Inclusion, AbbVie

The main focus will be on the efforts to engage New to AbbVie investigators as well as New to Research site teams including the training opportunities available to support health care providers to enhance their research capabilities. New site performance indicators will be shared, highlighting the various factors that are taken into account when assessing adoption and progress: screening, enrollment, protocol compliance, and risk-based quality management signals.

3:55 Data Partnerships + AI to Maximize Study Optimization

Rohit Nambisan, Co-Founder & CEO, Lokavant

Clinical trials are growing more complex as biopharma shifts to rarer indications, with fewer participants per study and site, and increased challenges like data biases and unrepresentative datasets. AI and cross-industry data collaboration can address these issues by aggregating diverse data to predict outcomes, optimize strategies, and control timelines/budgets. Join us as we discuss how data partnerships and AI can optimize study performance and accelerate access to life-saving therapies for underserved patients.

4:25 Presentation to be Announced

4:55 PANEL DISCUSSION: Integrating Diversity into Clinical Trial Feasibility & Site Engagement

Moderator: Lauren Chazal MBA, Chief Business Development Officer, Headlands Research

As we shape the future of clinical trials, it's critical to embed Diversity, Equity, and Inclusion (DEI) into the very fabric of feasibility studies. This panel will delve into the transformative power of technology, data-driven methodologies, and collaborative frameworks in revolutionizing site engagement. By examining successful case studies and sharing valuable insights, we aim to foster a discussion on making trials more efficient, patient-centered, and inclusive.

Panelists:

Gary Cobb, Head, Diversity & Inclusion in Clinical Trials, Boehringer Ingelheim Pharmaceuticals, Inc.

Asma Kasuba, Senior Director, R&D Data Science Global Development, Johnson and Johnson Innovative Medicine

Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Co.

5:25 Streamlining Study Start-Up: Accelerating Site Activation & Reducing Tech Burden for Sites

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

We hear you. Sponsors are challenged with lengthy study start-up processes and ongoing monitoring, while the clinical trial sites are burdened with technology redundancy and sign-on silos obstacles. In this talk, we will give the sponsor's and site's perspective on the progress made to overcome these issues and share real examples of how sponsors and sites are collaborating and streamlining the user's experience.

5:40 Presentation to be Announced

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

ACCELERATING FEASIBILITY & SELECTION PROCESSES

8:50 Chairperson's Remarks

Speaker to be Announced, PointClickCare

8:55 Trial Enrollment Modeling

Asma Kasuba, Senior Director, R&D Data Science Global Development, Johnson and Johnson Innovative Medicine

Site selection is the critical function of evaluating trial sites in specific geographical regions to ensure on-time and on-target enrollment. Historical performance alone has been shown to be a weak predictor of future success. To enhance site selection and planning, Johnson & Johnson Innovative Medicine has developed an advanced analytics pipeline. This framework offers robust enrollment predictions and simulations for multi-center clinical trials, while maintaining flexibility across various therapeutic areas.

9:15 Towards an Automated Site Feasibility with Use of Ontologies

Thierry Escudier, Portfolio Lead, Pistoia Alliance

The Pistoia Alliance provides a unique pre-competitive collaborative platform. The Clinical Operations Ontology project aims to automate clinical trial processes by making data machine-readable through ontologies. Site feasibility is vital for aligning protocol requirements with site capabilities. Our POC targets efficiency in trial planning by enhancing the manual site feasibility process. By automating processes through ontologies and existing databases, we foresee to expedite decision-making and reduce redundant efforts.

9:35 Data-Driven Approach to Prioritize Site Selection for Patient Enrollment

Vladimir Ivanov, PhD, Director, Group Lead, AI/ML Quantitative Data Sciences, Pfizer Inc.

We propose an AI/ML approach to identify and prioritize sites for patient's enrollment for sickle cell disease clinical trials. We used spatial disease prevalence, healthcare provider and Pfizer sites data and coupled it with the geo-spatial analysis. Our analysis produced the list of Pfizer sites ranked by the potential to maximize patient's enrollment.

9:55 Finding the Sweet Spot for Study Start-Up Collaboration

Speaker to be Announced, Advarra
Ashley Davidson, Vice President, Product Lead, Advarra

In this session, we will uncover the often-overlooked needs of sites during study start-up, addressing the need for connectivity between study-specific and site operations technology. We'll explore how to achieve the perfect balance of site centricity, highlighting practical strategies to enhance site engagement and streamline processes, while ensuring critical visibility for sponsor teams. By understanding the diversity of site technologies and need for standardized feasibility and contract operations, we'll aim to create a startup landscape that works for every study stakeholder.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

SUPPORTING SITES TO ACCELERATE START-UP

11:20 Chairperson's Remarks

Nick Whitney, Senior Director & Commercial Lead, Site Suite, IQVIA Technologies

11:25 PANEL DISCUSSION: Balancing Innovation Options to Enable Adoption: Perspectives from Sponsors, CROs, and Sites

Moderator: Jane Myles, Co-Lead, Priority Initiative 3B, DCT Playbook, Decentralized Trials & Research Alliance (DTRA)

Change is hard—for everyone who is part of it. There are lots of innovative ways to operationalize trials—and yet they are rarely adopted at scale. How do we better balance the drive to innovate with the friction of adoption? What might we do better, together, to create better conditions for adoption? What can we use to progress, and what are the challenges that need attention?

Panelists:

Christopher Herrick, Vice President, Research Technology, Mass General Brigham
Jean Kelly, Head of Clinical Operations, Rochester Clinical Research
Teri Wright, Director Clinical Lab Sciences & Devices Innovation, Clinical Trial Lab & Diagnostic Design, Eli Lilly and Company

11:55 Effective Strategies for Pharma to Engage Naive Sites in Clinical Research

Carrie Lewis, Executive Director, Clinical Program Optimization, Endo
Suzy Montanye, Site Relationship Manager, Endo
Terry Oehler, MD, Founder, Colorado Clinical Research

As an industry, it is essential to continuously bring on new sites and new physicians, ensuring they do not become a one-and-done site or Principal Investigator (PI). Therefore, Endo will share strategies to help Sponsors find effective ways to guide naive sites on where to start in clinical research and support them every step of the way, from pre-study visits to study closure.

12:25 pm AI, Simulation, Avatars: Increase Content Velocity in Clinical Research Training

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

In this talk, I will discuss simulation as a means to mitigate deviations before they occur in your clinical program, the implementation of avatars for drafting of content and scalability of global programs, and AI-enabled agility to adjust content rapidly, based on the ever-changing needs of life science programs (protocol drafting, amendments, and deviation mitigation).

12:55 Sponsored Networking Luncheon
Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced
SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

2:35 Chairperson's Introduction
Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization
April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine
This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond
Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson
Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.
Panelists:
James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing
We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies
Speaker to be Announced, PAREXEL International
Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl
Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

DATA & TECHNOLOGY PLATFORMS: ACCELERATING SITE FEASIBILITY PROCESSES

8:20 Chairperson's Remarks
Stacey Burghdoff, Executive Director, Strategic Alliance Management, ProPharma

8:25 Streamlined Clinical Trial Feasibility with Technology, Tools, and Process Excellence
John Yannone, Director, Feasibility Strategy, Innovative Health Engagement and Advocacy, Johnson and Johnson
How do we enable teams to navigate complex organizational dynamics, synthesize disparate data sets, and maximize trial efficiency all while balancing costs and speed? A suite of enabling tools and improved processes has shown the potential to drive fit-for-purpose protocols, efficient country strategy, and enhanced site selection while improving transparency and leveraging AI/ML + advanced analytics. This discussion will empower teams to discuss best practices in feasibility.

8:55 Optimizing Clinical Strategy with Innovative Technology in a Dynamic Organization
Amy McCormick, Associate Director, Global Trial Optimization, Regeneron
Mark Springer, Director, Global Trial Optimization, Regeneron
During a period of significant growth and change, Regeneron implemented an innovative digital-first strategy to overcome challenges in trial feasibility, patient engagement, and site identification. Using an agile methodology and an Appreciative Inquiry model, the team identified workflow issues, designed a comprehensive solution, and delivered a flexible, scalable application. This

approach improved data quality, standardized deliverables, and optimized resources, providing a foundation for future business needs.

9:25 Are Questionnaire Licensing and Translation Hurdles Slowing Down Your Trials?

Jasmine Walker, Director, COA Partnership, Linguistic Validation, RWS Group

Jonathan Norman, Director, Localisation, Linguistic Validation & eCOA SME, Y-Prime

Are questionnaire licensing and translation hurdles slowing down your trials? Early and strategic engagement with your licensing, localization, and eCOA partners might be the solution you're looking for. In this session, two seasoned experts in eCOA and localization will dive into key preparatory steps to make your study more feasible from both a licensing and localization standpoint—driving smoother regulatory approvals and helping you meet critical timelines. You'll gain practical insights on successful early engagement, including essential questions to ask your providers, the value of connecting partners early, setting realistic expectations, and assessing content suitability—empowering you to streamline diverse global study start-ups.

9:55 The Value of Quest Lab Data in Clinical Trial Design and Recruitment

Steve Schlachter, Director Product Portfolio, Healthcare Analytics Solutions, Quest Diagnostics, Inc.

Learn the value of lab data in clinical trials and the power of Quest to help optimize site feasibility and selection, improve investigator selection, and optimize patient identificaiton and recruitment. Make more informed decisions with Quest and enhance the overall success of your trials.

10:10 Feasibility Process Update to Ensure Active Site Engagement: One Year Later

Katie Bonner, Director of Strategic Feasibility, AstraZeneca

Nadia Kallu, Strategic Feasibility Associate Director, AstraZeneca

A year has passed since AstraZeneca implemented enhancements to our feasibility process, aimed at fostering active engagement from the initial interaction through site selection. Over the past year, we've had the opportunity to test these improvements, gather insights, and refine our approach. In this session, we will share the valuable learnings from this journey, discuss the additional updates we've made, and outline our future plans to further optimize the process.

10:40 Building Meaningful Engagement: PCORI's Foundational Expectations for Partnerships in Research

Caroline Davis, MPP, Senior Program Associate, Public and Patient Engagement, PCORI Patient Centered Outcomes Research Institute

PCORI's Foundational Expectations for Partnership in Research incorporates 10 years of evidence on engagement from PCORI awardees, staff, and the larger research field to update the guidance on engagement into one systematic framework. We consider these expectations to be building blocks of effective engagement. This session will review the various methodological approaches used to complete the update and present the guidance along with information on how to access this tool.

11:10 Networking Coffee Break

INTEGRATING CLINICAL RESEARCH INTO CLINICAL CARE

11:50 Chairperson's Remarks

Speaker to be Announced, HealthMatch

11:55 Taking Research to the People: Decentralized Trials, Leveraging Technology to Enable Community-Based Approaches

Amy Yarker, Senior Business Development Manager, Life Sciences Partnership & Growth, NIHR Clinical Research Network

This session will explore the transformative power of decentralized clinical trials, taking research beyond traditional hospital clinics to reach participants in social care settings and underserved communities. Discover how cutting-edge technology and innovating methods are breaking down barriers, improving accessibility, and generating valuable real-world evidence. From mobile research units to patients' homes, learn how decentralized trials are bringing research directly to people.

12:25 pm Talk Title to be Announced

Alison Bawden, Director, Regulatory Affairs, Veristat

12:55 Integrating Community Health Solutions: A Case Study

Shelly Barnes, Global Clinical Innovations and Digital Lead, UCB

Is it feasible to develop a clinical research plan that incorporates community-based health entities into clinical research? The FDA supports this, but challenges persist, especially when community solution providers struggle with establishing a favorable cost model. Additionally, is there evidence that investigators and providers are willing to adopt this model? This UCB case study explores the advantages, disadvantages, and potential of integrating community health solutions into clinical trials.

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Rethinking Trial Design with Real-World Data

Kwame Marfo, Senior Director, Product Strategy, Clinical Development, Komodo Health

Discover how Komodo's innovative no-code solution, MapView with MapAi, is reshaping the way clinical development teams understand and address the diverse healthcare journeys of patients from different racial and ethnic backgrounds.

Komodo's presentation will explore how streamlined data insights can uncover disparities, enhance trial inclusivity, and optimize patient representation, empowering teams to design more equitable and effective clinical trials.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 17th Annual

Enrollment Planning and Patient Recruitment

Strategies to Accelerate Patient Recruitment and Achieve Enrollment Goals

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 12th Annual

Patient Engagement and Retention through Communities and Technology

Leveraging Technology, Community Engagement, and Advocacy to Improve Recruitment and Retention

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.
**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.
Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace
Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials
INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche
While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials.
Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.
INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)
U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing
INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP
This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There
Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA
In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

PARTNERING TO ACCELERATE AND IMPROVE RECRUITMENT

11:00 Chairperson's Remarks

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

11:05 Early Patient Advocacy Group Engagement: Best Practices for Establishing Efficient Partnerships

Patricia Roselle, Global Head, Patient Stakeholder Engagement, Sanofi

Speed is often the determinant of whether patients will be able to inform the development program and/or clinical trial. Some industry partners hesitate to engage PAGs early in R&D, in part due to the perception of slowing study timelines and engagement cycles. The PALADIN Consortium shares Patient Advocacy Groups and Industry Partner insights on why collaboration is important and how to get partnerships up and running faster and more efficiently.

11:35 Innovative Partnerships: Enhancing SGM Inclusivity in Clinical Operations

Garo Kiledjian, Founder & CEO, SGM Alliance

Explore how SGM Alliance's strategic partnerships are transforming clinical operations. Learn how collaborations with industry leaders and advocacy groups are driving inclusive protocol development, improving data collection, and enhancing staff education. Discover actionable insights and successful case studies that highlight the impact of these alliances on advancing SGM participation in clinical research.

12:05 pm Patient, Community, Academia, and Industry Partnerships to Promote Clinical Trial Diversity

Edward J. Bentlyewski, Assistant Director, Clinical Research Nursing & Quality Assurance, Columbia University

Industry sponsors, patients, and communities all have an interest in diverse and equitable clinical trials. The Herbert Irving Comprehensive Cancer Center (HICCC) advances this with its Diversity, Equity, and Inclusion in Clinical Trials Symposium and training programs. These initiatives engage stakeholders, fostering collaboration and bridging gaps between sponsors, patients, and researchers. This presentation highlights how HICCC is driving more inclusive and representative clinical trials.

12:35 Redefining Research Through Patient and Community Collaboration

Speaker to be Announced, Publicis Healthcare Communications Grp
Sarah McKeown-Cannon, Sr VP & Head, Clinical Research, Heartbeat
Jennifer Horonjeff, Founder & CEO, Savvy Cooperative
Sasha Tyndale, Director, Diversity and Patient Inclusion, AbbVie
Patricia Roselle, Global Head, Patient Stakeholder Engagement, Sanofi
Jeff Huntsman, Chief Commercial Officer, PCM Trials

This panel will explore how authentic, community-led engagement transforms clinical research by fostering trust and empowering patients. Learn how to co-create culturally relevant strategies with local leaders, organizations, and communities to achieve inclusion, equity, and sustained impact. The discussion will focus on balancing study-specific needs with long-term community value, providing a roadmap for transitioning from traditional recruitment to sustainable activation. Through real-world examples, actionable takeaways, and a focus on implementation, this session bridges theory to practice, offering insights on how to build meaningful, lasting relationships in clinical research.

1:05 Partnering with Sponsors and Investigators to Accelerate Patient Recruitment and Enhance Retention and Compliance

Mike Andino, Senior Director, Patient Recruitment & Retention, ICON

This session will explore site engagement methodologies, patient optionality and navigating the complex landscape between strategic alignment and operational practicality. This includes the importance of early engagement, the patient voice, diversity, site support and endpoint protection. We'll also discuss how to balance scale, precision, and impact to deliver content and support to the right person, at the right time, with the right frequency through the most appropriate channels.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

PATIENT CENTRICITY AND PATIENT SATISFACTION IN RECRUITMENT

3:20 Chairperson's Remarks

Seth Halvorson, General Manager, Site & Clinical Research Solutions, WCG

3:25 Enhancing Clinical Trials: Building Trust, Engagement, and Real-Time Impact

Mary Costello, Evinova
Elisabeth Piault-Louis, Scientific Lead, Digital Science, Evinova
Bradley Hightower, CEO, Hightower Clinical
Deirdre BeVard, Sr VP R&D Strategic Operations, R&D Strategic Operations, CSL Innovation GmbH
Abigail Dirks, Data Scientist, Tufts Univ

As the industry navigates the evolving landscape of decentralized clinical trials (DCTs), early implementations of digital technologies for collection of patient-generated data have faced resistance from sites, sparking a re-evaluation of sponsor-site dynamics for the delivery of care while generating evidence for treatment clinical benefit demonstration. This panel dives into the pivotal question: how can we harness patient-centric tools and related data collection to create tangible benefits for site teams such as enabling remote patient monitoring and enhancing their engagement and oversight capabilities? Join an esteemed panel of experts as they share innovative strategies, actionable recommendations, and diverse perspectives on overcoming barriers. Abby Dirk will also unveil insights from The Tufts Center for the Study of Drug Development, offering a fresh lens on the future of engagement and trial optimization.

3:55 Competitive Enrollment: Has This Strategy Run Its Course?

William Smith, CEO, Alliance for Multispecialty Research

This presentation will discuss the benefits of competitive patient enrollment and if they are real or perceived. Also, will present a thorough review of the risks and potential associated costs to the research site in a competitive recruitment atmosphere. Does competitive enrollment hinder quality data and diverse enrollment? And if so, can a research site overcome those obstacles? Should competitive enrollment remain part of the standard recruitment process?

4:25 Agency + Digital + Database: Perfecting Patient Recruitment in Clinical Trials

Tobias Kruse, Managing Director Europe, Trials24 GmbH

When it comes to patient recruitment many choose an either-or strategy. They invest in custom collateral or they leverage digital marketing. However, when both strategies are combined with a powerful patient database, magic happens! Join Dr. Tobias Kruse from SubjectWell and discover how to combine agency, digital, and database strategies, what are the characteristics of a powerful patient database, and how to accelerate global and local clinical studies.

4:55 PANEL DISCUSSION: Empowering Patients: New Sampling Technologies and Processes to Improve Recruitment and Retention

Moderator: Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML/LLS

We will discuss the current landscape regarding blood biomarker data collection focusing on enabling convenient, less painful, and patient-centric small-volume sampling (including bloodless), reducing the burden on patients, healthcare systems, and clinical trials. The speakers/panelists will review protocols, logistics, and regulatory acceptance for this approach. By harmonizing stakeholders and creating data-rich environments for ongoing research and innovation, true patient-centricity moves one step closer to reality.

Panelists:
Jas Bajwa, Manager, Biosample Operations, Roche
Dmitri Mikhailov, PhD, Director & Global Head, Biomarker Coordination, Novartis Institutes for BioMedical Research, Inc.
Elena "Ella" Sinclair, President and Founder, FlexPoint Bio
Pirinka Tuttle, Associate Director, Clinician, Biomeasures, Endpoints & Study Technologies, Pfizer Inc.
Teri Wright, Director Clinical Lab Sciences & Devices Innovation, Clinical Trial Lab & Diagnostic Design, Eli Lilly and Company

5:25 What if Patients Chose You? Rethinking Recruitment and Retention with Empathy and Innovation

Alicia Asgari, Dir Technology Solutions, Bus Dev, StudyKIK

What if clinical trial recruitment and retention were no longer about convincing patients to participate, but about creating an experience so seamless, supportive, and personalized that they stay engaged from start to finish? Join us as we explore how human-centered technology flips the script – meeting patients where they are in their journey and making every step feel personal, empowering, and aligned with their needs. Explore how unified tech solutions simplify outreach, foster communication, and build trust, ensuring that patients feel supported at

every stage. Learn how this patient-first approach drives enrollment, improves engagement, and transforms the patient journey into a more compassionate and connected experience.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

INNOVATIVE APPROACHES TO ENHANCE AND OPTIMIZE RECRUITMENT EFFORTS

8:50 Chairperson's Remarks

Suzanne Harris, Senior Vice President of Marketing, SubjectWell

8:55 PANEL DISCUSSION: Empowering Partnerships: Collaborating with Patients and Advocacy Groups to Accelerate Clinical Research

Moderator: Joan Chambers, Senior Consultant, Tufts Center for the Study of Drug Development

Industry stakeholders recognize the importance of leveraging and cultivating meaningful non-profit partnerships to enhance patient advocacy and accelerate the start-up of clinical trials. This session will discuss and provide insight into how to operationalize these partnerships, focusing on the tactical approaches to accelerating the start-up of clinical trials early on, working together, and maintaining the partnerships.

Panelists:

Monique Adams, PhD, MS, Executive Director, Global Head Diversity & Inclusion in Clinical Trials, Sanofi

Denise Archilla, MSW, Founder, Chronic Illness Life Coach, Patient Advocate, Chronic Warrior Coaching, LLC

Patrick Lank, Medical Director, Specialty Development, AbbVie

Roy Reese, Sr Advisor & Head, Healthcare Practice, Ichor Strategies

9:25 Patient Remuneration: Results from a Review across IRB Types and Potential Impact on DEI and Recruitment

Tricha Shivas, Chief of Staff & Strategy, Foundation for Sarcoidosis Research

Industry presentations on DEI and patient recruitment have tended to focus on access to research and not other identified areas that drive participation—such as patient remuneration and time commitment. This presentation compiles data across multiple IRB types (central, community, academic) to explore similarities and differences in patient remuneration approach and potential impact to recruitment and DEI initiatives.

9:55 Presentation to be Announced

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

11:20 Chairperson's Remarks

Matt Sowards, Chief Innovation Officer, Executive Leadership, Scout

11:25 Bridging Barriers in Patient Recruitment

Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Co.

Walgreens is uniquely positioned to leverage access to patients and trust of communities to address gaps in evidence and relevance resulting from underrepresented groups in clinical trials. Bringing clinical trials into the community and engaging people where they're comfortable provides structure for sustained education, which builds community capacity of knowledge and skills about clinical trials processes. Explore Walgreens Patient Advisory Board and learnings from community engagement approaches.

11:55 Why patients ignore your trials - and listen to consumer brands

Mark Evans, Managing Director, Faze

Faze, part of one of the world's largest communications group Havas who work with global brands including Adidas, KFC and Coca Cola and their record label manage artists including Taylor Swift.
Demonstrating case studies from the field in how applying consumer brand approaches can accelerate clinical trial recruitment, connecting authentically with patients, engaging and supporting them through to randomization.

12:25 pm Future of Medicine Community Health Screening: A Revolutionary Approach to Enrolling Clinical Trials

Ralph Passarella, Co-Founder, Care Access

Our industry has been working hard to improve trial enrollment for decades with only limited progress. We need a new paradigm for planning and enrolling trials. Care Access is introducing the Future of Medicine, a community health screening and education program that increases access to, and education about, clinical research. Sponsors can transform the economics of recruiting through a protocol-agnostic, "always on" approach to screening where participants are screened once – including for novel biomarkers – and considered for a number of trials at

the same time. Care Access's community footprint allows us to provide health and research education, offer diagnostic testing, and connect Members to local trials across the US and Brazil (with new countries coming online soon). Hear from Ralph Passarella, Co-Founder of Care Access, during this session and learn how you can help bring Future of Medicine to communities around the world.

12:55 Sponsored Networking Luncheon
Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced
SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

2:35 Chairperson's Introduction
Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization
April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine
This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond
Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson
Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.
Panelists:
James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing
We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies
Speaker to be Announced, PAREXEL International
Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl
Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

TOOLS AND PROCESSES TO REACH ENROLLMENT TARGETS & RETAIN PATIENTS VIA TRUST & TRANSPARENCY

8:20 Chairperson's Remarks
Speaker to be Announced, Clariness UK Ltd

8:25 Enhancing Diversity in Clinical Trials through External Partnerships
Kemi Williams, Senior Director, Patient Science, AstraZeneca
Concerted engagement is necessary to increase equity, diversity, and inclusion, and address barriers to clinical trial recruitment & participation. AstraZeneca has established a repeatable and scalable strategy for collaborating with cross-sector external partners to improve trial diversity. This session will provide valuable insights into the challenges and opportunities that exist in trial diversity partnerships and, through a case study review, showcase our experience with the partnerships.

8:55 LLMs and the Science of Diversity in Clinical Trials: Case Studies from an American Heart Association's Strategically Funded Research Network
Muhammed Idris, PhD, Co Director, Digital Health & Medicine, Morehouse School Of Medicine

There is a lot of hype surrounding large language models (LLMs), but few demonstrations of their practical applications in advancing clinical trial diversity. This session will highlight opportunities and challenges applying these tools to enhance recruitment strategies, optimize outreach, and provide tailored training opportunity for principal investigators and research coordinators based on our leadership within the American Heart Association's Strategically Funded Research Network on the Science of Clinical Trial Diversity.

9:25 What Are You Missing in Recruitment and Enrollment?

Alyssa Vincze, Principal & Director, R&D, 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. Collect a HIPAA authorization to access our proprietary, nationwide data and make better, faster eligibility decisions.

9:40 How to Overcome Trial Planning & Recruitment Challenges

Lindsay Stahl, VP, Global Head of Patient Engagement & Recruitment, Citeline

Hélène Raptis, Head of Feasibility Intelligence, Chiesi Farmaceutici

Chiesi Farmaceutici is a multinational pharmaceutical company focused on the development of advanced treatments for respiratory, special care and rare disease patients. In 2023, Chiesi identified a gap in the digital footprint of its clinical research, which affected its efficient, timely recruitment of patients and ability to build strong relationships with trial stakeholders. This prompted Chiesi to closely examine its internal processes/procedures and seek the support of Citeline. The collaboration encompassed both technical and tactical support to drive enrollment and, ultimately, to raise awareness of its clinical research. Through this collaboration, Chiesi learned many valuable lessons along the way, which it will incorporate in the roll-out of its pivotal US-based asthma study on a new environmentally friendly inhaler in 2025 — and elaborate on in this insights-filled session.

9:55 A New Way Forward—Applying GenAI to Solve the Clinical Trial Recruitment Conundrum at Scale

Dennis Akkaya, Chief Commercial Officer, myTomorrows

Danny Den Hamer, Product Manager, Software Engineering, myTomorrows

Recognize upstream opportunities to engage larger groups of patients, patient advocacy groups (PAGs), healthcare professionals (HCPs), and clinical trial referral networks to significantly reduce timelines and achieve enrollment targets. Gain practical insights into how co-pilot approaches can address stakeholder challenges in the patient recruitment journey while maintaining a human-centered approach. Additionally, watch a live demo and explore real-world examples showcasing how referring physicians and sites benefit from and utilize these innovative technologies.

10:10 A Paradigm Shift in Personalizing the Clinical Trial Experience for Patients and Their Care Partners

Jean Stimola-Sposaro, Director, Global Clinical Trial Industry Collaborations, Global Drug Development & Global Development Operations, Bristol Myers Squibb Co.

Enabling options for timely and ethical return and management of health data generated during clinical trials to increase equity, inclusion, and access. What solutions can be used now to reduce burdens to implementation, what barriers remain, and why. Measuring the value of study participant experiences, stakeholder decision-making, and overall trust in the research enterprises, securing incentives that matter most to study participants and their care providers.

10:30 The Top 5 Most-Requested Resources Patients Ask for to Support Their Continued Participation: Considerations toward Creating Equitable, Engaging Clinical Trial Participation Experiences

Rachel Melloul, MPH, Project Manager, CISCRP

Enrolling and retaining patients in clinical trials is a persistent challenge, especially among underrepresented groups like Hispanic, Latino, Black, and African American communities. Our findings identify five key resources to improve retention: conducting visits closer to home, offering flexible visits, reimbursing out-of-pocket expenses, providing study updates, and compensating for time. This talk will explore these strategies and actionable ways sites can implement them to better support participants.

10:50 Multichannel and Multidisciplinary Approach to Accelerating Patient Recruitment in Rare Disease Clinical Trials

Chris Cirillo, Senior Director, Clinical Operations, Chemomab Therapeutics

We will share the approaches used to accelerate recruitment in a Phase 2 clinical trial in a rare disease. We utilized a combination of efforts including direct-to-patient outreach, partnership with patient advocacy, and concierge service to identify patients to move through the enrollment funnel. These tools were complementary to established site resources. We will also share the return of investment and impact that these efforts had on clinical development.

11:10 Networking Coffee Break

MAKING TRIALS MORE ACCESSIBLE TO PATIENTS

11:50 Chairperson's Remarks

Rachel Wagner, VP Business Development, Business Development, Care Access

11:55 Incorporating Patient-Centric Sampling into Multicenter Clinical Trials: Output from the PCSIG Workshop

Jas Bajwa, Manager, Biosample Operations, Roche

The Patient Centric Sampling Interest Group (PCSIG) is a non-profit focused on advancing patient-centric sampling technologies for blood, plasma, urine, and other matrices to improve healthcare. A recent PCSIG workshop developed a comprehensive roadmap for implementing these technologies in decentralized clinical trials. This presentation will explore the workshop's findings, offering valuable insights for organizations aiming to adopt patient-centric sampling and accelerate progress by learning from shared experiences.

12:25 pm Learnings and Performance of a 50,000 Patient-Activated Community, Centered around Vaccine Clinical Trial Participation

Manuri Gunawardena, CEO, Executive, HealthMatch

HealthMatch & Velocity Clinical Research created a 50,000 patient activated vaccine community in 2024, months in advance of any specific study launch. The community was educated, nurtured and insights gathered to ultimately shape recruitment strategy and outcomes across multiple vaccine studies at the end of 2024. The speakers will share learnings from the project including performance around randomizations and patient education and discuss how this methodology can be applied successfully to other therapeutic areas

12:55 "This Won't Work": Establishing Study Conduct at Retail Pharmacy

Adam Samson, Head Clinical Delivery Operations, Walgreens Clinical Trials

Walgreens Clinical Trials is standing up study sites at retail pharmacies across the country. Learn how these community-centered research locations are set up and how they impact the communities they're in.

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Future of Medicine: Community Health Screenings and Research Education Across America

Jennifer Hillner, Vice President, Strategic Accounts, Care Access

Get an on-the-ground view into the Future of Medicine program and how Care Access is making advanced health screenings, research education, and study opportunities accessible to hundreds of communities across the nation and beyond.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's Inaugural

Collaborative Strategies to Improve Trial Execution

Innovative Solutions to Reduce Site Burden and Modernize Clinical Trials

FEBRUARY 3-5, 2025
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 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

PARTNERING TO ACCELERATE AND IMPROVE TRIAL DELIVERY

11:00 Chairperson's Remarks

Kelsey Jakee, Managing Consultant, Global Life Sciences, PA Consulting

11:05 Establishing Long-Term Partnerships for Study Success: AstraZeneca's Biopharmaceuticals Partners in Care Network and Site Engagement Model

Joshua Hershelman, Director, US Site Engagement, Site Management & Monitoring, AstraZeneca

As part of AstraZeneca's vision to be sponsor of choice for sites and patients we are establishing our Biopharmaceuticals Partners in Care Network and Site Engagement Model. The goal of this collaboration is to create long term partnerships coupled with collaborative scientific engagement. Now that the team is entering our sophomore season we have real world examples to share of how the team has supported study delivery in the US.

11:35 AZ (AstraZeneca) & MGB (Mass General Brigham): Innovative Partnership to Deliver Clinical Trials of the Future

Christopher Herrick, Vice President, Research Technology, Mass General Brigham

Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award

Michele Teufel, Site Management & Monitoring Therapy Area Strategy & Portfolio Delivery, Development Operations, AstraZeneca

Join us for a panel discussion on the groundbreaking partnership between MGB, a premier Academic Medical Center, and AstraZeneca, including its digital health subsidiary, Evinova. This collaboration utilizes advanced technology for trial feasibility, AI-powered study design, and innovative recruitment strategies. Discover how integrating hospital-based multimodal datasets and operational workflows enhances trial efficiency and diversity. Gain insights into the future of clinical research.

12:05 pm Site Partnerships—Developing Site Relationships beyond Study-Level Engagement

Sven Knapinski, PhD, Director, Site Partnerships, Clinical Development, CSL Vifor

The aim of the newly created CSL Site Partnership Team is to build long-lasting relationships with the investigational sites and institutions that are key to our success beyond clinical trial participation. In addition to partnership-building efforts, this presentation highlights several initiatives the Team is launching to reduce site burden, expand the network, and improve feasibility outcomes, with direct positive impact on the delivery of CSLs trial portfolio.

