SCOPE STARTS ON A **SUNDAY**

FINAL AGENDA

# 15th Annual SCOPE

**FEBRUARY 11-14, 2024**

## SUMMIT FOR CLINICAL OPS EXECUTIVES

Rosen Shingle Creek • Orlando, FL

**FINAL WEEKS TO REGISTER**

*Driving Innovation in Clinical Trials & Digital Health*

## CONFERENCE PROGRAMS:

- PATIENT-CENTRIC TRIAL DESIGN & DEI
- FEASIBILITY & STUDY START-UP
- RECRUITMENT & ENGAGEMENT
- BUDGETING & RESOURCES
- OUTSOURCING
- CLINICAL OPERATIONS FOR SMALL BIOPHARMA
- DATA
- DECENTRALIZED & HYBRID
- DIGITAL MEASUREMENTS
- REAL WORLD EVIDENCE
- QUALITY & MONITORING
- BIOMARKERS & PRECISION MEDICINE
- CLINICAL SUPPLY
- MED DEVICE TRIALS
- CLINICAL TRIAL TECH: VENTURE, INNOVATION & PARTNERING

## KEYNOTE SPEAKERS:

Uli Broedl
Boehringer Ingelheim

Kevin Bugin, PhD
FDA's Center for Drug Evaluation and Research (CDER)

Angela DeLuca
Takeda

Jessica Federer
Supernode Ventures

Ken Getz
Tufts University School of Medicine

Robert Goodwin
Pfizer Inc.

Michael Greeley
Flare Capital Partners

Christoph Koenen
Bayer

Brian Martin
AbbVie, Inc.

Samar Noor
Bristol Myers Squibb Co.

Prasanna Rao
Pfizer Inc.

Marsha Samson, PhD
FDA

### Signature Sponsors

ADVARRA · Care Access · ELLIGO HEALTH RESEARCH · HealthMatch · KPS LIFE · MEDIDATA · ORACLE · SubjectWell · wcg · yprime · Zelta by merative · ZS

Organized by Cambridge Healthtech Institute

**#SCOPEsummit** **SCOPEsummit.com**

# TABLE OF CONTENTS

## CONFERENCE PROGRAMS:




## A FEW SHORTCUTS TO HELP YOU AT SCOPE:

SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

15th Annual

February 11-14, 2024 | Rosen Shingle Creek | Orlando, Florida

# CONFERENCE-AT-A-GLANCE

| CONFERENCES | SUNDAY, FEBRUARY 11–TUESDAY, FEBRUARY 13 | TUESDAY, FEBRUARY 13–WEDNESDAY, FEBRUARY 14 |
|---|---|---|
| C1: PATIENT-CENTRIC TRIAL DESIGN & DEI | Patient-Centric Trial Design and Protocol Development | Developing and Executing Effective Diversity Plans |
| C2: FEASIBILITY & STUDY START-UP | Feasibility and Global Site Selection | Site Activation, Study Start-Up and Performance Optimization |
| C3: RECRUITMENT & ENGAGEMENT | Enrollment Planning and Patient Recruitment | Patient Engagement and Retention through Communities and Technology |
| C4: BUDGETING & RESOURCES | Clinical Trial Forecasting, Budgeting and Contracting | Resource Management and Capacity Planning for Clinical Trials |
| C5: OUTSOURCING | Mastering an Outsourcing Strategy | Relationship and Alliance Management in Outsourced Clinical Trials |
| C6: CLINICAL OPERATIONS FOR SMALL BIOPHARMA | Building New Clinical Programs, Teams and Strategies in Small Biopharma | Managing Your Clinical Trials to Succeed in Small Biopharma |
| C7: DATA | Clinical Data Strategy and Analytics | Artificial Intelligence in Clinical Research |
| C8: DECENTRALIZED & HYBRID | Decentralized and Hybrid Trials | Decentralized Trials and Clinical Innovation |
| C9: DIGITAL MEASUREMENTS | Digital Biomarkers and Endpoints in Clinical Trials | Digital Health Technologies in Clinical Research |
| C10: REAL WORLD EVIDENCE | Accessing and Generating RWD | Leveraging RWD for Clinical and Observational Research |
| C11: QUALITY & MONITORING | Clinical Quality and Risk Management | Central and Remote Monitoring |
| C12: BIOMARKERS & PRECISION MEDICINE | Operationalizing Biomarker & Precision Medicine Trials | Modernizing Lab, Biospecimens and Biobanking Operations |
| C13: CLINICAL SUPPLY | Data Technology for End-to-End Clinical Supply Management | Clinical Supply Chain Strategies to Align Process, Products and Patients |
| C14: MED DEVICE TRIALS | Medical Device Clinical Trial Design and Operations | Device Trial Regulations, Quality and Data Management |
| CLINICAL TRIAL TECH: VENTURE, INNOVATION & PARTNERING | Clinical Trial Tech: Venture, Innovation & Partnering Conference | |

# DAILY HIGHLIGHTS

Now more than ever, the important work of this clinical research community requires collaboration and innovation. In its 15th year of fostering these goals, SCOPE Summit will take place February 11-14, 2024, 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 2023 attracted more than 3,300 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 — SUNDAY February 11

### AM

- Welcome to Florida!
- SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament with Breakfast & Lunch Buffets*

### PM

- Sunday Kick-off Plenary Keynote
- 8th Annual Participant Engagement Award
- SCOPE's Big Game Tailgate Party
- Sponsor-Hosted SCOPE's Big Game Viewing Parties *(Sponsorship Available)*

## Day 2 — MONDAY February 12

### AM

- SCOPE's Monday Morning Fun Run!
- Get Up and Go! Jumpstart your morning with a specialty made-to-order coffee and delicious treats, courtesy of our sponsors
- Monday Morning Opening Keynotes
- Grand Opening Coffee & Refreshment Break in the Exhibit Hall
- Conference Tracks (1-14)
- 1-on-1 Networking

### PM

- Lunch 'n Learn in Conference Tracks
- Coffee & Dessert Break in the Exhibit Hall
- Conference Tracks (1-14)
- Welcome Reception in the Exhibit Hall
- SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle
- 1-on-1 Networking
- Clinical Trial Tech: Start-Up Pitch Contest
- Clinical Trial Tech: Venture, Innovation & Partnering

## Day 3 — TUESDAY February 13

### AM

- Breakfast Presentations
- Conference Tracks (1-14)
- Coffee Break in the Exhibit Hall
- 1-on-1 Networking
- Clinical Trial Tech: Venture, Innovation & Partnering

### PM

- Lunch 'n Learn in Conference Tracks
- Coffee & Dessert Break in the Exhibit Hall
- Tuesday Afternoon Plenary Keynotes
- Conference Tracks (1-14)
- SCOPE Site Innovation Award
- 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 Tech: Venture, Innovation & Partnering

## Day 4 — WEDNESDAY February 14

### AM

- Breakfast Presentations
- Conference Tracks (1-14)
- 1-on-1 Networking

### PM

- SCOPE Send-off Luncheon Presentations
- 1-on-1 Networking
- User Group Meetings 1:30–4:30

# CALCULATE. ACCOMMODATE. **INNOVATE.**

Clinical trials 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 **15th year** of fostering these joint efforts to advance our medical knowledge inclusive of all stakeholders, **SCOPE Summit 2024** will take place February 11-14, 2024, in Orlando, FL, at the Rosen Shingle Creek. Over **four stimulating days** of in-depth discussions and networking in **28 different conferences**, a bustling **exhibit hall with 200 companies**, 3 plenary keynote sessions, the 8th annual Participant Engagement Awards, the inaugural Site Innovation Award, special cross-department panels, the 3rd annual Master of Clinical Research **Golf Tournament**, a **Big Game Tailgate Party**, and a boutique **investor conference**, the programming focuses on advances and innovative solutions in all aspects of **clinical trial innovation**, planning, management, operations, and investment. SCOPE welcomes more than **3,300 attendees, 850 different organizations, from 27 countries** in clinical operations, clinical trials, innovation, and research.

## IN 2023...

- **3,300+ Participants**
- **75%+ of Delegates Titled as Decision-Makers**
- **200+ Industry-Leading Sponsors/Exhibitors**

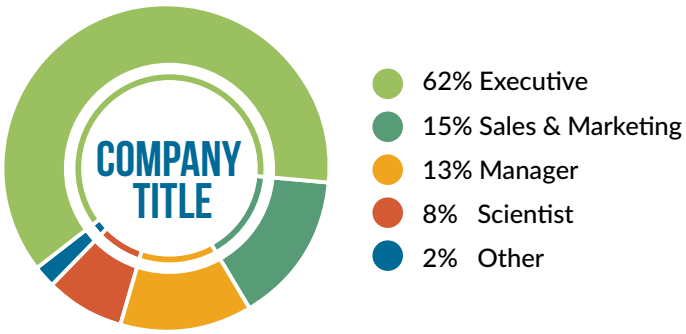
Attention Pharma!
**50 for 25**

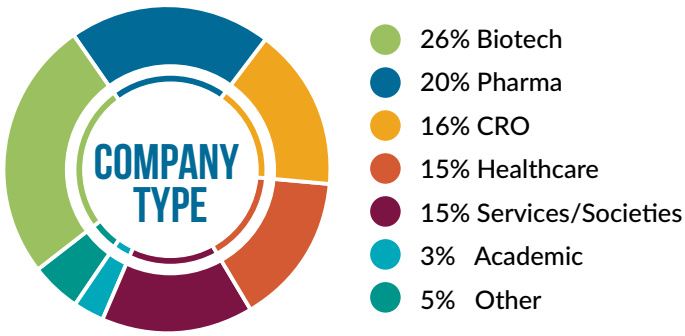
**Team Discounts for Small Biopharma**

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

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


## 2023 ATTENDEE DEMOGRAPHICS




## For additional information, please contact:

Companies A-I

**Ilana Quigley**

Director, Sales
(+1) 781-972-5457
iquigley@healthtech.com

Companies J-Q

**Jon Stroup**

Sr. Manager, Business Development
(+1) 781-972-5483
jons@healthtech.com

Companies R-Z

**Patty Rose**

Senior Director, Sales
(+1) 781-972-1349
prose@healthtech.com

# 2024 SPONSORS

## SIGNATURE SPONSORS


## PREMIER SPONSORS


## CORPORATE SPONSORS


## CORPORATE SUPPORT SPONSORS

# PLENARY KEYNOTE PRESENTATIONS

## SUNDAY, FEBRUARY 11, 2024

### SUNDAY MORNING GOLF TOURNAMENT

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*

Connect with your peers and colleagues at SCOPE's 3rd 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**

### SUNDAY AFTERNOON PLENARY SESSION: SUSTAINABLE TRIALS AND CLINECO WORKSHOPS, KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE, AND PARTICIPANT ENGAGEMENT AWARD

**1:00 – 1:45 pm Open Workshop: Introducing ClinEco, the New B2B Clinical Trial Community and Marketplace**

Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering and vendor selection. We are currently onboarding leaders in clinical research to: Explore the Ecosystem. Engage Partners. Exchange Capabilities. Join the ClinEco community now at: clineco.io/register. To register, please opt into this workshop by selecting the checkbox under 'Conference Selection.' Open to all SCOPE attendees.

**1:00 – 2:30 pm The Path Towards Sustainable Trials Workshop: Reducing the Environmental Impact of Global Clinical Trials**

***CHI, SCOPE, and Sustainable Healthcare Coalition***

As the climate crisis escalates, so does scrutiny of how companies are addressing environmental sustainability challenges. Healthcare contributes substantially to greenhouse gas emissions, so it is imperative to appreciate and remediate the role that clinical research and development play in that contribution. Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each.

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.

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

***David Lumby, Executive Director, EHS, Thermo Fisher Scientific***

**3:00 pm Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**

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

**3:10 pm Chairperson's Introduction**

***Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata, a Dassault Systèmes company***

**3:15 pm CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**

This panel will foster discussion between a diverse set of biopharma leaders representing Health Authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.



