NETWORK WITH 2,000+ INTERNATIONAL CLINICAL OPS SPECIALISTS

FEBRUARY 3-6, 2025

CLINICAL SUPPLY & LOGISTICS

Managing the Supply Chain and Maintaining Resiliency in a Complex Ecosystem

REGISTER EARLY FOR MAXIMUM SAVINGS!

TOPICS INCLUDE:

PRE-CONFERENCE WORKSHOP *(In-Person Only)*

- Efficient Importation of Biological Materials into the U.S.

DATA TECHNOLOGY FOR END-TO-END CLINICAL SUPPLY MANAGEMENT

- Developing, Integrating, and Optimizing Reliable and Flexible IRT/RTSM Systems
- The Critical Role of Collaboration and Communication in Clinical Supplies Management

CLINICAL SUPPLY CHAIN STRATEGIES TO ALIGN PROCESS, PRODUCTS AND PATIENTS

- Building the Supply Infrastructure for Cell and Gene Therapies
- Biospecimen Supply-Chain Logistics
- Transformative Sampling Technologies to Reduce Patient Burden and Reach Broader Populations

Signature Sponsors

ADVARRA · Care Access · HealthMatch · IQVIA TECHNOLOGIES · KPS LIFE · MEDIDATA · parexel · SUBJECTwell · wcg · YPrime · ZS

PART OF:

16th Annual

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

Rosen Shingle Creek • Orlando, FL

IN-PERSON + VIRTUAL

Organized by Cambridge Healthtech Institute

SCOPEsummit.com/Clinical-Supply-Management

CLINICAL SUPPLY & LOGISTICS

FEBRUARY 3-6, 2025
All Times EST

Patient-centric clinical trials rely on efficient, streamlined supply chain processes to ensure investigational drugs are delivered to the right patient, at the right time, and in the right place. **SCOPE's 8th Annual Clinical Supply & Logistics** stream presents case studies and best practices that highlight the pivotal role of supply chain management in navigating the complexities of modern clinical trials. The **6th Annual Data Technology for End-to-End Clinical Supply Management** conference explores how digitalization is transforming relationships across the clinical trial supply chain ecosystem. By integrating insights from multiple data sources, organizations can enhance data quality and volume, leading to more accurate forecasting, improved efficiency, and significant time and cost savings. The **8th Annual Clinical Supply Management to Align Process, Products, and Patients** conference focuses on the critical role of patients and their biospecimens, gathering supply chain logistics experts who are constantly challenged to innovate and make swift, effective decisions. Discover strategies to optimize supply planning, gain actionable insights, implement cutting-edge tools, and ultimately, ensure the best outcomes for patients.

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
florence woodley TRIAL SOLUTIONS
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 Metalographic
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
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

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

PLENARY KEYNOTE PRESENTATIONS

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 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.

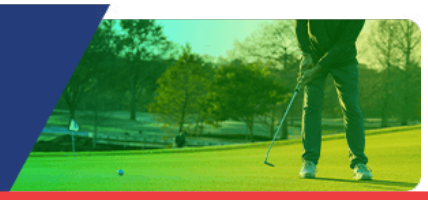
7:00 pm **Close of Day**

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)*	

SCOPE's 4th Annual
Golf Tournament

Masters of Clinical Research



February 3 at 8:00 am

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, contact our sales managers Ilana Quigley, Katelin Fitzgerald, Jon Stroup and Patty Rose.

SCOPEsummit.com/sponsor-exhibitor/masters-of-clinical-research

Interested in taking part in the 4th Annual Golf Tournament? For complete event information, including registration details visit the website.*

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

2025 SPONSORS

SIGNATURE SPONSORS

ADVARRA · Care Access · HealthMatch · IQVIA TECHNOLOGIES · KPS LIFE · MEDIDATA · parexel · SUBJECTwell · wcg · Prime · ZS

PREMIER SPONSORS

ALMAC · CITELINE a norstella company · CLARIO · flatiron. · H1 · Infosys Navigate your next · ORACLE · perceptive · Pro-ficiency · pwc · Syneos Health · ThermoFisher SCIENTIFIC · Veeva

CORPORATE SPONSORS

Health · Advanced Clinical · AlphaLife Sciences · anju · AutoCruitment · avantor · babycenter what to expect · Clinical ink · CIMS · CluePoints · ConcertAI · CONTINUUM CLINICAL · Credible Planning · Datacubed Health · DEEP6 AI · Deloitte. · EDETEK LIFE SCIENCE · EGNYTE · ELLIGO HEALTH RESEARCH · Emmes Group · EmVenio RESEARCH · Endpoint Clinical · EVERNORTH · evinova · EXOSTAR We build trust. · faro · florence · Fortrea · gci health · greenphire · Halloran · Hawthorne Health · ICON · inato · inspire · komodo · labcorp · LexisNexis RISK SOLUTIONS · Lightship · Lokavant · MAXIS · Medable · medrio · MEDnet · Milliman IntelliScript · MYONEX · tomorrows · natera · nurocor · OM1 · Optum · PA Bringing Ingenuity to Life. · PM TRIALS · Pi Health · PROOFPILOT · PUBLICIS HEALTH · PurpleLab · quartzbio · Quest Diagnostics · Replior · RWS · saama · salesforce · sas · Science 37 · ScienceMedia · SCORR MARKETING · segmed · servicenow · SIGNANTHEALTH · SLOPE · surgo HEALTH · SUVODA · tasso · TRANSPERFECT LIFE SCIENCES · TRI · TriNetX · trialbee · UBC · umotif · univo · Veristat · VERISTAT · vivosense · WEP · Worldwide · Zelta by merative