12:35 Rethinking Recruitment: The Value of Site-Centric Enablement with Sponsor, Site & Vendor Alignment

Tate Stubbs, COO, Executive, HealthMatch

Kelly McKee, Head, Innovative Patient Recruitment Evinova, AstraZeneca Pharmaceuticals

HealthMatch's portfolio recruitment approach has provided significant advantages for site driven recruitment strategies, leveraging the efficiency of multi-study screening to maximise patient and site results. This presentation examines the next frontier of how sponsors can maximize recruitment outcomes through a collaborative recruitment strategy design with both sites and vendors, leading to better overall performance and more efficient sponsor investment.

1:05 Unlocking Cost and Time Savings: The Impact of Workflow Technology on Site Enablement

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

Discover the direct benefits of enabling research sites with cutting-edge workflow technology. Learn how leading pharma companies achieve significant cost and time savings by streamlining document exchange and participant enrollment. Through real-world case studies, we'll explore how global implementation of advanced solutions enhances document management and enrollment tracking, leading to faster, more efficient trial timelines.

1:20 Reimagining Clinical Trial Collaboration with AI: Boosting Engagement & Efficiency for Sites & Sponsors

Sharmin Nasrullah, General Manager, Life Sciences and Clinical, Salesforce.com, Inc.

Discover how AI agents and collaboration tools embedded in the flow of work accelerate clinical trials for sites and sponsors. With Life Sciences Cloud, powered by Agentforce, study teams are guided through study start-up documentation, site feasibility and selection, and study conduct activities. Life Sciences Cloud connects study teams across sponsors, CROs and clinical sites, providing real-time assistance in the flow of work to enable faster trials.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

BUILDING TRUST AND COLLABORATION BETWEEN PATIENTS, HCPs, AND RESEARCH TEAMS

3:20 Chairperson's Remarks

Camille Cook, Sr Dir Strategy & Innovation, Risk Solutions, LexisNexis Risk Solutions

3:25 PANEL DISCUSSION: Enhancing Patient and HCP Engagement for Improved Accessibility, Enrollment, Retention, and Outcomes

Moderator: Angela Bilkhu, Senior Global Patient Partnership Director, Sickle Cell Disease and aHUS, Roche

This session will explore strategies for deepening our understanding of patient needs and HCP perspectives to create more inclusive and patient-centric trials. By examining case studies and discussing innovative approaches, participants will gain insights into how to improve communication, build trust, and foster collaboration between patients, HCPs, and research teams. Join this discussion to learn how to drive better engagement, enhance trial participation, and achieve more meaningful clinical outcomes.

Panelists:

Kristen Andrews, Head Research Site Enablement, Clinical Trial Enablement, Labcorp LabCorp

Mary Brantner, Senior Director, Clinical Program Optimization and Innovation, Insmed

Margaret Ikpoh, National Settings Lead for Primary Care, NIHR Clinical Research Network; Vice-Chair, Professional Development & Standards, Royal College of General Practitioners

Evan Ko, Strategic Operations Manager, SGM Alliance

3:55 Optimizing Our Focus on Site-Facing Training

Mette Flindt Heisterberg, PhD, Competency Development Specialist, Clinical Operations Office, Global Trial Portfolio, Novo Nordisk AS

Bjorn Larsson, Director, Clinical Learning & Training, Novo Nordisk AS

In the past year, Novo Nordisk has meticulously optimized site-facing training, emphasizing user-centric learning journeys. By establishing a dedicated site learning unit and refining processes, we can deliver best-in-class learning experiences. Shifting our focus, we aim to explore optimal training delivery and foster flexible, engaging experiences for our site staff. We invite you to join us in exploring our challenges, solutions, and reflections, as we embark on this transformative journey.

4:25 Driving Clinical Trial Innovation: A Collaborative Approach to AI-enabled Patient Pre-screening

Kourosh Davarpanah, CEO

Liz Beatty, Co Founder & CSO

Today, sites struggle with time-consuming chart reviews that delay screenings, miss potentially eligible participants, and, ultimately, lead to trial delays. Addressing these long-standing challenges and building a better future requires that pharma companies, technology vendors, and clinical research sites all come together. In this session, we'll explore an innovative partnership between Sanofi, Inato, and research sites that resulted in a cutting-edge, AI-enabled tool to transform patient pre-screening. Through this collaboration, the teams discovered a new way to leverage the latest technology and meaningfully reduce site burden, accelerate patient screening, and unlock access for a broader range of patients. This panel will provide a behind-the-scenes look at the joint effort that led to developing this solution and discuss how it is helping sites overcome daily challenges while paving the way for more efficient, inclusive, and scalable clinical trials.

2nd ANNUAL SITE INNOVATION AWARD

4:55 Celebrating Creativity in Site-Centric Approaches to Advance Clinical Trials for All Stakeholders

Co-Moderators:

Irfan Khan, CEO, Circuit Clinical

Amanda Wright, Vice President, Partnership Development, Javara

Panelists:
Katherine Broecker, Senior Director, Design Hub Data Insights, Eli Lilly and Company
Jill Johnston, Chief Innovation Officer, WCG Clinical
Manny Lazaro, Senior Vice President, Clinical Development Operations, Kailera Therapeutics
Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS
Michele Teufel, Site Management & Monitoring Therapy Area Strategy & Portfolio Delivery, Development Operations, AstraZeneca

5:25 Presentation to be Announced

5:40 Smarter Studies, Better Outcomes: Automated Data Collection for Prospective Research and Registries
Catherine Richards, President and COO, OM1 Inc.
Traditional data collection methods in clinical research are plagued by inefficiencies, rigid designs, and limited diversity—resulting in costly delays and incomplete insights. This presentation will explore how AI-powered, tech-enabled solutions are transforming prospective studies and registries for sites and sponsors. Learn how flexible, adaptive study designs reduce site and patient burden, achieve unparalleled cost savings, and deliver more comprehensive real-world data to achieve better outcomes with unmatched efficiency.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials
Kyle Hogan, CEO, Datacubed Health
This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design
Christopher Riley, Director, Strategic Insights, Solutions, H1
In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs
Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee
Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

IMPROVING SITE/SPONSOR COLLABORATION: PERSPECTIVES FROM BOTH SIDES

8:50 Chairperson's Remarks
David Rosa, Director, Business Development, Summit Clinical Research

8:55 PANEL DISCUSSION: What Sites Really Want from Study Sponsors and CROs
Moderator: Norman M. Goldfarb, Executive Director, Site Council
After over 40 years of clinical research, sponsors and CROs should have a good understanding of what sites want from the relationship. However, sites continue to be amazed by the apparent lack of understanding. Don't miss this opportunity to hear what leading sites really, really want from sponsors and CROs. You may be surprised.
Panelists:
Lauren Chazal MBA, Chief Business Development Officer, Headlands Research
Sergio Garcia, Director, Clinical Research Business, Hackensack Meridian Health
Troy Hamilton, Director of Operations, CaRe Clinic

9:25 PANEL DISCUSSION: What Sponsors Don't Seem to Understand about Site Costs
Moderator: Norman M. Goldfarb, Executive Director, Site Council
Clinical research is complicated and is getting more complicated every day. Every complication carries a cost. Take a look behind the curtains to learn how leading sites devour money to meet the many sponsor, regulatory, and other priorities they face every day—and how sponsors and CROs can lighten the load.
Panelists:
Stephanie Berger, Director, Clinical Research, Urology Clinics of North Texas
Victor Chen, Managing Director, Clinical Trials Program, Kaiser Permanente
Jesse Hoffman, Chief Business Officer, Business Development, Alliance For Multispecialty Research LLC

9:55 Helping Sites Succeed: An Industry-Wide Approach to Reduce Tech Burden
Nick Whitney, Senior Director & Commercial Lead, Site Suite, IQVIA Technologies
Sponsors of clinical trials are keenly aware that to speed up study start-up and conduct, they need to help clinical research sites manage the array of technology they require them to use. This panel of site, sponsor, and technology leaders will discuss approaches they are deploying to reduce site tech overload, and what more needs to be done to make an impact on site efficiencies and study timelines.

10:25 Coffee Break in the Exhibit Hall
SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing
Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

TECHNOLOGY ADVANCEMENTS TO REDUCE SITE BURDEN

11:20 Chairperson's Remarks
Norman M. Goldfarb, Executive Director, Site Council

11:25 PANEL DISCUSSION: Interoperability Will Slash the Technology Burden on Sites
Moderator: Norman M. Goldfarb, Executive Director, Site Council
Technology proliferation is crushing clinical research sites under a landslide of passwords, training, patient support, "anomalies," and redundant data entry. But wait! There is a path through the wilderness—interoperability will save the day and perhaps sooner than we expect.
Panelists:
Michelle Hartmann, Director/Owner, South Broward Research
Christine Senn, Senior Vice President, Site-Sponsor Innovation, Advarra
Jay Smith, Head, Product & Trial Interactive, TransPerfect

11:55 PANEL DISCUSSION: Real AI at Real Sites Today
Moderator: Norman M. Goldfarb, Executive Director, Site Council
Artificial intelligence is the cure for every clinical research ailment -- anyway, that's the dream. The reality, as usual, is like everything else in clinical research: incremental steps forward. Learn how cutting-edge sites are already setting AI to work on practical solutions to pressing problems—and that's the reality.
Panelists:
Todd Albin, President, Cedar Health Research
Michael Koren, Medical Director & CEO, Jacksonville Center for Clinical Research, Encore Research Group
Scott Whitt, General Manager, Triad Clinical Trials

12:25 pm Increasing Access to New Patients by Enabling Sites to Run Trials in their Own Communities through Site Network Support
Caroline Potts, General Manager, MRN Site and Patient Services, Medical Research Network
Nearly 80% of trials fail to meet initial enrollment targets and timelines, only 25% of global trial participants are people of color and approximately 30% of a trial budget is dedicated to recruitment.
Creating more equitable and efficient trials begins with engaging and empowering clinical research sites to run trials in their own communities.
By providing individualized support through advanced training and operational delivery capabilities, site networks can lower the risk of trials failing to recruit enough patients, ensure a representative sample of patients, create equitable access to participation, and retain patients for the duration of the trial.

12:55 Sponsored Networking Luncheon
Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced
SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

2:35 Chairperson's Introduction
Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization
April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine
This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond
Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson
Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.
Panelists:
James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing
We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies
Speaker to be Announced, PAREXEL International
Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

DATA & TECHNOLOGY PLATFORMS: ACCELERATING SITE FEASIBILITY PROCESSES

8:20 Chairperson's Remarks

Stacey Burghdoff, Executive Director, Strategic Alliance Management, ProPharma

8:25 Streamlined Clinical Trial Feasibility with Technology, Tools, and Process Excellence

John Yannone, Director, Feasibility Strategy, Innovative Health Engagement and Advocacy, Johnson and Johnson

How do we enable teams to navigate complex organizational dynamics, synthesize disparate data sets, and maximize trial efficiency all while balancing costs and speed? A suite of enabling tools and improved processes has shown the potential to drive fit-for-purpose protocols, efficient country strategy, and enhanced site selection while improving transparency and leveraging AI/ML + advanced analytics. This discussion will empower teams to discuss best practices in feasibility.

8:55 Optimizing Clinical Strategy with Innovative Technology in a Dynamic Organization

Amy McCormick, Associate Director, Global Trial Optimization, Regeneron

Mark Springer, Director, Global Trial Optimization, Regeneron

During a period of significant growth and change, Regeneron implemented an innovative digital-first strategy to overcome challenges in trial feasibility, patient engagement, and site identification. Using an agile methodology and an Appreciative Inquiry model, the team identified workflow issues, designed a comprehensive solution, and delivered a flexible, scalable application. This approach improved data quality, standardized deliverables, and optimized resources, providing a foundation for future business needs.

9:25 Are Questionnaire Licensing and Translation Hurdles Slowing Down Your Trials?

Jasmine Walker, Director, COA Partnership, Linguistic Validation, RWS Group

Jonathan Norman, Director, Localisation, Linguistic Validation & eCOA SME, Y-Prime

Are questionnaire licensing and translation hurdles slowing down your trials? Early and strategic engagement with your licensing, localization, and eCOA partners might be the solution you're looking for. In this session, two seasoned experts in eCOA and localization will dive into key preparatory steps to make your study more feasible from both a licensing and localization standpoint—driving smoother regulatory approvals and helping you meet critical timelines. You'll gain practical insights on successful early engagement, including essential questions to ask your providers, the value of connecting partners early, setting realistic expectations, and assessing content suitability—empowering you to streamline diverse global study start-ups.

9:55 The Value of Quest Lab Data in Clinical Trial Design and Recruitment

Steve Schlachter, Director Product Portfolio, Healthcare Analytics Solutions, Quest Diagnostics, Inc.

Learn the value of lab data in clinical trials and the power of Quest to help optimize site feasibility and selection, improve investigator selection, and optimize patient identificaiton and recruitment. Make more informed decisions with Quest and enhance the overall success of your trials.

10:10 Feasibility Process Update to Ensure Active Site Engagement: One Year Later

Katie Bonner, Director of Strategic Feasibility, AstraZeneca

Nadia Kallu, Strategic Feasibility Associate Director, AstraZeneca

A year has passed since AstraZeneca implemented enhancements to our feasibility process, aimed at fostering active engagement from the initial interaction through site selection. Over the past year, we've had the opportunity to test these improvements, gather insights, and refine our approach. In this session, we will share the valuable learnings from this journey, discuss the additional updates we've made, and outline our future plans to further optimize the process.

10:40 Building Meaningful Engagement: PCORI's Foundational Expectations for Partnerships in Research

Caroline Davis, MPP, Senior Program Associate, Public and Patient Engagement, PCORI Patient Centered Outcomes Research Institute

PCORI's Foundational Expectations for Partnership in Research incorporates 10 years of evidence on engagement from PCORI awardees, staff, and the larger research field to update the guidance on engagement into one systematic framework. We consider these expectations to be building blocks of effective engagement. This session will review the various methodological approaches used to complete the update and present the guidance along with information on how to access this tool.

11:10 Networking Coffee Break

INTEGRATING CLINICAL RESEARCH INTO CLINICAL CARE

11:50 Chairperson's Remarks

Speaker to be Announced, HealthMatch

11:55 Taking Research to the People: Decentralized Trials, Leveraging Technology to Enable Community-Based Approaches

Amy Yarker, Senior Business Development Manager, Life Sciences Partnership & Growth, NIHR Clinical Research Network

This session will explore the transformative power of decentralized clinical trials, taking research beyond traditional hospital clinics to reach participants in social care settings and underserved communities. Discover how cutting-edge technology and innovating methods are breaking down barriers, improving accessibility, and generating valuable real-world evidence. From mobile research units to patients' homes, learn how decentralized trials are bringing research directly to people.

12:25 pm Talk Title to be Announced

Alison Bawden, Director, Regulatory Affairs, Veristat

12:55 Integrating Community Health Solutions: A Case Study

Shelly Barnes, Global Clinical Innovations and Digital Lead, UCB

Is it feasible to develop a clinical research plan that incorporates community-based health entities into clinical research? The FDA supports this, but challenges persist, especially when community solution providers struggle with establishing a favorable cost model. Additionally, is there evidence that investigators and providers are willing to adopt this model? This UCB case study explores the advantages, disadvantages, and potential of integrating community health solutions into clinical trials.

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Rethinking Trial Design with Real-World Data

Kwame Marfo, Senior Director, Product Strategy, Clinical Development, Komodo Health

Discover how Komodo's innovative no-code solution, MapView with MapAi, is reshaping the way clinical development teams understand and address the diverse healthcare journeys of patients from different racial and ethnic backgrounds.

Komodo's presentation will explore how streamlined data insights can uncover disparities, enhance trial inclusivity, and optimize patient representation, empowering teams to design more equitable and effective clinical trials.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 14th Annual

Clinical Trial Forecasting, Budgeting and Contracting

Innovative Strategies for Cost-Efficient Trials

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 7th Annual

Resource Management and Capacity Planning for Clinical Trials

Strategies for Efficient Resource Forecasting and Supporting Your Workforce

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

CONSIDERATIONS FOR SITE BUDGETS AND CONTRACTS

11:00 Chairperson's Remarks
Cassandra Erato, CEO, Spaulding Clinical Research

11:05 Budgeting for Patient-Centric Solutions to Alleviate Patient Burden
Marina Malikova, PhD, Executive Director, Surgical Translational Research, Operations and Compliance, Boston University School of Medicine
Social determinants of health (SDOH) factors such as socioeconomic status, education, access to healthcare, social support, and neighborhood environment play a significant role in shaping the landscape of clinical trials. While the primary focus of clinical trials is typically on the efficacy and safety of medical interventions, SDOH can influence both clinical trial contracts and budgets. All stakeholders need to proactively account for these factors in their contracts and budgets.

11:35 PANEL DISCUSSION: Redesigning Site Contract and Budget Negotiations to Accelerate Study Start-Up
Moderator: Debora Sobral, Director, Site Budget Management, Kyowa Kirin
Panelists:
Jennifer Sydney Goldman, Clinical Business Operations, Consultant
Jenn Hill, Director, Clinical Site Contracting and Payments, Vertex Pharmaceuticals
Erik Sokolowski, Senior Director, Global Trial Optimization, Alnylam Pharmaceuticals
Serpil Tutan, Director, Clinical Research, Baylor College of Medicine

12:35 pm Transform Procurement: Harnessing AI for Strategic Sourcing
Anca Copaescu, CEO, Strategikon Pharma
In the fast-paced procurement landscape, staying ahead is crucial. We will highlight how AI is revolutionizing clinical business operations, from strategic sourcing to vendor management and cost optimization. Explore AI-driven tools that enhance decision-making, streamline workflows, and accurately predict study costs. Ideal for outsourcing managers, clinical operations, and R&D finance professionals, learn to leverage AI for smarter, more efficient procurement with Clinical Maestro.

1:05 End-to-End Financial Management: Challenges and Opportunities
Zahiah Gueddar, Senior Director & Commercial Lead Financial Strategy, IQVIA Technologies
As soon as your protocol is finalized, the financial management mega-process begins, and a series of interconnected steps must be executed flawlessly to avoid delays. Currently, this process is fragmented and manual, leading to tedious and error-prone tasks that burden your team. Join our session to learn how leveraging a blend of SaaS and tech-enabled services can help you streamline budgeting and financial management, ensuring smooth operations whether your trials are insourced or outsourced.

1:35 Sponsored Networking Luncheon
Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall
SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

BEST PRACTICES IN CONTRACTING

3:20 Chairperson's Remarks
Anca Copaescu, CEO, Strategikon Pharma

3:25 Contractual and Legal Implications when Working with AI Suppliers and How to Address Them
Jennifer Trevor, PhD, Director and Global Category Lead, Development and R&D Procurement, Astellas Pharma US Inc
This talk explores the critical contractual and legal considerations when engaging AI suppliers in clinical research outsourcing. We will cover key challenges such as data ownership, liability for AI-driven decisions, intellectual property rights, and regulatory compliance. Attendees will gain insights into structuring contracts to mitigate risks, ensuring transparency, and safeguarding ethical standards. Learn strategies to effectively navigate the evolving legal landscape of AI in clinical trials and supplier partnerships.

3:55 Lessons from a Small Biotech to Large Pharma: Streamlining the Contracting Process and Minimizing Change Orders
Richard O'Hara, Director, R&D Business Operations, OncoC4, Inc.

4:25 Introducing Next-Generation Study Forecasting to Optimize Strategies & Budgets - Credible Planning & Parexel Case Study
Dhvanil Karia, PhD, Director, Clinical Solutions, Credible Planning
Dharmesh Mashru, CEO, Credible Planning
Claire Plewes, Senior Director, Head of Strategic Feasibility, Global Strategic Feasibility, Parexel Intl Corp
This talk presents PACE, an innovative SaaS platform for comprehensive clinical trial planning, tracking and forecasting across all phases. Find out how PACE enables efficient study planning, empowers operational/feasibility teams with timely, consistent risk forecasting & provides performance KPIs at various levels whilst integrating seamlessly with existing systems. Parexel shares their experience demonstrating how PACE's comprehensive & adaptable solution outperforms current planning systems.

BUDGETING FOR SUSTAINABILITY

4:55 Environmental Impact of a Phase 1 Study—A Carbon Accounting Journey
Michael J. Cohen, Senior Director, Environmental Sustainability, Strategy & Innovation, Thermo Fisher Scientific
Clinical research, while clearly focused on improving patient health, isn't performed in a vacuum. The surrounding environment is impacted by our clinical research, and the first step towards limiting the greenhouse gas emissions (like CO_2) related to clinical research is to quantify those emissions. But where do we start? Join us on a journey through evaluating and tabulating the carbon emissions of a Phase 1 Study conducted at our clinic.

5:25 It's Time for Pharma Feud! Two Pharma Teams Compete to Guess Top Drivers of Patient Recruitment
Joseph Kim, Chief Strategy Officer, ProofPilot, Inc.
Shivi Stanley, Senior Manager, Patient Engagement & Clinical Strategy, Astellas Pharma US, Inc.
Randy Brown, Vice President, Clinical Operations, Altimmune
Eva Topole, Lead, Clinical Digital Health & Innovation, Chiesi Farmaceutici SpA
Amanda Decoker, Sr Dir & Head Patient Recruitment & Retention, Patient Recruitment & Retention, Takeda Pharmaceutical Co Ltd
Peter O'Neill, VP Clinical Operations, Clinical Operations, TuHURA Biosciences
James Carroll, Head, Real World Evidence & Clinical Trials, Walgreens
Let's face it, sites are a business. Successful patient recruitment is the key to ensuring the rest of the projected revenue is realized. But patient recruitment is a multidimensional capability influenced by a variety of drivers. While it's easy to blame restrictive I/E criteria for slowing down recruitment, there are actually many more drivers that will influence successful recruitment at the site. In this session, we pit two Pharma teams against each other to see who knows more about what successful recruitment looks like!

5:40 Presentation to be Announced

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

BUDGETING STRATEGIES FOR PHARMA AND BIOTECH FOR INVESTIGATOR-INITIATED RESEARCH

8:50 Chairperson's Remarks

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

8:55 PANEL DISCUSSION: Investigator-Initiated Studies: Budgeting Practices for Time and Cost Savings

Moderator: Meghan Harrington, Vice President, Clinical Trial Financial Management, Medidata, a Dassault Systemes Co.

Investigators must budget not only for protocol activities, but also estimate the time commitment required from each team member, including investigators, coordinators, and support staff, ensuring these estimates are precise and comprehensive. Learn about time and cost saving practices of the IIS budget management practice by a Sponsor, the critical role of accurate fair market value data in optimizing the budgeting process, and operational considerations for an effective IIS program.

Panelists:
Karen Hartman, Vice Chair, Research Administration, Mayo Clinic
Michael Salvatore, Director, Process & Systems, Merck

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

AI AND THE FUTURE OF THE CLINICAL TRIAL WORKFORCE: ARE YOU READY FOR IT?

11:20 Chairperson's Remarks

Richard Scaife, Head, Outsourcing, Windward Bio AG

11:25 FIRESIDE CHAT: How Are Companies Preparing and Upskilling Their Workforce to Innovate in the Changing AI Landscape?

Solomon Babani, Senior Vice President, Business Development, Syneos Health
Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Endo
Scott Sawicki, SJS Consultative LLC, Consultant
Wanda Shoer, Chief Learning Officer, Sanofi

This fireside chat brings together leaders across the clinical trial ecosystem to discuss how sponsors, CROs, and sites are preparing their workforces in our changing technological landscape. How does the implementation of AI impact the processes and procedures companies have spent years developing? Are companies willing to change? Are they innovators, early adopters, early majority, late majority, or laggards? How will the different adopters be impacted?

12:25 pm Bridging the Last Mile: A Hybrid Approach to Patient Access and Retention

Gerald Finken, CEO, RXE2
Josh Rose, CEO, Hawthorne Health
Christopher Church, Chief Commercial Officer, Hawthorne Health

The last mile in clinical trials—where patient access, engagement, and retention converge—is critical to the success of modern research. Bridging this gap requires a hybrid model that seamlessly integrates technology and human connectivity to meet patients where they are. By addressing the challenges of accessibility and engagement through a patient-centric lens, clinical trials can achieve improved outcomes while maintaining the essential human connections that drive trust and participation.
This session will explore actionable approaches to patient-centric studies that leverage technology to enhance the patient experience while maintaining essential human connections.
Key Topics:
- Hybrid Models in Action
- Patient-Centric Design: Enhancing the Experience
- Automation in Action: Technology-Driven Solutions
- Achieving Better Outcomes with a Hybrid Approach

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

KEY STRATEGIES FOR SMALL & MIDSIZE BIOPHARMA SUCCESS FOR FUTURE PLANNING

8:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:25 Mastering Acquisitions: A Clinical Ops Guide to Successful Biopharma Transitions

Scott T. Megaffin, CEO, Adiso Therapeutics

oin a seasoned C-level leader as they outline the key steps clinical operations executives need to navigate when a small biopharma company is acquired. This session will cover how to evaluate and integrate acquisition opportunities, manage operational transitions, and ensure data continuity. Gain practical strategies for maintaining clinical trial integrity, optimizing resources, and leveraging acquisitions to strengthen your company's market position and drive sustainable growth.

8:55 PANEL DISCUSSION: Weathering the Drama of Change in Biotech: A Clinical Operations Perspective

Moderator: Valerie Reynaert, Vice President, Global Clinical Operations, Immunocore

Join us for an insightful session on navigating the turbulent waters of change in the biotech industry. From mergers and acquisitions to going public, dramatic portfolio shifts, and new co-development ventures, learn how to build robust strategies to manage these significant transitions. Gain practical insights and actionable strategies from clinical operations experts who have successfully steered their organizations through these challenges.

Panelists:

Ann-Marie Hulstine, Vice President, Clinical Operations, Alpheus Medical

Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK

Doug A. Schantz, Senior Vice President, Clinical Operations, Asklepios BioPharmaceutical, Inc.

9:25 Faster Submissions, Smarter Workflows: Lessons from Sanofi's AI-Powered Translation Strategy

Georges Tavares, Clinical Translation Services Global Manager, Sanofi

In this session, learn how Sanofi has transformed its translation processes using centralized management by expert project managers, automated workflows, and integration of TransPerfect's GlobalLink platform with Veeva eTMF. You'll gain insights into Sanofi's pragmatic, phased approach, including leveraging automation and AI-powered workflows. The result is a dynamic digital ecosystem that captures feedback, drives continuous improvement, and achieves over 30% savings in time and resources. Join us to hear actionable strategies you can take back to your teams to accelerate timelines, enhance inspection-readiness, and cut costs.

DEMONSTRATING VALUE OF CLINICAL OPERATIONS TO THE C-SUITE

9:40 Advanced Therapies: C-Suite Considerations for Navigating Development Challenges

Amanda Moore, Vice President, Program Leadership & Clinical Operations, Abeona Therapeutics

Shaheen Limbada, Chief Operating Officer, Operations, WEP Clinical

The development of advanced therapies, such as cell and gene therapies, presents unparalleled opportunities and challenges for biotech companies. This presentation will focus on how the C-suite can effectively navigate the complexities of advanced therapy development, including manufacturing scalability, logistics complexity, regulatory requirements and commercialization planning. As part of the discussion, we'll touch on the critical role of vendor selection, exploring how to identify and engage partners with the expertise required to address the unique demands of advanced therapies.
Key topics include:
• Overcoming technical and operational challenges in advanced therapy development.
• Managing logistical complexities and regulatory intricacies.
• Integrating patient perspectives
• Incorporating vendor selection into a broader operational strategy.
• Preparing for the commercial launch of advanced therapies.

10:10 PANEL DISCUSSION: Advocating for Clinical Operations before Clinical Development

Moderator: Dawn Buchanan, Vice President, Clinical Development Operations, AffyImmune Therapeutics, Inc.

Panelists:

Ed Tumaian, Senior Vice President, Clinical Operations, Cyclo Therapeutics, Inc.

Caro Unger, Clinical Trial Strategy & Management Leader, Asher Biotherapeutics

Nithiya Ananthakrishnan

11:10 Networking Coffee Break

TACKLING OPERATIONAL CHALLENGES IN OUTSOURCING FROM START TO FINISH: STRATEGIES FOR EFFECTIVE TRIAL EXECUTION

11:50 Chairperson's Remarks

Akhil Rachamadugu, Director, Life Sciences Industry Solutions, ServiceNow

11:55 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 less critical—but are they? For small biopharmas, especially new players, these relationships can be pivotal. Shouldn't the CRO handle this? Why should sites care? Discover why building strong sponsor-site connections still matters and how it can make a difference in your trial's success.

12:25 pm Creating and Leveraging an Outsourcing Strategy for Smaller Biotechs

Kelly L. Smith, AD, Operations, Viracta Therapeutics, Inc.

How do you leverage vendors to engage while not being able to rely on a book of business? This will advise on step-by-step approaches, engagement strategies, and considerations for your own study.

12:55 PANEL DISCUSSION: Bridging the Gap: A Case Study in Hiring through Bridge Programs and the Impact on Clinical Operations Effectiveness

Moderator: Carrie Lewis, Executive Director, Clinical Program Optimization, Endo

How can pharma and biotech companies think outside the box and hire candidates interested in entering clinical research but may not have the industry experience? How do these companies then retain these employees and grow their careers? How can hiring, training, and growing employees be done in a way to minimize the impact to ongoing trials?

Panelists:

Suzy Montanye, Site Relationship Manager, Endo

Joan Ramella, Associate Director, Oversight & Training, Endo

Krista Wilson, Director, Clinical Operations, ICON

1:25 Transition to Lunch

1:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 9th Annual

Mastering an Outsourcing Strategy

Innovative Outsourcing Models and Determining Success through Metrics and Governance

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 11th Annual

Relationship and Alliance Management in Outsourced Clinical Trials

Strategies for Building Successful Partnerships and Alliances in a Competitive Landscape

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.
**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.
Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 OPEN WORKSHOP: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace (IN-PERSON ONLY)
Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our "Ask a ClinEco Luminary" program where embers can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. To register for the workshop, please opt into this workshop by selecting the checkbox under "Conference Selection." Open to all SCOPE attendees.

1:00 OPEN WORKSHOP: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trial (IN-PERSON ONLY)
INSTRUCTORS:
Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/Thermo Fisher Scientific
While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a "Sustainability 101" to help anyone in our industry get started towards developing more environmentally responsible clinical trials. To register, please opt into this workshop by selecting the checkbox under 'Conference Selection. Open to all SCOPE attendees. Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.
INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)
U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing
INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP
This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There
Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA
In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

ARTIFICIAL INTELLIGENCE AND ITS IMPACT ON OUTSOURCING

11:00 Chairperson's Remarks

Michelle Verhaeghe, Vice President, FSP Clinical Operations, FSP Leadership Team, Parexel International

11:05 PANEL DISCUSSION: Macro Trends in Pharma: AI, Innovation, and the Impact on Outsourcing Strategy

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

Join us as this expert panel discusses how macro-level trends are impacting biopharma companies. We will discuss the latest data from Jefferies' own David Windley in the context of resourcing, funding, portfolio prioritization, and of course AI, and how all these converging factors affect outsourcing and relationship management paradigms for Sponsors both small and large. Come have fun and don't be surprised if a spot-poll shows up again this year!

Panelists:

Lynette Bojko, Head, Sourcing Compliance Management, Pfizer

Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.

David Windley, Managing Director, Jeffries LLC

12:05 pm How Procurement Can Lead the Way in Using AI to Automate Outsourcing

Sameer Tandon, Senior Director & Strategic Transactions Lead, R&D Procurement, Bristol Myers Squibb Co.

The use of generative AI is exploding in pharma, and the biggest area of opportunity is how it can be utilized in procurement. This talk will dive into how AI can help automate the outsourcing process by creating autonomy within the outsourcing system.

12:35 Futureproofing Your Outsourcing Model in an Era of Innovation parexel

Michelle Verhaeghe, Vice President, FSP Clinical Operations, FSP Leadership Team, Parexel International

The biopharma industry is undergoing rapid transformation, driven by technological advancements, market dynamics, and global events. This progression necessitates a shift towards agile outsourcing partnership models to address the growing complexity and scale of clinical studies.

With a substantial increase in trials over the past five years and significant geographical diversification, the industry faces both opportunities and challenges. To optimize trial design, enhance patient-guided development, and leverage technology effectively, a new approach to partnerships is critical. We'll explore strategies for building agile, high-performance partnerships between sponsors, patients, and CROs, moving beyond traditional outsourcing models to optimize trial design and leverage technology effectively.