***Janice Chang, CEO, TransCelerate BioPharma, Inc.***

***Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim***

***Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer***

**3:45 pm SCOPE's 8th Annual Participant Engagement Awards**

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 and is **accepting submissions** at: https://www.scopesummit.com/participant-engagement-award









***MODERATORS:***

***David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator, SCOPE Participant Engagement Award***

***Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata***

***PANELISTS:***

***Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals***

***Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.***

***Otis Johnson, PhD, Chief Diversity, Inclusion & Sustainability Officer, Clario***

***Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory***

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

***Tarra D. Shingler, Senior Vice President, Global Business Solutions, Commercial, StudyKIK***

***Jeffrey Zucker, Senior Vice President, Trial Optimization & DCT, Worldwide Clinical Trials***

**4:35 pm SCOPE's Big Game Tailgate** *(Sponsorship Opportunities Available)*

Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 pm Close of Day**

# PLENARY KEYNOTE PRESENTATIONS

## MONDAY, FEBRUARY 12, 2024

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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.

### MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 am Organizer's Welcome Remarks**
***Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco***

**8:35 am Chairperson's Introduction**
***Chris Crucitti, Chief Revenue Officer, Executive, Citeline***

**8:40 am PLENARY KEYNOTE PRESENTATION: Time is Life: Pfizer's Approach to Accelerating Clinical Development**
***Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.***
How do we transform the development paradigm to make trials more accessible, more convenient for the participants, less costly, and most importantly, get us the answers we need faster? Because when you're a patient waiting for a new treatment, every minute matters. Pfizer recognizes that time is life and has set a bold ambition to reduce three additional years off their development timelines, after successfully cutting down more than two years already since 2016. Hear from Rob Goodwin, SVP and Head of Clinical Development & Operations, on what it takes to accelerate development without compromising quality, compliance, or patient safety.

**9:05 am INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
Where are we now as an industry with integrating and utilizing AI in clinical research? What is next is an open question and the possibilities are many and the hype is loud, but the more important question to ask is "why should we?" in each case. AI is a tool, but not always the right one or the most efficient one. Where do we choose not to use AI in clin ops and why? How do we measure value and outcomes for our projects? How do we consider and measure risks? Dive in with our expert panel.





MODERATOR:
***Brian Martin, Head of AI, R&D Information Research, Research Fellow, AbbVie, Inc.***
*PANELISTS:*
***Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.***
***Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.***
***Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson***
***Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research***

**9:35 am Grand Opening Coffee and Refreshment Break in the Exhibit Hall**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented, it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

## TUESDAY, FEBRUARY 13, 2024

**1:20 pm Coffee and Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*
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!

### TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 pm Organizer's Welcome Remarks**
***Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco***
***Marina Flishtinsky, MD, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco***

**2:25 pm Chairperson's Introduction**
***Mike Martin, Principal, ZS***

**2:30 pm PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
Prospectively randomized, placebo-controlled clinical trials are often the most powerful tool that we have for answering fundamental questions about the safety and efficacy of new medical products. But greater efficiency is needed, as clinical trials are becoming more costly and complex to administer. Moreover, many of the new products that we're being asked to evaluate aren't easily evaluated using these traditional approaches. At the same time, new technologies and sources of data and analysis make better approaches possible. FDA has been engaged in a comprehensive effort to advance new innovations and to enable the modernization of clinical trials, so what does this mean to you and to our industry?




*MODERATOR:*
***Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine***
*PANELISTS:*
***Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA's Center for Drug Evaluation and Research (CDER)***
***Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer***
***Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA***

# PLENARY KEYNOTE PRESENTATIONS

**3:00 pm CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**

New to SCOPE 2024—we bring together for the first time, a business-focused panel of strategics from the pharma, investor, healthcare, CRO, and technology start-up communities, to discuss partnership models that drive much needed innovation in clinical trials and impact development at the portfolio level. How can Pharma manage risks and investments while continuing to remain at the forefront of drug development, clinical research, and trial technology? What alternative business models and risk-sharing partnership can support innovation, in a resource constrained environment? Where are the opportunities and the ROI from such partnerships? What emerging technologies are showing growth and investment and are moving the needle in clinical research?

***MODERATOR:***

***Jacob LaPorte, PhD, Patient; Co-Founder & Vice President, Global Head of BIOME – The Digital Innovation Lab, Novartis***

***PANELISTS:***

***Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda***

***Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners***

***Michelle Longmire, Co-Founder & CEO, Medable, Inc.***

***Sam Srivastava, CEO, WCG***

**3:30 pm Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)***. Last Chance for Exhibit Viewing**

Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

"The pleasure is all mine to participate as a chair and speaker at the Summit. I always learn so much about the current trends in clinical research and look forward to seeing new innovation."

– Clinical Research Project, NIH, NINDS

Cambridge Healthtech Institute's Inaugural

# Patient-Centric Trial Design and Protocol Development

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

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's Inaugural

# Developing and Executing Effective Diversity Plans

Tools and Strategies to Improve Diversity and Achieve Enrollment Goals

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*
Eileen Murphy, Associate Conference Producer, Production, Cambridge

Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth
7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## INCORPORATING PATIENT AND SITE VOICE IN PROTOCOL DEVELOPMENT AND TRIAL PLANNING

**10:45 Chairperson's Remarks**
*Jane Myles, Co-Lead, Priority Initiative 3B, DCT Playbook, Decentralized Trials & Research Alliance (DTRA)*

**10:50 How Boehringer Ingelheim Has Made It Systematic to Incorporate the Patient Voice into Trial Design and Conduct**
*Kimberley Kallsen, Head of Patient & Site Engagement, Global Clinical Development & Operations, Boehringer Ingelheim*
End of 2021, BI decided to transform our clinical development. One goal was to systematically incorporate patient feedback into our trial designs. Before 2021, we had incorporated patient feedback only into two trials. In 2022, we incorporated patient feedback into 64% of our trial designs, and in the first half of 2023, into 86%. In this session, we will share our approach, experiences, and learnings.

**11:20 Are We There Yet? DCT and Patient Centricity—Bayer's Journey through DCT Adoption and Adaption in Interventional Trials**
*Karen Van Benschoten, Associate Director, DCT Operations Manager, DCT Strategy and Implementation, Bayer*
We have successfully implemented hybrid and fully remote DCT approaches across four Phase III interventional trials, each progressively broader in approach. Recently, we have launched our first large-scale, fully remote arm—in a pivotal trial—in parallel with a traditional model. Building on previously shared early operational and implementation experiences, this talk focuses on the participant experience, and whether we have yet achieved true patient centricity.

**11:50 PANEL DISCUSSION: Better Trials through Design Collaboration**
*Moderator: Jane Myles, Co-Lead, Priority Initiative 3B, DCT Playbook, Decentralized Trials & Research Alliance (DTRA)*
Drug development organizations understand the need to include patient and site perspective in protocol design and planning. It's not a standard process yet, and perhaps it's because it's hard to start. In this mini-simulation and discussion, the panel will demonstrate how to create and deliver a protocol design input session that includes patient and site voices. After a short simulation, a discussion will highlight best practices and lessons learned.
*Panelists:*
*Shelly Barnes, Global Clinical Innovations Lead, UCB*
*Angela Bilkhu, Senior Global Patient Partnership Director, Sickle Cell Disease and aHUS, Roche*
*Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata*

**12:20 pm Prioritizing the Site and Patient Technology Experience in Trial Planning**
*Elisa Cascade, MBA, Chief Product Officer, Advarra*
Technology can drive process efficiency, improve study compliance, and enhance site and patient engagement – but at what burden to our sites? Attend this session to discuss pragmatic trial delivery options for consideration during trial planning and hear real site feedback on ways to deliver value while reducing friction in site, sponsor, and patient interactions.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: The Possibility of Now: Current Integration Opportunities for AI in Medical Research Planning**
*Alexandra Moens, PharmD, Director, Product Marketing, H1*
From patient selection to data collection, how advances in AI and technology are transforming clinical trial feasibility, planning and operations teams into more efficient units that reach out to a broader range of patients and run more successful, cost efficient trials.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## NEW TRENDS IN TRIAL DESIGN TO IMPROVE PATIENT EXPERIENCE AND TRIAL OUTCOMES

**2:20 Chairperson's Remarks**
*Emily Jordan, Senior Director, Sponsor Transformation, Customer Success, OneStudyTeam*

**2:25 Protocol Design Trends and Their Impact on Performance**
*Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
Examine the results of a new study conducted by the Tufts Center for the Study of Drug Development characterizing trends in protocol design. Despite growing awareness of the importance of simplifying protocol designs,

nearly every design variable has increased in complexity during the past decade. We will examine the impact of protocol design practices on clinical trial performance and provide new insights into optimizing protocol design leveraging patient-centric design principles.

**2:55 A Multi-Stakeholder Approach to Bringing the Patient Voice to Protocol Development**
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
Patient-centered clinical trials significantly increase the likelihood of success, yet traditional methods to include the patient voice offer occur too late in the development process to make a meaningful difference. This session explores the benefits of of introducing the patient voice earlier into protocol development, and how taking a global approach to co-creation in partnership with patients, care partners, and sites furthers learnings and ensures ALL key stakeholders are heard.

**3:25 Fostering Patient-Centricity & DEI: Leveraging Patient Insurance? You're Missing Out**
*Samit Bhatt, Vice President, Clinical Trial Patient Solutions, Myonex*
Explore the impact of DEI and enrollment barriers in clinical trials during Fostering Patient-Centricity & DEI: Leveraging patient insurance? You're missing out. Learn how Patient Insurance issues contribute to delayed enrollment and dropouts and discover how the CTRx model removes financial obstacles, reduces costs, enhances patient flexibility, and improves DEI–creating an equitable and inclusive environment for diverse patients.

**3:55 Improving Clinical Trial Protocol Design**
*Tuba Bas, PhD, Senior Director, Clinical Center of Excellence, Bristol Myers Squibb Co.*
In this session, BMS shares its innovative process of incorporating patient perspectives throughout the drug development process across markets and therapeutic areas within the organization, through its Patient Expert Engagement Resource (PEER) and Patient Voice capability. Explore how they achieve patient-centric protocol design, including partnering with advocacy organizations, obtaining timely expert and lay patient feedback, and integrating patient feedback into trial designs and recruitment efforts.

**4:25 Using Patient Feedback to Fuel Technology Innovation and Improve the Clinical Trial Patient Journey**
*Dave Hine, Senior Director, Solutions Consulting, Greenphire*

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

### BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

**9:10 Chairperson's Remarks**
*Paige Bingham, CEO, Scout Clinical*

**9:15 PANEL DISCUSSION: Brainstorming to Break Down Barriers: Real Talk about What We Can Do Collaboratively to Move the Needle on DEI**
*Moderator: Kim Doggett, Senior Director, Clinical Trial Diversity, Clinical Operations, BeiGene*
Join this group of industry innovators who are leading efforts to overcome barriers to recruiting racially, ethnically, and socioeconomically diverse populations. Engage with them and your colleagues in candid dialogue, share innovative ideas, and collectively strategize actionable steps towards advancing 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*
*Amanda Beasley, PhD, Director, Representation in Clinical Research (RISE), Amgen*
*Crystal Parker, Clinical Operations Lead, Diversity Equity and Inclusion in Clinical Trials, Oncology, Janssen*
*Michel Reid, Senior Director & Head, Global Demographics & Diversity, GSK*
*Kate Wilson, Head of Clinical Trial Diversity, Global Clinical Operations, Biogen*

**10:15 The Root Cause of All Problems in Life Science**
*Brian Ongioni, Vice President, ClinOne*
Okay, maybe not all.
You're a busy person engaged in clinical research. If I gave you a magic wand and told you that you could fix one problem in the industry, it's possible—or should I say probable?—that API standardization may not be on the top of your list, but it is on the top of ours, and here is why.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

**11:40 Chairperson's Remarks**
*Alexandra Moens, PharmD, Director Product Marketing, Marketing, H1*

**11:45 Diversity by Design: Accessing Solutions from the Start**
*Sandra Amaro, Head, Clinical Trial Divesrity, Pfizer Inc.*
Learn about solutions available to support the diversity of participants in clinical trials, including an aggregated collection of insights and considerations gathered from sponsor interviews that can help inform operational strategies and identify how practical implementation of FDA Diversity Plans may progress as industry thinking matures, and a regulatory landscape resource designed to identify key US legislation, policy, regulation, and guidance to consider when working to improve diversity & inclusion.