CORPORATE SUPPORT

Actalent · ActiGraph · ALLIANCE Clinical Network · AMR · ANCILLARE · ARTHUR LITTLE · Atreo.io · BANOOK GROUP · Barrington James · BEST BUY Health · BIORCE · Bitfount · BodyCAP · BRANY · bsi Software for Life Sciences · castor · CATALYST FLEX · CellCarta · cencora PharmaLex · CLARINESS · ClinChoice The Standard of Excellence · CLINIRX · CRIO clinicalresearch.io · CRScube · crucial · CTI · Curebase · Cyntegrity · Dr. Vince Clinical Research · ECN Elite Clinical Network · embleema · Emmes Group · empatica · FIRMA CLINICAL RESEARCH · FLOURISH · Greenlight · healthverity · HIRO · IgniteData · IAG IMAGE ANALYSIS GROUP · inovalon · innovativetrials · IMOHealth · intercash · JAVARA · jumohealth. · Just In Time GCP · Keiji AI · LABCONNECT · LadderRun · M3 · mdgroup · MERCLINCO · mlm medical labs · MMG · Mushroom Solutions · MUV · ObjectiveHealth · OpenClinica · Paradigm Health · patientwing · PATIRO HEALTH · phastar · phesi · PointClickCare · Precision Digital Health · premier research · Princeton Blue · propharma · PULMONIX · RadMD · ripple · ROVIA · Scout · SGC · SMC · SiteCentric · sitero · SMARTLING · SPAULDING CLINICAL · spencer health solutions · SterlingIRB · stitch · Summit Clinical Research · SunshineMD · SWITCHER · TEKTON RESEARCH · TrialSTAT · TruTechnologies · TRUVETA · UpTrials · VPG HEALTH · verily · Verified clinical trials · viedoc · vitalograph · VIVALINK · woodley TRIAL SOLUTIONS · YOURWAY · yunu · Zifo

AWARDS

Submit your best work for these Awards at SCOPE!

Sunday, Feb. 3, 2025

PARTICIPANT ENGAGEMENT AWARD

Submission Deadline: Nov. 15
Learn more at: SCOPEsummit.com/participant-engagement-award

WHAT IS IT?

Now in its 8th 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 2024 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—best work in the Patient Recruitment and Retention Communications field.

Tuesday, Feb. 4, 2025

SITE INNOVATION AWARD

Submission Deadline: Nov. 15
Learn more at: SCOPEsummit.com/site-innovation-award

WHAT IS IT?

We are excited to announce our inaugural 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 advancing 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.

Wednesday, Feb. 5, 2025

BEST of SHOW AWARD

Submission Deadline: Jan. 24
Learn more at: SCOPEsummit.com/best-of-show-awards

Recognizing Exceptional Innovation in Technologies Used By Clinical Research Professionals

The 2024 Best of Show Awards offer exhibitors of the SCOPE Summit an exclusive opportunity to distinguish and highlight their products, ranging from innovative applications, technologies, 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 your products via the online submission form below. Attendees are encouraged to explore the novel technologies and solutions firsthand in the exhibit hall and vote for the People's Choice Award once the conference has begun. Please note, selection is not based upon level of sponsorship or exhibit participation.

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
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

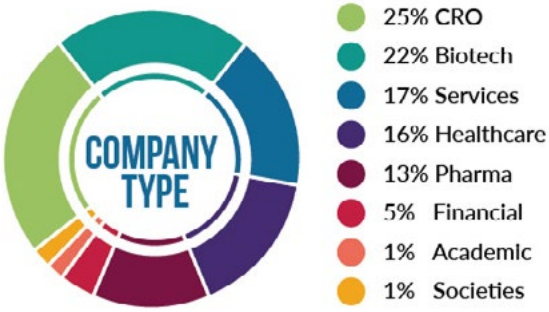
Companies K-T

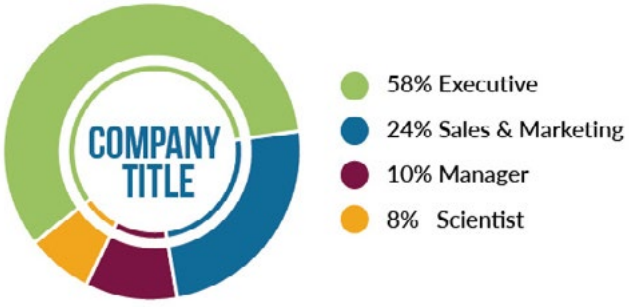
Jon Stroup
Lead Business Development Manager
(+1) 781-972-5483
jons@healthtech.com

Companies U-Z

Patty Rose
Vice President, Sales
(+1) 781-972-1349
prose@healthtech.com

2024 ATTENDEE DEMOGRAPHICS





CONFERENCE VENUE & HOTEL

ROSEN SHINGLE CREEK

9939 Universal Boulevard
Orlando, FL 32819

Discounted Room Rate: $265 s/d

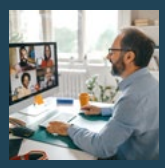
Discounted Room Rate Cut-Off Date:
January 1, 2025

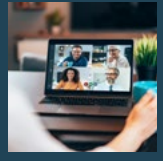
For hotel reservations please go to the Travel Page of **SCOPEsummit.com »**

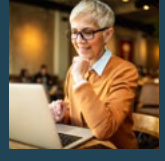
Can't Make it to Florida?

Join via our Robust Virtual Platform:

- INTUITIVE INTERFACE
- LIVE CHAT
- RECORDED SESSIONS
- COMPANY BRANDING
- LIVE SESSIONS
- DOWNLOADS







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 10, 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 10, 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!