1:05 Presentation to be Announced KPS LIFE

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall AMR Vitalograph

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

EVALUATION, METRICS, GOVERNANCE: SETTING OUR PARTNERS UP FOR SUCCESS

3:20 Chairperson's Remarks

Colleen Butler, Vice President, Clinical Operations & Delivery, Lightship

3:25 Intelligent Automation in Clinical Trial Vendor Selection

Matthew Failor, Director & Head, Clinical Operations, MAIA Biotechnology

This presentation will outline how intelligent automation helped create, send, and receive RFPs online to more efficiently select clinical trial vendors. Using case studies, it will describe how instant comparative analytics enabled real-time, 1:1, and side-by-side RFP comparisons. Equipped with this information, the sponsor was able to make informed decisions, save significant time and resources, and most importantly, select the right vendor in terms of price and quality.

3:55 Effective Governance Models in CRO-Sponsor Partnerships: Lessons from the Bayer-Parexel Collaboration parexel

Holger Liebig, Executive Director, Partnership Center of Excellence, Parexel

Melissa Bencivengo, MBA, Director, Alliance and Partnership Management, Bayer

This presentation explores the critical elements of successful governance in strategic CRO-sponsor collaborations, using the Bayer-Parexel partnership as a case study. We'll examine key aspects including performance metrics, process alignment, team dynamics, and communication frameworks. Additional topics cover risk management, cultural integration, technology sharing, and continuous improvement initiatives. Join us to gain insights into building and maintaining high-performing partnerships in the evolving landscape of clinical research.

4:25 The Power of Partnerships perceptive

Speaker to be Announced, inviCRO LLC

Andrea Abram, Eli Lilly

4:40 What keeps a 20-year partnership alive? The secret sauce behind collaborating with your imaging CRO for successful registrational trials perceptive

Renee Tschoop, Perceptive Inc

4:55 Refreshing Partner KPIs and Metrics: Where Did They Come From and Where Do We Go From Here?

Kimberly Payton, Senior Director, Vendor Management—Operations, Alnlyam

This presentation explores the elements of a partnership refresh of KPIs and metrics for successful governance in strategic CRO-sponsor collaborations. We'll examine key aspects including performance metrics, process alignment, team dynamics, and communication frameworks. Additional topics include cultural integration, technology sharing, and continuous improvement initiatives for a hybrid and scalable partnership. Join us to gain insights into building and maintaining high-performing partnerships in the evolving landscape of clinical research.

5:25 How to Maximize ROI on Patient Recruitment Spend: Strategies for Smarter Investments and Faster Results AutoCruitment

Jill Pellegrino, Chief Executive Officer, AutoCruitment

Traditional site-based recruitment strategies often fall short, with limited patient access and unreliable recruitment timelines. Direct-to-patient recruitment flips the script with a more patient-centric alternative, but not all recruitment strategies or partners are created equal.

Choosing the right recruitment partner requires evaluating measurable outcomes, proven methodologies, and partner expertise. This presentation will highlight recruitment strategies that lead to faster enrollment timelines, optimized budgets, and consistently reliable results.

5:40 Ditch Quarterly Vendor Meetings: Embrace Agile Governance for Better Results UNIVO IRB

Julie Blasingim, CEO & Institutional Official, Univo IRB

Frequent vendor governance meetings can be a drain on resources without providing proportional benefits. This presentation argues for replacing quarterly vendor meetings with real-time monitoring and agile touchpoints. By leveraging technology and fostering transparent communication, companies can enhance vendor performance, reduce administrative burdens, and foster innovation.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi

Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

BEST PRACTICES IN ADAPTABILITY IN OUTSOURCING MODELS AND RELATIONSHIPS

8:50 Chairperson's Remarks

Speaker to be Announced, Kellman Pharmaceutical Services (KPS)

8:55 Evolving Sourcing Needs and Models of a New Biopharmaceutical Company in Women's Healthcare

Mohan R. Bangalore, PhD, Head & Senior Director, Procurement & Vendor Management, Summit Therapeutics

As a newly spun-off biopharma company focusing on unmet medical needs in Women's Health, our clinical R&D sourcing needs and models have evolved over the past couple of years. We are transitioning to a function-driven sourcing model where we can have a set of fit-for-purpose preferred suppliers to bring in flexibility and agility. Challenges in Women's Health sourcing, pros and cons of different sourcing models will be discussed.

9:05 Talk Title to be Announced

Richard Scaife, Head, Outsourcing, Windward Bio AG

9:55 Maximizing FSP Partnerships: Selecting the Right Partner, Improving Outcomes, and Driving Innovation

Diana Cucos, President, FSP 360, Syneos Health

Adam Kinsey, Assoc VP Clinical Operations & Regional Head, N America, Merck & Co Inc

This presentation explores the evolving landscape of clinical partnerships, emphasizing outcome-oriented models that deliver sustained value. By aligning goals, culture, resources and expertise, partnerships can achieve predictable trial success, accelerate innovation, streamline processes and scale new technologies. Drawing on sponsor and vendor experience, we highlight strategies for building collaborative relationships that drive long-term impact across the drug development lifecycle.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

STRENGTHENING RELATIONSHIPS DURING CHALLENGING TIMES

11:20 Chairperson's Remarks

Mike Hutton, Director - Strategic Partnerships and Commercializ, Clinical Technologies, Almac Group

11:25 CASE STUDY: Driving Success in a Complex Partnership

Jodi Coughlin, Senior Director, Vendor Performance and Strategy, Deciphera Pharmaceuticals

Craig Dorer-Abadia, Executive Director, Project Management, Oncology, Worldwide Clinical Trials

Ashley Fitzgerald, Senior Manager, Vendor Performance and Strategy, Deciphera

Stacey Limauro, Executive Director, Clinical Operations, Deciphera

Nicola Thorne, Vice President, Oncology Project Management, Worldwide Clinical Trials

Clare Wallis, Executive Vice President, Global Clinical Development, Worldwide Clinical Trials

Transforming a transactional, third-party vendor relationship into a relational partnership with shared values and vision takes commitment, passion, and effort. Join us as we tell the story of how Deciphera and Worldwide Clinical Trials elevated a basic relationship between a CRO and Sponsor, and transformed it into a "One Team" partnership showcasing shared cultural alignment, robust operational processes, team recognition resulting in a Phase III, priority review by the FDA.

11:55 Leveraging External Partners & Capabilities to Deliver on Organizational Transformation Goals

James Chennells, Strategic Alliances Lead, Product Development & Performance Excellence, Clinical Development & Operations, Bayer

What happens when a company undergoes a massive change in trials? This talk will discuss understanding transformation drivers & levers, prioritizing short, medium & long-term outcomes, and building an overarching strategic framework to meet those outcomes while strengthening existing partnerships.

12:25 pm Implementing FDA DEI Guidance Using Next-Gen Approaches to Recruitment & Trial Design

David MacMurchy, CEO, Lightship

Tim Joy, Head of Strategic Solutions, Information Mgmt, Pfizer

Lightship's CEO, David MacMurchy, and Pfizer's Head of Strategic Solutions, Timothy Joy, will explore innovative, community-based, and culturally-competent approaches to delivering DCTs, examine how to effectively implement the FDA's guidance on DEI)to ensure trials are more inclusive and representative of the populations they aim to serve.
Key topics include:
- Overview of FDA DEI expectations
- Historical challenges that have hindered progress, and
- Modern strategies for overcoming these barriers

We will highlight community-driven outreach, culturally sensitive recruitment methods, and how to apply these practices to comply with DEI guidelines.
We'll also review how Pfizer implemented these strategies to achieve tangible outcomes for their patients and clinical team.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

2:35 Chairperson's Introduction
Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization
April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine
This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond
Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson
Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.
Panelists:
James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing
We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies
Speaker to be Announced, PAREXEL International
Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl
Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

KEY STRATEGIES FOR SMALL & MIDSIZE BIOPHARMA SUCCESS FOR FUTURE PLANNING

8:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:25 Mastering Acquisitions: A Clinical Ops Guide to Successful Biopharma Transitions
Scott T. Megaffin, CEO, Adiso Therapeutics
oin a seasoned C-level leader as they outline the key steps clinical operations executives need to navigate when a small biopharma company is acquired. This session will cover how to evaluate and integrate acquisition opportunities, manage operational transitions, and ensure data continuity. Gain practical strategies for maintaining clinical trial integrity, optimizing resources, and leveraging acquisitions to strengthen your company's market position and drive sustainable growth.

8:55 PANEL DISCUSSION: Weathering the Drama of Change in Biotech: A Clinical Operations Perspective
Moderator: Valerie Reynaert, Vice President, Global Clinical Operations, Immunocore
Join us for an insightful session on navigating the turbulent waters of change in the biotech industry. From mergers and acquisitions to going public, dramatic portfolio shifts, and new co-development ventures, learn how to build robust strategies to manage these significant transitions. Gain practical insights and actionable strategies from clinical operations experts who have successfully steered their organizations through these challenges.
Panelists:
Ann-Marie Hulstine, Vice President, Clinical Operations, Alpheus Medical
Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK
Doug A. Schantz, Senior Vice President, Clinical Operations, Asklepios BioPharmaceutical, Inc.

9:25 Faster Submissions, Smarter Workflows: Lessons from Sanofi's AI-Powered Translation Strategy
Georges Tavares, Clinical Translation Services Global Manager, Sanofi

In this session, learn how Sanofi has transformed its translation processes using centralized management by expert project managers, automated workflows, and integration of TransPerfect's GlobalLink platform with Veeva eTMF. You'll gain insights into Sanofi's pragmatic, phased approach, including leveraging automation and AI-powered workflows. The result is a dynamic digital ecosystem that captures feedback, drives continuous improvement, and achieves over 30% savings in time and resources. Join us to hear actionable strategies you can take back to your teams to accelerate timelines, enhance inspection-readiness, and cut costs.

DEMONSTRATING VALUE OF CLINICAL OPERATIONS TO THE C-SUITE

9:40 Advanced Therapies: C-Suite Considerations for Navigating Development Challenges

Amanda Moore, Vice President, Program Leadership & Clinical Operations, Abeona Therapeutics

Shaheen Limbada, Chief Operating Officer, Operations, WEP Clinical

The development of advanced therapies, such as cell and gene therapies, presents unparalleled opportunities and challenges for biotech companies. This presentation will focus on how the C-suite can effectively navigate the complexities of advanced therapy development, including manufacturing scalability, logistics complexity, regulatory requirements and commercialization planning. As part of the discussion, we'll touch on the critical role of vendor selection, exploring how to identify and engage partners with the expertise required to address the unique demands of advanced therapies.
Key topics include:
• Overcoming technical and operational challenges in advanced therapy development.
• Managing logistical complexities and regulatory intricacies.
• Integrating patient perspectives
• Incorporating vendor selection into a broader operational strategy.
• Preparing for the commercial launch of advanced therapies.

10:10 PANEL DISCUSSION: Advocating for Clinical Operations before Clinical Development

Moderator: Dawn Buchanan, Vice President, Clinical Development Operations, AffyImmune Therapeutics, Inc.

Panelists:

Ed Tumaian, Senior Vice President, Clinical Operations, Cyclo Therapeutics, Inc.

Caro Unger, Clinical Trial Strategy & Management Leader, Asher Biotherapeutics

Nithiya Ananthakrishnan

11:10 Networking Coffee Break

TACKLING OPERATIONAL CHALLENGES IN OUTSOURCING FROM START TO FINISH: STRATEGIES FOR EFFECTIVE TRIAL EXECUTION

11:50 Chairperson's Remarks

Akhil Rachamadugu, Director, Life Sciences Industry Solutions, ServiceNow

11:55 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 less critical—but are they? For small biopharmas, especially new players, these relationships can be pivotal. Shouldn't the CRO handle this? Why should sites care? Discover why building strong sponsor-site connections still matters and how it can make a difference in your trial's success.

12:25 pm Creating and Leveraging an Outsourcing Strategy for Smaller Biotechs

Kelly L. Smith, AD, Operations, Viracta Therapeutics, Inc.

How do you leverage vendors to engage while not being able to rely on a book of business? This will advise on step-by-step approaches, engagement strategies, and considerations for your own study.

12:55 PANEL DISCUSSION: Bridging the Gap: A Case Study in Hiring through Bridge Programs and the Impact on Clinical Operations Effectiveness

Moderator: Carrie Lewis, Executive Director, Clinical Program Optimization, Endo

How can pharma and biotech companies think outside the box and hire candidates interested in entering clinical research but may not have the industry experience? How do these companies then retain these employees and grow their careers? How can hiring, training, and growing employees be done in a way to minimize the impact to ongoing trials?

Panelists:

Suzy Montanye, Site Relationship Manager, Endo

Joan Ramella, Associate Director, Oversight & Training, Endo

Krista Wilson, Director, Clinical Operations, ICON

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Clinical Trials Outside of a Vacuum: Leveraging ServiceNow and Generative AI to Transform End-to-End Trial Delivery

Akhil Rachamadugu, Director, Life Sciences Industry Solutions, ServiceNow

As the clinical trial landscape grows more complex, the need for integrated, intelligent solutions has never been more critical. This session explores how ServiceNow, combined with cutting-edge generative AI capabilities, is reshaping the way trials are planned, executed, and managed—bridging silos, streamlining operations, and fostering seamless collaboration across sponsors, CROs, and sites.
Attendees will discover how to unlock efficiency and agility in trial delivery, from accelerating patient recruitment to enhancing data management and regulatory compliance. Learn from real-world case studies that showcase the transformative power of generative AI in breaking down operational barriers, reducing cycle times, and driving innovation across the entire clinical trial lifecycle.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 6th Annual

Partner Selection and Trial Design

Small Biopharma, Smart Partnerships: Design Trials for Success

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 8th Annual

Vendor Oversight & Resource Management

Streamline Success: Optimize Vendor Oversight and Outsourcing for Small and Mid-Size Biopharma

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

POWER-PLAYS: STRATEGIC PARTNERSHIPS FOR SMALL BIOPHARMA SUCCESS

11:00 Chairperson's Remarks

Antoinette Frankum, Vice President & Head of Clinical Development, North America Clinical Development, ClinChoice, Inc.

11:05 Choosing the Right Allies: Ensuring Clinical Trial Success for Small Biopharma

Peter Ronco, CEO, Emmes

This presentation will dive into the critical factors that small biopharma companies must consider when selecting partners for clinical trials. Peter will share insights on making the right choices to enhance efficiency, reduce risks, and drive growth, drawing from his extensive experience in the life sciences sector. His leadership and operational expertise will be invaluable as we enter our next phase of growth.

11:30 Strategic Partnerships for Accelerating Biotech Startups: From Pre-Clinical to Clinical Success

Alex Pastuszak, MD, PhD, Co-Founder & CEO, Paterna Biosciences

Learn how strategic partnerships and smart vendor selection are key to advancing biotech startups from pre-clinical to clinical stages. By collaborating with top-tier service providers and specialized vendors, startups can leverage cutting-edge technologies, regulatory expertise, and optimized resources to streamline research, mitigate risks, and accelerate clinical progress—positioning them for long-term success in a competitive, highly regulated market.

11:55 CRO Selection—Finding the Right Fit

Brandie M. Jonas, MS, Senior Director, Program Management, Geron Corporation

It can feel overwhelming for a small biotech or biopharma company to find the right CRO fit as there are so many options these days. I've developed and implemented a strategy and tool kit that will enable CRO evaluation and ultimately lead to selecting a CRO who is fit-for-purpose.

12:10 pm Scaling Efficiency in Clinical Vendor Identification and Selection Processes

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

Tina Karunaratne, Executive Advisor, Biopharma Relations, ClinEco

This presentation will feature several case studies of ClinEco' s capabilities and innovative approaches for connecting clinical research stakeholders, ranging from vendor comparative analysis to tracking information and obtaining informed referrals.

12:20 Optimizing CRO Partnerships for Small Biopharma Success

Melanie Goodwin, Director, Clinical Outsourcing, Immunocore

Choosing the right CRO is critical for the success of clinical operations, especially for small biopharma companies. This presentation outlines a strategic approach to CRO selection, beginning with a comprehensive set-up of requirements and a thorough landscape analysis. By narrowing down potential CROs, and rigorously questioning to ensure alignment with your company's goals, we reveal how to streamline the selection process.

12:35 Small Yet Mighty: The Critical Role of Study Start-Up Tech for Small Biopharma

ADVARRA

Speaker to be Announced, Advarra

Ashley Davidson, Vice President, Product Lead, Advarra

In this session, we will explore why site-centric study startup technology is essential for small biopharma companies, highlighting the significant ROI and streamlined workflow it offers for sites and study teams alike. Additionally, we'll emphasize the importance of site centricity, showing how focusing on site needs and challenges can enhance trial success and patient experiences. We'll delve into specific projects to show how site-centric technology helps smaller organizations achieve efficient study start-ups, demonstrating why investing in this tech is crucial for staying competitive in today's fast-paced biopharma and biotechnology landscape.

1:05 FDA's Diversity Guidance & Small BioPharma: Total Quality Management Lesson for Representative Recruitment

1nHealth

Dan Brenner, CEO & Founder, Business Development, 1nHealth

Sponsors progressing assets through the clinical development cycle are seeking to cut through the industry buzz words and noise to properly comply with the FDA's guidance on diversity and representation in clinical trials. Most sponsors have a plan, some execute it, but even fewer achieve their diversity objectives. 1nHealth has successfully supported some of the most significant studies to date by supporting recruitment to diversity cohort targets.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

AMR Vitalograph

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

PRECISION PLANNING: MASTERING CLINICAL TRIALS FOR SMALL BIOPHARMA BREAKTHROUGHS

3:20 Chairperson's Remarks

Donna Dorozinsky, Founder and CEO, Just in Time GCP

3:25 Adopting a Hybrid FSP Model in a Fast-Paced Clinical Trial Environment

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

Alissa Calaway, RN, MSN, Manager, Medical Device Clinical Project Management, Galderma

Galderma has implemented a hybrid Functional Service Provider (FSP) model for select clinical trials, outsourcing specific functions while still maintaining control over data and processes. This presentation will highlight the pros and cons of implementing a hybrid FSP model in a fast-paced clinical trial environment with tight timelines and lean in-house cross-functional teams.

3:40 PANEL DISCUSSION: Trial Planning for Small- & Mid-Sized Biotechs: Free of Legacy Systems and Processes—But Short on Time and Money

Moderator: Suzanne Vyvoda, Independent Consultant

Smaller biopharma companies need CRO partners who understand their unique needs, avoiding the typical big pharma approach. With smaller teams, they value flexibility in outsourcing, building capabilities, and choosing partners. This freedom allows for innovation, but it also requires careful planning and execution, as each trial demands a tailored approach.

Panelists:

Tim Foley, Chief Business Officer, Scailyte

Robert Goldman, Head of Clinical Operations, Contraline

Jeffrey S. Yablon, Head Business Development & Strategic Operations, Ubuntu Research, Inc.

4:10 Streamlining Trial Planning for Small Biotechs: Key Lessons to Maximize Impact on a Tight Budget

Jeffrey S. Yablon, Head Business Development & Strategic Operations, Ubuntu Research, Inc.

This presentation will provide practical strategies for clinical operations executives in small and mid-sized biotech companies to overcome common trial planning hurdles. Presenters will share valuable lessons learned, offering actionable insights into how small biotechs can leverage limited resources effectively. Topics include optimizing trial processes, driving clinical proof-of-concept, and navigating partnerships—while avoiding the inefficiencies of legacy systems.

4:25 Managing Your Clinical Trial Effectively: Engaging Patients and Sites for Success

ALMAC

Cheryl Kole, Vice President, Strategy & Commercialization, Clinical Technologies, Almac Group

Kees Van Ooik, Vice President - eClinical Development, Almac Group

Explore how small biopharma companies can achieve clinical trial success using tools that effectively engage patients and sites. Using a case study of a fully remote study, we will discuss the unique challenges faced by small biopharma, such as limited resources and short timelines, and how an integrated eClinical solution can help overcome these obstacles. Join us to learn how to transform clinical trial processes and drive success.

4:55 Blueprints for Success: Trial Planning & Design Insights from a Small Biopharma Leader

Kevin Eisenfrats, Founder & CEO, Contraline, Inc.

Gain actionable insights into clinical trial planning and design from Kevin, CEO and co-founder of Contraline. With over $30M in funding and a groundbreaking product in reproductive health, Kevin will share key takeaways and lessons learned from leading a biotech startup through the journey from concept to clinical stage. This session is a must for clinical operations executives launching and running trials.

5:25 Protocol and Feasibility Simulations to Optimize Trial Planning

Advanced Clinical

Cheryle Evans, Senior Vice President, Global Clinical & Biometric Operations, Advanced Clinical
Donna Hanson, Vice President, Strategy & Optimization, Advanced Clinical
Tamara Costopoulos, Patient Recruitment Leader, Advisory Board, Individual Consultant
Leverage protocol simulations and strategic tech partnerships to enhance trial predictability and streamline planning.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*
Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials
Kyle Hogan, CEO, Datacubed Health
This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design
Christopher Riley, Director, Strategic Insights, Solutions, H1
In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs
Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee
Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

MANAGING DATA INDEPENDENTLY

8:50 Chairperson's Remarks
Lisa Jennings, Senior Director, Business Development, Catalyst Clinical Research - Catalyst Flex

8:55 Enhancing Clinical Trial Efficiency through Best Practices in Data Management
Michelle Joseph, Director, Clinical Data Management, Mural Oncology

9:10 Securing Clinical Trial Data: Navigating Cyber Threats and Regulatory Challenge
Christopher Hart, Partner, Co-Chair, Privacy and Data Security Group, Foley Hoag LLP
As clinical trials become more data-dependent, the risk of cybersecurity threats grows, especially in a shifting legal landscape with increasing multi-jurisdictional complexities. For clinical operations executives, staying ahead of regulatory changes is crucial to ensure data security and compliance. Chris Hart, Partner at Foley Hoag LLP, will discuss how small biopharma can proactively address cybersecurity, build robust data infrastructure, and strategically select outsourcing partners to safeguard clinical trial data.

9:25 What to Consider in Managing External Data for the Small Biopharma
Kara Titus, Senior Director, Procurement, Dragonfly Therapeutics

9:40 Navigating the Diverse Future of Trial Data: Real World Data & Devices
Gaelan Ritter, Executive Director, Innovation and Digital Health Analytics, Bristol Myers Squibb Co.
The evidence generation required for clinical development is evolving rapidly. Many trials include various data types and sources, labs, biomarkers, wearable devices, and real world EHR. Gaelan will discuss the current and future state of these data types, how to think about strategic partnerships with vendors in these areas, and how to navigate the evidence planning required to drive value in the integrated data future.

9:55 Presentation to be Announced

10:25 Coffee Break in the Exhibit Hall
SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing
Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

11:20 Chairperson's Remarks
Collier Wright, Vice President of Solutions, Sales, TruTechnologies

11:25 PANEL DISCUSSION: Requirements for Managing Clinical and Non-Clinical Data
Moderator: Lorenzo Balsamo, Director, Clinical Informatics & Innovation, Tango Therapeutics
Panelists:
Stacey Arrambide, Sr VP Functional Svc Solutions, Functional Svc Solutions, Advanced Clinical
Michelle Joseph, Director, Clinical Data Management, Mural Oncology
Leila Cupersmith, Founder & CEO & Principal Consultant, Choice ClinOps LLC, Individual Consultant
Manny Lazaro, Senior Vice President, Clinical Development Operations, Kailera Therapeutics
Gaelan Ritter, Executive Director, Innovation and Digital Health Analytics, Bristol Myers Squibb Co.

12:25 pm Empowering Success in Small Pharma/Biotech: Leveraging People and Process for Optimal Results
Sheila Gwizdak, Vice President, Head of Consulting, Halloran Consulting Group
This session will provide insights on how best to align people with process, essential for fostering innovation and sustainable growth. Learn how to strategically integrate human capital with process optimization, a cornerstone for success in the small pharma sector. Leveraging real-world examples and best practices, learn how organizations can effectively harness the potential of their teams—promoting a culture of collaboration and continuous improvement. We will focus on process-driven strategies that streamline operations, enhance quality

control, and expedite time-to-market, all while maintaining high standards of quality and regulatory compliance.

12:55 Sponsored Networking Luncheon
Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced
SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

2:35 Chairperson's Introduction
Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization
April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine
This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond
Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson
Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.
Panelists:
James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing
We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies
Speaker to be Announced, PAREXEL International
Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl
Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

KEY STRATEGIES FOR SMALL & MIDSIZE BIOPHARMA SUCCESS FOR FUTURE PLANNING

8:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:25 Mastering Acquisitions: A Clinical Ops Guide to Successful Biopharma Transitions
Scott T. Megaffin, CEO, Adiso Therapeutics
oin a seasoned C-level leader as they outline the key steps clinical operations executives need to navigate when a small biopharma company is acquired. This session will cover how to evaluate and integrate acquisition opportunities, manage operational transitions, and ensure data continuity. Gain practical strategies for maintaining clinical trial integrity, optimizing resources, and leveraging acquisitions to strengthen your company's market position and drive sustainable growth.

8:55 PANEL DISCUSSION: Weathering the Drama of Change in Biotech: A Clinical Operations Perspective
Moderator: Valerie Reynaert, Vice President, Global Clinical Operations, Immunocore
Join us for an insightful session on navigating the turbulent waters of change in the biotech industry. From mergers and acquisitions to going public, dramatic

portfolio shifts, and new co-development ventures, learn how to build robust strategies to manage these significant transitions. Gain practical insights and actionable strategies from clinical operations experts who have successfully steered their organizations through these challenges.

Panelists:

Ann-Marie Hulstine, Vice President, Clinical Operations, Alpheus Medical

Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK

Doug A. Schantz, Senior Vice President, Clinical Operations, Asklepios BioPharmaceutical, Inc.

9:25 Faster Submissions, Smarter Workflows: Lessons from Sanofi's AI-Powered Translation Strategy

Georges Tavares, Clinical Translation Services Global Manager, Sanofi

In this session, learn how Sanofi has transformed its translation processes using centralized management by expert project managers, automated workflows, and integration of TransPerfect's GlobalLink platform with Veeva eTMF. You'll gain insights into Sanofi's pragmatic, phased approach, including leveraging automation and AI-powered workflows. The result is a dynamic digital ecosystem that captures feedback, drives continuous improvement, and achieves over 30% savings in time and resources. Join us to hear actionable strategies you can take back to your teams to accelerate timelines, enhance inspection-readiness, and cut costs.

DEMONSTRATING VALUE OF CLINICAL OPERATIONS TO THE C-SUITE

9:40 Advanced Therapies: C-Suite Considerations for Navigating Development Challenges

Amanda Moore, Vice President, Program Leadership & Clinical Operations, Abeona Therapeutics

Shaheen Limbada, Chief Operating Officer, Operations, WEP Clinical

The development of advanced therapies, such as cell and gene therapies, presents unparalleled opportunities and challenges for biotech companies. This presentation will focus on how the C-suite can effectively navigate the complexities of advanced therapy development, including manufacturing scalability, logistics complexity, regulatory requirements and commercialization planning. As part of the discussion, we'll touch on the critical role of vendor selection, exploring how to identify and engage partners with the expertise required to address the unique demands of advanced therapies.

Key topics include:

- Overcoming technical and operational challenges in advanced therapy development.
- Managing logistical complexities and regulatory intricacies.
- Integrating patient perspectives
- Incorporating vendor selection into a broader operational strategy.
- Preparing for the commercial launch of advanced therapies.

10:10 PANEL DISCUSSION: Advocating for Clinical Operations before Clinical Development

Moderator: Dawn Buchanan, Vice President, Clinical Development Operations, AffyImmune Therapeutics, Inc.

Panelists:

Ed Tumaian, Senior Vice President, Clinical Operations, Cyclo Therapeutics, Inc.

Caro Unger, Clinical Trial Strategy & Management Leader, Asher Biotherapeutics

Nithiya Ananthakrishnan

11:10 Networking Coffee Break

TACKLING OPERATIONAL CHALLENGES IN OUTSOURCING FROM START TO FINISH: STRATEGIES FOR EFFECTIVE TRIAL EXECUTION

11:50 Chairperson's Remarks

Akhil Rachamadugu, Director, Life Sciences Industry Solutions, ServiceNow

11:55 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 less critical—but are they? For small biopharmas, especially new players, these relationships can be pivotal. Shouldn't the CRO handle this? Why should sites care? Discover why building strong sponsor-site connections still matters and how it can make a difference in your trial's success.

12:25 pm Creating and Leveraging an Outsourcing Strategy for Smaller Biotechs

Kelly L. Smith, AD, Operations, Viracta Therapeutics, Inc.

How do you leverage vendors to engage while not being able to rely on a book of business? This will advise on step-by-step approaches, engagement strategies, and considerations for your own study.

12:55 PANEL DISCUSSION: Bridging the Gap: A Case Study in Hiring through Bridge Programs and the Impact on Clinical Operations Effectiveness

Moderator: Carrie Lewis, Executive Director, Clinical Program Optimization, Endo

How can pharma and biotech companies think outside the box and hire candidates interested in entering clinical research but may not have the industry experience? How do these companies then retain these employees and grow their careers? How can hiring, training, and growing employees be done in a way to minimize the impact to ongoing trials?

Panelists:

Suzy Montanye, Site Relationship Manager, Endo

Joan Ramella, Associate Director, Oversight & Training, Endo

Krista Wilson, Director, Clinical Operations, ICON

1:25 Transition to Lunch

1:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 17th Annual

Clinical Data Strategy and Analytics

Optimizing Data Management for Evolving Trials

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 8th Annual

Data Science, ML, and AI

AI to Lead Clinical Trial Modernization

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

ECOSYSTEM OF DATA: BREAKING AWAY FROM SILOS

11:00 Chairperson's Remarks

David Herron, CEO, Perceptive Inc

11:05 Optimizing Clinical Data Integration: A Path to Efficiency

Narayanarao Pavuluri, Senior Director & Global Head, Clinical Database Services, Merck

Clinical research requires seamless integration of data for maximum efficiency and accuracy. Clinical Data Integration connects various sources and systems, minimizing errors and delays. It provides real-time access to patient information, enabling faster trial initiation and informed decision-making. This approach streamlines workflows, offers scalability, and reduces site burden, resulting in greater research productivity. Embracing Clinical Data Integration transforms clinical trials, enhancing efficiency and accelerating research outcomes.

11:30 Practical Governance Strategies for Large-Scale R&D Data & Analytics

Gian Prakash, Director, Data & Analytics, Information Research, AbbVie, Inc.

Effective governance is essential for unlocking the full potential of large-scale R&D data & analytics. This presentation presents practical strategies for establishing and implementing a robust governance framework to support data-driven innovation. By addressing key challenges such as data quality, access, security, and ownership, organizations can foster a data-centric culture and accelerate time-to-value from R&D initiatives. This presentation offers actionable insights and recommendations for R&D leaders seeking to scale analytics.

11:55 Help Is Here: Interpreting the New ICH E6 R3 Data Governance Requirements

Arlene Lee, Director, Product Management, Data Quality and Risk Management Solutions, Medidata

Tashan K. Mistree, MS, Senior Director Business Operations, GSK

The upcoming ICH E6 R3 guideline introduces a new section related to data governance in clinical trials. Given the critical nature of data in clinical research, proper governance is essential to maintain the reliability of trial results, protect participants' rights and safety, and ensure compliance with regulatory requirements. ACRO and TransCelerate collaborated to deliver a data governance framework and diverse solutions to support understanding and interpretation of these new requirements.

12:20 pm Clinical Data Democratization Through Data Products

Sophia Nuijens, Director, Data Product, Drug Development Operations & Real World Evidence, Bristol Myers Squibb Co

Pharma companies need to democratize data access for clinical within their organization and make it easier for end users to run data and analytics use cases faster to accelerate clinical trials, patient care and outcome. With the evolution of various data management techniques such as Data Mesh, it's important to tactically learn how to strategize and create domain driven "Data products" and enable seamless data access for end users

12:35 Using eCOA Technology to Drive Endpoint Protection, Clinical Data Strategies, and Analytics

Melissa Mooney, Director, eCOA Solution Engineering, IQVIA Technologies

eCOA implementation begins with a solution design strategy that efficiently collects, stores, and manages data in a way that will optimize clinical data review and analytics while ensuring endpoint protection. IQVIA expert Melissa Mooney will explore the positive impact eCOA solutions are making on clinical data strategies, specifically:

- How eCOAs are being used to ensure endpoint protection
- The importance of planning and defining clinical data strategies in parallel to eCOA setup/design
- eCOA design considerations that create efficiencies in data analytics and monitoring

1:05 Is It Too Risky to Deploy AI in Your Clinical Trial? Understanding the Real Costs of Leveraging AI

Todd Rudo, CMO & Executive Vice President, Clario

Jay Ferro, Executive Vice President, Chief Information & Technology Officer, Clario

While the speed and efficiency that AI offers to development programs is so commonly hyped, the risks potentially introduced are usually minimized or completely dismissed. We will talk candidly about these risks and discuss how to responsibly deploy AI-enabled solutions, without compromising confidence in your clinical trial results.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

DATA COLLECTION AND REUSE

3:20 Chairperson's Remarks

Speaker to be Announced, Viedoc

3:25 Clinical Content Reuse (CCR) with Development Data Flow (DDF) for Study Optimization

Siddharth Shah, Executive Director, Product Management, Data Science and Digital Innovation, BeiGene

Oanh Stephan, PhD, Executive Director, Head, Global Medical Writing, BeiGene

Leveraging industry thought leadership, accelerators (TransCelerate, CDISC etc.), and content from critical path clinical documents to achieve optimal trial productivity by focusing on a mindful roadmap that balances the need for process-people and product(s).