**12:15 pm Why Disability Inclusion & Digital Accessibility are Critical to a Successful DEI Strategy**
*Stephen Framil, PhD, Corporate Global Head Accessibility, Office of Corporate Accessibility, Merck & Co., Inc.*
At Merck, we have a global digital accessibility policy that has embarked on a companywide initiative to provide equal access to our digital landscape for our workforce, patients, and consumers. This session will explore the Why, What, and How disability inclusion and digital accessibility are critical to a successful DEI strategy in global pharma.

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Achieving Study Objectives and Maximizing Participant and Site Experience through Effective Stakeholder Collaborations**
*Caroline Jackson, Executive Vice President, Patient Services, Patient Primary, mdgroup*
*Katie Vogel, BSN RN, Clinical Trial Manager, Clinical Trials, New Day Diagnostics*
In this presentation, Caroline Jackson from mdgroup and Katie Vogel from New Day Diagnostics explore some of the typical challenges impacting site and participant experience with clinical trials and discuss examples of successful collaboration between clients, vendors and sites that have led to positive study outcomes.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**

Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

**4:30 Chairperson's Remarks**
*Colleen Hoke, CEO, ObjectiveHealth, Inc.*

**4:35 CO-PRESENTATION: From Barriers to Best Practice: Increasing the Participation of Underrepresented Populations in U.S. Clinical Trials**
*Jodie Allen, PhD, Senior Director, Clinical Trial Diversity, AstraZeneca*
*Magnus Franzen, Partner, PEN*
*Paris Johnson, Senior Local Study Associate Director, AstraZeneca*

AstraZeneca conducted research into the barriers and opportunities to increase the participation of underrepresented populations clinical trials in the U.S. We conducted a review of internal processes and engaged >50 site staff with the aim of identifying practical and impactful ways to increase the recruitment, retention, and trial experience of underrepresented populations. This presentation will share actionable insights, and how we are further developing capabilities to improve clinical trial diversity.

**5:05 PANEL DISCUSSION Diversity Action Plans—The Expectation, Development, Implementation, and Feedback**
*Moderator: Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck*

As an industry, we have been solving for solutions to address the lack of diversity in clinical trials for a long time. The Draft FDA Guidance on Diversity Plans and the 2022 FDORA Act have brought the issue of diversity in clinical trials front and center. The goal of this conversation is to learn from each other as we implement this new requirement to advance inclusive research.
*Panelists:*
*Monique Adams, PhD, MS, Executive Director, Global Head Diversity & Inclusion in Clinical Trials, Sanofi*
*Kelly Clark, Head of US Partnerships and Global Site Development, Merck*
*Tony Pearson, Senior Director, Diversity & Inclusion in Clinical Trials, Eli Lilly & Co.*

**5:35 Using Technology to Build and Adhere to Patient-Centric Trial Design**
*Emily Jordan, Senior Director of Sponsor Transformation at OneStudyTeam, OneStudyTeam*

For clinical trials to be successful, it's critical to not only reach patients and ensure easy access to trials, but also to make it as easy as possible for patients to continue participating in those trials. By building patient centricity into trial design, we can improve patient recruitment, engagement, and retention for better outcomes. Hear about best practices for achieving this with technology.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## TRANSFORMING HEALTHCARE FOR THE LGBTQIA+ COMMUNITY: INNOVATIVE APPROACHES TO INCLUSIVITY

**8:25 Chairperson's Remarks**
*Tate Stubbs, COO, Executive, HealthMatch*

**8:30 PANEL DISCUSSION: Inclusivity for the LGBTQIA+ Community: Count Me In**
*Moderator: Garo Kiledjian, Founder & CEO, SGM Alliance*

Join us for a thought-provoking session as we kick off with the introduction of SGM Alliance who's paving the way in addressing health inequities faced by the LGBTQIA+ community. Hear from sexual and gender diverse individuals as they share their lived experiences encountering barriers in healthcare systems and clinical research Gain valuable insight into the health disparity challenges faced by SGM (sexual and gender minorities).
*Panelists:*
*Amanda Beasley, PhD, Director, Representation in Clinical Research (RISE), Amgen*
*Evan Ko, Study Management Associate, AbbVie, Inc.*
*Shir Netanel, Associate Director of Patient Advocacy and Clinical Trial Advocacy, Global Medical Affairs Oncology, Janssen*
*Jeffery Pettit-Williams, Principal Project Manager, Patient Diversity, PPD*
*Solomon Yakubov, Associate Director, Global Clinical Operations, GSK*

**9:30 Sponsored Presentation** *(Opportunity Available)*

**9:45 PANEL DISCUSSION: Overcoming Access Barriers to Healthcare for the LGBTQIA+ Community: Bridging Gaps, Driving Change**
*Moderator: Jessica Brescher, Chief Research Officer, SGM Alliance*

Delve into innovative strategies to achieve inclusive clinical research that supports the LGBTQIA+ community. Explore how to directly address systemic barriers in clinical research through inclusive language, expanded demographic data collection, and culturally inclusive and responsive education for clinical site staff and healthcare providers. Learn about actionable measures you can take to include sexual and gender minorities (SGM) in clinical study design, spanning from protocol design through recruitment and retention.

***Panelists:***

***Sandra Amaro, Head, Clinical Trial Divesrity, Pfizer Inc.***

***Denise Johnson Sura, Associate Vice President, Design Hub Foundations, Eli Lilly & Co.***

***Shir Netanel, Associate Director of Patient Advocacy and Clinical Trial Advocacy, Global Medical Affairs Oncology, Janssen***

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

***Kim Ribeiro, Head, Diversity and Patient Inclusion, AbbVie***

**10:45 Networking Coffee Break**

**11:05 Chairperson's Remarks**

***Michael Stadler, CEO, Clariness***

**11:10 CO-PRESENTATION: We Identified the Barriers to Trial Diversity, According to 4,000 Patients across the Globe—Breaking Down the Barriers**

***Amy Froment, Head, Global Trial Optimization, Regeneron***

***Kristin Parkhurst, Associate Director, Global Trial Optimization – Diversity, Equity and Inclusion (DEI), Development Operations & Portfolio Management, Regeneron***

Gain a wholistic understanding of what prevents patients from marginalized backgrounds—socioeconomic status, poor insurance coverage, LGBTQ+ identity, and more—from participating in clinical trials and what motivates them to do so; and how simple changes to study design, site selection, study materials, terminology, and language can overcome many of the issues identified.

**11:40 Early Insights to Support Diverse Enrollment**

***Diane Lijfrock, RN, Patient Insights and Inclusion Lead, Sanofi***

How does an organization make the transition from having a diversity plan to successfully enrolling diverse patients in their clinical trials? COVID-19 shone a light on the need to improve on the diversity of clinical trial participants across all disease areas. Sanofi's experience thinking outside the box to accomplish this will be of value to any organization struggling to move the needle and achieve realistic goals for diverse enrollment.

**12:10 pm CO-PRESENTATION: Applying Modeled Population Data to Improve Diversity in Clinical Trial Recruitment in European Countries**

***Baris Guc, Senior Data Scientist, Roche***

***Johnny Wharton, Portfolio Analytics Manager, Insights and Analytics, Product Development Global Operations (PDG), Roche***

In recent years, attention has been increasingly focused on trying to improve the diversity of patients recruited to clinical trials. We have been assisting clinical teams with data-driven recommendation of sites most likely to be able to diversely recruit. However, lack of data availability in European countries has made this very difficult. Here we discuss methods we are using to improve data-driven diverse patient recruitment in Europe.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Real-Time Patient Insights: Flexible Patient Engagement, in Days Not Months**

HealthMatch

***Tate Stubbs, COO, Executive, HealthMatch***

The value of timely and representative patient insights is well established not just as a social but commercial imperative in the clinical development process.

Leveraging direct connection to a rapidly growing patient user base of 1.3 million users, HealthMatch's Real-Time Patient Insights provides engagement to industry at scale.

Two case studies will be explored, on quantifying DEI in Clinical Trials and lived experience in psychiatry, conducted with Abbvie.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 14th Annual

# Feasibility and Global Site Selection

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

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 11th Annual

# Site Activation, Study Start-Up and Performance Optimization

New Processes and Technologies to Accelerate Study Start-Up, Reduce Site Burden, and Improve Operational Outcomes

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## SITE-CENTRICITY IN FEASIBILITY AND SITE SELECTION PROCESSES

**10:45 Chairperson's Remarks**
*Kris MacDermant, Senior Vice President, Sales, Mid-Market, Advarra*

**10:50 Feasibility: Process Update to Ensure Active Site Engagement**
*Michele Teufel, Site Management & Monitoring Therapy Area Strategy & Portfolio Delivery, Development Operations, AstraZeneca Pharmaceuticals, Inc.*
During this discussion, you will learn how AstraZeneca has made process changes and shifted the mindset of the feasibility process. We will share the process and template changes we have implemented to ensure we are actively engaged from our first interaction through site selection.

**11:20 PANEL DISCUSSION: Increasing Transparency & Trust in Site Selection: A Conversation with Sponsors and Sites**
*Moderator: Marcy Kravet, Head, Oncology Strategy, Inato*
Join this insightful panel discussion to explore topics such as what sponsors and sites need from each other to accelerate site selection, how to increase transparency and accuracy in enrollment and startup projections, and assessing diverse enrollment potential.
*Panelists:*
*Lilly Frohlich, Director, Clinical Operations, Cerevel Therapeutics*
*Jennifer Matson Hunter, CCRP, BAAS, Director of Research Operations, Mary Crowley Cancer Research*
*Ade Lawrence, MD, MSc, Founder/CEO, Bioluminux Clinical Research*
*Jonathan Salazar, Development Feasibility Manager, Global Study Operations, Amgen*

**11:50 PANEL DISCUSSION: Modernizing Site Engagement and Enablement for the Trials of the Future**
*Moderator: Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)*
Revolutionizing site engagement and enablement for the trials of tomorrow is essential for the future of our trials and their success. Learn how technology, data-driven approaches, and collaborative strategies are transforming the clinical research landscape. Explore successful examples, share insights, and be part of the conversation shaping the future of efficient and patient-centric trials. Drive innovation in site engagement for long-term success.
*Panelists:*
*Cerdi Beltre, COO, Innovo Research*
*Savine DaCosta, Health Equity Lead, Biogen*
*Brad Hightower, CEO, Hightower Clinical*
*Ryan Jones, CEO, Florence Healthcare*

**12:20 pm CO-PRESENTATION: Leveraging Data and Analytics to Drive More Efficient and Diverse Trials**
*Robert Buka, Director, Intelligent Trials, Medidata*
*Jason Josie, Director, Site Management, BeiGene*
Clinical Trials are growing in volume and complexity as patient enrollment rates trend downward and site competition increases. Meanwhile, new regulatory guidelines have introduced challenging, yet essential, requirements to improve clinical trial diversity.

This discussion will teach you how to leverage industry-wide, site-level data to make more informed site selection decisions and deliver faster, more representative trials. Key takeaways will include an overview of complexities in the clinical trial landscape today, current industry trends, and data that can be leveraged to address challenges. This session will also consider methods to meet regulatory requirements around diversity while taking into account operational needs. Finally, it will discuss tools pharmaceutical companies and CROs can utilize leveraging operational and clinical data to accelerate trial enrollment and achieve diversity goals.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: An Ecosystem Approach to Site Tech Overload**
*Aruna Adhikari Thapa, Senior Director, Product Strategy, IQVIA Technologies*
*Melissa Easy, Vice-President, Digital Products & Solutions, IQVIA Technologies*
*Matthew Jones, Senior Product Owner - Study Start Up, Site Engagement & Trial Operations, R&D Technology, GSK*
*Speaker To Be Announced*
Facing staffing shortages, clinical research sites are turning down studies they find unworkable. How can we get the clinical trial ecosystem in balance so that everyone benefits, most importantly the patients we serve?
In this panel discussion, leaders across the clinical trial ecosystem will discuss viable strategies that move beyond single-vendor and single-sponsor solutions to make a real impact on site centricity and tech overload.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## DATA-DRIVEN STRATEGIES TO IMPROVE FEASIBILITY

**2:20 Chairperson's Remarks**
*William B. Smith, MD, PI, Alliance for Multispecialty Research (AMR)*

**2:25 Discover How Human Intelligence Is Potentialized by Artificial Intelligence to Target the Best Sites**
*Sarah McClure, Global Data Engagement Lead, Feasibility Management, R&D, Sanofi*
Sanofi is leveraging AI to rethink how to transform trials including accelerating the process of finding the most relevant trial sites: in addition of globally improving patients' enrollment, we enlarge the scope to also address the enrollment of underrepresented populations. The AI-powered data and analytics approach has become a real springboard to reach this challenging but so important goal.