3:45 It's Been a While—10 Years of Data Sharing and Reuse: Highs, Lows, and What's Next

Medha Patel, Clinical Design Analytics Director, Amgen

This is an opportunity to 'zoom out' on clinical data sharing and reuse. We've been working to share and reuse data for 10 years. Time travel with us to the early days, through highs and lows, and the outlook for what's next. We have seen that amazing things are possible when we collaborate: this is a chance to renew our 'why' and move forward with curiosity and courage.

4:05 Streamlining Secondary Analysis of Clinical Studies—Lessons Learned

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

AbbVie clinical trial data is housed in multiple databases. Locating and accessing clinical data was a time-consuming challenge. We created one source of truth for study data to create efficiencies while supporting enhanced patient care through predictive analyses. This allowed researchers to search and identify the right set of clinical studies to run secondary analyses. Harmonizing the study data access process eliminated duplicative effort and helped manage enterprise risk.

4:25 The Three Little Pigs' Tale: A Blueprint for Strategic Clinical Trial Feasibility

Barbara Argibay Gonzalez, Vice President & General Manager Data Division, Anju Software

Is your clinical trial built with straw, sticks, or bricks?
Access to data has made clinical feasibility more robust and efficient, but successful studies blend clinical intelligence with team knowledge and real-world experience. As trials target specific patient populations, granular historical data is crucial for precision. Join us to explore how combining clinical intelligence with operational insights can drive accurate enrollment models, prioritize sites, and provide dynamic, data-driven insights for success.

4:55 Catalyzing Clinical Study Data Collection

Paul Jacobs, Associate Director, Development Innovation, Regeneron Pharmaceuticals, Inc.

Progress in the field of clinical study data capture has been relatively slow, but recent boosts in interoperability, technology and opinion is enabling a rapid transformation driven by the integration of Electronic Health Records (EHR) with Electronic Data Capture (EDC) systems. We will discuss this journey and propose our thoughts for future direction, with the potential for further reinvention of data collection and the emergence of an entirely new paradigm.

5:25 Impact of PRO Type, Frequency and Modality on Patient and Site Burden: Insights from BMS/Tufts/ZS Research Study

Arnab Roy, Associate Principal, R&D , ZS

Chelsea Gallagher, Sr Dir Drug Dev Innovation & Digital Health, Business Insights & Analytics, Bristol Myers Squibb Co

Join BMS, ZS, and Tufts CSDD to explore the impact of clinical outcome assessments on trial participation burden. We will explore the insights from our insights from our 2024 global study with patients and sites to highlight the nuances of clinical outcome assessments and its impact on perceived burden of participation, including significant differences in perceptions, the impact of digital vs. non-digital modalities, and how pharma can use data driven burden analytics to design better trials.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

CLINICAL DATA IN ONCOLOGY TRIALS

8:50 Chairperson's Remarks

8:55 "Science, Sealed, Delivered": Bringing Efficiency to Complex Oncology Trials

John Manlay, Senior Director, Clinical Data Sciences, Pfizer
Muz Mirza, Senior Director, Senior Group Lead, Oncology, Pfizer

In this session we will review Pfizer's strategy for supporting accelerated oncology trials and Clinical Data Sciences' role using innovative tools, technologies, and strategies. We will discuss the evolution of how the concept of "critical data" streamlines efficiency through clinical trial operations; the incorporation of automation in our daily data review process; and the development of customized study metrics and analytics to support milestone deliverables.

9:15 Technology and Data-Driven Solutions for Increasing Enrollment of Diverse Patients in Oncology Trials

Ariel Bourla, MD, PhD, Senior Director, Data Science and Digital Health, Johnson & Johnson R&D
Reed Few, Director, External Innovation, Data Science & Digital Health, Research and Development, Johnson & Johnson

Increasing the representativeness of clinical trials has been an ongoing goal, which has only increased following FDA draft guidance on Diversity Action Plans in 2024. To achieve diverse enrollment, we have implemented several data-driven strategies, including collaborating with external partners to leverage novel technologies. We will discuss these efforts and our learnings from using data and technology to drive representative clinical trial enrollment.

9:35 Key Considerations for Utilizing AI/ML Screening Algorithms to Identify Patients with Immunotherapy

Usama Javed, PharmD, Associate Principal Scientist, Regulatory Digital Health, Merck & Co.

This presentation explores the development of screening criteria for trial participants using AI/ML algorithms. The criteria are formulated collaboratively by clinical specialists in the relevant field, defining inclusion and exclusion based on biomarkers and other diagnostic tests.

9:55 Accelerating Study Build with Generative AI

Wayne Walker, Senior Vice President, Rave Platform Technology, Medidata, a Dassault Systemes Co.

The complexity of study builds poses challenges in terms of time, cost, and accuracy. Generative AI (GenAI) transforms study builds by automating processes like generating the schedule of events, EDC forms, eCOA questionnaires, edit checks, quality control scenarios, and synthetic test data. This session highlights real-world examples of GenAI reducing study build effort and timelines, and ensuring a high-quality study start.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

DATA INTEROPERABILITY

11:20 Chairperson's Remarks

Chris Weiss, VP, Sales, OpenClinica

11:25 Interoperability Being a Value for Product Companies Enables the Patient Value and Delivery Agility to Sponsor Organizations

Donald Thampy, Executive Director, Merck

Every product company in industry seeks to develop solutions that facilitate successful processes and functions. Data transverses multiple products in the ecosystem, and we have numerous connectors to weave the magical movement of data, but is there a more effective approach? Should product companies adopt interoperability? Will interoperability address challenges associated with integrations, data movement, transitions, and cost burden on patients? Come and engage in a conversation!

11:50 Modern Clinical Data Management: Data Enablement for Tiered Clinical Data Review

Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.

This session explores the approach to data enablement of tiered clinical data review to ensure data quality and integrity throughout clinical development. By leveraging modern data engineering and technologies, we can enable complex back-end checks, patient profiles, listings, and anomaly detection in addition to Electronic Data Capture (EDC) point-of-entry checks. This tiered approach allows for efficient identification and resolution of data issues, ultimately contributing to development of innovative therapies.

12:10 pm Presentation to be Announced

12:25 Unlocking the Potential of Generative AI in Clinical Trials

Paul Mancinelli, CTO, WCG

Silvio Galea, Chief Data & Analytics Officer, WCG

Are you ready to explore the potential of Generative AI in clinical trials? In this session, you'll learn more about how you can leverage the power of Generative AI through a privacy-safe clean room. Through this secure environment, sponsors and CROs can bring their data together with WCG's data for collaboration and analysis. Specifically, we'll discuss how this technology enables faster trials with actionable and insights.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

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On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

ARE WE THERE YET WITH ETHICAL CONSIDERATIONS?

8:20 Chairperson's Remarks

Suzanne Caruso, General Manager, Clinical & Regulatory, Citeline

8:25 Content Generation and Knowledge Extraction for Clinical Documents

Vaishali Goyal, MS, AI Lead, Development, AstraZeneca Pharmaceuticals

With over 240 global clinical trials, we are currently running multiple pilots across our R&D pipeline, testing a range of AI technologies to simplify our processes. Specifically, AstraZeneca is investing in the AI technology to expedite content generation and insight extraction of key clinical assets.

8:50 AI-Powered Protocols: Breaking the Design Cycle with Data-Driven Retrospectives

Laura Russell, Senior Vice President, Head of Data and AI Product Development, Advarra

The protocol design process is ripe for innovation to address persistent challenges, including inefficiencies in trial operations and high participant attrition. The next wave of advancements will look to leverage emerging AI technologies and unified data ecosystems to break the cycle of inefficiency by tackling foundational issues rather than focusing solely on surface-level friction points. This session will delve into how smarter protocol design can become a reality by applying these advancements to data-driven retrospectives for continuous improvement.

9:05 How AI Document Automation Can Support Our Clinical Trials for EU Submissions: EU-CTR Synopsis Case Study

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

In this session, BMS shares the creation of a BOT to support submissions to the EU Clinical Trial Regulation (EU-CTR). EU-CTR Regulations now requires submissions to include a synopsis understandable to a layperson. A BOT was developed to create the synopsis from the protocol and with AI technology, it converts the language to the required laymans terms. This is time saving technology to produce a document to support EUCTR submissions.

9:25 Dynamic Trial Monitoring for Ongoing Clinical Trials

Tai Xie, Founder & CEO, CIMS Global

Effective trial monitoring is essential for participant safety, data integrity, and regulatory compliance, yet existing tools fall short in meeting these demands. Dynamic Trial Monitoring (DTM) offers a real-time, integrated approach to trial oversight, enhancing efficiency and decision-making. This presentation will highlight DTM's principles and case studies, showcasing its ability to predict enrollment trends, detect safety signals, and enable agile, high-quality trial management.

9:40 Using Predictive AI To Optimize Recruitment Content for Diverse Audiences

Matt Graffeo, Managing Director, Clinical Trial Communications, GCI Group

Kianta Key, Group Sr VP Digital & Head of Identity Experience, Digital Healthcare, GCI Health

Data-driven insights are transforming clinical trial recruitment. This presentation explores how predictive AI streamlines content creation by analyzing pre-publication messaging and visuals against historical benchmarks, ensuring resonance with target audiences and eliminating the need for A/B testing. We'll demonstrate how our proprietary platform leverages AI to predict content performance across demographics, leading to optimized messaging, increased efficiency and better recruitment outcomes.

9:55 Digital Health Technology Data Integrity: Mitigating Data Loss and Poor Data Quality to Ensure Actionable ROI

Jen Blankenship, Senior Research Scientist, Clinical Research & Development, VivoSense

This presentation addresses the critical issue of data integrity in digital health technologies and wearable sensors, focusing on mitigating data loss, inconsistencies, and poor data quality. These issues can undermine decision-making, thereby reinforcing stereotypes that "we are not there yet" in utilizing wearable sensor derived data in clinical validation. Strategies such as robust error detection, sensor wear compliance, data validation, artifact detection, and improved system integration are explored to ensure reliable, high-quality data. By partnering with external end-to-end solutions, sponsors can maximize actionable insights, improve patient outcomes, and drive a higher ROI.

10:10 Evaluating Generative AI in Regulated Environments: A Statistical Rigorous Framework for Regulatory Compliance and Safety

Venky Iyer, Director, Data Strategy & Enablement, Pfizer Inc.

Sheraz Khan, PhD, Director, Operational AI & Data Sciences, Pfizer Inc.

The need for rigorous statistical evaluation of generative AI in clinical trials is paramount to ensuring regulatory compliance and patient safety. This talk explores an assessment of whether AI-generated contents are non-inferior to human-generated contents across key dimensions such as accuracy, clarity, consistency, and reasoning. The insights gained will shape future integration of generative AI in regulated environments, transforming how we approach clinical trials and drug development.

10:40 PANEL DISCUSSION: Ethical Consideration for AI Applications in Clinical Trials

Moderator: Dominic De Bellis, PhD, Executive Director, AI Strategy & Operations Lead; Global Clinical Trial Operations, Medical Writing & Disclosure, Merck & Co., Inc.

This panel will introduce the concept of AI ethics and its significance to the pharmaceutical industry. Industry experts will discuss the progression of AI in the pharmaceutical industry and its impact on various operations, as well as the ethical considerations in using AI for drug discovery. Considerations include biases in AI algorithms, patient privacy concerns, and quality control. Finally, panelists will provide key messages and actionable insights.

Panelists:

Sheraz Khan, PhD, Director, Operational AI & Data Sciences, Pfizer Inc.

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

Jonathan Shough, CIO, PAREXEL International

11:10 Networking Coffee Break

DIGITAL PROTOCOL: FROM DESIGN TO IMPLEMENTATION

11:50 Chairperson's Remarks

Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson

11:55 The Role of AI in Powering Digital Protocols

Yugang Jia, PhD, MPH, Director, AI & Data Science, Verily

Lauren Sutton, Head of Product, Clinical Trial Recruitment & Site CTMS, Verily

Protocols often live in documents, requiring sponsors to manually configure data across many systems, and leading to inaccuracies and extended timelines. Global standards groups are calling for protocols to be digitized, but how will sponsors adjust to new digital formats? In this talk, we'll share published research on the use of AI/LLM agents to digitize protocols and how this approach can drive more efficient research for sponsors and sites.

12:25 pm PANEL DISCUSSION: Transforming the Clinical Trial Protocol—Moving from a Document-Centric to a Data-Centric World

Moderator: Chris Decker, President & CEO, CDISC

For many years, the industry has been writing protocols in Word and manually transcribing protocol information to downstream systems, which is time-consuming and error-prone. Recently, the industry is moving towards a data-centric protocol, helping to reduce cycle times and improve data reliability. The panel will bring together TransCelerate, CDISC, HL7, and ICH M11 to discuss digital protocol initiatives protocol and the opportunities to transform the clinical trial lifecycle.

Panelists:

Amy Cramer, Founder and Director, Vulcan; Data Acquisition, eSource, Johnson & Johnson Innovative Medicine

Stacy Tegan, Program Director, TransCelerate Biopharma, Inc.

Mary Lynn Mercado, PhD, Global Head Protocol Delivery & US Site Head, Regulatory Writing & Submissions, Novartis Pharmaceuticals

Donald Jennings, Senior Advisor of Systems, Tech@Lilly Clinical Design and Operations, Eli Lilly and Company

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: The Perfect Pairing: How RWD Elevates Every Stage of Your Clinical Trial

Steve Lesser, Vice President of Growth for Clinical Trial Solutions, Optum Life Sciences

There's no substitute for real-world data to get to the most complete patient picture—before, during, and after a clinical trial. Understand your target population to inform evidence and diversity strategies, accelerate recruitment with EHR patient screening, and drive market success post-trial. Steve Lesser, Vice President, Clinical Trials, Optum Life Sciences, will discuss the ways real-world data acts as a key ingredient at the different stages of a clinical trial.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 4th Annual

Decentralized and Hybrid Trials

Enabling DCT Adoption for Trial Flexibility

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 14th Annual

DCTs and Clinical Innovation

Innovative and Hybrid Approaches to Clinical Trials

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

BUILDING THE FOUNDATION FOR DECENTRALIZED AND HYBRID TRIALS

11:00 Chairperson's Remarks

LaQuinta Jernigan, COO, Operations, mdgroup

11:05 Accelerating Drug Development through Clinical Trial Delivery Innovation

Kim O'Day, Senior Director, Emerging Technology Operations, Clinical Trial Foundations, Eli Lilly & Co.

Participants will identify key learnings from the use of innovative research methods used to execute clinical trials in Patient Engagement and Decreased Patient/Investigator Burden. Attendees will hear specific examples of where innovative strategies were successful and understand future applications for clinical trial innovation.

11:30 Statistical Considerations for Effective Decentralized Clinical Trials

Charmaine Demanuele, PhD, Executive Director, Head, Quantitative Sciences for Digital Sciences & Translational Imaging, Pfizer Inc.

Decentralized Clinical Trials offer a patient-centered approach to engage with participants in their homes or communities. DCTs provide patients with greater flexibility, reduce study visit frequency, lower costs, facilitate recruitment, and improve compliance. This presentation highlights key statistical considerations for designing and implementing DCTs, including selecting appropriate data types and DHTs for remote data collection, assessing data quality and completeness, determining relevant endpoints, estimating data heterogeneity, and handling missing data.

11:55 From Concept to Reality: Innovation and Use Cases in Trials with Decentralized Approaches

Isaac R. Rodriguez-Chavez, PhD, MHSc, MSc, CEO, 4Biosolutions Consulting (Sci/Clin/Reg Affairs) & Co-Chair, EEE-SA, Clinical Trial Technology Modernization Network (CTTMN)

Anna H. Yang, PharmD, Clinical Innovation & Technology Leader, Genentech, Inc.

This presentation provides key information and explores innovations in DCTs, highlighting their impact on revolutionizing medical product development globally. We'll examine technologies and trends supporting DCTs, including regional adaptations. Two trials will showcase real-world applications, logistical outcomes, challenges, and metrics impacting trial efficiency and data quality. Join us to discover how DCTs transform patient-centric clinical research and shape the future of healthcare innovation.

12:15 pm Novel DCT Approaches for Public Health Emergency Preparedness: BARDA's D-COHRe Program

Gina Conenello, PhD, Interdisciplinary Scientist, DRIVe & BARDA, US Department of Health & Human Services

BARDA within the ASPR at HHS has launched the Decentralized Clinical Operations for Healthcare and Research (D-COHRe) program. Strategic partnerships have been established with clinical research organizations that have access to healthcare sites to create an opportunity for clinical research where patients seek care and medical products are utilized in real world environments. D-COHRe will address the challenges in DCTs to create a sustainable business model beyond BARDA support.

12:35 Unsupervised Risk Detection in Decentralized Clinical Trials CluePoints

Laura Trotta, Vice President, Research, Research Operations & Statistical Innovation, CluePoints SA

Unsupervised Risk Detection in DCTs

1:05 Being Pragmatic About Pragmatic Trials Veeva

Drew Garty, CTO, Clinical Data Management, Veeva Systems

Gracy Crane, Senior Principal Scientist, Roche Products Ltd.

Chris Komelasky, CEO and Co-Founder, SiteBridge Research

The growing interest around Pragmatic Clinical Trials (PCTs) is about more than assessing interventions within routine clinical settings. It also reflects an appetite for greater pragmatism in our clinical technologies and processes. Hear from an executive panel of data management leaders discussing strategies for modernizing their clinical data infrastructures and the pragmatic enhancements they are pursuing around patient and site data strategies, rolling data locks, eCOA delivery, and more.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall AMR Metalographi

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

DCTs IN ONCOLOGY

3:20 Chairperson's Remarks

Melissa Nezos, Executive Vice President, Clinical Operations, Firma Clinical Research

3:25 Double Jeopardy! When Oncology DCTs Are Not the Answer, Are We Asking the Right Question?

Peter O'Neill, Vice President, Clinical Operations, TuHURA Biosciences

In the world of oncology clinical trials, decentralized clinical trials (DCTs) are often presented as the answer, but are we sure we're asking the right questions? This session will explore the limitations of DCTs in oncology and delve into how emerging innovations like digital twins may provide the missing answers that DCTs cannot. By rethinking our approach, can we finally align the right questions with the right tools?

3:55 Using Innovation and Hybrid Approaches in Oncology to Lessen Site and Patient Burden

Laurie Berry, PhD, Director, Strategic Solutions, Pfizer Inc.

Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.

How can you improve the quality of your tools/toolbox for oncology patients? What tools are most used for oncology studies/what makes sense for oncology studies? How can we prepare for the future? The way in which we engage with today's patients will not be the way in which we engage with tomorrow's patient; how can we set ourselves up for success for that transition?

4:25 Exploring eClinical Innovations: Enhancing the Patient Journey and Driving Clinical Trial Efficiency SUVODA

Andres Escallon, Vice President, eCOA Solutions Strategy, Suvoda

Explore practical technology innovations that ease the clinical trial patient journey and advance health outcomes.
Learn what drives successful technology uptake among sponsors, sites, and patients.
Discover how patient feedback shapes technology solutions for a smoother trial experience.
Explore AI-driven eClinical technologies to enhance trial efficiency and simplify patient interactions, from Consent to reimbursement.

4:55 PANEL DISCUSSION: Innovation and Hybrid Approaches for Oncology DCTs

Moderator: Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.

Panelists:

Peter O'Neill, Vice President, Clinical Operations, TuHURA Biosciences

Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.

Laurie Berry, PhD, Director, Strategic Solutions, Pfizer Inc.

5:25 Talk Title to be Announced umotif

Steve Rosenberg, CEO, uMotif

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn

Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

DCT ELEMENTS TO IMPROVE DIVERSITY

8:50 Chairperson's Remarks

Donna Mongiello, Senior Vice President, eCOA Strategy, Commercial, YPrime

8:55 Representation in Recruitment at Retail Pharmacy

Jim Carroll, Head, Real World Evidence & Clinical Trials, Walgreens

With the recent OIG report and latest FDA guidance on Diversity Action Plans, there is a heightened awareness around improving representation in clinical research. Walgreens will share recent case studies and success stories demonstrating the value of including a retail pharmacy-based approach in your recruitment plan.

9:15 PANEL DISCUSSION: Decentralized Clinical Trial Elements to Improve Participant Access and Representation

Moderator: Marjorie Zettler, PhD, MPH, Consultant, Clinical Sciences, Conjugate Group

The potential for decentralized or hybrid clinical trials to mitigate disparities has received much attention, but are DCTs/hybrid trial populations actually more representative than those of traditional site-based trials? With increased emphasis on diversity in registrational clinical trials, can the use of DCT elements serve as one strategy to effect change? This panel discussion will explore opportunities and challenges in deploying DCT solutions to promote more representative clinical trials.

Panelists:
Timil Patel, MD, Clinical Team Leader (Acting), Thoracic, Head & Neck Oncology, FDA
Aneta Woroniecka-Osio, MD, Decentralized Clinical Trial (DCT) Strategy Development Lead, Bayer
Brad Hightower, CEO, Hightower Clinical
Abigail Dirks, MS, Data Scientist, Center for the Study of Drug Development (CSDD), Tufts University

9:55 How Medable is Making the Design, Configuration and Launch of Studies Easier, More Efficient, and with Better Outcomes

Andrew Mackinnon, Senior Vice President & Executive General Manager, Customer Value, Medable, Inc.

Medable Studio is a fully featured SaaS suite of study design, configuration, translation and launch tools that enables easy and efficient study builds. In this presentation Medable, with a partner from a key customer, will talk about design best practice, how Studio has enabled faster study launch, and the adherence and satisfaction outcomes that have been observed in live studies.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

SITE AS THE KEY STAKEHOLDER IN DCTs

11:20 Chairperson's Remarks

Isaac R. Rodriguez-Chavez, PhD, MHSc, MSc, CEO, 4Biosolutions Consulting (Sci/Clin/Reg Affairs) & Co-Chair, EEE-SA, Clinical Trial Technology Modernization Network (CTTMN)

11:25 Decreasing Site Burden to Adopt DCT Methods

Joe Dustin, Founder & Managing Partner, eClinical Consulting
Sylvie Kruyner, Director, DCT Operations, Bayer Pharmaceuticals
Caroline Redeker, Chief Strategy Officer, Advanced Clinical

Please join us for a talk that will discuss ongoing efforts to address site needs and reduce barriers to Decentralized Clinical Trial methods (DCT) adoption. Topics may include "bring your own tech" strategies for sites, clarifying roles in DCT implementation at sites, and embedding site input on including DCT methods in trials.

11:50 The Triple Lens and Dual Roles of Decentralized Trials: Insights from Patients, Providers, and Researchers

Faith Holmes, CMO, Medical Affairs, Elligo Health Research

We will approach the efficiencies and agility of decentralized trial models from the perspective of the patient/study participant, the medical provider/principal investigator, and the CRO/sponsor. Using a central core team as a single point of contact for contracts, budgets, regulatory, and managing the participant journey throughout the study with fit-for-purpose technology and processes.

12:20 pm PANEL DISCUSSION: Decreasing Site Burden to Adopt DCT Methods

Moderator: Jane Myles, Co-Lead, Priority Initiative 3B, DCT Playbook, Decentralized Trials & Research Alliance (DTRA)

Please join us for a panel discussion focused on the ongoing efforts to address site needs and reduce barriers to Decentralized Clinical Trial methods (DCT) adoption. Expert panelists and the audience will discuss relevant perspectives on how partnering with sites can help to enable fit-for-purpose clinical trials for the patient, sponsor, site, and ecosystem stakeholders.

Panelists:
Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Sylvie Kruyner, Director, DCT Operations, Bayer Pharmaceuticals
Caroline Redeker, Chief Strategy Officer, Advanced Clinical
Joe Dustin, Founder & Managing Partner, eClinical Consulting

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

PLANNING AHEAD; INTEGRATING HEALTHCARE SETTINGS IN CLINICAL TRIALS

8:20 Chairperson's Remarks

Lamisa Parkar, GVP, Business Planning and Development, Oracle

8:25 Incorporation of Decentralized Clinical Trial Components in Early Clinical Trial Planning

Jessica Marer, Director, Global Clinical Operations, Trial Optimization and Planning, Teva Pharmaceutical Industries Ltd.

Attendees will be presented a key element in the incorporation of decentralized components: the planning. Attendees will hear how developing a 3-step strategy (explore, evaluate, and implement) may drive successful implementation of decentralized components into clinical trials.

8:45 PANEL DISCUSSION: Recognizing, Classifying, and Mitigating Patient and Site Burden Induced by Digital Health Technologies in Clinical Trials

Moderator: Krista Russell, Head Digital Health Solutions, Takeda Pharmaceuticals

Developing a strategy and implementation of modern Digital Health Technologies for collecting data in clinical trials presents vast opportunities for patients and discovery of data not previously available. However, new challenges are also introduced that present burden across the care continuum sponsor, clinical sites, and study participants. In this presentation, we pinpoint various root causes of DHT-induced burden and suggest strategies to ensuring an optimal experience for stakeholders involved.

Panelists:

Sophie Bartram, Fourth Year Undergraduate Student, Health Sciences Studies, Ohio State University

Andrea Paraboschi, PhD, Associate Director, Digital Solutions, Takeda

9:25 Simpler, Faster Trials Using Patient-Centric Solutions for Blood-Based Data Collection

Erwin Berthier, PhD, CTO, Tasso, Inc.

Clinical trial success hinges on well-coordinated data collection before, during, and after the trial occurs. Technologies that enable data collection at home can improve patient engagement and data density. In this presentation, we expand on learnings from the implementation of leading remote, patient centric blood testing solutions in clinical trials. We provide insight on key features and strategies that drive patient engagement, operational success, and high-quality data collection.

9:40 Transforming Recruitment: Harnessing Community Research Sites to Engage Rare CKD Populations

Jack Evans, Vice President, Site Operations, EmVenio Research

This presentation will explore the use of community-based research sites to recruit rare participants for Chronic Kidney Disease (CKD) studies, with a focus on those with the APOL-1 genotype. We will delve into the strategic selection of site locations and the critical role of community engagement in fostering trust and participation. By leveraging diverse site placements, we will demonstrate how we have effectively connected with underrepresented populations, expanding access to clinical trials and enhancing recruitment for precision medicine.

10:10 PANEL DISCUSSION: Access for All: How HCPs Are the Key to Changing Clinical Trial Participation

Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

This panel will explore engaging healthcare professionals (HCPs) in clinical research, featuring HCPs and representatives from community care organizations (CCOs). Discussion will focus on HCPs' interest in participating, the roles they might perform, and the barriers to their involvement. Panelists will share insights on strategies to facilitate HCP participation in research, aiming to enhance collaboration and improve clinical trial recruitment and diversity.

Panelists:

Shelly Barnes, Global Clinical Innovations and Digital Lead, UCB

Joe O'Rourke, Head, Commercial Development, RWE Clinical Trials, Walgreens

Hassan Kadhim, Head of Clinical Operations and Development Business Capabilities, Vertex Pharmaceuticals

10:40 Decentralized Clinical Trials from the World-Saving Idea to the Inevitable Reality

Istvan Attila Kerekes, PharmD, Senior Clinical Project Manager, Global Medical Division, Global Clinical Operations, Gedeon Richter Plc

This presentation will give an overview and describe the planned and unexpected obstacles experienced during a Phase 2 exploratory clinical study that implemented a hybrid study design, including telehealth visits, home visits, and electronic patient outcome measurements. The presentation would detail the reason for implementing such hybrid approach and show solutions for risk mitigation and actions taken to resolve arising issues during the study.

11:10 Networking Coffee Break

ADVANCING DIGITAL HEALTH AND CLINICAL TRIALS CONVERGENCE

11:50 Chairperson's Remarks

Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

11:55 Applying Social Determinants of Health (SDoH) in Clinical Planning and Site Strategy

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

SDoH data can enhance our understanding of the barriers to participation in clinical trials and improve access for study participants. This presentation examines various types of SDoH data for site and patient strategies, and discusses how to effectively leverage these insights in clinical studies.

12:25 pm PANEL DISCUSSION: Achieving Flexibility and Expanding Access While Preserving Data Quality

Moderator: Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

Is trial flexibility a threat to data quality? Concerns are often raised that offering flexible approaches to trial design and conduct, such as collecting data in various settings and offering a flexible schedule of visits, will result in risks to data quality. This session will explore multi-partner perceptions around when and how data quality is maintained when flexible approaches are introduced and how flexibility can improve access to clinical trials.

Panelists:

Pamela Tenaerts, MD, MBA, CSO, Medable

Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Wes Burian, Patient

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: From Sync to Swim: Alimentiv's Journey with Zelta ePRO

Wes Fishburne, Principal Product Manager, Zelta by Merative

Chris Walker, Director, Data Sciences, Alimentiv

Amid growing responsibilities and expanding clinical operations, data managers are increasingly challenged by the increasing number of eClinical solutions required to support a clinical trial. Join us to learn how the data managers at Alimentiv have leveraged Zelta's ePRO module to streamline their eClinical data collection scheme to include patient-reported outcomes with the rest of their study data, achieving more control over their clinical trials and confidence in their outcomes.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 8th Annual

Digital Biomarkers and End Points in Clinical Trials

Digital Measurements and End Points in Clinical Trials

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 14th Annual

Digital Measurements Implementation at Scale

Collaboration to Harness Digital Biomarkers and End Points

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

HARNESSING DIGITAL BIOMARKERS

11:00 Chairperson's Remarks

Brett Kleger, CEO, Inspire

11:05 Harnessing Digital Biomarkers and Data Science: Paving the Way for Accelerated Drug Development in Parkinson's Disease

Marissa Dockendorf, Executive Director, Head of Digital Clinical Measures, Merck & Co., Inc.

Jie Ren, PhD, Director, Data Science, Global Digital Analytics & Technologies, Merck & Co., Inc.

Digital biomarkers have the potential to track Parkinson's Disease (PD) progression with increased objectivity, sensitivity, and reduced variability compared to standard clinical scales. We discuss considerations in the development of PD progression digital biomarkers and present a machine learning-based framework for developing composite digital measures. We apply this framework to longitudinal PD study data and demonstrate the potential for digital biomarkers to enable smaller PoC trials and accelerated drug development.

11:35 Variability in Human Signal Device Readings: An Analysis of Contributing Factors and Experimental Design

Sherrine M. Eid, Global Head, Real World Evidence & Epidemiology, SAS Institute, Inc.

Karthik Nakkeeran, Senior Data Scientist, Lingo, Abbott Labs

This study explores variability in human signal device readings due to factors such as sensor placement, tissue composition differences, calibration errors, and external interferences. By fitting subjects with devices from different manufacturers and collecting data over 14 days, the research analyzes significant differences in readings using parametric and non-parametric tests. The findings, illustrated with simulated data, highlight broader applicability of these methods in synthetic data-generation and drug-simulation studies.

11:55 PANEL DISCUSSION: eCOA BYOD: Exploring the Pros and Cons

Moderator: Melissa Sesi, MBA, Associate Director, R&D Sourcing & Procurement, Merck & Co., Inc.

Electronic Clinical Outcome Assessments (eCOA) bring significant advancements in clinical trials, and the Bring Your Own Device (BYOD) approach has gained traction in the industry. It is crucial to understand the potential benefits and challenges associated with eCOA BYOD to have a comprehensive understanding of its implications in clinical research.

Panelists:

Valerie Balosso, Director, Data Management, Infectious Diseases, GSK

Lynne Cesario, Executive Director, Global Lead Risk Based Monitoring Program, Pfizer Global R&D Groton Labs

Dan Kearney, CEO, CNS Healthcare

Pankaj Shukla, Senior Director, Strategic Accounts, Clario

12:35 pm An Overview of Pi Health

Bobby Reddy, Co-Founder & COO, Pi Health

Pi Health is a health technology and clinical research organization that is committed to transforming global access to innovative medicines and clinical trials starting with Oncology.
Pi Health has a unique software platform that connects sites and sponsors around the world enabling breakthrough efficiencies and cost savings for clinical trials.
Pi Health's mission is to drive innovation and enable access to patients around the globe equalizing access and opportunities for the highest quality of care and research.

12:50 The Missing Link: How Smart Design Unlocks Real-World Healthcare Data

Tom Rhoads, CEO, Spencer Health Solutions LLC

Join us for "Collecting Longitudinal Patient Survey Data Via an In-Home Smart Medication Dispenser: Analysis of Panel Persistency, Response Rates, and Psychometric Properties." This session will showcase how intuitive smart medication dispensers improve patient adherence and engagement, facilitating the collection of reliable, real-world healthcare data.

We'll explore how these innovations drive higher response rates, improve panel persistency, and ensure quality data, ultimately supporting better healthcare outcomes and empowering payers and providers with actionable insights.

1:05 Presentation to be Announced

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

DIGITAL BIOMARKERS IN ONCOLOGY STUDIES

3:20 Chairperson's Remarks

Jeremy Wyatt, CEO, ActiGraph

3:25 Digital Health Technology (DHT)-Derived Physical Activity and Performance in Cancer Cachexia

Carrie A. Northcott, PhD, Head of Digital Sciences, Biomeasures, Endpoints and Study Technologies (BEST), Pfizer

Cachexia is prevalent across cancer types and results in weight loss, muscle wasting, reduced physical activity (PA), and increased mortality. DHTs provide passive, unbiased, patient-focused, and quantitative measures of continuous PA/function. We will share evidence on the importance of PA to patients, and what a meaningful change is in cancer patients with cachexia. Moreover, we will discuss the use of the DHT-derived PA measures to assess function and support clinical trials.

3:55 LLS Sponsored Use of a Medical-Grade Wearable into the Beat AML Master Trial—The Oncology Journey

Len Rosenberg, PhD, RPh, Head, Clinical Operations, Beat AML/LLS

LLS/BAML initiated a sub-study to evaluate shortening the backbone treatment cycle from 28 to 14 days in a randomized Phase 2 trial for newly diagnosed AML patients. The study also incorporates an FDA-cleared wearable medical device complemented by PRO assessments and fatigue questionnaires. The study aims to provide insights into whether objective data from wearables aligns with PROs in oncology.

BUSINESS CONSIDERATIONS FOR DIGITAL BIOMARKER IMPLEMENTATION

4:25 Digital Health Solutions & Digital Accessibility

Stephen Framil, Corporate Global Head Accessibility, Office of Corporate Accessibility, Merck & Co., Inc.

With the increase in demand for personalized patient therapies through digital health-solution apps, digital accessibility design standards for patients with disabilities can be critical to drug dosage, adherence, verification, and information. With the Web Content Accessibility Guidelines (WCAG) design standards for Information & Communication Technologies (ICT)—inclusive of digital health solutions and software as a medical device—explore the why, the what, and the how for digital accessibility.

4:50 PANEL DISCUSSION: Building the Business Case for Adopting Digital Endpoints in Clinical Trials

Moderator: Rachel Chasse, Associate Director, Digital Science Strategy, AbbVie

While use of digital endpoints has grown immensely in recent years, widespread adoption remains a challenge. The Digital Medicine Society (DiMe) has established a pre-competitive project team to include decision-makers to address this long-standing challenge. This session will discuss the framework and resources developed by the project team to help those developing a compelling case to continued investment in digital strategies aligning with business goals and industry standards.

Panelists:

Stephen Ruhmel, Director, Clinical Strategy Lead for Digital Endpoints, Sanofi

Sarah Valentine, Partnerships Lead, Life Sciences, Digital Medicine Society (DiMe)

Elisabeth Piault-Louis, Scientific Lead, Digital Science, Evinova

Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron

5:25 Practical Innovations with AI and Automation

Sanjiv Waghmare, Chief Product Officer, Signant Health

The clinical research landscape is evolving rapidly, driven by demands for faster, more efficient trials. This presentation explores how automation and AI are transforming the clinical technology stack, and ultimately transforming clinical trial operations through enhanced efficiency without sacrificing data quality. Join us to discover how these technologies are shaping the future of clinical research and accelerating treatment development.

5:40 The Wearable Revolution: Meet the Smart Ring, Unlocking Objective Data

Christer Nilsson, CEO, Replior

Discover how wearable sensor technology is revolutionizing data collection in clinical trials. Join Christer Nilsson, CEO of Replior, as he introduces the Scratch Ring—an innovative finger-worn device designed to capture continuous, objective,

and actionable patient data. Learn how this cutting-edge platform reduces patient burden, enhances compliance, and delivers deeper insights into scratching behavior, sleep, and overall health metrics. Explore the future of patient-centric, real-time analytics and its transformative impact on trial outcomes.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

CASE STUDIES

8:50 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:55 Analytical Validity and Clinical Evaluation of the Moticon Insole System for Assessing Gait in Parkinson's Disease

Rolando J. Acosta Nuñez, PhD, Manager, Biostatistician, Regeneron Pharmaceuticals
Shawn Mishra, PhD, Senior Lead, Digital Biomarkers, Regeneron Pharmaceuticals

This study explores the clinical potential of digital insoles for continuous, real-world gait assessment in Parkinson's Disease (PD) patients. We evaluated 21 PD patients using digital insoles and a reference system during ON and OFF levodopa states. Results showed excellent reliability for gait parameters and sensitivity to medication. The technology offers more frequent, objective assessments in clinical and home environments to improve personalized care, enhance disease monitoring, and optimize treatment.

9:25 Internal Development to Phase 1 Clinical Validation of Bend Ease, a Novel Digital Measure of Morning Stiffness in Axial Spondyloarthritis

Dee-Dee Shiller, DO, Medical Director, AbbVie, Inc.
Dan Webster, PhD, Director, Digital Sciences, AbbVie, Inc.

Morning joint stiffness presents a problem for clinical measurement: By the time a patient presents in a rheumatology clinic for assessment, morning stiffness has subsided and mobility appears more "normal." To address this measurement problem, our cross-functional team initiated Project Bend Ease, involving internal development and Phase 1 clinical validation of a smartphone app for self-measurement of spinal mobility at home in axial spondyloarthritis patients.

9:55 Ready, Set, Localize: Smarter Strategies for Global Trials

Jonathan Norman, Director Localisation Services, Linguistic Validation & eCOA SME, YPrime

In an industry striving to innovate with AI and other new technologies, achieving operational efficiencies are a pressing need for clinical trial leaders. This session explores practical strategies to accelerate globalization of clinical trials and expand patient diversity through proven tools and methodologies.
Key Takeaways:
• Global Trial Efficiencies: How leveraging pre-built libraries and modernized localization processes can cut startup timelines while maintaining quality and compliance.

• Diversity through Language: The role of comprehensive language and cultural adaptation in reaching underrepresented populations and improving trial outcomes.

• Simplifying AI: AI-driven efficiencies in clinical trial localization that are possible today without the controversy surrounding the creation of target language content.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

CASE STUDIES (CONT.)

11:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:25 Accelerating Innovation in Sleep Measurement through Sibel's Integrated Digital Health Platform

Jie Shen, PhD, Research Fellow, Digital Science, AbbVie, Inc.
Shuai Steve Xu, Assistant Professor of Dermatology & Medical Director, Querrey Simpson Institute for Bioelectronics, Northwestern Memorial Hospital

Reliable and user-friendly sleep measurement is critical for assessing patients' quality-of-life in various clinical indications. While polysomnography (PSG) provides detailed data, it is impractical for many clinical trials. Wrist-based actigraphy, though convenient, often lacks accuracy. This presentation explores the collaboration between AbbVie and Sibel Health to develop and validate adhesive sensor technology, offering PSG-level accuracy and advancing sleep measurement in clinical development and patient care.

11:55 Validating a DHT for Late-Stage Clinical Trials

David Morra, Senior Director, Regulatory Digital Health, Merck & Co., Inc.

Discover the intricacies of validating a late-stage clinical trial's primary endpoint in this captivating talk. This talk will showcase a real-world use case, exploring the FDA feedback that led to a Complete Response Letter, and share their experience

in negotiating with global pharmaceutical and medical device health authorities to develop and execute a successful validation plan.

12:25 pm From Data to Discovery: AI-Powered Trials in the Digital Health Era

Noble Shore, Vice President Technology Strategy & Product Adoption, Customer Success, Emmes

Explore how AI and real-world data (RWD) are transforming clinical trials. Learn how sponsors can accelerate startup with tools like Generative AI for protocol authoring and leverage RWD to ease site burdens and unify trial data. See how AI-enabled data platforms streamline processes, improve data quality, and provide real-time insights. Discover a roadmap to modernize trials, reduce timelines, and deliver results faster in the digital health era.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

PARTNERSHIPS AND PATIENT-FRIENDLY APPROACHES

8:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:25 The Future of Regulatory Acceptance of Digital Measures Is Happening Now

Martha Azer, PharmD, Associate Director, Regulatory Policy NA, Johnson & Johnson

Digital measures can enhance drug development by potentially unlocking new ways of measuring efficacy and safety for medicinal products. The regulatory pathways for digital measures in R&D are emerging along with regulatory guidance on evidence generation of digital endpoints. To ensure the successful use of digital measures in R&D, these need to be further shaped to accelerate

implementation of digital measures in R&D in drug development and health authority acceptance.

8:50 PANEL DISCUSSION: Driving DHT Adoption and Utility through Advocacy and Multi-Organizational Collaboration

Moderator: Kai Langel, CEO, DEEP Measures

Digitally derived measures of health can help unlock a whole new perspective into human health, but developing them is a complex effort needing involvement from multiple stakeholders. This session brings together the entire journey and illustrates the key pitfalls and solutions through real-world examples shared by leaders from key pharmaceutical and technology companies.

Panelists:

Martha Azer, PharmD, Associate Director, Regulatory Policy NA, Johnson & Johnson

Scottie Kern, Executive Director, eCOA Consortium, Critical Path Institute

Carrie A. Northcott, PhD, Head of Digital Sciences, Biomeasures, Endpoints and Study Technologies (BEST), Pfizer

Bola Grace, PhD, MBA, Senior Director, Digital Biomarkers, GSK; Professor, University College London

9:25 Unifying Multi-Vendor Wearables/Sensors Data Collection for Clinical Trial Regulatory Compliance

Steve Polyak, SVP, Head of Global Production Innovation, Engineering, Clinical Ink

The adoption of wearables/sensors in clinical trials remains low despite the relatively recent predictions of their success. Why is that? What are the challenges e.g. regulatory hurdles, usability, security, etc. we are facing and what benefits do we perceive we might have if we can overcome these aspects? Adding to that is the fact that several trials may need to integrate across multiple vendor solutions that can have different wearables/sensor integration patterns and needs. How can clinical trial technology companies leverage their partnership agreements to act as a DHT integration hub saving the need for pharmaceutical companies to explore/establish their own point-to-point integrations.

9:55 Generative AI-Powered Medical Writing

Sharon Chen, Founder and CEO, AlphaLife Sciences

Generative AI is projected to bring $60–$110 billion in annual value to the pharmaceutical industry by driving efficiency, innovation, and competitive advantage. In clinical development, GenAI optimizes workflows, reduces costs, and accelerates timelines. AlphaLife Sciences' AuroraPrime platform harnesses this potential, providing end-to-end automation in medical writing to improve quality, compliance, and efficiency in creating essential regulatory documents.

10:10 PANEL DISCUSSION: Unlocking New Frontiers in Alzheimer's Disease Research through Digital Measures

Moderator: Sarah Valentine, Partnerships Lead, Life Sciences, Digital Medicine Society (DiMe)

Imagine a world where the progression of Alzheimer's disease and related dementias (ADRD) could be detected earlier, monitored more precisely, and treated more effectively—all through the power of digital health technologies. We will share exciting findings from a DiMe collaboration across academia, industry, clinic, and patient advocacy groups engaging in ADRD research to harness digital innovation to accelerate scientific progress and improve outcomes for patients and caregivers.

Panelists:

Ann M. Hake, MD, Executive Director, Digital Health Research and Development, Eli Lilly & Co.

Jeffrey A. Kaye, MD, Director, ORCATECH (Oregon Center for Aging & Technology), Oregon Health & Science University

10:40 Magnol.AI—Engineering Large Wearable Sensor Data towards Digital Measures

Andrew D. Kaczorek, Data Engineer, Eli Lilly & Co.

While many industry players promote the ability to ingest wearable sensor data, what matters more than that is how to uncover data insights and turn these data into intelligence. Come hear about one of the industry's best examples of what a sensor cloud should (and can) do to ensure dBM research is done efficiently and rigorously.

11:10 Networking Coffee Break

ADVANCING DIGITAL HEALTH AND CLINICAL TRIALS CONVERGENCE

11:50 Chairperson's Remarks

Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

11:55 Applying Social Determinants of Health (SDoH) in Clinical Planning and Site Strategy

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

SDoH data can enhance our understanding of the barriers to participation in clinical trials and improve access for study participants. This presentation examines various types of SDoH data for site and patient strategies, and discusses how to effectively leverage these insights in clinical studies.

12:25 pm PANEL DISCUSSION: Achieving Flexibility and Expanding Access While Preserving Data Quality

Moderator: Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

Is trial flexibility a threat to data quality? Concerns are often raised that offering flexible approaches to trial design and conduct, such as collecting data in various settings and offering a flexible schedule of visits, will result in risks to data quality. This session will explore multi-partner perceptions around when and how data quality is maintained when flexible approaches are introduced and how flexibility can improve access to clinical trials.

Panelists:

Pamela Tenaerts, MD, MBA, CSO, Medable

Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Wes Burian, Patient

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: From Sync to Swim: Alimentiv's Journey with Zelta ePRO

Wes Fishburne, Principal Product Manager, Zelta by Merative

Chris Walker, Director, Data Sciences, Alimentiv

Amid growing responsibilities and expanding clinical operations, data managers are increasingly challenged by the increasing number of eClinical solutions required to support a clinical trial. Join us to learn how the data managers at Alimentiv have leveraged Zelta's ePRO module to streamline their eClinical data collection scheme to include patient-reported outcomes with the rest of their study data, achieving more control over their clinical trials and confidence in their outcomes.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 14th Annual

Accessing and Generating RWD

Harnessing RWD to Drive Clinical Trial Efficiency

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 10th Annual

Leveraging RWD for Clinical Research

Real World Data for Next-Generation Studies

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

UNITING STAKEHOLDERS AND INTEGRATING EVIDENCE

11:00 Chairperson's Remarks

Speaker to be Announced, Zifo Technologies

11:05 PANEL DISCUSSION: Regulatory Initiatives to Enable Pragmatic Trials

Moderator: Gracy Crane, PhD, International Regulatory Policy Lead for RWD, Roche Products Ltd.

This panel will delve into regulatory initiatives that have been launched in pragmatic trials, including demonstration projects announced by the new CDER center C3TI, the crowdsourcing effort by FDA, and recent efforts within the EU, including the position paper by EFPIA on pragmatic trials and the recent ACT-EU meeting. The panel will also discuss how to reduce hurdles that drug developers may encounter while designing pragmatic trials.

Panelists:

Melodi McNeil, Director, Regulatory Policy & Intelligence, AbbVie, Inc.

Meghana Chalasani, Associate Director for Clinical Trial Innovation, Office of New Drugs, FDA CDER

Henry Wei, MD, Executive Director, Development Innovation, Regeneron

11:50 PANEL DISCUSSION: Data, Data Everywhere, and Not a Byte to Use

Moderator: Robert DiCicco, Vice President, Portfolio Management, TransCelerate BioPharma, Inc.

The 21st Century Cures Act created opportunities to leverage electronic health data to improve clinical outcomes and support regulatory decision-making. But in the pharma R&D environment, there has been limited ability to unlock the potential of that data in a scalable way. The good news? Recent advances in technology, along with cross-sector collaborations, present renewed opportunity to take another leap forward in accelerating clinical research.

Panelists:

Su Chen, MD, Clinical Science Principal, MITRE; Steering Committee Chair, CodeX HL7 FHIR Accelerator

Jesper Kjaer, Global Director Public & Private Partnerships, Strategic Operations Global Medical Affairs, Novo Nordisk; Co-Chair, Vulcan Advisory Committee

Trevan Locke, PhD, Assistant Research Director, Duke-Margolis Institute for Health Policy

Chris Decker, President & CEO, CDISC

12:35 pm Uncovering Causal Relationships from Real-World Data (RWD) for Better Patient Outcomes: Use Case Presentation

Kavita Lamror, Partner, RWE & Digital Transformation, Maxis Clinical Sciences

Geriatric patients with non-small cell lung cancer (NSCLC) and late-stage diabetes mellitus complications represent a highly complex and vulnerable population. Co-morbidities, co-medications, age-specific frailty, and the interplay between cancer progression and diabetic complications make optimizing treatment outcomes very challenging. Chemotherapy exacerbates these complications, increasing risks of adverse events, and impacting quality of life. Causal graphs, rooted in graph theory and causal inference principles, provide a framework to address these complexities by uncovering causal relationships in real-world data (RWD), enabling personalized treatment strategies. This framework allowed MaxisIT to disentangle the intricate interplay between NSCLC, diabetes complications, and chemotherapy outcomes, accounting for confounding factors like age, comorbidities, and baseline health status, to personalize treatment for better patient outcomes and clinical decision-making.

1:05 Operationalize Post-Trial Access: Opportunities for Longitudinal Data Collection and Registry Creation

Becky Thompson, Senior Director, Solutions Consulting – Real World Research, Real World Evidence & Market Access Solutions, Parexel

Traditional approaches to post-trial access often lead to inefficiencies and missed opportunities for data collection. In this session, we explore how to develop a post-trial access platform that not only ensures continued patient access to treatment but also facilitates long-term data collection and potential registry creation. We'll examine the benefits for patients, sites, and sponsors, and explore how this model can be leveraged for real-world evidence generation and long-term safety monitoring, using practical examples and insights from lessons learned.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

GLOBALIZATION, INNOVATION, DATA INTEGRATION

3:20 Chairperson's Remarks

Adam Gottesman, Principal, Clinical Research Partnerships, Flatiron Health

3:25 Patients, Connection, Clinical Trials

Sara Pierson, Senior Director, Participant Ecosystem Group Lead, Pfizer Inc.

Melinda M Rottas, Head of Optimization, Analytics & Recruitment Solutions, Clinical Development & Operations, Pfizer Inc.

The selfless act of volunteering for a clinical trial enables the delivery of medical breakthroughs. At Pfizer, we believe that the participant experience, and the ability for a person to remain connected to research over time, is a critical component of their journey. Learn more about Pfizer's seamless experience from initial information seeking through study closure and beyond.

3:45 Multi-Stakeholder Real-World Evidence (RWE) Partnerships and Collaborations: International Experiences and Examples

Kelly H. Zou, PhD, Head, Global Medical Analytics and Real-World Evidence, Viatris; Founder, AI4Purpose

Learning objectives for this talk are: 1) showcasing multi-stakeholder partnerships and collaborations to harness real-world data (RWD) and evidence (RWE), 2) illustrating both successes and barriers for such efforts across geographical regions/countries and business functions, and 3) sharing some best practices in health innovations during this era of big data, digital health, and artificial intelligence (AI).

4:05 EHR to EDC: Shared Astellas Experience

Thanh Tran, Director, Immuno-Oncology Primary Focus Lead, Data Management, Astellas

Electronic Health Records (EHR) to Electronic Data Capture (EDC): Astellas Data Management is happy to share their learned experiences collaborating with a middleware vendor and clinical site. This presentation will provide Astellas's purpose, start-up, conduct, and lessons learned with actual real-world outputs.

4:25 Integrated Evidence Teams—Top or Flop?

Dorothee B. Bartels, PhD, Associate Professor (Apl. Professor) for Public Health and Epidemiology, Medizinische Hochschule Hannover; Founder, HealthData-Advisors, Board BBraun US

Xin Ma, Senior Vice President, Head, Integrated Evidence Generation & Business Innovation, MA&PV, Bayer

Integrating evidence in clinical and observational research is a growing challenge, given the variety of sources and data requirements. This talk will offer case studies and solutions on how to integrate evidence from various sources.

4:55 PANEL DISCUSSION: Real-Time Point-of-Care Patient Identification

Moderator: John D. Chelico, MD, System Vice President & Chief Medical Information Officer, CommonSpirit Health

This panel will explore innovative approaches to identifying patients at the point-of-care using real-time data. Experts will discuss the integration of healthcare systems, data analytics, and technology to improve patient identification, ensuring timely access to clinical trials and personalized treatment options. Attendees will gain insights into overcoming challenges in implementing these solutions

Panelists:

Trejeeve Martyn, MD, Cardiologist, Advanced Heart Failure and Transplant, Director, Heart Failure Population Health, Cleveland Clinic

Eirini Schlosser, Founder & CEO, Dyania Health

5:25 Talk Title to be Announced

Craig Serra, Head of Clinical Research , Scientific and Technical Engagement, Flatiron Health, Inc.

Henry Wei, MD, Head of Development Innovation at Regeneron

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

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi

Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.

Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

TOKENIZATION UPDATE

8:50 Chairperson's Remarks

Speaker to be Announced, HealthVerity Inc

8:55 How to Tokenize a Clinical Trial to Facilitate Follow-Up with RWD

Simon Dagenais, RWE Lead, Internal Medicine, Pfizer Inc.

This presentation will explore how tokenization can be applied to clinical trials to streamline patient follow-up using real-world data (RWD). By linking trial data with external healthcare sources while preserving privacy, tokenization enables long-term tracking of outcomes and more comprehensive insights. Practical case studies and strategies for implementation will highlight the benefits and challenges of this approach.

9:25 Challenges and Key Considerations while Conducting a Trial Tokenization Study across the US, EU, and UK

Emily Zacherle, Senior Director, Healthcare Data Strategy, Novo Nordisk, Inc.

This presentation will examine the challenges and key considerations of conducting a trial tokenization study across the US, EU, and UK. It will explore varying regulatory frameworks, data privacy concerns, and cross-border data-sharing complexities. Attendees will gain insights into strategies for navigating these obstacles, ensuring compliance, and successfully implementing tokenization in diverse healthcare environments.

9:40 Complexities and Solutions Used to Conduct a Global RWE Program in COVID-19 and Immunocompromised Indications

Sylvia M. Taylor, PhD, Executive Director, Head, Medical & Payer Evidence, Vaccines & Immune Therapies, AstraZeneca

Conducting a global real-world evidence (RWE) program in COVID-19 and immunocompromised populations presents unique challenges, including data collection across diverse healthcare systems, varying regulatory requirements, and patient variability. This presentation will explore the complexities encountered in these global studies and highlight innovative solutions used to overcome these barriers, ensuring robust data integration and meaningful outcomes in real-time clinical settings.

9:55 Rich Clinico-Molecular Real-World Data is Transforming and Accelerating Cancer Clinical Research

Mike Rossi, VP, Translational & MM RWE Solutions, RWE, ConcertAI

Clinical trial and randomized clinical trials remain the accepted gold standard of clinical research. In oncology research it is today possible to extract clinical and clinic-genomic co-variates from real-world patient records and preserve patient anonymity. The process is proving to tangibly and quantitatively increase confidence in matching of the right patient to the right targeted therapeutic agents as part of clinical trial design. We will be providing distinctive evidence through cases studies of analyzing human derived Medical Records linked with NGS panels bearing both DNA and RNA sequencing data and Whole Slide Imaging to de-risk clinical development, accelerating pathways to high medical unmet need patient populations

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials

Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*

Location: Gatlin Foyer, ClinEco Booth #1

ACTIONABLE SOLUTIONS: GLOBALIZATION, AI, AND MORE

11:20 Chairperson's Remarks

Ryan Ahern, CMO & Co-Founder, Truveta

11:25 PANEL DISCUSSION: Conducting Effective Global RWD Studies

Moderator: Aaron W. Kamauu, MD, MS, MPH, CEO, Navidence LLC

This panel will explore the challenges and best practices in conducting global real-world data (RWD) studies. Experts will discuss strategies for managing diverse regulatory landscapes, integrating data across multiple sources and regions, ensuring data quality, and addressing patient variability. Attendees will gain insights into overcoming obstacles and maximizing the value of RWD in a global context.

Panelists:

Sylvia M. Taylor, PhD, Executive Director, Head, Medical & Payer Evidence, Vaccines & Immune Therapies, AstraZeneca

Emily Zacherle, Senior Director, Healthcare Data Strategy, Novo Nordisk, Inc.

11:55 PANEL DISCUSSION: Advancements in the Use of GenAI in Real-World Research

Moderator: John Cai, MD, PhD, Executive Director, Real-World Data Analytics and Innovation, Merck

This panel will highlight the latest advancements in applying generative AI to real-world research. Industry leaders will discuss how GenAI is transforming data analysis, improving patient insights, and driving efficiencies in healthcare research. The session will cover key developments, ethical considerations, and future potential of AI technologies in real-world evidence generation.

Panelists:

Thomas Dougherty, Lead, Data Science & AI Innovative Partnership, Novo Nordisk

Hua Xu, PhD, Robert T. McCluskey Professor and Vice Chair for Research and Development, Department of Biomedical Informatics and Data Science; Assistant Dean for Biomedical Informatics, Yale School of Medicine

12:25 pm Generating Evidence with Relevance, Reliability, and Traceability

Speaker to be Announced, Evernorth Health Inc

Ria Westergaard, Director, Product Strategy, Clinical Trial Solutions, Evernorth Health Services

An all-time high amount of data is being captured and analyzed, 90% of pharmaceutical companies have real-world evidence teams, yet "data quality" is the challenge most frequently cited in literature. Join Ria Westergaard, Director of Product Strategy for Evernorth Clinical Trial Solutions, as she leads an interactive panel discussion to review use cases that demonstrate ways to overcome challenges and implement best practices.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

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THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

RWD TO TRANSFORM CLINICAL TRIALS

8:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:25 Challenges and Recent Developments in RWD—Augmented Study-Control Arms

Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.

In trials where the control arm is limited, it is essential to augment, borrowing information from external data sources. Guidelines have been issued to inform such study designs; effective implementation requires minimizing bias associated with lack of homogeneity among participants. Available techniques often fail to meet regulatory requirements. We will review recent developments and alternative approaches to achieve homogeneity and reduce bias.

8:55 Historical Placebo Controls to Characterize Event Rates in Ongoing RCTs

Chris Schneiderman, MPH, Director, Global Epidemiology, AbbVie, Inc.

The 'Adverse Events in Placebo Controls of AbbVie Clinical Trials' (AEPACT) database leverages placebo control or standard-of-care arms from historical RCTs to estimate background AE rates and provide evidence in decision-making. By utilizing MedDRA SMQs, estimates of SAEs can be generated, offering a range of expected emerging AEs in these trials. This approach allows for unique insights into the background event rates of AEs in ongoing trials.

9:25 Data Won't Solve It, But It Does Help...

Karina D'Angelo, Scientific Director, Real World Data Strategy, Parexel International

Diane Faraone, Senior Director, Pharmacy Analytics, Clinical, PurpleLab

Neurological diseases, such as Alzheimer's, have some of the most underrepresented clinical trials – but that's about to change. With a lens into recent reimbursement policy and legislation changes, we discuss how SDoH-enriched RWD is supporting the industry's due diligence to design more representative and accessible clinical trials, as well as real world studies. Data won't solve it, but it does help guide our efforts to improve patient access and outcomes.

9:55 Presentation to be Announced

10:10 Utilizing Pharmacy Data in Observational Pharmacoepidemiology Studies

Scott Chavers, PhD, Senior Director, Epidemiology, Real-World Evidence Clinical Trials, Walgreens Co.

Pharmacy data has been a relatively untapped resource to the RWE industry. This talk will overview how to use pharmacy data for post-marketing RWE research and the overall impact on the product lifecycle. By learning which insights are available and how they can be used, sponsors may uncover new uses for this important data.

10:40 Gathering RWE on Life-Saving Devices: A 5-Year Review

Barbara Fink, Associate Director, Clinical Affairs, Emergency Care, Philips

Public access defibrillation programs continue to be one of the most important factors when a patient has a sudden cardiac arrest. But how do you gather and analyze RWE on this type of device? We will share what we have learned over a 5-year period.

11:10 Networking Coffee Break

DIGITAL PROTOCOL: FROM DESIGN TO IMPLEMENTATION

11:50 Chairperson's Remarks

Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson

11:55 The Role of AI in Powering Digital Protocols

Yugang Jia, PhD, MPH, Director, AI & Data Science, Verily

Lauren Sutton, Head of Product, Clinical Trial Recruitment & Site CTMS, Verily

Protocols often live in documents, requiring sponsors to manually configure data across many systems, and leading to inaccuracies and extended timelines. Global standards groups are calling for protocols to be digitized, but how will sponsors adjust to new digital formats? In this talk, we'll share published research on the use of AI/LLM agents to digitize protocols and how this approach can drive more efficient research for sponsors and sites.

12:25 pm PANEL DISCUSSION: Transforming the Clinical Trial Protocol—Moving from a Document-Centric to a Data-Centric World

Moderator: Chris Decker, President & CEO, CDISC

For many years, the industry has been writing protocols in Word and manually transcribing protocol information to downstream systems, which is time-consuming and error-prone. Recently, the industry is moving towards a data-centric protocol, helping to reduce cycle times and improve data reliability. The panel will bring together TransCelerate, CDISC, HL7, and ICH M11 to discuss digital protocol initiatives protocol and the opportunities to transform the clinical trial lifecycle.

Panelists:

Amy Cramer, Founder and Director, Vulcan; Data Acquisition, eSource, Johnson & Johnson Innovative Medicine

Stacy Tegan, Program Director, TransCelerate Biopharma, Inc.

Mary Lynn Mercado, PhD, Global Head Protocol Delivery & US Site Head, Regulatory Writing & Submissions, Novartis Pharmaceuticals

Donald Jennings, Senior Advisor of Systems, Tech@Lilly Clinical Design and Operations, Eli Lilly and Company

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: The Perfect Pairing: How RWD Elevates Every Stage of Your Clinical Trial

Steve Lesser, Vice President of Growth for Clinical Trial Solutions, Optum Life Sciences

There's no substitute for real-world data to get to the most complete patient picture—before, during, and after a clinical trial. Understand your target population to inform evidence and diversity strategies, accelerate recruitment with EHR patient screening, and drive market success post-trial. Steve Lesser, Vice President, Clinical Trials, Optum Life Sciences, will discuss the ways real-world data acts as a key ingredient at the different stages of a clinical trial.

2:00 SCOPE Summit 2025 Adjourns

Partnering Organizations

SCOPEsummit.com/partnering-organizations

Cambridge Healthtech Institute's Inaugural

Generative AI in Clinical Research

Leveraging Gen AI to Enhance Clinical Operations

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's Inaugural

AI for Trial Optimization

Driving Efficiency with AI/ML Applications

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

GenAI IN CLINICAL TRIALS: SEPARATING CHAFF FROM GRAINS

11:00 Chairperson's Remarks

Siddhartha Bhattacharya, Life Sciences AI Leader, PwC

11:05 Scalable AI-Powered Approaches

Jonathan Crowther, PhD, Head Predictive Analytics, PRD (OARS), Pfizer Inc.

Maca Fernandez, Disease Intelligence Analytics Lead, Pfizer Inc.

This talk explores scalable AI-powered approaches that enhance efficiency and innovation across various sectors. It examines cutting-edge technologies, methodologies, and frameworks that facilitate the seamless integration of AI solutions within existing infrastructures. Attendees will gain insights into overcoming challenges related to scalability, data management, and resource allocation, ultimately empowering organizations to harness AI's full potential for transformative impact.

11:30 Challenges in Reaching the Desired Altitude for GenAI Applications in Clinical Trials

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

The desire to scale the impact of GenAI in applications for clinical trials comes with lofty ambitions and significant anticipated impact. Reaching the altitude necessary to deliver that impact means navigating many different kinds of turbulence on the way to 30,000 feet. Let's talk about how to anticipate and potentially avoid some of those challenges - the pilot has illuminated the seatbelt sign, please buckle up.

11:50 A 30,000ft View of AI Applications in Clinical Trials

Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.

This talk addresses the impact of generative AI in clinical trials, highlighting its ability to optimize trial designs, enhance patient recruitment, and improve data analysis. By utilizing AI-driven simulations, researchers can predict outcomes and streamline processes, ultimately increasing efficiency and accuracy in clinical research. The session will also explore the ethical considerations surrounding the integration of AI technologies in this critical field.