**2:55 CO-PRESENTATION: Using Data Science to Accelerate Feasibly, Site Selection & Study Start-Up—Site Intelligence Hub**
*Sheela Iyer, Director Associate, Janssen R&D Data Science*
*Monica Jain, Director, R&D Data Science, Johnson & Johnson Innovative Medicine*
*Asha Mahesh, Senior Director, Data Science Solutions, Privacy & Ethics, Janssen R&D*
This presentation will explore how the data stewardship processes within clinical trials feasibility can be enhanced with data science & technology. Gain insight into how Janssen developed and deployed new tools to accelerate and improve clinical trial feasibility.

**3:25 How BioPharma Can Overcome Stakeholder Challenges through the Use of AI and an Integrated Platform**
*Dennis Akkaya, Chief Commercial Officer, Commercial, myTomorrows*
*Danny den Hamer, Product Manager, Software Engineering, myTomorrows*
This presentation highlights how innovative technology is elevating clinical trial recruitment. The myTomorrows platform introduces a 'Green Wave', enhancing stakeholder engagement. It addresses key challenges in patient and physician journeys, introducing TrialSearch AI as a solution. This approach significantly helps BioPharma in effectively recruiting a larger pool of patients, optimizing the entire recruitment process.

**3:55 PANEL DISCUSSION: Empowering Predictable & Representative Clinical Trial Planning: Trustworthy and Scalable AI for Enhanced Feasibility and Site Selection**
*Moderator: Ronald Du, Associate Principal, ZS Associates*
In the rapidly evolving landscape of clinical trials, the integration of trustworthy and scalable AI tools is revolutionizing standard feasibility methodologies. These advanced data analytics techniques enhance trial planning, facilitate the identification of diverse patient populations, and provide a deeper understanding of site performance. Join our four industry experts as they delve into real-world success stories and discuss the challenges and triumphs of implementing AI.
*Panelists:*
*Michael Dawson, Director, Study Feasibility, AbbVie, Inc.*
*Jade Dennis, Executive Director, Clinical Trial Design Capabilities, Eli Lilly and Company*
*Sylvia Marecki, PhD, Head, Operational Design Center (ODC), Global Development Operations, EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany*
*Dana Iommazzo, Global Head, Clinical Operations Program Management, Novartis*

**4:25 Speed to Access—Simplifying Study Start-Up for All Clinical Users**
*Martin O'Malley, Director Life Sciences/Health IT Business Solutions, Exostar*
Join us as we discuss innovative strategies to empower sponsors to streamline study start-up processes, enhance the clinical site experience, and eliminate the technology burden that often hinders research efficiency. Uncover practical solutions that will drive smoother operations, enhance collaboration, and ultimately accelerate advancements in clinical research. Don't miss this opportunity to explore options that elevate the sites experience and help speed drugs to market.

**4:40 CO-PRESENTATION: Leveraging Scaled Patient Insights to Inform Trial Strategy**
*Kevin Hudziak, Clinical Trial Design Capabilities, CoDESIGN Clinical Design Delivery & Analytics, Eli Lilly*
*April Lewis, Associate Principal, ZS*
As an industry we lack a mature programmatic approach to ensure the voice of our key end-user—the patient—is integrated in real-time across the clinical development life cycle. This interview with Eli Lilly will share innovation in the use of scaled, quantified and representative insights in line with patient-informed drug development.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## THE FUTURE SITE: INNOVATION, CREATIVITY & COLLABORATION TO ADVANCE CLINICAL RESEARCH

**9:10 Chairperson's Remarks**
*Donna Hanson, Vice President, Strategy & Optimization, Advanced Clinical*

**9:15 Data-Informed Investigator Selection That Drives Patient Enrollment and Health Equity**
*Katherine Broecker, Senior Director, Design Hub Data Insights, Eli Lilly & Co.*
There is much data available to inform historical site performance; however, the world of clinical trials is changing. We must have a patient focus during investigator selection. This presentation will explore the use of multiple data sources and analytics that give insight into geographies, investigators, and novel opportunities to reach patients. All this with an emphasis on diversity of patient population to have a positive impact on health equity.

**9:45 PANEL DISCUSSION: Making Diversity, Equity, and Inclusion an Integral Part of Feasibility**
*Moderator: Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)*
Join our expert panel as they explore key strategies to infuse diversity, equity, and inclusion into the core of clinical trial feasibility assessments. Discover innovative approaches to enhance participant recruitment, improve study design, and address disparities. You will gain insights into the evolving landscape of inclusive research practices. Don't miss this vital discussion shaping the future of clinical research.
*Panelists:*
*Denise Bronner, PhD, Director DEICT, Immunology, Janssen Pharmaceuticals, Inc.*
*Shafaat Ali Kahn, Associate Director – Investigator Engagement Clinical Research Lead (CRL), Eli Lilly and Company*
*Sandra Amaro, Head, Clinical Trial Divesrity, Pfizer Inc.*

**10:15 Site Activation and Start-Up Optimisation: Reducing Operational Burden**
*Tamara Hughes, Vice President, Study Start-Up, ICON Clinical Reserach*
Reducing operational burden during the site activation and start-up phases is essential to ensuring that clinical trials start efficiently and run smoothly. Explore ways to enable greater transparency in study start-up processes and workflows to enhance collaboration, manage risk, and align stakeholder expectations for more successful initiation of clinical trials.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

**11:40 Chairperson's Remarks**
*Sidd Bhattacharya, Principal, PwC*

**11:45 Practical Tactics for Diversity in Clinical Trial Implementation**
*Zoma Foster, Head of Strategic Feasibility, UCB Biosciences, Inc.*
The presentation will focus on the strategic steering of planning, tracking, and reporting for diversity in clinical trials. We will detail some practical approaches to consider at different stages to enhance diversity in clinical trials; e.g., during site selection, patient recruitment, diversity vendor considerations, etc.

**12:15 pm SITE INNOVATION AWARD: Celebrating Creativity in SiteCentric Approaches to Advance Clinical Trials for All Stakeholders**
*Co-Moderators:*
*Irfan Khan, CEO, Circuit Clinical*
*Amanda Wright, Vice President, Partnership Development, Javara*
*Panelists:*
*Denise Bronner, PhD, Director DEICT, Immunology, Janssen Pharmaceuticals, Inc.*
*Joe Dustin, Vice President of Product Strategy, Medable, Inc.*
*Brad Hightower, CEO, Hightower Clinical*
*Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda*
*Sean Soth, Senior Vice President, Strategy and Global Business Partnerships, SCRS*

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: A Novel Framework for Quantifying Site Burden in Protocol Complexity Assessment**
*Marigrace Ambrosia, Director, PwC*
*Eddie Valaitis, Director, PwC*
While clinical trial sponsors have invested in capabilities to reduce protocol complexity by lowering patient burden and streamlining inclusion/exclusion criteria and endpoints, site perspectives have not been generally incorporated into the protocol complexity assessment processes. We propose a novel quantitative framework for evaluating site burden as part of protocol complexity assessment; and show how it relates to other protocol complexity dimensions and downstream operational outcomes.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## APPLYING AI TO IMPROVE OPERATIONS AND OUTCOMES

**4:30 Chairperson's Remarks**
*Suzanne Caruso, SVP, Product Strategy, Citeline*

**4:35 CO-PRESENTATION: Transforming Operations to Cut Time out of the Development Continuum**
*Nikki Amaratunge, Vice President, Clinical Development Operations, Aesthetics & Eyecare & Specialty, AbbVie, Inc.*
*Lorena Gomez, Global Head, Study Start-Up, COA, and Digital Implementation, AbbVie, Inc.*
Hear from AbbVie clinical leadership on how they are forming specialized functional groups, compressing tasks, and applying AI solutions to improve operational outcomes and accelerate clinical development. Explore the impact of organizational change with a focus on key areas including study planning, study start-up, and site engagement.

**5:05 CO-PRESENTATION: Journey to Industry-Leading Predictive Analytics**
*Alyson Higgins, Director, Study Feasibility and Patient Platform, AbbVie, Inc.*
*Li Wang, PhD, Senior Director & Head, Statistical Innovation, AbbVie, Inc.*
Trial enrollment timeline prediction is a crucial aspect of clinical development, Our presentation will outline the key steps in building a predictive enrollment model using machine learning and NLP. We will also introduce a combined approach based on a Quasi-Poisson model that integrates the domain knowledge of experts, together with the machine learning model to build an ensemble model structure. Internal validation results will be discussed as well.

**5:35 CO-PRESENTATION: The Perfect Technology Combination to Maximize Your Clinical Trial Platform — From Start-Up to Close Out**

*Mark Laney, Sales Engineering & Product Partnerships Lead, Business Development, Merative*

*Jan Nielsen, Community Manager, BSI Life Sciences*

It's hard to find a "one size fits all" platform that meets your clinical trials technology needs, but the collaboration between BSI Life Sciences and Zelta brings you one step closer to building an integrated system. Join us for a session to learn how proven CTMS, eTMF and CDMS solutions are accessible in one established ecosystem and how you can easily navigate the modules you need throughout your trial.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

### BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**

*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

### TECHNOLOGY AND COLLABORATION TO STREAMLINE START-UP AND OPTIMIZE PERFORMANCE

**8:25 Chairperson's Remarks**

*Dennis McMillan, Vice President, Global Feasibility, Parexel*

**8:30 CO-PRESENTATION: Transforming Trials: Actionable EHR-to-EDC Strategies for Sites, Sponsors, and Evaluating Success**

*Amy Cramer, Focus Area Leader: Capitalizing on Data Assets, The Janssen Pharmaceutical Companies of Johnson & Johnson*

*Joe Lengfellner, Senior Director, Clinical Research Informatics, Memorial Sloan Kettering Cancer Center*

This presentation offers pragmatic EHR-to-EDC strategies for sites, sponsors, and CROs. We will illuminate the essential steps for EHR-to-EDC implementation, underlining its immediate applicability and moving beyond theoretical discussions. Participants will be presented with the initial outcomes of collaboration between Memorial Sloan Kettering, Janssen, and IgniteData. This session is crucial for clinical research experts who are eager to quickly and efficiently update their data integration strategies.

**9:00 CO-PRESENTATION: Research Site Technology: Fostering Understanding and Collaboration**

*Mark King, Vice President, Research & Innovation, Novant Health*

*Denise Snyder, Associate Dean, Clinical Research, Duke University School of Medicine, Duke Office of Clinical Research*

*Ross Watson, Director, Global Site Partnerships, CSL Behring*

The session will feature site and sponsor leadership perspectives on how we can collaborate to address common challenges that slow study start-up. The audience will gain an understanding of how sites, sponsors, and CROs are working together to solve longstanding process and workflow challenges while improving patient centricity and bringing treatments to market safely and efficiently.

**9:30 CO-PRESENTATION: Trust in Innovation: Site & Patient Education Driving Change in Clinical Trial Quality, Efficiency, and Engagement**

*Philip Bedrin, Vice President, Medical & Clinical Solutions, ScienceMedia, Inc.*

*Malachi Bierstein, Chief Commercial Officer, ScienceMedia, Inc.*

*Dawn Furey, Senior Vice President, Enterprise Client Delivery Operations, Signant Health*

*Colleen Graham, Vice President, Head of Clinical Operations, Mediar Therapeutics*

Effective education of study staff and diverse patient populations is crucial for your study's conduct. Old ways of burdensome documents and PPT training cause slow enrollment, staff turnover, and a lack of common training language. It is time to trust innovative training solutions that produce high-quality data, reduce risk, time, and cost, while improving engagement and patient experience. With so many options available, how do you determine a high-quality training solution?