12:15 pm Implementing Gen AI in Clinical Research

Janie Hansen, Business Systems Transformation, Global Development Information Management, Daiichi Sankyo Inc

Successfully bringing Generative AI from concept to reality in clinical research requires a shift from traditional system implementation approaches. Common challenges, including limited understanding, concerns about job security, insufficient training, and unclear perceived benefits, often result in resistance to change. To drive successful adoption, these barriers must be addressed proactively—starting with a compelling business case, followed by effective change management strategies, and culminating in a focus on delivering measurable ROI.

12:35 GenAI: Pioneering the Next Era of Clinical Content Generation Deloitte.

Daniel Tortora, Pfizer

Lew Klein, IT Clinical Lead, R&D IT, AstraZeneca

Amy Cheung, Principal, Deloitte Consulting LLP

Discover the journey of biopharma executives as they integrate GenAI into clinical content generation, from initial stages to practical application. Gain insights into their starting points, challenges faced, lessons learned, and the benefits realized from utilizing this technology.

1:05 Harnessing Generative AI for Clinical Development faro

Patrick Leung , CTO, Development, Faro Health, Inc.

Vivian DeWoskin, Chief Strategy Officer, Strategy, Faro Health, Inc.

Clinical development is complex and increasingly costly. Recent advances in generative AI promise to reduce the time and cost of clinical trials through automation and data-driven insights. However, challenges remain, and the cost of failure is high. In this presentation, Patrick Leung (CTO) and Vivian DeWoskin (CSO) of Faro Health Inc. will discuss how Faro leverages its expertise in clinical science and AI to create solutions that advance clinical development tools and technology.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall AMR Vitalograph

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

CASE STUDIES OF AI-POWERED DOCUMENT AUTOMATION

3:20 Chairperson's Remarks MEDIDATA

Wayne Walker, Senior Vice President, Rave Platform Technology, Medidata, a Dassault Systemes Co.

3:25 Project GAIA: Structured Content Authoring Using a Generative AI Assistant

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

Bryan Feldman, Senior Director, Business Technology for Clinical Development, Regulatory Affairs, and R&D QA, AbbVie

Rapid progress in genAI has enabled advanced structured content authoring of diverse clinical, regulatory, & safety documents. We created an enterprise-wide application, Project GAIA, to autogenerate documents including the Clinical Study Report, Informed Consent Form, and Product Safety Update Report using an extensible content template. The GAIA application creates whole documents in minutes by synthesizing and adding each section according to the template including AI-generated text, tables, images, and diagrams.

3:45 Transforming Regulatory Document Authoring: The Promise of Human-Led Generative AI

Rogier Landman, PhD, Associate Director, Digital Medicine Data Science, Pfizer Inc.

Generative AI is revolutionizing the entire spectrum of regulatory document authoring, from protocols to clinical study reports, promoting standardization, ensuring compliance, and maximizing efficiency. This presentation will highlight the paradigm shift in how these critical regulatory documents are drafted, emphasizing the transformative impact of Gen AI on the pharmaceutical industry. The presentation will also advocate for a collaborative "human-led" Generative AI approach that delivers the best outcomes.

4:05 Accelerate Clinical Content Generation and QC with GenAI and Knowledge Graphs

Jenny Wei, PhD, Senior Director, R&D Informatics and Technology, Kite Pharma

Clinical trial documents authoring and quality control is still riddled with inefficiency due to the time-consuming, expensive, and manual way of working. AI has the potential to transform this space. At SCOPE, we will share our experience in automating content generation (CSR, IB, ICF, protocol, etc.) and document review (through evidence lineage tracking) with integrated NLG, genAI, and knowledge graph technologies.

4:25 Navigating AI for Clinical Trials: Simplifying the Path to Insights medrio

Mike Stocks, CTO, Executive Leadership, Medrio

Nicole Latimer, CEO, Medrio, Inc.

Clinical trials are becoming increasingly complex, with more data points, forms, and rules to manage. As biomarkers emerge as key endpoints, the volume of data to clean, monitor, and analyze grows exponentially. These processes are not just time-consuming—they're costly and critical to a trial's success. Continually, sponsors and CROs are faced with the challenge of how to balance the surge in data while maintaining speed, quality and compliance Join Medrio CTO, Mike Stocks, and CEO, Nicole Latimer, as they explore how Medrio is integrating AI into the clinical trial process to streamline and accelerate data management. Learn practical applications for balancing machine learning and automation with human oversight, enabling more efficient workflows and reducing the burden on study teams.

4:55 Lessons Learned on Realizing GenAI/LLM Values for Clinical Document Automation

Dagmar McCaughey, Senior Director, Head of Study Start-Up, Vertex Pharmaceuticals, Inc.

Lily Xu, PhD, Senior Principal Data Scientist, Data Science, Vertex Pharmaceuticals, Inc.

Clinical document drafting is manual, time-consuming, and process-heavy. To address this, our cross-functional teams developed an "Autodrafter" using GenAI/LLMs to streamline clinical document drafting workflows. We will share lessons learned on the pilot design to demonstrate the quantifiable benefits of GenAI in clinical operations. We will also discuss scaling the GenAI pilot for broader business use. Join us to learn about the transformative potential of GenAI in clinical document drafting.

5:25 Mythbusters: Uncovering the Real and Right Now with GenAI in Clinical Trials sas

Matt Becker, Advisory Life Sciences Industry Consultant, Life Science Industry R&D, SAS Institute, Inc.

There's a lot of hype around generative AI in life sciences, but what's the real application? How does your platform stack up to support this technology? Using data and AI as the foundation, and GxP guardrails as the navigating guide, both sponsors and CROs can advance drug development with cutting-edge technologies—but only if the myths are busted, and the real, applicable uses of GenAI are tapped into. Join this session to grasp a real, right now understanding of GenAI in clinical trials.

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

IMPLEMENTING AI IN CLINICAL TRIALS: WHAT ARE THE KEY CONSIDERATIONS?

8:50 Chairperson's Remarks

Alyssa Farrell, Director, Global Health & Life Sciences Market Strategy, SAS Institute, Inc.

8:55 A Multi-Company Study Examining the Adoption and Use of AI

Maria Florez, Senior Consultant, Tufts CSDD
Mary Jo Lamberti, PhD, Director and Research Associate Professor, Tufts Center for the Study of Drug Development (CSDD)

This talk will review where sponsors and CROs are deploying AI (artificial intelligence) and ML (machine learning) in clinical development based on a collaborative industry study; examine pharma investment levels in use of AI/ML in clinical research; and gather insights on the challenges of implementing AI/ML.

9:25 PANEL DISCUSSION: Overcoming Challenges and Managing Costs in Industrializing Generative AI

Moderator: Srivatsan Nagaraja, Founder, Vidya Seva

The adoption of generative AI into clinical trials offers transformative potential, enhancing efficiency, accuracy, and innovation. However, scaling generative AI involves addressing significant challenges and managing costs effectively. This session will delve into these issues, providing practical solutions and insights through expert discussions and practical case studies. Discover how to effectively industrialize generative AI in clinical trials to drive innovation and efficiency.

Panelists:
Prasanna Rao, Chief Products and Innovation Officer, Saama
Kannan Natarajan, PhD, Head, Global Biometrics & Data Management, Pfizer Inc

9:55 AI in Clinical Trials—Case Studies & Lessons From Real Implementations, Featuring a Fireside Chat with Eli Lilly

Siddhartha Bhattacharya, Life Sciences AI Leader, PwC
Lora Todd, VP Emerging Tech and Information Management, Eli Lilly and Company
Mike Luker, VP, Data & Analytics Clinical Design & Delivery, Eli Lilly and Company

This session explores AI's transformative role in clinical trials, using a case study driven approach to highlight real-world use cases and lessons learned from successful implementations. It also features a Fireside Chat with Clinical AI leaders from Eli Lilly, sharing insights on how they are harnessing AI to create digital FTE capacity in clinical development.

Additionally, the session will cover top AI use cases driving success in clinical trials, best practices for implementing AI in clinical operations, and key lessons learned and potential risks to navigate. Don't miss this unique opportunity to hear directly from industry leaders and gain insights into the future of clinical trials with AI.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

AI TO IMPROVE TRIAL EFFICIANCY AND OPTIMIZE PROTOCOL DESIGN

11:20 Chairperson's Remarks

Gary Lubin, CEO, Ledger Run, Inc.

11:25 Gaining 70% Efficiencies by Using AI in Clinical Study Data Conformance

Daniel Bachalis, MS, MBA, Senior Director, Engineering & Operations, Drug Development IT, Data, and Analytics, Bristol Myers Squibb Co.

Pharma companies conduct exploratory analytics on legacy clinical studies to uncover insights that inform current and future trial phases. Combining legacy studies is prone to friction due to the complexity of clinical data and because legacy studies can differ dramatically across therapeutic areas and study phases.

With AI, we developed a platform that reduced the time to conform, improved quality of data, and reduced the need for subject matter expertise.

11:45 CATALYST Trial Timeline Planning—Enhancing Predictions with Advanced Machine Learning and Large Language Models

Sheng Zhong, PhD, Director of Statistics, Data and Statistical Sciences, AbbVie, Inc.

Accurate prediction of trial enrollment timelines at the portfolio-planning stage is essential to strategic planning and the efficient allocation of resources for pharmaceutical sponsors. Traditional methods rely heavily on structured datasets and manual data curation, often resulting in suboptimal outcomes. This presentation introduces an enhanced approach that leverages advanced machine learning (ML) algorithms and large language models (LLMs) to accurately forecast trial enrollment timelines.

12:05 pm Data Driven Evaluation of Clinical Trial Inclusion and Exclusion Criteria to Optimize Study Design

Brandon Rufino, Computational Science Manager, Sanofi

Clinical trials are key to drug development, but 55% of terminated clinical trials fail due to slow recruitment. We hypothesize that this is, in part, due to restrictive and perhaps poorly justified inclusion/exclusion criteria. To combat this issue, we developed simulation techniques to evaluate criteria and propose a set of inclusion/exclusion criteria such that we maximize the size of the potential patient population whilst retaining a high probability of success.

12:25 Digitalization - Study Design, AI, Specimen Management, and Beyond

Viral Vyas, Dir IT, Global Clinical Dev, Bristol Myers Squibb Co

Mike Sullivan, Executive Director, Global Development Operations, Drug Development IT, Bristol Myers Squibb Co

Jolene Hill. Vice President, Solutions Consulting, Nurocor Inc.

Bristol Myers Squibb and Nurocor will share the real world experience of executing a digitalization strategy for clinical development incorporating a digital protocol. Stories from the trenches will highlight the challenges and successes in executing a strategy and the results and benefits of a digital protocol and digital specimen management process. GenAI then unlocks the potential for automating other clinical operations processes like contracting.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

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On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-

fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

ARE WE THERE YET WITH ETHICAL CONSIDERATIONS?

8:20 Chairperson's Remarks

Suzanne Caruso, General Manager, Clinical & Regulatory, Citeline

8:25 Content Generation and Knowledge Extraction for Clinical Documents

Vaishali Goyal, MS, AI Lead, Development, AstraZeneca Pharmaceuticals

With over 240 global clinical trials, we are currently running multiple pilots across our R&D pipeline, testing a range of AI technologies to simplify our processes. Specifically, AstraZeneca is investing in the AI technology to expedite content generation and insight extraction of key clinical assets.

8:50 AI-Powered Protocols: Breaking the Design Cycle with Data-Driven Retrospectives

Laura Russell, Senior Vice President, Head of Data and AI Product Development, Advarra

The protocol design process is ripe for innovation to address persistent challenges, including inefficiencies in trial operations and high participant attrition. The next wave of advancements will look to leverage emerging AI technologies and unified data ecosystems to break the cycle of inefficiency by tackling foundational issues rather than focusing solely on surface-level friction points. This session will delve into how smarter protocol design can become a reality by applying these advancements to data-driven retrospectives for continuous improvement.

9:05 How AI Document Automation Can Support Our Clinical Trials for EU Submissions: EU-CTR Synopsis Case Study

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

In this session, BMS shares the creation of a BOT to support submissions to the EU Clinical Trial Regulation (EU-CTR). EU-CTR Regulations now requires submissions to include a synopsis understandable to a layperson. A BOT was developed to create the synopsis from the protocol and with AI technology, it converts the language to the required laymans terms. This is time saving technology to produce a document to support EUCTR submissions.

9:25 Dynamic Trial Monitoring for Ongoing Clinical Trials

Tai Xie, Founder & CEO, CIMS Global

Effective trial monitoring is essential for participant safety, data integrity, and regulatory compliance, yet existing tools fall short in meeting these demands. Dynamic Trial Monitoring (DTM) offers a real-time, integrated approach to trial oversight, enhancing efficiency and decision-making. This presentation will highlight DTM's principles and case studies, showcasing its ability to predict enrollment trends, detect safety signals, and enable agile, high-quality trial management.

9:40 Using Predictive AI To Optimize Recruitment Content for Diverse Audiences

Matt Graffeo, Managing Director, Clinical Trial Communications, GCI Group

Kianta Key, Group Sr VP Digital & Head of Identity Experience, Digital Healthcare, GCI Health

Data-driven insights are transforming clinical trial recruitment. This presentation explores how predictive AI streamlines content creation by analyzing pre-publication messaging and visuals against historical benchmarks, ensuring resonance with target audiences and eliminating the need for A/B testing. We'll demonstrate how our proprietary platform leverages AI to predict content performance across demographics, leading to optimized messaging, increased efficiency and better recruitment outcomes.

9:55 Digital Health Technology Data Integrity: Mitigating Data Loss and Poor Data Quality to Ensure Actionable ROI

Jen Blankenship, Senior Research Scientist, Clinical Research & Development, VivoSense

This presentation addresses the critical issue of data integrity in digital health technologies and wearable sensors, focusing on mitigating data loss, inconsistencies, and poor data quality. These issues can undermine decision-making, thereby reinforcing stereotypes that "we are not there yet" in utilizing wearable sensor derived data in clinical validation. Strategies such as robust error detection, sensor wear compliance, data validation, artifact detection, and improved system integration are explored to ensure reliable, high-quality data. By partnering with external end-to-end solutions, sponsors can maximize actionable insights, improve patient outcomes, and drive a higher ROI.

10:10 Evaluating Generative AI in Regulated Environments: A Statistical Rigorous Framework for Regulatory Compliance and Safety

Venky Iyer, Director, Data Strategy & Enablement, Pfizer Inc.

Sheraz Khan, PhD, Director, Operational AI & Data Sciences, Pfizer Inc.

The need for rigorous statistical evaluation of generative AI in clinical trials is paramount to ensuring regulatory compliance and patient safety. This talk explores an assessment of whether AI-generated contents are non-inferior to human-generated contents across key dimensions such as accuracy, clarity, consistency, and reasoning. The insights gained will shape future integration of generative AI in regulated environments, transforming how we approach clinical trials and drug development.

10:40 PANEL DISCUSSION: Ethical Consideration for AI Applications in Clinical Trials

Moderator: Dominic De Bellis, PhD, Executive Director, AI Strategy & Operations Lead; Global Clinical Trial Operations, Medical Writing & Disclosure, Merck & Co., Inc.

This panel will introduce the concept of AI ethics and its significance to the pharmaceutical industry. Industry experts will discuss the progression of AI in the pharmaceutical industry and its impact on various operations, as well as the ethical considerations in using AI for drug discovery. Considerations include biases in AI algorithms, patient privacy concerns, and quality control. Finally, panelists will provide key messages and actionable insights.

Panelists:

Sheraz Khan, PhD, Director, Operational AI & Data Sciences, Pfizer Inc.

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

Jonathan Shough, CIO, PAREXEL International

11:10 Networking Coffee Break

DIGITAL PROTOCOL: FROM DESIGN TO IMPLEMENTATION

11:50 Chairperson's Remarks

Sina Djali, Head, Data Management and Central Monitoring, Immunology and Medical Affairs, Johnson & Johnson

11:55 The Role of AI in Powering Digital Protocols

Yugang Jia, PhD, MPH, Director, AI & Data Science, Verily

Lauren Sutton, Head of Product, Clinical Trial Recruitment & Site CTMS, Verily

Protocols often live in documents, requiring sponsors to manually configure data across many systems, and leading to inaccuracies and extended timelines. Global standards groups are calling for protocols to be digitized, but how will sponsors adjust to new digital formats? In this talk, we'll share published research on the use of AI/LLM agents to digitize protocols and how this approach can drive more efficient research for sponsors and sites.

12:25 pm PANEL DISCUSSION: Transforming the Clinical Trial Protocol—Moving from a Document-Centric to a Data-Centric World

Moderator: Chris Decker, President & CEO, CDISC

For many years, the industry has been writing protocols in Word and manually transcribing protocol information to downstream systems, which is time-consuming and error-prone. Recently, the industry is moving towards a data-centric protocol, helping to reduce cycle times and improve data reliability. The panel will bring together TransCelerate, CDISC, HL7, and ICH M11 to discuss digital protocol initiatives protocol and the opportunities to transform the clinical trial lifecycle.

Panelists:

Amy Cramer, Founder and Director, Vulcan; Data Acquisition, eSource, Johnson & Johnson Innovative Medicine

Stacy Tegan, Program Director, TransCelerate Biopharma, Inc.

Mary Lynn Mercado, PhD, Global Head Protocol Delivery & US Site Head, Regulatory Writing & Submissions, Novartis Pharmaceuticals

Donald Jennings, Senior Advisor of Systems, Tech@Lilly Clinical Design and Operations, Eli Lilly and Company

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: The Perfect Pairing: How RWD Elevates Every Stage of Your Clinical Trial

Steve Lesser, Vice President of Growth for Clinical Trial Solutions, Optum Life Sciences

There's no substitute for real-world data to get to the most complete patient picture—before, during, and after a clinical trial. Understand your target population to inform evidence and diversity strategies, accelerate recruitment with EHR patient screening, and drive market success post-trial. Steve Lesser, Vice President, Clinical Trials, Optum Life Sciences, will discuss the ways real-world data acts as a key ingredient at the different stages of a clinical trial.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 11th Annual

Risk-Based Quality Management

Navigating Risk with High-Level Strategy and Best Practices

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 11th Annual

Central and Remote Monitoring

Unlocking Study Insights through Central Monitoring and Data Analytics

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

FUNDAMENTAL PIECES OF THE RBQM PUZZLE

11:00 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:05 RBQM Revealed: A Decade of Discovery & the Blueprint for Tomorrow's Breakthroughs

Joanne Benedict, Senior Director, Clinical Operations, Head, Risk Based Quality Management, Gilead

Risk-based quality management (RBQM) of clinical trials has evolved over the past decade. This talk will explore the lessons learned and innovations that have shaped more effective trial monitoring and risk mitigation. This presentation will also outline forward-thinking initiatives at Gilead in reducing inefficiencies in monitoring and the application of RBQM.

11:30 In Pursuit of Adoption: Risk-Based Quality Management and ICH E6 R3

Vimi A Shukkoor, Advisor, Medical Quality Systems, Eli Lilly & Co

Nicole Stansbury, Senior Vice President, Global Clinical Operations, Premier Research; Co-Lead, Risk-Based Monitoring Working Group, Association of Clinical Research Organizations (ACRO)

The ICH renovation of good clinical practice represents a shift in clinical research away from a one-size-fits-all approach to a more proactive, risk-based approach. Our goal is to enhance understanding and increase implementation of key topics detailed in ICH E6 R3. After soliciting direct feedback from our respective member companies, ACRO and TransCelerate have developed a set of tools to support a strong foundation for quality in clinical development.

11:55 Critical-to-Quality Factors (CTQs)—Beginning with the End in Mind

Cilla Mistry, Central Monitoring Process Manager, Central Monitoring and Data Analytics, GSK

This talk will provide an overview of RbQM, how to implement CTQs, when CTQs should be identified, and dealing with mindset shifts from the study team when implementing RbQM. Increasing awareness of CTQs will help deliver and conduct our trials with a RbQM mindset. Quality of data, patient safety, and reliable data are key as per our ICH GCP guidelines.

12:15 pm Right From the Start? Story on How Risks Identified at the Study Design Phase Foster Cross-Functional Early Engagement and Pay Off During the Study Conduct Phase

Maha Raheb, MD, Associate Director, Risk-Based Quality Management, AstraZeneca

This presentation will focus on a new strategy for fostering cross-functional early engagement during the design phase, aimed at developing quality risk management strategy. Enhancements to quality will be achieved by prioritizing critical data and de-prioritizing efforts on non-critical data

12:35 Patient Voice as the Next Frontier in Trial Quality

Laura Engerman, Principal, R&D, ZS Associates

Incorporating patient voice into clinical trial design and planning is crucial for identifying and mitigating quality risks. Diverse patient voice enhances trial quality and safety by ensuring study objectives are meaningful and scientifically valid, but it can be difficult to apply at scale. At ZS, we've developed the Patient Experience Bank, a scalable solution enabling the integration of 5 million+ data points of diverse patient insights into development decisions. This capability can prevent risks derived from misunderstandings and operational challenges, aligning with regulations such as ICH guideline E8 (R1) to identify critical-to-quality factors at the risk assessment. Join ZS leaders Laura Engerman and Jonathan Rowe as they explore the transformative power of integrating patient voice into clinical.

1:05 RBx: Empowering study conduct teams with seamless process and technology integration

Aamir Jaka, VP Life Science Strategy, Commercial, Saama

Study conduct teams have invested time and resources in technologies that improve the quality and speed of work in Data Management and Medical Monitoring. Understanding these capabilities can unlock a better risk-based strategy if you design your framework with these enabling technologies in mind. With the right approach such advances can be incorporated end to end, providing benefits to multiple stakeholders during study conduct.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

THE ROLE OF CLINICAL DATA IN STUDY QUALITY

3:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

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.

Alicia Worrall, Associate Director, Centralized Monitoring and TA Analytics, Data & Statistical Sciences, 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. This talk will explore how our technology streamlines risk detection and management, while discussing the challenge of 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.

3:55 Sponsored Presentation *(Opportunity Available)*

4:25 Using Audit Trail Data to Ensure Fit-for-Purpose Data for Clinical Trials

Nechama Katan, Director, Innovative Analytics, Data Monitoring and Management, Pfizer Inc.

Why is audit trail critical for ensuring quality fit-for-purpose data? How do we start with business context to define and implement a robust audit trail analytics platform?

4:45 Elevating Quality Management through Analytics

Kevin Richards, Head, Quality Investigations & Analytics, AstraZeneca

There is a clear conceptual link between Quality Management and Analytics, encapsulated in the maxim, "You can't manage what you can't measure." In practice, however, many pharmaceutical organizations struggle to operationalize this idea: quantifying quality is filled with challenges, both technical and organizational. Through detailed case studies, it will be illustrated how quality analytics can drive meaningful impact, providing a roadmap to true proactive quality in your organization.

5:05 Analytics for Automated Outlier Detection of ePRO Data: Ensuring Data Integrity and Quality in Clinical Trials

John Samuelsson, PhD, Senior Data Scientist, Artificial Intelligence & Machine Learning Quantitative & Digital Sciences, Pfizer Inc.

Here we present a method for automated detection of low-integrity ePRO data at sites. This approach is data-driven and multivariate, acting as a complement to the heuristic and univariate analyses currently done by central monitors in CluePoints. The algorithm converts ePRO data into numerical format, computes site-level features and detects outlier sites using an ensemble of Empirical-Cumulative-distribution-based Outlier Detection (ECOD) and Density-Based Spatial Clustering of Applications with Noise (DBSCAN).

5:25 PANEL DISCUSSION: Advancements and Challenges in Clinical Trial Data Quality Control: A Roadmap for Audit Trail Analysis

Moderator: Olgica Klindworth, Vice President, Data Quality and Risk Management Solutions, Medidata a Dassault Systemes Co.

Considering increasing complexities in data acquisition, data managers and operational users must enhance their approach to data quality oversight by utilizing a wider array of data sources. The volume of audit trail data can be overwhelming, and users often struggle to identify critical insights or analyze this information despite regulatory guidance. Consequently, the industry must develop more efficient methods for analyzing audit trail data to ensure robust data integrity controls.

Panelists:

Jennifer Krohn, MS, Associate Director, RBQM, Clinical Operations, Gilead Sciences. Inc.

Kevin Stephenson, MBA, MS, Executive Director, Data Management, Karyopharm Therapeutics

Simon Walsh, Head, Data Acquisition and Coding, Johnson & Johnson Innovative Medicine

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of

the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials
Kyle Hogan, CEO, Datacubed Health
This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design
Christopher Riley, Director, Strategic Insights, Solutions, H1
In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs
Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee
Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

MONITORING QUALITY THROUGHOUT STUDY CONDUCT

8:50 Chairperson's Remarks
Jay Ferro, Executive Vice President, Chief Information & Technology Officer, Clario

8:55 Integrating Meaningful Diversity Metrics into Clinical Monitoring
Martha Dockery, MS, Associate Director, Clinical Monitoring, Health Equity Champion Exact Sciences
By identifying essential demographic and site-specific characteristics, monitoring teams can transform diversity data into actionable performance indicators. These metrics guide quality measures, ensuring continuous improvement in oversight activities. Incorporating diversity metrics into monitoring plans and risk assessments fosters more equitable and representative clinical trial environments.

9:15 Leveraging RBQM Technologies to Achieve Diversity Action Plan Goals
Damalie Akuamoah, Diversity Program Lead, Merck
Naveen KK, Vice President & Global Head, CMR, CM & Safety Services, Fortrea
Lydia Matombo, Director, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.
This talk will build upon previous work in leveraging RBQM technologies and central monitoring strategies to develop, execute, and oversee Diversity & Inclusion in clinical trials. A case study will be presented on leveraging RBQM technology for implementing Diversity Action Plan goals.

9:35 Debate: Fraud and Misconduct in Clinical Trials: Marginal Nuisance or Major Problem?
Marcin Makowski, PhD, Head, Centralized Monitoring & Data Analytics, GlaxoSmithKline
Jonathan Rowe, PhD, MS, MA, Principal, ZS
Misconduct cases in clinical trials world get significant attention. Are the discovered and publicized situations a tip of an iceberg or isolated incidents? During the session, two experienced RBQM leaders: Marcin Makowski, GSK and Lukasz Bojarski, AZ will clash in a debate on the topic of scale and importance of fraud and misconduct.

9:55 Beyond the Benchmarks: Setting New Standards for Speed in Clinical Trials
Charlie Paterson, Associate Partner and Clinical Development Expert, PA Consulting
Gino Pirri, VP Product & Technology, Product & Technology, PPD Part of Thermo Fisher Scientific
We'll demonstrate how to accelerate drug development by enhancing study speed, quality, and outcomes through a centralized platform that consolidates all data sources. This advanced technology integrates seamlessly into existing workflows, leveraging machine learning algorithms to filter noise, enable real-time monitoring, and optimize workflows. These advancements, radically reduce manual data transfers and errors, ensuring data consistency and boosting data flow and communication.

10:25 Coffee Break in the Exhibit Hall
SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing
Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

BEST PRACTICES FOR STUDY RISK ASSESSMENT

11:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:25 Best Practices for Study Risk Assessment
Rachael Geedey, Director, Customer Success, Cluepoints
Kristin Stallcup, MS, Director, RBQM Operations, Takeda
Discover the future of clinical trial risk assessments with a presentation from PHUSE's Risk Assessment Working Group co-chairs, Kristin Stallcup and Rachael Geede. The working group is tackling the challenge of time-intensive risk assessments by refining processes and emphasizing Critical-to-Quality (CtQ) risks. Don't miss this presentation highlighting their progress and collaborative efforts to solve this industry challenge.

11:55 Your Roadmap to RBQM Rollout: Applying Change Management for Lasting Impact
Rebecca Bichard, Director, Clinical Process Excellence and Training, Insmed
Leslie Sam, President, Leslie Sam & Associates LLC
This session will explore how a well-designed change management roadmap, anchored in the 4 R's—Right Information, Right People, Right Way, Right Time—can effectively eliminate barriers that often hinder RBQM initiatives. A real-world case study will be presented to demonstrate how these principles were applied to overcome obstacles, ensuring a smooth, efficient, and impactful RBQM rollout that drives lasting success across studies and projects.

12:25 pm 360° Monitoring: A New Approach to Dynamic Clinical Oversight Using Centralized Insights
Olgica Klindworth, Vice President, Data Quality & Risk Management Solutions, Medidata, a Dassault Systemes Co.

Lauren Price, Director, CTMS Product Management, Medidata, a Dassault Systemes Co.

Manual data interrogation. Overlooked risks. Inefficient monitoring. It's time to transform the outdated paradigm of clinical oversight with centralized, automated data insights that improve performance end-to-end, from guiding site selection decisions to fueling dynamic monitoring strategies. Anchored in a risk-based framework, this approach bridges protocol objectives with operational execution to maximize quality and efficiency. Join this session to learn how integrated solutions are redefining trial oversight and quality management for today's complex clinical landscape.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.

Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

MAXIMIZING THE VALUE OF CENTRAL MONITORING

8:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:25 Protecting Data Quality: Implementing and Demonstrating the Value of Centralized Monitoring

Jennifer Krohn, MS, Associate Director, RBQM, Clinical Operations, Gilead Sciences. Inc.

Centralized monitoring (CM) is widely accepted as an integral component of robust clinical-trial monitoring strategy due to its ability to identify data-quality risk that traditional monitoring does not have the vantage point to detect. However, there are challenges in implementing and demonstrating its value. This talk will review PHUSE's investigation into these topics and seeks to inspire additional industry collaboration in further developing open-source CM capabilities.

8:55 A Unique Transition from Outsourced Centralized Monitoring to an in-House Process in a Very Short Timeframe

Anne Smith, Director, Central Monitoring, Regeneron Pharmaceuticals, Inc.

This talk will highlight our team's transition from outsourced centralized monitoring to an in-house model within a shortened timeframe. We used a unique approach, working with internal and external stakeholders to implement the new model. This presentation will go through the challenges and lessons learned, and provide a blueprint upon which to model similar efforts.

9:25 How RBQM Is Core To The Evolving Needs Of Clinical Research

Duncan Hall, CEO, Executive, Triumph Research Intelligence Ltd.

As clinical trials become more complex, the utility of RBQM is increasing, as are the technical demands. The need for experienced CRO support and a strong relationship between Sponsor, CRO and technology is more important than ever. Duncan looks at emerging demands on both parties and how great RBQM process and technology is the foundation of trust and performance.

9:40 Accelerating Clinical Success: Egnyte's Unified Platform for Data Governance and Secure Collaboration

Catherine Hall, Head of GXP Quality Assurance, Sales, Egnyte, Inc.

Life sciences organizations face intricate data handling challenges and compliance requirements in today's clinical trial environment. With evolving regulatory frameworks like ICH E6 (R3) emphasizing more robust data governance, these challenges continue to grow. This session showcases how Egnyte's cutting-edge platform addresses these complexities by employing seamless data governance over diverse data and content in a secure collaborative platform

10:10 The Many Faces of Clinical Data Integrity

Bartosz Wylot, PhD, Associate Director, Risk Based Quality Management, AstraZeneca

ICH E6 (R3) requires data monitoring to extend across multiple data integrity aspects, from patient eligibility to lack of variability and potential data manipulations. From a centralized monitoring perspective, such a broad scope requires various data analysis techniques and approaches to handling generated insights. In this session, I am going to discuss how a "one size does not fit all" principle applies to signal detection methods and findings management.

10:40 PANEL DISCUSSION: Challenges and Strategies for Managing Central Monitoring Action Fatigue

Moderator: Olivia Feiro, Director, Clinical Risk and Document Management, CSL Behring

Not every risk can be mitigated with a direct action and confirmed as resolved in the subsequent review cycle. What happens to the dynamics between the RBQM and study team when risks persist over a long period of time or when RBQM is performed on a long-term study? This panel will explore the challenges of such risks and strategies for collaboration and communication across teams.

Panelists:

Kristin Stallcup, MS, Director, RBQM Operations, Takeda

Danilo Branco, Director, Central Monitoring Operations, Fortrea

11:10 Networking Coffee Break

ADVANCING DIGITAL HEALTH AND CLINICAL TRIALS CONVERGENCE

11:50 Chairperson's Remarks

Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

11:55 Applying Social Determinants of Health (SDoH) in Clinical Planning and Site Strategy

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

SDoH data can enhance our understanding of the barriers to participation in clinical trials and improve access for study participants. This presentation examines various types of SDoH data for site and patient strategies, and discusses how to effectively leverage these insights in clinical studies.

12:25 pm PANEL DISCUSSION: Achieving Flexibility and Expanding Access While Preserving Data Quality

Moderator: Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

Is trial flexibility a threat to data quality? Concerns are often raised that offering flexible approaches to trial design and conduct, such as collecting data in various settings and offering a flexible schedule of visits, will result in risks to data quality. This session will explore multi-partner perceptions around when and how data quality is maintained when flexible approaches are introduced and how flexibility can improve access to clinical trials.

Panelists:

Pamela Tenaerts, MD, MBA, CSO, Medable

Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Wes Burian, Patient

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: From Sync to Swim: Alimentiv's Journey with Zelta ePRO

Wes Fishburne, Principal Product Manager, Zelta by Merative

Chris Walker, Director, Data Sciences, Alimentiv

Amid growing responsibilities and expanding clinical operations, data managers are increasingly challenged by the increasing number of eClinical solutions required to support a clinical trial. Join us to learn how the data managers at Alimentiv have leveraged Zelta's ePRO module to streamline their eClinical data collection scheme to include patient-reported outcomes with the rest of their study data, achieving more control over their clinical trials and confidence in their outcomes.

2:00 SCOPE Summit 2025 Adjourns

"I would also like to thank you for the opportunity to attend SCOPE and for all your help during the preparation. It was a great event with lots of interesting and enthusiastic people and great discussions! I enjoyed it a lot, learned a lot and definitely came back with new ideas! "

– Consultant, Roche Pharma

Cambridge Healthtech Institute's 10th Annual

Modernizing Lab, Biomarker & Data Management Operations

Biomarker-Driven Trial Design, Operational Frameworks, and Standardization Efforts

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 9th Annual

Biomarker & Biospecimen Technology & Innovation

Patient-Centric Collection, Sample Tracking, Vendor Management, and Data Considerations

FEBRUARY 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.
**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.
Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 OPEN WORKSHOP: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace (IN-PERSON ONLY)
Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our "Ask a ClinEco Luminary" program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. To register for the workshop, please opt into this workshop by selecting the checkbox under 'Conference Selection.' Open to all SCOPE attendees.

1:00 OPEN WORKSHOP: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trial (IN-PERSON ONLY)
INSTRUCTORS:
Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/Thermo Fisher Scientific
While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a "Sustainability 101" to help anyone in our industry get started towards developing more environmentally responsible clinical trials. To register, please opt into this workshop by selecting the checkbox under 'Conference Selection. Open to all SCOPE attendees. Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.

1:00 OPEN WORKSHOP: Efficient Importation of Biological Materials into the U.S. (IN-PERSON ONLY)
SPEAKERS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)
U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing
INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP
This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:58 Chairperson's Introduction
Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There
Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA
In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

INDUSTRY COLLABORATION TO STANDARDIZE AND ACCELERATE CLINICAL RESEARCH

11:00 Chairperson's Remarks

Ryan Gifford, Vice President, Global Laboratory Services, CTI

11:05 Biospecimen Industry Collaboration: Pioneering Best Practices to Standardize, Accelerate, and Transform Clinical Research

Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

Specimen Management is often overlooked in clinical trials despite its importance in improving data pipelines, reducing queries, and enhancing research quality. While data management dominates industry discussions, few focus on specimen practices that boost reproducibility and AI confidence. The Biospecimen Industry Collaboration, formed by leading biopharma companies, addresses this gap by developing a best practices framework to standardize processes, paving the way for next-gen tools and technologies in clinical trials.

11:10 Operationalizing Precision Medicine: Best Practice from Protocol Design through Study Start-Up

Nancy DeFusco, Director, Specimen Lifecycle Management, Merck Sharp & Dohme LLC

Kenna Sayers, Director, Vendor Management, Integrated Biomarker Operations, Merck

This presentation will review the output of a workshop attended by 10 major global biopharma companies discussing areas of opportunity for industry standardization from Protocol Design through Study Start-Up, to streamline clinical trial operations.

11:35 Operationalizing Precision Medicine: Best Practice from Site Activation through Study Closeout and Final Disposition of the Specimen

Deborah Shepard, PhD, Director, Group Lead—Biomarkers Clinical Data Acquisition, Pfizer Inc.

John Smutko, Head of Specimen Management Oncology, GSK

This presentation will review the output of a workshop attended by 10 major global biopharma companies discussing areas of opportunity for industry standardization during Study Conduct through Closeout, to streamline clinical trial operations.

12:05 pm PANEL DISCUSSION: Biospecimen Industry Collaboration Q&A

Moderator: Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

Don't know where your specimens are? Frustrated with the status quo? Come hear from specimen management, data management, and biobanking experts who participate in the Biospecimen Industry Collaboration about how the best practices they are developing can benefit you and your team!

Panelists:

Nancy DeFusco, Director, Specimen Lifecycle Management, Merck Sharp & Dohme LLC

Arkady Gusev, PhD, Head, Lab Excellence & Operations in Biomarker Development, Novartis Institutes for BioMedical Research, Inc.

Anna Kosenko, Associate Director, Biomarker Operations, BioNTech US Inc.

Rose Redfield, Director, Support & Optimization Biosample Management, Daiichi-Sankyo

Heather Shih, PhD, MBA, Senior Director Biomarker Operations, Global Clinical Development Operations, BioNTech US, Inc.

Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck

12:35 From Site to Result: Real-Time Sample Intelligence Unlocked with GenAI

Tobias Guennel, Senior Vice President, Product & Chief Architect, Data Management & Systems Integration & Innovation, QuartzBio

With QuartzBio's Biomarker Intelligence Platform, you can ask questions, get answers, and gain insights across the entire precision medicine data ecosystem. Powered by an ensemble of Precision Medicine Large Language Models (LLMs), QuartzBio's platform supercharges efforts of operations, translational, and informatics teams, using AI-driven integration of biomarker, sample, and clinical data. This unified, scalable, and interoperable solution enables real-time sample intelligence from point of collection to data generation.

1:05 The Road Less Traveled: Bridging the Research Gap in Rural and Tribal Communities

Jonathan Ernst, Vice President, Business Development, PCM Trials

This session will explore the unique challenges of conducting clinical trials in rural and tribal communities, inspired by insights from the Montana Pathways to Health Equity initiative. We will discuss logistical hurdles, such as extreme weather and long travel distances, and highlight innovative community-based research strategies to overcome these barriers. This discussion aims to provide a deeper understanding of the importance of inclusivity in clinical research through real-world examples and forward-thinking strategies, particularly for underrepresented populations. Attendees will:

- Understand the logistical and geographical challenges of conducting clinical trials in rural areas, illustrated through case studies.
- Identify innovative solutions and strategies to overcome these challenges.
- Recognize the importance of inclusivity in clinical research and the role of community-based research models in achieving it.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

OVERCOMING OPERATIONAL CHALLENGES OF SAMPLE MANAGEMENT

3:20 Chairperson's Remarks

Maria Gujral, Senior Director, Biospecimen & Imaging Management, Bristol Myers Squibb Co.

3:25 Optimizing Specimen Reconciliation to Improve Compliance and Data Integrity

Maria Gujral, Senior Director, Biospecimen & Imaging Management, Bristol Myers Squibb Co.

In clinical trials, accurate and timely biospecimen reconciliation is crucial for compliance and data integrity. This presentation explores strategies and best practices to enhance reconciliation processes, addressing common challenges like discrepancies, delays, and data inconsistencies. We will highlight innovative solutions, including automated tracking systems and real-time monitoring tools, to streamline these processes. Gain insights into robust protocols that improve compliance and enhance the quality and reliability of clinical trial data.

3:50 Creating Accountability through Dashboards and Trend Reporting of Sample Data

Roger Craveiro, Associate Director Specimen Lifecycle Management, Global Clinical Trial Operations, Merck Animal Health

This talk will demonstrate how compiled clinical sample data through dashboards and trend reporting can be leveraged to engage leadership teams and drive accountability. By providing a clear view of key performance indicators, dashboards empower leaders to understand organizational health, address trends, and make strategic decisions. We will showcase how specimen data from management databases can be transformed into actionable insights to enhance decision-making across the enterprise.

4:15 Specimen Lifecycle Management: Overcoming Challenges to Launch Biospecimen Management Technology

Nancy DeFusco, Director, Specimen Lifecycle Management, Merck Sharp & Dohme LLC

The new platform technology provides reporting, forecasting, and real-time dashboards to support sample assessments, which will enable proactive decision-making in our clinical trials. Our deployment efforts of this platform enhanced our change management process to support uptake within the organization, improving customer service to our stakeholders in the existing system, while further enhancements are tested directly, related to the feedback provided.

4:40 Using Gen AI for Content Extraction from ICFs to Ensure Compliance for Individual Site and Country to Meet Sample Destruction Timelines

Lisa Hersh, Senior Manager, Precision Medicine, Regeneron

Anamika Sarkar, PhD, Intelligent Automation Lead, Global Development Solutions, Regeneron Pharmaceuticals, Inc.

Generative AI used to extract country and site-specific sample retention timelines from individual ICFs across sponsored clinical trials resulting in a user-friendly dashboard created to document differences in sample retention timelines and to ensure compliance with sample destruction for all subjects. Using a sample destruction countdown feature, end users can see upcoming sample expiration dates and ensure sample destruction approvals and actions are completed and documented appropriately.

5:05 FDA Regulation of LDTs: The Impact on Clinical Trials for Precision Medicine

Christine P. Bump, JD, MPH, Principal, Penn Avenue Law & Policy

In May 2024, the FDA issued a final rule amending the definition of *in vitro* diagnostic products (IVDs) to include laboratory developed tests (LDTs). This change subjects LDTs to the agency's medical device regulations, including for investigational uses and clinical trials. Many tests for biomarkers and precision medicine are LDTs. This session will explain the new requirements for laboratories and the impact on clinical trials for precision medicine.

5:25 Leveraging Digital samples in Precision medicine trials - An operational perspective

Infosys® Navigate your next

Henry Hoffman, Senior Vice President R&D at Base life science, BASE Life Science

Dr. Shibeshih Belachew, Chief Medical Officer, Indivi

From targeted treatment to precision medicine – how did clinical trials change over time.
We will cover the below aspects:
1) What are the challenges of precision trials?
2) How can digital samples be leveraged in precision medicine trials from a medical or scientific point of view?
3) What is required to utilize digital samples in precision medicine trials?
4) Wel take a quick look at the benefits of a cross-industry platform vs individual solutions

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Datacubed Health

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

H1

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

trialbee

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi

Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

PERSPECTIVES ON HOW TO OPTIMIZE BIOMARKER & BIOSPECIMEN OPERATIONS

8:50 Chairperson's Remarks

Karina Bienfait, PhD, Executive Director, Consent, Biospecimen & Imaging Management, Bristol Myers Squibb Co.

8:55 The Other Side of the Protocol: Insights from a Clinical Research Site

Suzin Webb, Site Director, Velocity Clinical Research

In the era of precision medicine, we are witnessing a significant change in how clinical trials are designed and conducted. Advances in many areas including AI, laboratory testing, sample collection, digital health, and decentralized trials are truly transforming clinical research. Research sites will likely need to work creatively, take on new technologies, and adapt standard practices. Real world challenges and solutions will be discussed from the research site's perspective.

9:25 PANEL DISCUSSION: Biospecimen Management Consortium: Driving Sample Excellence in Clinical Research

Moderator: Amy Ripston, Executive Director, Biospecimen Management Consortium

The Biospecimen Management Consortium (BMC) was founded to drive sample excellence in clinical research—by setting standards and developing best practices, streamlining biospecimen operations and data, and shaping regulatory policy. This panel of founding members will discuss the goals and objectives of the consortium, progress on its initiatives, how industry can contribute, and its roadmap for the upcoming year.

Panelists:

Karina Bienfait, PhD, Executive Director, Consent, Biospecimen & Imaging Management, Bristol Myers Squibb Co.

Briana Sargent, Associate Director, Biosample Management, Astellas

Stephanie Wylie, Senior Scientist, Sample Management, Bioanalytical and Biomarker Sciences and Technologies, Takeda Pharmaceuticals, Inc.

Mark Melton, Co-Chair, Biospecimen Management Consortium

9:55 Presentation to be Announced

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10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

LEVERAGING AI TO IMPROVE INFORMED CONSENT PROCESSES

11:20 Chairperson's Remarks

Karina Bienfait, PhD, Executive Director, Consent, Biospecimen & Imaging Management, Bristol Myers Squibb Co.

11:25 IC-Scope: Use of LLMs to Evaluate Local Consent Scope and Enable Additional Research Use of Clinical Data and Samples

Dmitri Mikhailov, PhD, Director & Global Head, Biomarker Coordination, Novartis Institutes for BioMedical Research, Inc.

Use of clinical data and sample in research may go beyond what is planned in trial protocols. To respect participants rights, additional research projects should be covered by informed consents used locally at sites. Understanding local consent changes can be a daunting task for a project team seeking to use trial data or samples. This talk describes how LLMs can be used to streamline evaluation of local consent scope changes.

11:55 Leveraging AI to Codify Informed Consent

Cristin Freeman, Head, Informed Consent Management, Bristol Myers Squibb Co.

Informed consent codification to determine permissions and restrictions to utilize biospecimens and data is a manual and time-consuming task, but essential to ensure compliance and uphold commitments to participants. To increase efficiency and speed, BMS has developed an innovative AI tool to assist in IC codification. The tool can identify relevant IC documents, scan and assess language to inform sample storage for clinical trial samples, and provide outputs for review.

12:25 pm The Role of Radiology Imaging Biomarkers in Clinical Trials segmed

Aline Lutz, PhD, Vice President, Medical Affairs, Segmed, Inc.

Imaging biomarkers are highly relevant in drug clinical trials due to their ability to provide objective, quantifiable, and usually non-invasive measures of biological processes, disease progression, and treatment response. This talk explores the role of radiology and nuclear medicine in clinical trials, highlighting their impact on patient inclusion, stratification, endpoint assessment, and their use as predictive biomarkers to evaluate treatment response.

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced VPG Greenlight

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco

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

2:35 Chairperson's Introduction

Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization

April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine

This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations

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

Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*

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

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond

Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson

Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.

Panelists:

James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine

Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.

Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.

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

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing

We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

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Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.

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THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies parexel

Speaker to be Announced, PAREXEL International

Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl

Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)

Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

BIOSPECIMEN SUPPLY-CHAIN LOGISTICS

8:20 Chairperson's Remarks

Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

8:25 Logistics Considerations in a Global Clinical & Biospecimen Supply Chain

Thomas J. McDonald, MS, Consultant—Clinical Trials, Biospecimen & Vendor Relationship Management

Data derived from our clinical trial samples is essential to primary, secondary, and exploratory endpoints. Injecting human biospecimens into the global supply chain, however, can be a harrowing proposition. Often with limited stability, temperature control considerations, and analysis being performed on a different continent, this session will compare and contrast premium and network considerations when solutioning for a global biospecimen supply chain.

8:55 Exploratory Biomarkers in Clinical Trials: Right Clinical Site, Right Lab, Right Data, Right Time, and Right Quality

Arkady Gusev, PhD, Head, Lab Excellence & Operations in Biomarker Development, Novartis Institutes for BioMedical Research, Inc.

Exploratory biomarkers enable clinical decision-making and often paves the way for precision medicine approaches in drug development. This presentation will focus on systematic approaches to biomarker (soluble, cellular, and digital endpoints) implementation in clinical trials, de-risking and ensuring biomarker deliverables and impact. Planning and feasibility process, clinical site training, CRO selections, data flow considerations, quality, and compliance standards will be presented and discussed.

9:25 Accelerating Clinical Trials with Smart Variation Management

ZS

Ankit Bajpai, Associate Principal, ZS

Changes in clinical trials due to regulatory updates, logistical hurdles, & site-specific issues, are inevitable, leading to delays & inefficiencies. Effective variation management requires tailored strategies like process automation, workflow standardization, and enhanced oversight to address these complexities. This discussion explores how these solutions help reduce variation timelines by nearly 50%, optimizing resources and ensuring efficient trial execution.

9:40 Presentation to be Announced

HEXAWARE

9:55 Tissue and Blood Biospecimen Journey: Strategies to Avoid Logistical Uncertainty

Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck

A critical part of any biomarker rich clinical trial is the ability to de-risk logistical uncertainties. From collection, processing, tracking, analysis, and storage the lifecycle of a biospecimen can be filled with potential obstacles. All of which are at times assigned or outsourced to various clinical teams, sites, CROs, third party vendors, and biorepositories. We will discuss strategies to plan, de-risk, track and set up for biospecimen success.

10:25 PANEL DISCUSSION: Where Are My Samples? Deconvoluting Biospecimen Supply Chain Logistics

Moderator: Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

The rise of diagnostics and biomarker-based medicines shifts the conversation from "Where are my results?" to "Where are my specimens?" This is especially true of cell and gene therapies, in which the specimen *is* the drug. However, trial managers, clin pharm & biomarker operations leads, cell and gene manufacturing professionals, and data managers all know that this is not an easy question to answer.

Panelists:

Christine P. Bump, JD, MPH, Principal, Penn Avenue Law & Policy

Thomas J. McDonald, MS, Consultant—Clinical Trials, Biospecimen & Vendor Relationship Management

Jarod Prince, Senior Manager, R&D Operations, Amgen, Biospecimen Strategy and Operations

11:10 Networking Coffee Break

MAKING TRIALS MORE ACCESSIBLE TO PATIENTS

11:50 Chairperson's Remarks

Rachel Wagner, VP Business Development, Business Development, Care Access

11:55 Incorporating Patient-Centric Sampling into Multicenter Clinical Trials: Output from the PCSIG Workshop

Jas Bajwa, Manager, Biosample Operations, Roche

The Patient Centric Sampling Interest Group (PCSIG) is a non-profit focused on advancing patient-centric sampling technologies for blood, plasma, urine, and other matrices to improve healthcare. A recent PCSIG workshop developed a comprehensive roadmap for implementing these technologies in decentralized clinical trials. This presentation will explore the workshop's findings, offering valuable insights for organizations aiming to adopt patient-centric sampling and accelerate progress by learning from shared experiences.

12:25 pm Learnings and Performance of a 50,000 Patient-Activated Community, Centered around Vaccine Clinical Trial Participation

HealthMatch

Manuri Gunawardena, CEO, Executive, HealthMatch

HealthMatch & Velocity Clinical Research created a 50,000 patient activated vaccine community in 2024, months in advance of any specific study launch. The community was educated, nurtured and insights gathered to ultimately shape recruitment strategy and outcomes across multiple vaccine studies at the end of 2024. The speakers will share learnings from the project including performance around randomizations and patient education and discuss how this methodology can be applied successfully to other therapeutic areas

12:55 "This Won't Work": Establishing Study Conduct at Retail Pharmacy

Adam Samson, Head Clinical Delivery Operations, Walgreens Clinical Trials

Walgreens Clinical Trials is standing up study sites at retail pharmacies across the country. Learn how these community-centered research locations are set up and how they impact the communities they're in.

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Future of Medicine: Community Health Screenings and Research Education Across America

Care Access

Jennifer Hillner, Vice President, Strategic Accounts, Care Access

Get an on-the-ground view into the Future of Medicine program and how Care Access is making advanced health screenings, research education, and study opportunities accessible to hundreds of communities across the nation and beyond.

2:00 SCOPE Summit 2025 Adjourns

Cambridge Healthtech Institute's 6th Annual

Data Technology for End-to-End Clinical Supply Management

Controlling the Complexity of Clinical Supply Chain Forecasting and Contingency Planning

FEBRUARY 3-5, 2025
All Times EST

Cambridge Healthtech Institute's 6th 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 5-6, 2025

MONDAY, FEBRUARY 3

6:30 am Golf Check-In & Breakfast Buffet *(Sponsorship Opportunities Available)*

8:00 SCOPE's 4th Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

**Limited space available. Separate registration and fee required for golf.*

9:00 Registration Open

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

PRE-CONFERENCE WORKSHOPS: IN-PERSON ONLY

12:00 – 4:00 pm WORKSHOP 1: Innovation Day with IQVIA Technologies: Hear the vision. See the products. Join the journey.

Clinical trial sponsors are invited to join digital product leaders and industry colleagues for an afternoon of discussions, demos, and networking. This interactive event has been carefully curated to help clinical trial professionals crack key challenges across the clinical trial lifecycle: from participant and site user journeys to data security and workflows. Pharmaceutical executives with various roles in clinical operations, innovation, technology, finance/budgeting, data analytics, strategic sourcing, trial managers, medical directors, or patient and site engagement will enjoy an industry panel, interactive roundtables, live demos with product experts, and more! Pre-registration is requested, and IQVIA reserves the right to decline requests that don't fall within attendee guidelines above: Learn more and register here.

1:00 – 1:45 pm WORKSHOP 2: Join and Explore ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace

Join this hands-on session with ClinEco, SCOPE's B2B clinical trial community and marketplace featuring 850+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. At SCOPE 2024 we introduced the ClinEco Commons, a collaborative space where you can access, visit, and share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco Community. This year we launch our 'Ask a ClinEco Luminary' program where members can connect directly, and discreetly, with industry leaders and receive insights on a wide range of clinical trial topics. Join now at: clineco.io/register. Open to all SCOPE attendees.

1:00 – 2:30 pm WORKSHOP 3: The Path towards Sustainable Clinical Trials: Reducing the Environmental Impact of Global Clinical Trials

INSTRUCTORS:
Michael J. Cohen, Senior Director, Lead, Environmental Sustainability, PPD/ Thermo Fisher Scientific
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Hannah Sieber, Co-Founder, CEO, Artyc
Diana Steinbuesch, BioX Operations Portfolio Lead (Oncology), Roche

While developing leading and innovative therapies, we must not lose sight of the environmental impacts and greenhouse gas emissions. We can reduce the environmental impact of our studies by prioritizing remote visits and monitoring, by reducing kit wastage, and working together to find 'greener' solutions. This workshop will provide a brief overview of research and introductory strategies for reducing emissions as well as a 'Sustainability 101' to help anyone in our industry get started towards developing more environmentally responsible clinical trials. Open to all SCOPE attendees. *Sustainable Healthcare Coalition is a Partnering Organization at SCOPE.*

1:00 – 2:30 pm WORKSHOP 4: Efficient Importation of Biological Materials into the U.S.

INSTRUCTORS:
Jessica Hammes, Branch Chief, Biological Threat Exclusion, Agriculture Safeguarding and Risk Management, Agriculture Programs and Trade Liaison, Office of Field Operations, U.S. Customs and Border Protection
Jennifer Merriman, Senior Manager, Strategic Biospecimen & Vendor Logistics, Consent, Biospecimens, & Imaging, Global Development Operations, Bristol Myers Squibb Co.
(Additional speakers to be announced.)

U.S. Customs and Border Protection and partner government agencies regulate the importation of biological materials into the United States. The efficient importation of these items can be challenging, as Clinical Trial landscape is ever-evolving. The purpose of this workshop is to discuss current challenges, best practices, and possible solutions to navigate this landscape.

2:00 – 3:30 pm WORKSHOP 5: Sponsor and Site Perspectives: Addressing Current Challenges and Exploring Future Opportunities in Clinical Trial Financing

INSTRUCTORS:
Dawn Anderson, Partner, Consulting, Deloitte LLP
Ming Shen, Managing Director, Deloitte Consulting LLP

This workshop will explore sponsor and site perspectives on current challenges and future opportunities in clinical trial financing. It will address complexities in managing trial finance including estimation, budgeting, forecasting, invoicing, payments, reconciliation and others in clinical trial management. The workshop aims to identify innovative solutions to enhance finance management in clinical trials, fostering more accurate projections. Through discussions and interactive sessions, it seeks to provide insights for future opportunities to improve clinical trial finance.

MONDAY AFTERNOON PLENARY SESSION: CONVERGING CLINICAL RESEARCH AND CARE, PATIENT PANEL & PARTICIPANT ENGAGEMENT AWARDS

3:50 Organizer's Welcome Remarks & 4th Annual Masters of Clinical Research Golf Tournament Awards

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

3:58 Chairperson's Introduction

Jenny Denney, Executive Vice President, Global Head Parexel FSP, Parexel

4:00 KEYNOTE PRESENTATION: Fast-Forward to 2035: What Success Could Look like in Converging Clinical Research and Care—And How to Get There

Janice Chang, CEO, TransCelerate Biopharma, Inc.
Mark McClellan, MD, PhD, Director, Duke-Margolis Institute for Health Policy; Former Commissioner, FDA

In 2024, we outlined our mission to converge clinical research and care for patients globally, envisioning a world where participation in research at the point of care is seamless. While our vision and work are set, the results will emerge over time. This session explores our goals for 2035, including potential achievements, defining success, and the steps required. Let's look beyond the near-term and inspire future possibilities.

4:25 Tips for Getting the Most out of SCOPE
Micah Lieberman, Executive Director, 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 3-6, 2025, at the Rosen Shingle Creek in Orlando, Florida! https://www.scopesummit.com/faq-how-to-succeed-at-scope

4:33 Chairperson's Introduction
Dana Edwards, CCO, Endpoint Clinical

4:35 INTERACTIVE KEYNOTE PANEL: What Do Real Patients Actually Talk About?
Moderator: T. Hephner, CRO, Inspire
At industry events or focus groups, we often hear "real" patients share their stories. But how representative are they of the broader patient population? Our panel of experts from top patient advocacy groups will explore what life is truly like for most patients, including those with rare and chronic diseases. Join us to learn about the challenges of disease burden, unmet needs, treatment progression, and the clinical trial experience.
Panelists:
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Emily McCormack, Social Media Director, New York Blood Center Enterprises
Fabian Sandoval, PhD, President & CEO, Emerson Clinical Research Institute
Quynh Tran, Director of Patient Activation, Cystic Fibrosis Foundation

5:05 SCOPE's 9th Annual Participant Engagement Awards Introduction *(Sponsorship Opportunity Available)*

5:10 SCOPE's 9th Annual Participant Engagement Awards
Co-Moderators:
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco
Kelly McKee, Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 9th year, the Participant Engagement Award (PEA) honors innovation in clinical trial recruitment and retention. Dedicated to the late Jerry Matczak, the inaugural 2017 recipient, the award reflects his ideals and accomplishments. SCOPE's 2025 PEA, presented by Cambridge Healthtech Institute (CHI), is now accepting submissions at: https://www.scopesummit.com/participant-engagement-award
Panelists:
Tricia Barrett, CEO, Praxis
Brian Burkhardt, Co-Founder & Executive Director, Oliver Patch Project, Inc.
Michelle Everill, Vice President, Global Trial Optimization, Alnylam Pharmaceuticals
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative
Stacy Hurt, Chief Patient Officer, Patient Engagement, Parexel International
Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity
Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie

5:45 SCOPE's Kickoff Reception: A Luau to Remember!
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, we're turning up the tropical vibes with a luau theme.
DRESS CODE: Hawaiian shirts are encouraged! Show off your brightest, boldest, most tropical attire (grass skirts optional!) Let's bring the aloha spirit to life as we kick off another amazing SCOPE conference experience. Join us to reconnect with your old friends, make some new ones, and soak up the Florida sunshine in style!

7:00 Close of Day

TUESDAY, FEBRUARY 4

6:30 am SCOPE's 5K Rise and Shine Fun Run! *(Sponsorship Opportunities Available)*
Join SCOPE's Coordinators on Tuesday, February 4 for our 5K Rise and Shine Fun Run! Don't forget to pack your sneakers.
All of us at Cambridge Healthtech Institute recognize the importance of integrating well-being and fitness into our work travel routines. We're excited to offer our support to faculty, sponsors, and attendees in fostering a culture of wellness. This is an easygoing, informal running (or walking) event. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the Rosen Hotel's front lobby near the birdcage at 6:30 am sharp!
RUN COORDINATORS:
Eileen Murphy, Conference Producer, Production, Cambridge Healthtech Institute
Steve Wimmer, Vice President of Partnerships, 1nHealth

7:30 Registration Open

7:30 Morning Coffee *(Sponsorship Opportunities Available)*
Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and some delicious treats, courtesy of our sponsors.

TUESDAY MORNING PLENARY SESSION: REDUCING CYCLE TIMES WITH "IN-HOUSE" CAPABILITIES, DATING GAME WITH PATIENTS & NEW PARADIGM OF PATIENT-LED TRIAL SPONSORS

8:25 Grab Your Seat: Early-Bird Seat Raffle & Prize Giveaway! *
(Sponsorship Opportunity Available)
*Must be present to win.

8:30 Welcome to SCOPE 2025—Who's Here and Why, What's New, Annual Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

8:40 Chairperson's Introduction
Jonathan Rowe, Principal & Head, R&D Quality Operations & Risk Management, ZS Associates, Inc.

8:42 KEYNOTE PRESENTATION: Exquisite Clinical Trial Delivery in an Ever-Changing World—Evolution and Opportunity for Sustained Performance
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
This talk covers Merck's strategy to discover, develop, and bring innovative medicines to market by pursuing key scientific opportunities and adapting to industry changes. It delves into how Merck optimizes clinical trial operations and fosters collaboration between product development, clinical sub-teams, and trial teams. Key considerations include trial planning, site selection, and protocol design, as well as Merck's decision to retain core capabilities in-house and the rationale behind it.

9:10 THE CLINICAL TRIAL DATING GAME: Beyond the Real-World Data, What Are Patients Saying? Special LIVE Episode with Studio Audience–Patient Contestants will be Announced Onsite!
Brett Kleger, CEO, Inspire
The Bachelor: Kristopher Sarajian, Vice President, Marketing, Trialbee
In today's episode of "The Clinical Trial Dating Game," our pharma bachelor seeks a volunteer for his trial, relying on data but knowing there's more to consider. How will he ask the right questions, avoid bias, and meet recruitment deadlines? With patient centricity crucial to clinical research and high stakes involved, will he find the right match? What could go wrong in this high-pressure scenario? Join us to find out!

9:20 KEYNOTE PANEL DISCUSSION: How Patients Can—and Must—Disrupt Traditional Pharma Clinical Trials
Moderator: Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
Panelists:
Deirdre BeVard, Senior Vice President, R&D Strategic Operations, CSL Behring GmbH
Nasha Fitter, Co-Founder & CEO, FOXG1 Research Foundation
Craig Martin, Founder, CEO, The Orphan Therapeutics Accelerator
Grant Mitchell, MD, Co-Founder & CEO, Every Cure
Heidi Bjornson-Pennell, Senior Program Manager, Science in Society and Lead, Rare As One Network, Chan Zuckerberg Initiative LLC

9:50 Grand Opening Coffee & Refreshment Break in the Exhibit Hall—Best of Show Voting Opens
Join us for the Grand Opening Networking Coffee break in our biggest SCOPE Exhibit Hall ever! Mingle with friends, forge new connections, and exchange ideas over your morning cup of joe. Visit exhibitors and learn about their

latest and greatest innovations and products...voting opens for our Best of Show awards so don't forget to vote.

DEVELOPING, INTEGRATING, AND OPTIMIZING RELIABLE AND FLEXIBLE IRT/RTSM SYSTEMS

11:00 Chairperson's Remarks

Nitin Jain, President & CEO, Intrinseque Health

11:05 Unlocking IRT Potential for Maximum Leverage

Alminaz Noorani, Associate Director Clinical Systems, Ultragenyx Pharmaceutical, Inc.

Unlocking IRT Potential for Maximum Leverage explores the impact of Interactive Response Technology (IRT) in clinical trials. This talk focuses on how IRT can streamline the trial, enhance data accuracy, and improve patient management. Share insights into leveraging IRT systems for more efficient data collection, real-time monitoring, and adaptive trial designs, ultimately boosting trial efficacy and accelerating the path to critical therapeutic discoveries.

11:35 Connecting Teams and Promoting Collaboration around IRT

Dawn Sorenson, Director, IRT Center of Excellence, Innovation Management, CSP & O, Daiichi Sankyo, Inc.

This presentation aims to empower teams at any stage of their Interactive Response Technology (IRT) journey by sharing effective strategies for enhancing collaboration. Attendees will learn practical tips for establishing global IRT standards, fostering alignment among study teams, and optimizing partnerships with internal and external collaborators. By promoting a culture of connectivity, the session will equip participants with the tools needed to streamline communication and enhance overall project success.

12:05 pm Automating Invoice Reconciliation for Clinical Trial Material Distribution

Anamika Sarkar, PhD, Intelligent Automation Lead, Global Development Solutions, Regeneron Pharmaceuticals, Inc.

Kyle Skillins, Associate Director, Clinical Drug Supply & Logistics, Regeneron Pharmaceuticals, Inc.

Daniel Truxler, Associate Director, Clinical Supply Systems, Regeneron Pharmaceuticals, Inc.

The Clinical Drug Supply and Logistics group at Regeneron faced significant challenges in reconciling a high volume of vendor invoices (3000-5000 per year) for distribution of clinical supply materials, which required significant manual effort. Regeneron has developed automation of reconciliation tasks, integrated with Clinical Supply information stored in IRT (Interactive Response Technology) using RPA (Robotic Process Automation) and AI (Artificial Intelligence) to bring efficiency in clinical trial financial compliance.