**9:45 CO-PRESENTATION: The Secret to Recruitment Success Starts with Site Selection: How to Supercharge Site Selection in the UK to Deliver Results**

*Alex Hammond, Business Development Manager, National Institute of Health and Care Research (NIHR)*

*Nicola Yallup, National Head, Business Development & Marketing, National Institute of Health and Care Research (NIHR)*

Initiatives that have recently been implemented across the UK research ecosystem are promoting the power of partnership working to achieve better "speed and spread" of research. Emerging results reveal; better inclusivity in recruitment through use of joined-up data; increased recruitment of patients in general practice the front line of the National Health Service (NHS); and a 45% reduction in study set-up times.

**10:05 Effective Start-Up and Trial Optimization**

*Stephanie Abbott, Clinical Research Program Director, Clinical Trials, Western Washington Medical Group*

The information that will be presented is from over two decades of innovation at the site level to improve the efficiency by which trials are deployed and run. We will review tips and tricks for streamlining the start-up process, leveraging key technologies to facilitate optimization of the trial deployment process, and creating integrated workflows that simplify trial conduct.

**10:25 Sorting through the Noise to Accelerate Study Start-Up**

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

To accelerate clinical trials, JNJ Innovative Medicine has built an Intelligence Hub platform of internal and external RCTs. To accelerate site selection, the Hub provides daily updates on the "feasibility Flow" until selection and insights to the progress/roadblocks to site activation. The objective is to democratize the access to the data and have an integrated site engagement strategy from the central and local study teams.

**10:45 Networking Coffee Break**

### INNOVATIVE TACTICS TO IMPROVE ENROLLMENT & RETENTION: THE FUTURE OF CLINICAL TRIALS

**11:05 Chairperson's Remarks**

*Akiko Shimamura, Senior Vice President, Trial Design & Optimization, Clinical Sciences, TriNetX*

**11:10 PANEL DISCUSSION: Examining Site Activation and Patient Enrollment Benchmarks among Sponsors and CROs**

*Moderator: Mary Jo Lamberti, PhD, Director and Research Assistant Professor, Tufts Center for the Study of Drug Development (CSDD)*

Sponsors and CROs are encountering significant challenges identifying and activating investigative sites and recruiting and retaining study volunteers. This session will examine some of the study and site-level metrics that Tufts has gathered on patient enrollment and site activation rates as well as global

recruitment and retention tactics. A panel of sponsor companies will provide insights on the study results and discuss innovative practices and approaches being implemented.

*Panelists:*

*Amanda Decoker, Senior Director, Head of Patient Recruitment and Retention, Takeda*

*Saartje Vansteenkiste, Executive Director, Clinical Portfolio Execution, CDO, CSL*

*Jacklynn Wong, Associate Director, Investigator and Patient Engagement, Johnson & Johnson*

**11:40 The Power of Adaptability: Engagement and Retention in Majority-Minority Communities**

*Don Harder, Head of Trial Solution Design, Care Access*

**12:10 pm Self-Driving Cars, Patient Burden, and Net-Zero: How Environmentally Friendly Patient Solutions Can Also Be Patient-Friendly**

*Michael J. Cohen, Senior Director, Environmental Sustainability, Strategy & Innovation, Thermo Fisher Scientific*

Here we will discuss a pilot using self-driving, electric vehicles for patient travel to and from a site in a clinical trial through multiple lenses as we explore strategies for simultaneously reducing patient burden and carbon footprint. Bringing together experts from multiple stakeholders, we look forward to exploring key performance across environmental sustainability, patient and site experience as well as regulatory and other important factors uncovered in this pilot.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Unlocking Enrollment Success: Study Support to Accelerate Timelines**

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

As protocols become increasingly complex, a persistent challenge arises when the capacities and timelines of sites do not synchronize with the study timelines envisioned by sponsors. Additional study support is often necessary to accelerate enrollment of participants to meet the study demands.

In this session, we will explore a range of strategies aimed at reducing the gap between expected and actual enrollment timelines while maintaining the balance between speed and quality.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 16th Annual

# Enrollment Planning and Patient Recruitment

Strategies to Better Predict and Achieve Enrollment Goals

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 11th Annual

# Patient Engagement and Retention through Communities and Technology

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

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**

*RUN COORDINATORS:*
Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## PATIENT JOURNEY MAPPING: CRITICAL TO IMPROVING RECRUITMENT & RETENTION

**10:45 Chairperson's Remarks**
*Tarra Shingler, Chief Commercial Officer, StudyKIK*

**10:50 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.*
Clinical trial participants increasingly express interest in accessing the individual data they contribute during clinical trials; however, frequency, timing, and type of data returned to participants are inconsistent and not widespread. Enabling meaningful, flexible, personalized individual data return options may enhance trust in the research enterprise, facilitate partnerships, broaden understanding of clinical research, and support data ownership for informed decision-making. Learn about this topic and practical tools for consideration.

**11:20 Optimizing Patient Choice, Flexibility, and Outcomes by Personalizing the Clinical Trial Experience**
*Peter Schaeffer, Digital & Process Optimization Leader, Digital Analytics & Performance, GSK*
While an important component of a person's healthcare experience, participation in a clinical trial can be time-intensive and burdensome. The goal of personalized clinical trials is to integrate clinical trial requirements more seamlessly into the lives of our participants. Join us to learn about a practical framework, including existing tools and considerations, to help the R&D ecosystem to improve patient choice and the implementation of options into clinical trial.

**11:50 Creating a Scalable Digital Recruitment and Awareness Platform to Support Diverse Audiences**
*Nichole Noel, Associate Director, Digital Clinical Trial Recruitment, Merck & Co.*
Merck developed and launched a global digital platform to organize and promote all of Merck's clinical trials in a patient-centric, user-friendly manner, on a global scale. The platform enables new clinical trials to efficiently launch digital awareness campaigns, significantly reducing resource effort without sacrificing quality. This presentation will share how our digital platform was built, some of the challenges, and the value it's now providing on a local level.

**12:20 pm CO-PRESENTATION: Investing in Patient Engagement & Recruitment as a Strategic Initiative**
*Krystyna Chmura, MPH, Clinical Trial Solutions Senior Advisor, Life Sciences Data, Evernorth*
*Matthew Holms, Vice President, Sales-Patient Engagement and Recruitment, Citeline*
*Jessica Washington-Moore, Senior Director, Implementation, Citeline*
This session highlights scalable yet flexible solutions for optimizing enrollment planning, revolutionizing patient recruitment, and improving collaboration among multiple stakeholders across the trial lifecycle, with tips to help address the nuanced intricates of planning and executing successful clinical trials in this ever-evolving landscape.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Promoting Trust among Diverse Populations through Patient and Community Insights**
*Moderator: Robert Loll, SVP, Business Development & Strategic Planning, Praxis*
Explore the transformative potential of meaningfully embedding patient and community insights into awareness, education, and outreach initiatives to improve trust among diverse populations. Praxis and CISCRP share how they carefully develop campaigns through acting on insights shared by diverse communities. To highlight our guiding inspirations, we will present findings from CISCRP's 2023 Global Perceptions and Insights Study of patient and public attitudes towards, and experiences with, clinical research.
*Panelists:*
*Matt Low, Chief Creative Officer, Praxis*
*LaShell Robinson, MS, Director Diversity, Equity & Inclusion in Clinical Research, Takeda*
*Behtash Bahador, Director Health Literacy, Health Communication Services, Center for Information & Study on Clinical Research*

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## PROACTIVE PLANNING AND ENGAGEMENT TO ACCELERATE CLINICAL DEVELOPMENT & IMPROVE SUCCESS RATES

**2:20 Chairperson's Remarks**
*Neil Weisman, President, Continuum Clinical*

**2:25 PANEL DISCUSSION: Reducing the Burden of Clinical Trial Execution via Site-Focused Support**
*Moderator: Adrienne Walstrum, Program Director, Merck & Co.*
As sponsors expand their portfolio by executing more clinical trials, the workload of clinical trial sites continues to increase. In support of Merck Clinical Trials, the company has created an "on-demand" suite of services to ease the burden of clinical trial execution for our partnering sites. Tailored based on site feedback, our "on-demand" services include solutions for site augmentation, patient chart management, and patient payment/ reimbursement solutions.
*Panelists:*
*Tiffany Grardi, Associate Principle Scientist, Global Trial Optimization, Merck & Co., Inc.*
*Anisa Khan, Senior Scientist, Global Trial Optimization, Oncology Early Development, Merck & Co., Inc.*
*Russell Lampman, Associate Director, Global Trial Optimization, Merck & Co., Inc.*
*Gwenn Oakes, Director, Global Trial Optimization, Merck & Co., Inc.*

**2:55 CO-PRESENTATION: Mindset Shift from Rescue to Acceleration: Early Planning and Engagement**
*Shannon Duffany, Clinical Trial Early Planning Lead – Global Oncology, Sanofi*
*Patricia Matthews, RN, BSN, Clinical Science Operations Project Leader, Sanofi*
The mindset shift from rescue to acceleration in early planning and engagement involves a strategic shift in focus. Instead of solely focusing on reactive measures or rescue efforts, there is a transition toward proactively planning and engaging early to drive growth and progress. This approach emphasizes identifying opportunities, setting goals, and implementing proactive strategies to accelerate development and achieve desired outcomes.

**3:25 Improving Randomization Rates with Machine Learning and AI**
*Fred Martin, CEO, SubjectWell*
Applying Machine Learning and Artificial Intelligence to patient recruiting: Find out why study data is more impactful on predicting recruitment success than patient data. Discover how to combine your model's results with your business strategy to create reliable recruitment.

**3:55 PANEL DISCUSSION: Engaging and Understanding Patients and HCPs to Improve Accessibility, Enrollment, Retention, and Outcomes**
*Moderator: Kristine Koontz, PhD, Vice President, Global Clinical Operations, Daiichi Sankyo, Inc.*
Explore emerging trends and case studies that demonstrate how understanding patient needs, beliefs, and their healthcare journeys influences participation in clinical trials and impacts outcomes. What technologies and processes can be leveraged? Gain insight into efforts to incorporate patient and site voice into trial planning, what has worked and what has not.
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Alana J. Miller, Associate Director, Clinical Trial Diversity Program Lead, Merck*

**4:25 Breaking through the Clinical Wall**
*Ian Greenfield, Chief Strategy Officer, Executive Leadership, YPrime*
When it comes to the patient experience, a study is a single, long experience, from recruitment to post-study follow-up. Yet their experience usually involves myriad technologies, entities, and contacts, each one introducing an opportunity for them to become disengaged. How can we unify the patient experience, from beginning to end, and does that mean finally breaking through the clinical wall?

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## COLLABORATION TO IMPROVE OUTREACH AND COMMUNITY ENGAGEMENT

**9:10 Chairperson's Remarks**
*Kate Shaw, Founder & CEO, Innovative Trials*

**9:15 Elevating Clinical Trial Outreach: Innovative Community Engagement Approaches**
*Joan Chambers, CEO, Greater Gift*
This presentation delves into innovative community engagement strategies to enhance clinical trial outreach. It emphasizes the vital role of community involvement early in expediting clinical trials within the evolving medical research landscape. Key takeaways encompass trust-building tactics, partnerships to engage diverse populations effectively, and promoting inclusivity in clinical trials.

**9:45 PANEL DISCUSSION: Outreach and Engagement: Case Studies in Multi-Stakeholder Co-Development and Use of Educational Content**
*Moderator: Behtash Bahador, Director Health Literacy, Health Communication Services, Center for Information & Study on Clinical Research*
Improving Diversity, Equity, and Inclusion (DEI) requires collaboration with the communities who have been underrepresented. This session shares key insights from the co-development of video and brochure content and the process of working with, and receiving feedback from, 2,500 individuals from Black and African American, Latino and Hispanic, Asian, LGBTQ+, and Native and Indigenous communities. Panelists will also share insights on implementing these materials in DEI and trial strategies.
*Panelists:*
*Ngozi Afulezi, Advocacy Senior Manager, Oncology, Gilead*
*Tony Pearson, Senior Director, Diversity & Inclusion in Clinical Trials, Eli Lilly & Co.*
*Tammy Wilkins, Senior Manager, Applied Innovation & Process Improvement, Otsuka Pharmaceutical Development & Commercialization, Inc.*

**10:15 Content + Technology = A Better Clinical Trial Experience for Participants and Sites**
*Jonathan Moshinsky, Co-Founder and CEO, Stitch*
*Kate Wheeler, Managing Partner, Langland*
This joint session from Langland and UK clinical trial technology company Stitch will explore how creative content, delivered via an industry-first engagement and feedback platform, can reduce drop-out from the recruitment process, and improve the study experience for both participants and sites.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**

*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

**11:40 Chairperson's Remarks**
***Brett Kleger, CEO, Datacubed Health***

**11:45 CO-PRESENTATION: Participant Insights Inspired a Novel Approach to Community Engagement and Recruitment**
***Kevin J. Hudziak, Associate Director, Clinical Trial Design Capabilities, Eli Lilly & Co.***
***Allison Reddick, Senior Director Clinical Services & Capabilities, Clinical Trial Recruitment, Eli Lilly & Co.***
***Jordan Thompson, Director, Clinical Trial Patient Engagement, Eli Lilly & Co.***
Gathering patient insights is critical to the design and execution of clinical trials. Understanding key barriers to diverse and representative trial participation created a novel approach to patient engagement that Lilly developed to educate and screen potential participants in a community setting. Lilly has streamlined novel recruitment tactics to enable faster, smarter, and more personalized patient recruitment while providing sites with highly qualified referrals.