12:35 Bridging the Gap: How Consistent Data Integrations Improve the End-to-End Experience ORACLE

Sean Roy, Ph.D., Sr Director of Consulting, Life Sciences, Oracle

Luke Basta, Assoc Dir Clinical Data Mgmt, IRT & COA Svcs, Merck & Co Inc

Claire Rivera, M.S., Dir Delivery Mgmt, Delivery Mgmt, Merck & Co Inc

Consistent data integrations streamline clinical trial processes, enhancing efficiency and accuracy in data collection and analysis, ultimately benefiting patient outcomes. This session will also provide practical strategies for overcoming common data integration challenges, fostering collaboration among stakeholders, and ultimately improving patient outcomes.

Key Learning Objectives:

• Assess and identify gaps in existing clinical trial data integration systems to improve efficiency and accuracy

• Understand the importance of collaboration between IT, clinical, and operational teams

• Learn strategies to align objectives and streamline the data integration process to improve patient outcomes

1:05 Enhancing Clinical Supply and Logistics to Advance Patient-Centric Care and DEI in Clinical Trials MYONEX

Samit Bhatt, Vice President, Clinical Trial Patient Solutions, Myonex, Inc.

Clinical trials are critical to advancing medical innovation and improving patient outcomes. Attendees will gain insights into optimizing supply chain and logistics to improve the patient experience, emphasizing patient-centric approaches that align with the goals of DEI.

1:35 Sponsored Networking Luncheon

Take this opportunity to refresh and refuel and network, compliments of SCOPE sponsors! Take a well-deserved break outdoors in the sun, or indoors in the air conditioning.

2:35 Networking Coffee & Dessert Break in the Exhibit Hall AMR Metalographi

SCOPE's hall this year is bigger than ever; there's no way to cover it all in just one break. So, after lunch, grab some dessert and a cup of coffee and visit all those booths that you just couldn't make it to this morning. Stay to hear our Best of Show Winner announcement and congratulate the winner!

THE CRITICAL ROLE OF COLLABORATION AND COMMUNICATION IN CLINICAL SUPPLIES MANAGEMENT

3:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

3:25 Partnering with Internal Stakeholders and Vendors

Luis Vargas, IRT Manager, Global Clinical Drug Supply, Genmab US, Inc.

In today's dynamic organizational landscape, the ability to effectively partner with internal stakeholders and vendors is paramount to achieving organizational success. This discussion delves into the critical aspects of forming and nurturing these strategic alliances, providing insights and strategies to enhance collaboration, communication, and mutual benefit.

3:55 From Insight to Excellence: Leveraging Deep Domain Knowledge, Operational Leadership, and Clinical Supplies Expertise for Strategic Trial Success MEDIDATA

Stephanie Russell, Senior Director RTSM Solution Services, Professional Services, Medidata, a Dassault Systemes Co.

This session will explore how deep industry expertise and operational leadership can transform clinical trial design and execution, ensuring strategic success. By leveraging adaptive approaches and real world experiences, it highlights how expert-led teams collaborate with study teams to overcome challenges, optimize outcomes and maintain trial integrity.

Key Learnings:

• The importance of aligning trial design to anticipate and address challenges proactively.

• How experienced teams help sponsors avoid common pitfalls, such as randomization errors, to ensure trial success.

• Insights into navigating complex scenarios like First-In-Human (FIH) trials with expert-driven risk management.

• The role of operational excellence in maintaining data integrity and trial credibility.

4:25 To Outsource or Not to Outsource, That Is the Question

Lisamarie Georgen, Senior Director Clinical Supplies Operations, MacroGenics, Inc.

Should you outsource Clinical Supplies Management? Should you keep Clinical Supplies Management in-house? Come join this presentation as we dive into the debate of outsourcing Clinical Supplies Management and discuss the pros and cons of each scenario.

4:55 Clinical Sample Logistics Best Practices resonant

Genoa Garcia, Senior Business Development Manager, US Clinical Services, Avantor

Looking at supply-chain logistics options for emerging biopharma. Focusing on sample-collection kit design to sample logistics to help with process efficiency and minimize sample risk and spending.

5:25 PAIN POINTS PANEL: Peer-to-Peer Resolutions

Moderator: Lisamarie Georgen, Senior Director Clinical Supplies Operations, MacroGenics, Inc.

Clinical Supplies serves as the crucial link between numerous stakeholders, both internal and external. As clinical trials become increasingly complex, the pressure to deliver rapidly and efficiently intensifies. Consequently, Clinical Supplies teams are expected to be highly flexible and responsive. This session will delve into strategies for enhancing collaboration between Clinical Supplies and key partners, including Clinical Operations/Clinical Program teams, CMC/Manufacturing Teams, Vendors/CMOs, CDMOs, and IRT/RTSM developers.

Panelists:

Pablo Caiceo, Director, Global Clinical Supplies, PPD Clinical Research Services, Thermo Fisher Scientific Inc

Mia Carter, Senior Manager, Product Delivery IRT & CSM, ICON Clinical Research LLC

Barbara Versage, Senior Manager, Supply Chain Sourcing, Immunocore LLC

5:55 Welcome Reception in the Exhibit Hall *(Sponsorship Opportunities Available)*

Wind down at the end of a busy session day with colleagues and old and new friends. Networking is always in full swing at this reception, so raise a glass with your favorite exhibitors and take a chance at winning one of our fabulous raffle prizes (must be present to win). Continue your networking over dinner at one of the Rosen Shingle Creek's fine dining or casual restaurants and eliminate the need to face Orlando traffic.

7:15 Close of Day

7:15 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 7:00pm-11:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 5

7:45 am Registration Open

BREAKFAST PRESENTATIONS

8:15 BREAKFAST PRESENTATION OPTION #1: Digital Innovation's Role in Pediatric and Elderly Clinical Trials

Kyle Hogan, CEO, Datacubed Health

This presentation examines how targeted digital tools improve retention rates among pediatric and elderly participants. Our pediatric focus reveals how gamification can create meaningful connections and enhance the trial experience while engaging caregivers. For elderly participants, we examine the use of accessible interfaces and remote monitoring solutions to address age-specific challenges. Attendees will discover strategies for implementing these solutions within their research programs.

8:15 BREAKFAST PRESENTATION OPTION #2: Expanding the Patient Universe: Transforming Clinical Trials through Inclusive, Data-Driven Design

Christopher Riley, Director, Strategic Insights, Solutions, H1

In today's complex clinical research landscape, achieving patient-centricity and inclusivity is more critical than ever. This presentation introduces Patient Universe, a groundbreaking solution designed to optimize trial feasibility while addressing health equity challenges. Attendees will learn how leveraging real-world health equity data can transform patient recruitment strategies, create inclusive trial designs, and improve participant engagement. Through actionable insights and use cases, this session will demonstrate how advanced analytics and innovative technologies can bridge gaps in representation, support diversity action planning and enhance trial outcomes.

8:15 BREAKFAST PRESENTATION OPTION #3: Scaling Success: How Sanofi and Trialbee Drive Patient-centric Recruitment and Reduce Site Burden in Global Asthma Programs

Whitley Albright, Clinical Innovation and Operations Strategy Lead, Sanofi
Gaynor Anders, Chief Delivery Officer, Trialbee

Join Whitley Albright (Sanofi) and Gaynor Anders (Trialbee) to discuss how to keep patients at the center of focus while reducing site burden in a complex global asthma program by: connecting patients to the right trials with targeted outreach and a highly efficient global process; pre-qualifying all patients with live medical secondary screening to reduce the volume sent to sites, improve trust, and increase referral-to-consent ratio; keeping disqualified patients ready to enroll with program-level rematching; centralizing activity in a Patient Recruitment Platform (PRP) to manage progress, evaluate site performance, and measure campaign ROI; building a collaborative, supportive, and meaningful relationship.
Learn how these organizations are scaling recruitment success globally while achieving diversity and inclusion goals, reducing site burden, and keeping patients at the center of care.

8:45 Transition to Sessions

LEVERAGING DATA TO SUPPORT UNIQUE CLINICAL SUPPLY CHAINS

8:50 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:55 Sponsored Presentation *(Opportunity Available)*

9:25 Cell Therapy Patient Operations: Enhancing Customer Experience Through Data-Driven Support

Michael Mehler, Director, Cell Therapy Operations, AstraZeneca

In cell-and-gene therapy, the vein-to-vein process involves multiple teams and touchpoints, requiring seamless coordination and robust data collection and analysis to ensure efficiency and patient success. Manufacturers must provide consistent support throughout the entire journey, from apheresis to infusion, to ensure therapies are delivered on time. By combining high-touch operational support with data-driven insights, manufacturers can create a positive patient experience while improving the efficiency and reliability of cell-therapy delivery.

9:55 Mitigating Risk and Complexity in Cell & Gene Therapy Trials with IRT

Cara Woodruff, Director, Product Management, IT Design & Development, Clinical Technologies, IQVIA Technologies

Cell and Gene Therapies (CGT) promise critical and transformative benefits to patients. However, even with record funding and new launches in this sector, trial and patient journey complexities pose significant barriers to the success and sustainability of these treatments. CGT pioneers require supply chain partnerships that deliver experience in mitigating trial risk and complexity, along with a consultative approach to protocol execution. Let's explore how to succeed by optimizing pre-trial and pre-screening activities and reducing trial cost and risk with your IRT solution.

10:25 Coffee Break in the Exhibit Hall

SCOPE is ALL about networking—with clients, colleagues, sponsors and exhibitors. Take this chance to visit booths you haven't been to, build new relationships, and fuel up with coffee for the rest of the busy day ahead. Last chance to vote for the Best of Show award! Make your vote count!

10:45 Special Book Signing

Fundamentals of Decentralized Clinical Trials
Editors: *Isaac R. Rodriguez-Chavez & Anna Yang*
Location: Gatlin Foyer, ClinEco Booth #1

BUILDING THE SUPPLY INFRASTRUCTURE FOR CELL AND GENE THERAPIES

11:20 Chairperson's Remarks *(Sponsorship Opportunity Available)*

11:25 Ensuring Precision and Safety: Vein-to-Vein Tracking in Cell and Gene Therapy

Christine M. Fernandez, Consultant, Cell & Gene Therapy

Tracking cell and gene therapy (CGT) products from vein-to-vein is crucial to ensure their safety, efficacy, and regulatory compliance. Proper storage conditions and specialized containers are used to preserve cell products, with real-time tracking during transit to ensure timely and safe delivery to clinical sites. These advanced tracking technologies enhance accuracy and data integration, facilitating seamless information flow or the successful delivery of CGT products.

11:55 Innovative Strategies for a More Robust (Yet Adaptable, Accessible, and Cost-Effective) Global Advanced Therapies Supply Chain

Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America

Cell therapies require unique and complex starting material, production, and affordability supply chain challenges. This presentation will discuss innovative strategies being tested and employed to optimise the production and delivery of these therapies to patients in community settings—outside of large urban research centers—across the globe.

12:25 pm PANEL DISCUSSION: Scaling CGT: Cracking the Supply Chain Code

Moderator: Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America

The cell and gene therapy (CGT) supply chain presents distinct challenges that require specialized strategies. As demand for CGT continues to grow, scaling production while ensuring product integrity and quality is paramount. Success depends on maintaining cell viability and functionality throughout the process. This panel will focus on practical solutions for overcoming scaling obstacles, preserving product integrity, and fostering collaboration among stakeholders—spanning from patient to manufacturing and back.

Panelists:

Christine M. Fernandez, Consultant, Cell & Gene Therapy
Michael Mehler, Director, Cell Therapy Operations, AstraZeneca
Cara Woodruff, Director, Product Management, IT Design & Development, Clinical Technologies, IQVIA Technologies

12:55 Sponsored Networking Luncheon

Once again, join us for lunch, courtesy of our generous sponsors.

1:55 Networking Coffee & Dessert Break in the Exhibit Hall—Best of Show Winner Announced

SCOPE's Networking Coffee and Dessert Break is the perfect time to pick up a sweet treat, courtesy of our sponsors, and fuel up for the afternoon with a cup of coffee or soft drink. Visit our Game Card Sponsors to fill your Game Card with stickers and get in a little more networking time before afternoon sessions!

WEDNESDAY AFTERNOON PLENARY SESSION: FOSTERING INNOVATION IN PHARMA R&D, LEVERAGING DIGITAL TOOLS WITHOUT LOSING YOUR MIND & UNLEASHING GenAI FOR TRIALS

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

2:35 Chairperson's Introduction
Brad Stefanovic, PhD, Head Clinical Innovation, Pro-ficiency, a Simulations Plus Company

2:37 KEYNOTE PRESENTATION: Fostering Clinical Innovation in a Large Pharmaceutical Organization
April Lewis, Head, Innovative Health, Global Development, Johnson & Johnson Innovative Medicine
This presentation outlines strategies for fostering innovation in a large pharmaceutical organization, focusing on four areas: creating a clear mandate and vision, building an infrastructure that supports creativity, empowering a diverse, high-performance team, and promoting patient-centric, sponsor-agnostic innovation. By aligning these elements, the organization can establish a sustainable ecosystem that prioritizes patient outcomes and drives healthcare breakthroughs.

3:00 KEYNOTE PRESENTATION: Harnessing Tech & AI for Quality and Performance in Clinical Trial Operations
Angela DeLuca, Associate Vice President, Global Study Operations, Amgen
Sponsors can leverage increasing technology capabilities to enhance quality by integrating advanced data analytics, AI, and automation into their drug development and manufacturing processes. These technologies enable real-time monitoring, predictive analytics, and streamlined workflows, ensuring higher precision and consistency in product quality. Additionally, digital tools facilitate better compliance with regulatory standards and more efficient management of clinical trials, ultimately accelerating time-to-market while maintaining rigorous quality standards.

3:20 SCOPE Award Winners & Announcements *(Sponsorship Opportunities Available)*
Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

3:25 Chairperson's Introduction *(Sponsorship Opportunity Available)*

3:30 KEYNOTE PANEL DISCUSSION: The Unleashing of Gen AI: Revolutionizing Healthcare and Beyond
Moderator: Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson
Gen AI, integrating artificial intelligence into daily life, has transformative potential in healthcare and pharmaceuticals. It demands careful consideration of ethics, biases, and social impacts while focusing on real-world benefits. By leveraging advanced AI, Gen AI enables personalized medicine, improves patient care, and streamlines processes. Explore the value-driven use cases and groundbreaking opportunities this technology offers for revolutionizing healthcare.
Panelists:
James Gallagher, Senior Director, Innovative Health, Johnson & Johnson Innovative Medicine
Andrew Lee, Senior Vice President & Head, Global Clinical Trial Operations, Merck & Co.
Brian Martin, Chief AI Product Owner, BTS; Head of AI, R&D Information Research; Senior Research Fellow, AbbVie, Inc.
Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.

4:00 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorships Available) Last Chance for Exhibit Viewing
We know you're tired, we know the Exhibit Hall is huge, and we know you still have some booths to visit, some connections to make, some networking to do. SCOPE's Networking Booth Crawl is the time to do it! Crawl if you must, but be sure to visit our sponsored booths for some food, drinks, and enough energy to finish SCOPE strong! Our final Networking Exhibit Hall break is the final time to see the exhibits you haven't seen and meet the people you haven't yet met. The break ends with another amazing raffle prize, so be sure to get your Game Cards in and the lucky winner (must be present to win) could be you!

5:00 Close of Day

5:00 Evening Courtesy Shuttles to Pointe Orlando *(Sponsorship Opportunities Available)*
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop from 5:00pm-9:00pm (last pick up 30 minutes before end time) between Rosen Shingle Creek, Rosen Plaza, Residence Inn Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 6

7:15 am Registration Open

BREAKFAST PRESENTATION

7:45 BREAKFAST PRESENTATION: What Sites Really Need to Deliver Successful Patient Engagement Strategies
Speaker to be Announced, PAREXEL International
Leslie Ives, Senior Director, Patient Recruitment, Patient Strategy and Insights, Parexel Intl
Jimmy Betchel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)
Sites have shared that delivering successful patient recruitment is arguably one of the most persistent challenges they face. Despite this being well-known, not enough of the right support is provided to them, causing more than half of sites to pay out of pocket for unreimbursed recruitment expenses, all while the one-size-fits-all recruitment materials provided to them collect dust. By rethinking how we support sites in their patient engagement activities, sponsors and CROs can shift the paradigm to make patient enrollment delays and declining retention rates outliers, instead of the norm. This breakfast session will discuss strategies to transform patient engagement by leveraging site experience, incorporating patient insights and motivations, as well as AI solutions, to improve patient retention and deliver better study outcomes.

8:15 Transition to Sessions

BIOSPECIMEN SUPPLY-CHAIN LOGISTICS

8:20 Chairperson's Remarks
Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

8:25 Logistics Considerations in a Global Clinical & Biospecimen Supply Chain
Thomas J. McDonald, MS, Consultant—Clinical Trials, Biospecimen & Vendor Relationship Management
Data derived from our clinical trial samples is essential to primary, secondary, and exploratory endpoints. Injecting human biospecimens into the global supply chain, however, can be a harrowing proposition. Often with limited stability, temperature control considerations, and analysis being performed on a different continent, this session will compare and contrast premium and network considerations when solutioning for a global biospecimen supply chain.

8:55 Exploratory Biomarkers in Clinical Trials: Right Clinical Site, Right Lab, Right Data, Right Time, and Right Quality
Arkady Gusev, PhD, Head, Lab Excellence & Operations in Biomarker Development, Novartis Institutes for BioMedical Research, Inc.
Exploratory biomarkers enable clinical decision-making and often paves the way for precision medicine approaches in drug development. This presentation will focus on systematic approaches to biomarker (soluble, cellular, and digital endpoints) implementation in clinical trials, de-risking and ensuring biomarker deliverables and impact. Planning and feasibility process, clinical site training, CRO selections, data flow considerations, quality, and compliance standards will be presented and discussed.

9:25 Accelerating Clinical Trials with Smart Variation Management
Ankit Bajpai, Associate Principal, ZS
Changes in clinical trials due to regulatory updates, logistical hurdles, & site-specific issues, are inevitable, leading to delays & inefficiencies. Effective variation management requires tailored strategies like process automation, workflow standardization, and enhanced oversight to address these complexities. This discussion explores how these solutions help reduce variation timelines by nearly 50%, optimizing resources and ensuring efficient trial execution.

9:40 Presentation to be Announced

9:55 Tissue and Blood Biospecimen Journey: Strategies to Avoid Logistical Uncertainty

Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck

A critical part of any biomarker rich clinical trial is the ability to de-risk logistical uncertainties. From collection, processing, tracking, analysis, and storage the lifecycle of a biospecimen can be filled with potential obstacles. All of which are at times assigned or outsourced to various clinical teams, sites, CROs, third party vendors, and biorepositories. We will discuss strategies to plan, de-risk, track and set up for biospecimen success.

10:25 PANEL DISCUSSION: Where Are My Samples? Deconvoluting Biospecimen Supply Chain Logistics

Moderator: Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

The rise of diagnostics and biomarker-based medicines shifts the conversation from "Where are my results?" to "Where are my specimens?" This is especially true of cell and gene therapies, in which the specimen *is* the drug. However, trial managers, clin pharm & biomarker operations leads, cell and gene manufacturing professionals, and data managers all know that this is not an easy question to answer.

Panelists:

Christine P. Bump, JD, MPH, Principal, Penn Avenue Law & Policy

Thomas J. McDonald, MS, Consultant—Clinical Trials, Biospecimen & Vendor Relationship Management

Jarod Prince, Senior Manager, R&D Operations, Amgen, Biospecimen Strategy and Operations

11:10 Networking Coffee Break

MAKING TRIALS MORE ACCESSIBLE TO PATIENTS

11:50 Chairperson's Remarks

Rachel Wagner, VP Business Development, Business Development, Care Access

11:55 Incorporating Patient-Centric Sampling into Multicenter Clinical Trials: Output from the PCSIG Workshop

Jas Bajwa, Manager, Biosample Operations, Roche

The Patient Centric Sampling Interest Group (PCSIG) is a non-profit focused on advancing patient-centric sampling technologies for blood, plasma, urine, and other matrices to improve healthcare. A recent PCSIG workshop developed a comprehensive roadmap for implementing these technologies in decentralized clinical trials. This presentation will explore the workshop's findings, offering valuable insights for organizations aiming to adopt patient-centric sampling and accelerate progress by learning from shared experiences.

12:25 pm Learnings and Performance of a 50,000 Patient-Activated Community, Centered around Vaccine Clinical Trial Participation

Manuri Gunawardena, CEO, Executive, HealthMatch

HealthMatch & Velocity Clinical Research created a 50,000 patient activated vaccine community in 2024, months in advance of any specific study launch. The community was educated, nurtured and insights gathered to ultimately shape recruitment strategy and outcomes across multiple vaccine studies at the end of 2024. The speakers will share learnings from the project including performance around randomizations and patient education and discuss how this methodology can be applied successfully to other therapeutic areas

12:55 "This Won't Work": Establishing Study Conduct at Retail Pharmacy

Adam Samson, Head Clinical Delivery Operations, Walgreens Clinical Trials

Walgreens Clinical Trials is standing up study sites at retail pharmacies across the country. Learn how these community-centered research locations are set up and how they impact the communities they're in.

1:25 Transition to Lunch

1:30 LUNCHEON PRESENTATION: Future of Medicine: Community Health Screenings and Research Education Across America

Jennifer Hillner, Vice President, Strategic Accounts, Care Access

Get an on-the-ground view into the Future of Medicine program and how Care Access is making advanced health screenings, research education, and study opportunities accessible to hundreds of communities across the nation and beyond.

2:00 SCOPE Summit 2025 Adjourns

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CLINICAL TRIAL
VENTURE, INNOVATION & PARTNERING

Accelerating Innovation, Accessibility and Scale

February 4-5, 2025 | Rosen Shingle Creek | **Orlando, FL** | **In-Person**

Join us for the 3rd annual exclusive gathering of senior-level investors, corporate executives, entrepreneurs, and start-up leaders from the clinical trials space.

SCOPE Summit's **Clinical Trial Venture, Innovation & Partnering Conference** takes place February 4-5, 2025, in Orlando, FL. This premier boutique conference runs in parallel with the *16th Annual* **SCOPE Summit (Summit for Clinical Ops Executives).** The *3rd Annual* Clinical Trial Venture, Innovation & Partnering Conference brings together senior-level investors, corporate executives, entrepreneurs, and start-up leaders from the clinical trials space. This high-level event consists of thought-provoking, industry-led panels, fireside chats, and numerous networking opportunities for CEOs, investors, and potential acquirers to foster meaningful connections. You are invited to join us at this conference, focused on venture and innovation, to acquire valuable strategic insights, honest perspectives, and practical business recommendations for collaboration and investment. Additionally, you will have the opportunity to explore the exhibit hall and connect with both emerging and established companies in this field, enabling you to grasp the direction the industry is heading.

Meet Our Co-Chairs

Jessica J. Federer
Board Member
Angelini Ventures

Sunny Kumar
Partner
GSR Ventures

Rana Lonnen
Managing Director
Novartis

Learn more at SCOPEsummit.com/partnering

9th Annual

PARTICIPANT ENGAGEMENT AWARD

SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

IN MEMORY OF JERRY MATCZAK
#BELIKEJERRY #SCOPEsummit

Monday, February 3, 2025

WHAT IS IT?

Now in its 9th 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 2025 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 the ability to improve access, awareness, and participation in clinical trials; creativity, innovation, and regulatory and legal compliance; and the ability to improve diversity, equity, and inclusion. Awards will be given for 1st through 3rd place with special recognition for all presenters.
- Finalists will be invited to submit a 3-minute video showcasing their work which will be promoted prior to SCOPE.
- Discussion and judging will occur LIVE in-person at SCOPE during the opening plenary session taking place February 3-6, 2025, in Orlando, Florida. This exciting competition will bring awareness to you and your company for excellent and engaging work.

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.

Deadline for submissions: November 15, 2024

EVENT HOSTS & JUDGES

David Sall
President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award

Kelly McKee
Head of Innovative Patient Recruitment, Evinova; Co-Creator of the SCOPE Participant Engagement Award

Micah Lieberman
Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

Tricia Barrett
CEO, Praxis

Brian Burkhardt
Co-Founder & Executive Director, Oliver Patch Project, Inc.

Michelle Everill
CEO, Action from Data

Gretchen Goller
Senior Director, Head of Patient Recruitment, Clinical Development Operations, Seagen

Jen Horonjeff, PhD
Founder & CEO, Savvy Cooperative

Stacy Hurt
Patient Advocacy Ambassador, Patient Engagement, Parexel International

Otis Johnson, PhD, MPA
Principal Consultant, Trial Equity

Kim Ribeiro
Head, Diversity and Patient Inclusion, AbbVie

Learn more at: SCOPEsummit.com/participant-engagement-award

2nd Annual

SITE INNOVATION AWARD

SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

Tuesday, February 4, 2025 | 4:55 pm

WHAT IS IT?

We are excited to announce our 2nd 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.

Deadline for submissions: November 15, 2024

EVENT HOSTS & JUDGES

Irfan Kahn
CEO, Circuit Clinical

Amanda Wright
Co-Founder & COO, Javara

Jill Johnston
Chief Innovation Officer, WCG

Katherine Broecker
Senior Director, Design Hub Data Insights, Eli Lilly & Co.

Manny Lazaro
former Senior Vice President, Clinical Operations & Data Management, Cerevel Therapeutics SCRS

Michele Teufel
Site Management & Monitoring Therapy Area Strategy & Portfolio Delivery, Development Operations, AstraZeneca Pharmaceuticals, Inc.

Sean Soth
Senior Vice President, Strategy and Global Business Partnerships, SCRS

Learn more at: SCOPEsummit.com/site-innovation-award

SUMMIT FOR CLINICAL OPS EXECUTIVES

BEST of SHOW AWARD 2025

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 innovative applications, technologies, and tools, to solutions. 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 their 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, 2025

Learn more at: SCOPEsummit.com/best-of-show-awards

CONFERENCE VENUE & HOTEL

ROSEN SHINGLE CREEK

9939 Universal Boulevard
Orlando, FL 32819

Discounted Room Rate: $265 s/d

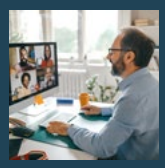
Discounted Room Rate Cut-Off Date:
January 1, 2025

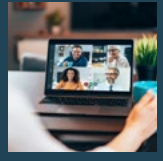
For hotel reservations please go to the Travel Page of **SCOPEsummit.com »**

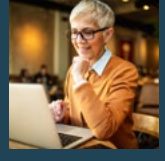
Can't Make it to Florida?

Join via our Robust Virtual Platform:

- INTUITIVE INTERFACE
- LIVE CHAT
- RECORDED SESSIONS
- COMPANY BRANDING
- LIVE SESSIONS
- DOWNLOADS







2025 EVENT HIGHLIGHTS

GOLF TOURNAMENT

Connect with your peers and colleagues at SCOPE's 4th Annual Masters of Clinical Research Golf Tournament, starting at 8:00am on Monday, February 3. Opportunities are available for those who would like to golf or attend. If you would like to sponsor the event, please refer to the packages below and contact our sales managers.

Interested in taking part in the 4th Annual Golf Tournament? For complete event information, including registration* details, visit the website.

Masters of Clinical Research
SCOPE's 4th Annual Golf Tournament

February 3 at 8:00 am

*Limited space available. Separate registration and fee required for Golf.

SCOPEsummit.com/sponsor-exhibitor/masters-of-clinical-research

(A portion of your green fee will be donated to "Cure SMA" Spinal Muscular Atrophy. The donated portion will also be matched by SCOPE Summit 2025)

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.

Bayer, moderna, Novo Nordisk Pharmatech A/S, Novo Nordisk, Novartis Molecular Diagnostics, Fresenius, CSPC, endo, Sumitomo Dainippon Pharma, gsk, Aurobindo, Organon, Regeneron, SPHBio Shanghai Pharma Biotherapeutics USA Inc, Menarini group, Roche, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Sanofi, Merck KGaA Darmstadt, Germany, Sun Pharma, Stada, Bristol-Myers Squibb, Lilly, Vertex, 中國生物製藥有限公司 Sino Biopharmaceutical Limited, Boehringer Ingelheim, Servier, Amgen, astellas, ucb, Merck Inventing for Life, Ipsen Innovation for patient care, Grifols, Daiichi-Sankyo, Pfizer, Alexion, Gilead, Viatris, CSL, abbvie, Takeda, Otsuka, Eisai, Bausch Health, biogen idec., Kyowa Kirin, Jazz Pharmaceuticals, teva, AstraZeneca, Abbott, Hengrui

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
iquigley@healthtech.com

Companies F-J

Katelin Fitzgerald
Sr. Manager, Business Development
(+1) 781-247-1824
kfitzgerald@cambridgeinnovationinstitute.com

Companies K-T

Jon Stroup
Lead Business Development Manager
(+1) 781-972-5483
jons@healthtech.com

Companies U-Z

Patty Rose
Vice President, Sales
(+1) 781-972-1349
prose@healthtech.com

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

Ilana Quigley
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(+1) 781-972-5457
iquigley@healthtech.com

Companies F-J

Katelin Fitzgerald
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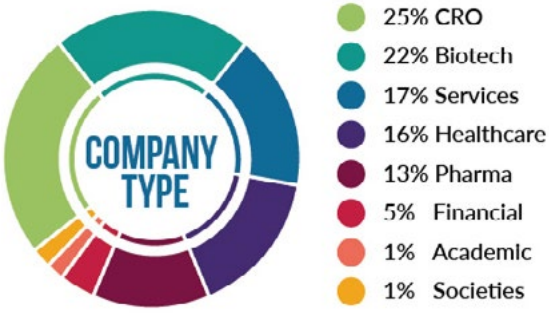
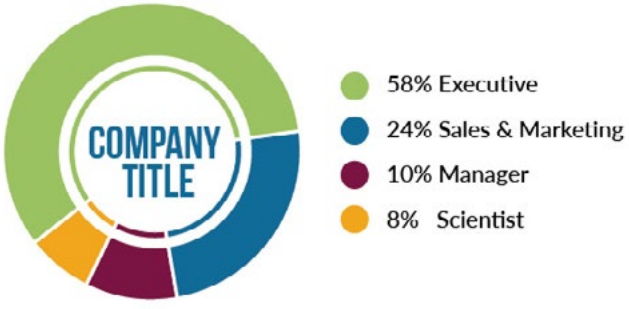
2024 ATTENDEE DEMOGRAPHICS





REGISTRATION

16th Annual SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

February 3-6, 2025
Orlando, Florida

INDIVIDUAL EVENT PRICING

Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Monday, February 3 access to the following:

- *Evening Kickoff Plenary Keynote and 9th Annual Participant Engagement Awards*
- *SCOPE's Kickoff Reception*

In addition, you will receive on-demand access to all presentations for one year.

If you wish to participate in SCOPE's Fourth Annual Masters of Clinical Research Golf Tournament, see the website registration page for further details (Separate registration required to golf, limited space available)

	Pharma-Biotech-Med Device	CRO-Vendor-Tech Consultancy-Services Provider	VC/Investment Firm, Academic-Government-Site-Hospital
Advance Registration Discount until January 17, 2025	$2999	$2949	$1599
Standard Registration after January 3, 2025 and Onsite	$3099	$3199	$1699

GROUP EVENT PRICING

Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Monday, February 3 access to the following:

- *Evening Kickoff Plenary Keynote and 9th Annual Participant Engagement Awards*
- *SCOPE's Kickoff Reception*

In addition, you will receive on-demand access to all presentations for one year.

If you wish to participate in SCOPE's Fourth Annual Masters of Clinical Research Golf Tournament, see the website registration page for further details (Separate registration required to golf, limited space available)

Advance Registration Discount until January 17, 2025	$2249	$2199	$1199
Standard Registration after January 5, 2025 and Onsite	$2299	$2399	$1299

ON-DEMAND CONFERENCE PRICING

For those who cannot attend SCOPE on February 3-6, 2025, 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	$2399	$2549	$1199

STAY ON AFTER SCOPE AND ATTEND THE FOLLOWING TRAINING SEMINAR

Risk-Based Quality Management for Clinical Trials: Implementing ICH E6 R3 Requirements
February 6-7, 2025 (IN-PERSON ONLY)

BARNETT INTERNATIONAL

Option 1: I have registered for SCOPE and wish to also attend this Training Seminar - $895

Option 2: I have not registered for SCOPE, but wish to attend this Training Seminar - $1,495

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.

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!