**12:15 pm The Intersection of Patient Advocacy and Clinical Operations in Enhancing Patient and Community Engagement**
***Cassandra Smith, Advocacy Relations Director, Health Equity, Amgen***
The future of clinical innovation depends on increasing enrollment of populations typically underrepresented in clinical trials and underserved in healthcare. Patient Advocacy Organizations play a unique role in supporting clinical trial diversity strategies. This presentation will explore the pivotal role Patient Advocacy Organizations can bring in elevating engagement, awareness, and trust-building with patients and communities.

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Successful Participant Engagement on a Global Scale**
***James Riddle, MCSE, CIP, CPIA, CRQM, Senior Vice President, Global Review Services Operations, Advarra***
How do region, country, and site specifics impact your participant recruitment and engagement strategies? These considerations can help you achieve better recruitment and retain patients throughout the study. Learn how international viewpoints on advertisements and language localization services, and analyze the ever-essential relationship between sites and their patient community.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
***Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco***
***Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco***

**2:25 Chairperson's Remarks**
***Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.***

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
***Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine***
***Panelists:***
***Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)***
***Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA***

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
***Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics***
***Panelists:***
***Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda***
***Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners***
***Michelle Longmire, Co-Founder & CEO, Medable, Inc.***
***Sam Srivastava, CEO, WCG***

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## ENGAGING HEALTHCARE PROVIDERS TO IMPROVE OUTREACH AND COMMUNITY ENGAGEMENT

**4:30 Chairperson's Remarks**
***Rachel Wagner, Head or Business Development, Care Access***

**4:35 Research Liaisons in Community Physician Networking: A Vital Role for Site Research Recruitment and Support**
***Tania Alidina, PhD, Director, Network Development, Flourish Research***
This discussion delves into the multifaceted responsibilities of research liaisons, emphasizing the capacity to identify research opportunities, educate physicians on research protocols, and offer ongoing guidance throughout the research lifecycle. We will underscore the indispensable role of research liaisons in physician-site partnerships propelling site recruitment and ultimately improving patient care outcomes. Attendees will leave with actionable insights and recommendations to optimize the effectiveness of research liaisons within their healthcare communities.

**5:05 Improving Enrollment in Oncology Clinical Trials via Clinical Engagement**
***Maureen M. Posik, Associate Director Global Trial Optimization, Global Trial Optimization, Merck***
Merck's Global Clinical Trial Operations team has implemented a solution to boost PI engagement in our most challenging studies through physician calls, interactions, and case-based learning. This session will examine specific circumstances and key learnings from an initial pilot focused on educating and engaging PIs to boost study enrollment, and improve site efficiency and physician reengagement in challenging studies.

**5:35 CO-PRESENTATION: Partnering with Social Influencers to Drive Enrollment: Case Study**
***Lara Lane, Director Clinical Operations, Ironwood Pharmaceuticals***
***Erica Mercado, Director Growth Strategy, BBK, Publicis Health***
When potential study participants distrust the healthcare system might they respond to social influencers' introduction to a study of a new treatment option? In this Case Study, BBK and Ironwood will share their experience with a new approach to recruitment of patients suffering from the severe pain and reduced quality of life brought on by their condition. The session explores new avenues for influencer and referral-based marketing programs.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

### BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**

*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

### TRANSFORMATIVE NEW TECHNOLOGIES TO REDUCE PATIENT BURDEN AND REACH BROADER POPULATIONS

**8:25 Chairperson's Remarks**

*Mike Martin, Principal, ZS*

**8:30 PANEL DISCUSSION: Hybrid Trials, DCTs, and Patient-Centricity: Where Are We Now and Where Are We Going?**

*Moderator: Ebony N. Dashiell-Aje, PhD, Executive Director & Head, Patient Centered Outcomes Science, BioMarin Pharmaceutical, Inc.*

Recently, clinical trial decentralization has held much promise – to increase operational efficiency, reduce patient burden, increase patient access, and enhance. In addition to enhancing data quality, patient-centricity has been a primary focus. However, challenges related to implementation remain. We will reflect on patient-centricity within the context of DCT adoption and discuss the future for model optimization to keep patients at the center of it all.

*Panelists:*

*Emily Epstein, LMSW, Trial Volunteer & Cancer Previvor, Research Coordinator, Genetic Social Worker, Division of Gynecologic Oncology , Genetics and Personalized Cancer Prevention, Weill Cornell Medicine*

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

*Alekhya Pochiraju, Senior Product Development Lead, Clinical Operations, Genentech*

*Isaac R. Rodriguez-Chavez, PhD, MHSc, MSc, Scientific & Clinical Affairs, IEEE*

**9:00 Microsampling and Shifting Paradigm of Decentralized Clinical Trials**

*Dmitri Mikhailov, PhD, Director & Global Head, Biomarker Coordination, Novartis Institutes for BioMedical Research, Inc.*

Microsampling technologies enable clinical trials to reach broader populations, collect additional samples during or post-study, and help reduce patient burden. This presentation will review various aspects for implementation in clinical trials and will cover several topics, including the main areas for microsampling impact on clinical trials, operational planning for microsampling implementation, and considerations for microsampling approach in relation to bioanalytical utility and data interpretation.

**9:30 A platform based approach to patient recruitment & enrolment: maximising patient & sponsor experience**

*Manuri Gunawardena, CEO, Executive, HealthMatch*

HealthMatch & Velocity Clinical Research have embarked on a pilot as part of a strategic partnership to trial platform wide recruitment across over 100 trials. By employing HealthMatch across over 100 trials simultaneously, significant gains in recruitment efficiency and patient experience have been achieved. The speakers, representing leadership of both organizations will share on the partnership, the benefits and how sponsors can likewise benefit from a broader based approach.

**10:00 PANEL DISCUSSION: Remote Blood Sampling Devices/Apps: The Next Transformative Approach to Optimizing Sample Data Collection—Are We There Yet?**

*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:*

*Kelli Aufderheide, Director, Decentralized Trial Solutions, Q2*

*Angela Tucker, Program Director, Decentralized Trials, Labcorp*

*Enaksha Wickremsinhe, PhD, Bioassay Development Lead, Bill & Melinda Gates Medical Research Institute*

**10:45 Networking Coffee Break**

### INNOVATIVE TACTICS TO IMPROVE ENROLLMENT & RETENTION: THE FUTURE OF CLINICAL TRIALS

**11:05 Chairperson's Remarks**

*Akiko Shimamura, Senior Vice President, Trial Design & Optimization, Clinical Sciences, TriNetX*

**11:10 PANEL DISCUSSION: Examining Site Activation and Patient Enrollment Benchmarks among Sponsors and CROs**

*Moderator: Mary Jo Lamberti, PhD, Director and Research Assistant Professor, Tufts Center for the Study of Drug Development (CSDD)*

Sponsors and CROs are encountering significant challenges identifying and activating investigative sites and recruiting and retaining study volunteers. This session will examine some of the study and site-level metrics that Tufts has gathered on patient enrollment and site activation rates as well as global recruitment and retention tactics. A panel of sponsor companies will provide insights on the study results and discuss innovative practices and approaches being implemented.

*Panelists:*

*Amanda Decoker, Senior Director, Head of Patient Recruitment and Retention, Takeda*

*Saartje Vansteenkiste, Executive Director, Clinical Portfolio Execution, CDO, CSL*

*Jacklynn Wong, Associate Director, Investigator and Patient Engagement, Johnson & Johnson*

**11:40 The Power of Adaptability: Engagement and Retention in Majority-Minority Communities**

*Don Harder, Head of Trial Solution Design, Care Access*

**12:10 pm Self-Driving Cars, Patient Burden, and Net-Zero: How Environmentally Friendly Patient Solutions Can Also Be Patient-Friendly**

*Michael J. Cohen, Senior Director, Environmental Sustainability, Strategy & Innovation, Thermo Fisher Scientific*

Here we will discuss a pilot using self-driving, electric vehicles for patient travel to and from a site in a clinical trial through multiple lenses as we explore strategies for simultaneously reducing patient burden and carbon footprint. Bringing together experts from multiple stakeholders, we look forward to exploring key performance across environmental sustainability, patient and site experience as well as regulatory and other important factors uncovered in this pilot.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Unlocking Enrollment Success: Study Support to Accelerate Timelines**

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

As protocols become increasingly complex, a persistent challenge arises when the capacities and timelines of sites do not synchronize with the study timelines envisioned by sponsors. Additional study support is often necessary to accelerate enrollment of participants to meet the study demands.

In this session, we will explore a range of strategies aimed at reducing the gap between expected and actual enrollment timelines while maintaining the balance between speed and quality.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 13th Annual

# Clinical Trial Forecasting, Budgeting and Contracting

Innovative Strategies for Cost-Efficient Trials

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 6th Annual

# Resource Management and Capacity Planning for Clinical Trials

Metrics and Strategies for Efficient Resource Forecasting and Management

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth
7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## ACCESSING AND OPERATIONALIZING PREDICTIVE ANALYTICS FOR IMPROVED FORECASTING AND BUDGETING

**10:45 Chairperson's Remarks**
*Speaker to be Announced*

**10:50 Eco Design Tool: Forecasting and Informing Trial Design with a Lens for Environmental Sustainability**
*Jason Lanier, Director, Janssen Clinical Innovation*
As focus and momentum build to deliver clinical research in a more environmentally sustainable way, forecasting environmental impacts of individual studies and entire portfolios becomes increasingly important for trial leaders. This talk will present benchmark data and several extrapolation techniques to help clinical leaders facilitate discussions. An online estimation tool will be demonstrated live for the purpose of helping trial leaders articulate the environmental sustainability trade-offs of different study designs.

**11:20 PANEL DISCUSSION: Creating a Defensible Budget in a World of Constant Change through AI and Predictive Analytics**
*Moderator: Meghan Harrington, Vice President, Clinical Trial Financial Management, Medidata, a Dassault Systemes Co.*
The calculus for developing an accurate site budget is increasingly more complex due to dynamic global financial markets and variability in both protocol endpoints and trial designs. Smart budgeting now requires a multidimensional approach that improves sponsor agility by accounting for market evolution and anticipating future shifts. Join this session of industry experts to learn how access to predictive analytics within financial budgeting can improve this critical business process.

**12:20 pm Clinical Business Operations Transformed: Harnessing AI for End-to-End Clinical Outsourcing, KPI Management and More**
*Anca Copaescu, CEO, Clinical Maestro by Strategikon*
Clinical research teams face immense complexity in planning, contracting, and oversight, relying on inefficient manual processes. AI is poised to revolutionize clinical operations by automating critical workflows: predicting study budgets and benchmarking costs, RFP and SOW generation, and accelerating contracting through intelligent automation. Learn how revolutionary AI advances remove pain points in sourcing and operations, and Clinical Maestro is leveraging AI to drive productivity gains for sponsors and CROs.

**12:50 Transition to Lunch**

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

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## MODERNIZING AND STREAMLINING SITE BUDGETING, CONTRACTING, AND PAYMENTS

**2:20 Chairperson's Remarks**
*Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)*

**2:25 Top Trends and Best Practices in Site Contracts, Budgeting, and Payments**
*Debora Sobral, Founder & CEO, CLinBiz*
This talk will address current trends and best practices pharma and biotech companies are employing for site contracts, budgeting, and payments. We'll discuss common challenges, novel approaches, and strategies for examining your own current processes and areas for improvement.

**2:55 CO-PRESENTATION: Sites Want to Work with You: A Large Academic Site's Streamlined Budgeting and Payment Processes**
*Catee Mullen, Director, Research Operations, Clinical Research, Duke University*
*Denise Snyder, Associate Dean, Clinical Research, Duke University School of Medicine, Duke Office of Clinical Research*
Every site has challenges, yet each is committed to collaborating with Sponsors and CROs to undertake research pivotal to transforming patient care. Dive into the intricacies of budgeting and payment processes at a large academic medical center. Discover the strategies Duke implemented to enhance budgeting, contracting, and payment workflows. Learn pragmatic measures that Sponsors can employ with sites to expedite start-up timelines and ensure accurate and timely invoicing and payment.

**3:25 PANEL DISCUSSION: Putting Site Experience at the Forefront: Minimizing Negotiations, Standardizing Timelines, and Streamlining Study Close-Out**
*Moderator: Jenn Hill, Director, Clinical Site Contracting and Payments, Vertex Pharmaceuticals*

Join the Vertex panel discussion as industry experts explore the critical theme of putting site experience first. Learn how to minimize negotiations, standardize timelines, and streamline study closeout processes to enhance clinical trial efficiency and success.

*Panelists:*

*Brenda Mull, Associate Director, Client Services, Cost Benchmarking, IQVIA Technologies*

*Kate Sherron, Principal Manager, Site Activation, Vertex Pharmaceuticals, Inc.*

*Phil Spinosa, Site Lead, Disease Area & Pain AAT, Vertex Pharmaceuticals, Inc.*

**4:25 Protocol Super Bowl: Live Head to Head of Digital vs. Paper**

*Joseph Kim, Chief Strategy Officer, PROOFPILOT*

Written protocols, slides & other manuals are a drag on execution, negatively impacting site resources and budgets. In this session, 2 teams of Sponsors & Sites will be pitted against each other to complete a set of "protocol tasks" live! ProofPilot will demonstrate the superiority of Digital Protocols to eliminate site burden, increase site revenue, all while delivering better study data, faster. Stop talking about "Sponsor of Choice." Be about it.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

### BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**

*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*

Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**

*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

### STREAMLINING PROCESSES TO MINIMIZE CHANGES AND HARMONIZE SPONSOR-CRO-SITE RELATIONSHIPS

**9:10 Chairperson's Remarks**

*Pat Harrington, PhD, Vice President, Elligo Solutions, Elligo Health Research*

**9:15 CO-PRESENTATION: Bayer/Fortrea Strategic Partnership: Successful Approach to Minimize Change Orders, Increase Collaboration, and Streamline Full-Service Outsourcing**

*Petko Baltov, Senior Director, Partnership Solutions, Fortrea*

*Piet Theisohn, Vice President, Resource Management, Clinical Development & Operations, Bayer AG – Pharma*

Contracting the conduct of clinical studies between sponsor and CROs can easily become painful for both parties. We would like to present our learnings and "best practice" from the last ten years for discussion. There is no silver bullet to solve the inherent complexity, but certain approaches drive efficiency and reduce unhealthy long discussions and surprises.

**9:45 Addressing Worldwide Contracting Practices and the Impact of the German Sample Contract Approach**

*Thorsten Ruppert, PhD, Senior Manager, R&D & Innovation, Verband Forschender Arzneimittelhersteller eV*

Global unified contracting templates are standard in many pharma companies when conducting clinical trials. But is this approach sufficient as different countries worldwide follow different strategies? Legally prespecified contracts on a national or regional basis, healthcare system-orientated approaches, or sample contracts exist worldwide. This approach should improve start-up timelines and ensure a streamlined inclusion of patients. It will describe the benefits of this harmonized contracting approach between sites and sponsors.

**10:15 How You Can Save Time and Money through Centralized Oversight**

*Pat Harrington, PhD, Vice President, Elligo Solutions, Elligo Health Research*

Centralized oversight at the site level can save time and money through contracting and regulatory consistency, a singular set of SOPs, expedited startup, central EHR analysis, internal recruitment assistance, medical and PM oversight, remote monitoring through a singular eSource, fast closeout and financial reconciliation, and experience working with CROs and Sponsors, all of which we will demonstrate how Elligo can facilitate drug development and diverse participant enrollment.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**

*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

### THE IMPACT OF THE BIOTECH MARKET ON BUDGETING AND CONTRACTING: MANAGING CLINICAL TRIALS IN FINANCIALLY UNCERTAIN TIMES

**11:40 Chairperson's Remarks**

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

**11:45 PANEL DISCUSSION: The Current Biotech Market and the Impact of Inflation, Fluctuating Staffing, and Hybrid Trials on Contracts and Relationships**

*Moderator: Rene Stephens, MSHS, Independent Consultant*

Inflation, layoffs, reorganizations, hybrid work, and DCTs all have a huge impact on contracts and budgets. How do we move forward with collaborative, innovative, and fair contracts and budgets while tightening our spending? How do sponsors, CROs, and sites maintain strong relationships through such times of constant change? Panelists will address these issues, as well as strategies to employ today and in the future.

*Panelists:*

*Tania Alidina, PhD, Director, Network Development, Flourish Research*

*Christopher Chan, Vice President, FP&A, IGM Biosciences, Inc.*

*David Windley, Managing Director, Jeffries LLC*

**12:45 pm Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Can Strategic Partnership Governance Models Help to Advance Budget Efficiencies?**

*Lily Grey, Global Strategic Sourcing Leader, F.Hoffmann-LaRoche AG*

*Holger Liebig, Executive Director, Partnership Center of Excellence, Parexel*

Strategic partnership governance models can help to advance budget efficiencies in organizations by enhancing collaboration and mutual understanding, enabling better coordination, alignment, and decision-making. By using the right governance structures and mechanisms, organizations can optimize resource allocation, streamline processes, manage risks and reduce redundant efforts, which ultimately leads to improved budget efficiencies. The presentation will use a cross-functional governance model to examine the mechanisms for creating favourable financial outcomes.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**

*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**

Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## RETAINING AND GROWING RESOURCES: CLINICAL TRIALS OF THE FUTURE DEPEND ON IT

**4:30 Chairperson's Remarks**
*Claudia Hesselmann, CEO & Founder, ARENSIA Exploratory Medicine GmbH*

**4:35 PANEL DISCUSSION: Developing Clinical Trial Professionals of the Future and Its Impact on Clinical Trials**
*Moderator: Dennis Salotti, MS, MBA, Executive Director & Head, Clinical Outsourcing & Innovation, Jazz Pharmaceuticals*
The impact of the COVID pandemic on how clinical trials operate, and indeed how companies conduct business, is ongoing. What impact does a more remote workforce have on skill development, relationship building, and investment in the patients and their experience? How can leaders of today not only grow their own careers but grow and retain the next generation of the workforce?
*Panelists:*
*Brian Arnold, MBA, Vice President, Development Operations, Insmed, Inc.*
*Caroline Jones, Senior Director, Clinical Operations, Global Head, Clinical Contracts (Site/ISR) and Pricing, Gilead Sciences*
*Carrie Lewis, Executive Director, Clinical Program Optimization, Endo Pharmaceuticals*

**5:35 Presentation to be Announced**

**5:50 Presentation to be Announced**

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*
Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## SCALING ORGANIZATIONAL CAPACITY FOR EFFECTIVE CLINICAL TRIALS THROUGH PARTNERSHIPS AND EFFICIENT USE OF RESOURCES

**8:25 Chairperson's Remarks**
*Peter Ronco, CEO, Emmes*

**8:30 Thinking of Going Smaller? What to Expect When Transitioning from a Large Pharma Company to a Small Biotech**
*Susan G. Mullin, Vice President, Clinical Operations, Ventyx Biosciences, Inc.*
This presentation will focus on the differences between the work experience at a large pharma vs. a small biotech, what to expect during the transition, and how to plan for success. Topics will include: infrastructure, choosing a CRO, relationships, technology and culture, recruitment, training, and development of team members.

**9:00 Why Following the Status Quo for a Pediatric Rare Disease Clinical Study Was Not the Optimal Approach for a Small Biotech**
*Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.*
Clinical study success depends on three "C" or core elements: communication, collaboration, and cooperation from all participating individuals. When it comes to working on rare diseases, the chances of outsourcing to a CRO or vendor with prior experience in that particular indication are often nonexistent. This presentation will focus on how Rezolute took a more direct, hands-on approach to executing a rare pediatric pivotal Phase 3 Global Program.

**9:30 CO-PRESENTATION: Operationalizing a Virtual Site: Insights from Bayer and Science 37**
*Darcy Forman, Chief Delivery Officer, Science 37*
*Speaker II to be Announced*
The optimal clinical trial design is not a one-size-fits-all approach. Just as each clinical trial has its own unique characteristics, the elements of a virtual clinical trial require tailored integration to harmonize with specific protocol requirements. Explore insights from Bayer and Science 37 as they discuss their journey, the importance of collaboration in fostering innovation and explore perspectives on virtual trial execution.

**9:45 CO-PRESENTATION:**
*Brandie Jonas*
*Courtney Maguire, Senior Director Clinical Program Management, Geron Corporation*
*Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical*

**10:15 Decentralized Approaches—Especially in Rare Disease/Oncology—Into Trials That Require Centers Well-Versed in Clinical Research**
*Caro Unger, Senior Director, Clinical Operations*
Running trials nimbly—utilizing in-house talent and managing a trial without a CRO. How to evaluate if this is the right model for you and look at the pros and cons for your team/organization. Which vendors and consultants will you need and which resources can be used from the company? Which processes and plans will need to be developed and which lessons learned?

**10:45 Networking Coffee Break**

## OPERATIONALIZING DEI EFFORTS THROUGH OUTSOURCING AND PARTNERSHIPS

**11:05 Chairperson's Remarks**
*Diana Foster, Vice President, Strategy and Special Projects & Diversity Awareness Program Lead, Society for Clinical Research Sites*

**11:10 Recruitment Planning to Ensure Diverse Clinical Trial Participation**
*Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics*
Discover strategies for diverse clinical trial participation by developing inclusive protocol designs, applying data-driven site identification, and proactively customizing outreach and support for diverse populations. Attendees will learn strategies for determining trial-specific benchmarks and measuring success to enhance their ability to contribute to equitable and representative clinical trials.

**11:30 Forging Inclusive Alliances: Collaborative Partnerships in Operationalizing DEI Initiatives**
*Janaka Karunaratne, Consultant, Individual Consultant*

**11:40 PANEL DISCUSSION: Breaking Barriers, Bridging Gaps: Strategies for Creating and Outsourcing Clinical Trial Diversity Plans**
*Moderator: Susan Erondo, Founder and COO, Uncharted Access/Uncharted Advocates*
The implementation of robust clinical trials diversity plans is critical for fostering inclusivity and advancing biomedical research that benefits diverse populations. By embracing innovative and collaborative strategies and outsourcing partnerships, CliniOps can enhance participant representation and embark on equitable access to biomedical solutions. This presentation aims to equip the audience with the knowledge and tools to develop effective diversity plans that drive impactful and inclusive clinical trials.
*Panelists:*
*Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics*
*Dinorah Villanueva, Associate Director, Diversity, Equity, & Inclusion on Clinical trials (DEICT) Processes, The Janssen Pharmaceutical Companies of Johnson & Johnson*
*Janaka Karunaratne, Consultant, Individual Consultant*
*Naomi Orebiyi, Uncharted Access/Uncharted Advocates*
*Karen Patterson, CEO and Executive Director, KPE Research Solutions*

**12:40 pm Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Digital Innovations for Patient-Centered Clinical Trials Using Real-World Data**
PurpleLab HEALTHCARE ANALYTICS
*Karina D'Angelo, PhD, Director, Scientific Real World Data Strategy, Parexel*
*Denis McMillan, Vice President, Global Feasibility, Parexel*
*Camilla Ramdeen, PhD, Executive Director, Strategic Feasibility, Parexel*
*Russell Robbins, MD, MBA, Chief Medical Information Officer, PurpleLab*
Supporting inclusion of underrepresented populations in clinical trials and real-world data studies requires a multi-faceted approach – access to real world data sources supports decision making to ensure diverse populations are considered proactively throughout research study phases. This presentation highlights ways to ensure studies have DEI in patient populations to meet FDA expectations and innovative ways of using healthcare data linked with deidentified SDOH attributes.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 8th Annual

# Mastering an Outsourcing Strategy

Innovative Outsourcing Models and Determining Success through Metrics and Governance

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 10th Annual

# Relationship and Alliance Management in Outsourced Clinical Trials

Strategies for Building Successful Partnerships and Alliances in a Competitive Landscape

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## MEASURING THE SUCCESS OF CLINICAL TRIAL PARTNERSHIPS: VENDOR OVERSIGHT AND METRIC ANALYSIS

**10:45 Chairperson's Remarks**
*Ben Benskin, Vice President, Strategic Partnerships, Lightship*

**10:50 Review of ICH E6 R3 and Its Impact on Outsourcing and Oversight**
*Andy Lawton, Director & Consultant, Risk Based Approach Ltd.*
The release of ICH E6 R3 (draft) has been a long time in its gestation, starting with the GCP Renovation document more then six years ago (January 2017). This presentation will take you step-wise through the following topics: the main changes in principles, investigators, sponsors, and appendices plus a new section on data governance as well as detailed areas of oversight.

**11:20 PANEL DISCUSSION: Noise vs. Value: Minimizing Redundancy and Duplication to Increase Quality in Your Metrics Framework**
*Moderator: Yusuf Ghadiali, Executive Director & Head, Clinical Trial Business Operations, Daiichi Sankyo, Inc.*
There are an endless amount of metrics that organizations can use to measure success in clinical trial operations and outsourcing partnerships, but how do organizations hone in on the most valuable ones—without reinventing the wheel? Once companies are clear on what metrics would bring value, what actions can they take to create meaningful change? How can we then understand if those actions achieved the desired result?
*Panelists:*
*Keith Dorricott, Director, Dorricott Metrics & Process Improvement Ltd.*
*Debbie Gilmore, Vice President, Strategic Alliance Management, ICON*
*Randy Krauss, Executive Director, Metrics, Analytics, & Performance, Merck*
*Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.*

**12:20 pm Talent Acquisition in the Post Pandemic Era – Challenges and Perspectives**
*Dana Durkan, Vice President, Global Recruitment, KPS Life*
As the industry has emerged from the Covid-19 pandemic, the landscape of talent acquisition has evolved. This session will discuss certain trends and factors that pose a challenge in matching qualified candidates with Sponsor needs in conducting their clinical trials. The session will also examine underlying trends within talent acquisition over the past decade that can affect the process of finding the right person for the right role.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Rethinking Clinical Trial Community Engagement Through End-to-End Collaborative Approach**
*Sepehr Shojaei, Vice President, Design Solutions, Lightship*
*Shayla Wilson, Head of Community and Digital Engagement, Acclinate*
Improving trial participation can streamline timelines and bring innovative care to more people, but the challenge is complex. It is necessary to rethink how we approach community engagement, with a focus on collaboration.
Join Lightship's Sepehr Shojaei and Acclinate's Shayla Wilson to discover new methods to mobilize participation, educate community members, and keep patients engaged and retained throughout the trial journey through end-to-end collaboration.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## CHANGE MANAGEMENT IN OUTSOURCING: ADDRESSING THE IMPACT OF OUTSOURCING DECISIONS ON VENDORS, SITES, AND PATIENTS

**2:20 Chairperson's Remarks**
*Scott Sawicki, MA, Senior Director, Strategic Sourcing & Vendor Management, ADC Therapeutics*

**2:25 Be Prepared: Good Outsourcing Survival Tools in the Small/Biotech Acquisition Scenario**
*Richard Scaife, Vice President, Strategic Outsourcing & Vendor Management, VectivBio AG, PCMG Committee Member*
The acquisition scenario is not a rare event for small/biotech companies, but investing in outsourcing management is. Good outsourcing can increase asset value and be pivotal to a successful acquisition process. Early outsourcing strategy definition, a diligent selection process, practical contracting, and thorough, pragmatic vendor governance are not only essentials to overall clinical trial management, but they can also prepare the ground for a mutually successful, possibly pain-free acquisition.

**2:55 Impact of Outsourcing Strategy Changes and Vendor Selection on Study Sites**
*Marina Malikova, PhD, Executive Director, Surgical Translational Research, Operations and Compliance, Boston University School of Medicine*

Understanding challenges associated with changes in outsourcing strategy, vendor selection in digital era, and change management in accordance with current regulatory requirements will allow for the timely and successful completion of the projects, while minimizing exposure to the risks of stakeholders, such as participating sites. Key factors to consider when developing protocols and techniques to minimize complexity, adequately select vendors, mitigate risks and ensure trial success, will be discussed.

## BUILDING GOVERNANCE MODELS AND SHARED ACCOUNTABILITY FOR LONG-TERM SPONSOR-CRO SUCCESS

**3:25 PANEL DISCUSSION: Building a Governance Model and Developing CRO/Sponsor Accountability for Successful Long-Term Partnerships**
*Moderator: Jodi Coughlin, Director, Vendor Relationship Management, Deciphera Pharmaceuticals*

In this diverse panel of governance oversight experts, we will discuss the approaches and strategies on how to build and develop successful CRO/Sponsor dual accountability partnerships. We will provide an overview of the elemental foundations of a governance model created "from scratch," as well as effective supplemental tools and processes that can be utilized to deepen established partnerships to drive performance.

*Panelists:*
*Gary Ellsworth, Vice President, Strategic Alliances, IQVIA*
*Stacey Limauro, Executive Director, Clinical Operations, Deciphera Pharmaceuticals*
*Rene Stephens, MSHS, Independent Consultant*

**4:25 Case Study: The Impact of Simulation on a Complex Global Phase 3 Study**
*David Hadden, President & Founder, Strategy, Pro-ficiency*

This presentation will review: The use of predictive analytics in avoiding adverse events and patient safety risk in a global Phase 3 study; simulation; predictive analytics; AI-enabled protocol optimization and simple decision support tools combined to create a novel study performance management system; and overcoming language and cultural hurdles in global studies. A look at the ROI of the approach.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

# TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*

Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## INNOVATION IN OUTSOURCING: CREATING AND MAINTAINING FLEXIBILITY AND SCALABILITY

**9:10 Chairperson's Remarks**
*Kevin Duffy, Chief Commercial Officer, KPS Life*

**9:15 PANEL DISCUSSION: How Can BioPharma Take Advantage of the Latest Innovation, Emerging Vendors, and Evolving CRO Services While Creating and Maintaining a Flexible and Scalable Outsourcing Model?**
*Moderator: Jason Gubb, Co-Founder, ClinOpsClarity and Emergent Teams*

With many new entrants in the supplier arena, and big CROs evolving their services, how do you stay on top of the latest innovations and create/maintain a flexible and scalable outsourcing model? There is a false dichotomy in outsourcing that hiring newcomers increases risk. This panel will discuss overcoming this inertia, why new players are important for the ecosystem, and how to unlock crucial ingredients for a successful outsourcing partnership.

*Panelists:*
*Valerie Balosso, Director, Data Management, Infectious Diseases, GSK*
*Martina Endzhova, Global Category Lead, Clinical Trial Technologies, Bayer*
*Melanie Goodwin, Director, Clinical Outsourcing, Immunocore*
*Patricia Leuchten, Founder & CEO, Diligent Pharma*
*Michelle Shogren, CEO & Owner, Innovate in What You Do!; Senior Director of Innovation, Pharma R&D Clinical Operations, Bayer*

**10:15 Exploring New Perspectives in Modern Clinical Research**
*Zhe Rachel Angerer, Senior Director of Marketing Operations, Patient Solutions, PPD, part of Thermo Fisher Scientific*
*Brittany Erana, Senior Vice President, Digital and Decentralized Solutions, Virtual Trials, PPD, part of Thermo Fisher Scientific*
*Kate Pavlik, Executive Director, Project Management, PPD, part of Thermo Fisher Scientific*
*Margaret Twomey, MD, Director, Strategic Clinical Development Consulting, PPD, part of Thermo Fisher Scientific*

New technologies and regulatory and payor pathways are evolving to accommodate rapid progression of innovative therapies to global markets. Patients are more engaged and educated in their own health decisions than ever before. Access to more and diverse data sources is growing, and the use and acceptance of real-world evidence is expanding. Companies are facing increasing pressure to be first to market. Join our diverse panel of PPD experts to get insights on new and open perspectives that could be considered in clinical trial design and implementation to harness this evolution to your advantage.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

## OUTSOURCING MODELS: ADDRESSING GROWTH AND CHANGE

**11:40 Chairperson's Remarks**
*Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson*

**11:45 CO-PRESENTATION: Addressing the Impact of Carbon Footprint on Outsourced Activities: A Case Study on CRA Visits**
*Michael Cohen, Senior Director, Environmental Sustainability, Strategy & Innovation, Thermo Fisher Scientific*
*John Manns, Senior Director, Strategy, Innovation and Consultancy, Digital and Decentralized Solutions, PPD, part of Thermo Fisher Scientific*

Recognizing the importance of CRA visits, it is also crucial to realize the carbon footprint of this activity. Here, we will present new data on carbon footprint for global CRA visits from plane, train, car, and taxi travel from both before and after the COVID-19 pandemic. We have initialized a localized CRA model reducing the carbon footprint associated with these visits. We will explore options for technology both remote and onsite to replace and augment onsite visits and discuss potential options to reduce the carbon footprint from this outsourced activity.

**12:15 pm FIRESIDE CHAT: Clinical Trial Outsourcing Models—How Does a Customized Outsourcing Model Drive Success?**
*Kelly Artherholt Klatt, Associate Director, Clinical Strategic Outsourcing, Jazz Pharmaceuticals, Inc.*
*Allison Billups, Vice President, Business Development, Advanced Clinical*
*Amanda Hovda, Director, Strategic Outsourcing, Jazz Pharmaceuticals*

This is an interactive discussion addressing growth and change to implement/cater outsourcing models for success (Full Service CRO vs. FSP vs. Contract Support). It's essential to execute a thoughtful approach by customizing the outsourcing model to company/business needs. What's the best method

for maximizing cost savings and achieving operational efficiencies while addressing growth targets? Competition for industry talent remains at a peak. Which model touts staff retention and delivery quality?

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Factors to Consider When Outsourcing Your Late-Phase CNS and Oncology Imaging Trials**
*Denise Ferraiolo, Senior Vice President, Clinical Operations, Imaging Services, Invicro*
*Beth Rodriguez, CNMT, Vice President, Project Management, Invicro*

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## OPTIMIZING RELATIONSHIPS ACROSS THE CLINICAL ECOSYSTEM

**4:30 Chairperson's Remarks**
*Anca Copaescu, CEO, Clinical Maestro by Strategikon*

**4:35 FIRESIDE CHAT: Optimizing Goal Alignment across Sponsors, CROs, and Sites**
*Solomon Babani, CEO, Crovelis*
*Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)*
*Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Endo Pharmaceuticals*
*Scott Sawicki, MA, Senior Director, Strategic Sourcing & Vendor Management, ADC Therapeutics*
*Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson*
In order to develop an effective and cohesive partnership, sponsors, CROs, and sites must all align on not only the goals of their studies but corporate and individual goals as well. This fireside chat will address how sponsors, CROs, and sites can develop strong relationships through strategic discussions, goal alignment, and mutual interest in driving the success of each other.

**5:35 Is Hybrid Outsourcing the Right Approach for Me? Key Considerations for Drug Development Sponsors**
*Erin Koch, RN, BSN, PMP, Global Head of Adaptive Operational Solutions, Fortrea*
Drug development sponsors need to determine whether they require full service, FSP or a hybrid solution from CROs on their clinical trials. The term "hybrid" is challenging as no two hybrid solutions are identical. Picking the right outsourcing strategy requires sponsors to rethink their approach, and this session shares several key questions helping define optimal service delivery models to ensure they can completely meet the unique needs of a program.

**6:05 Close of Day**

# WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*
Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## SCALING ORGANIZATIONAL CAPACITY FOR EFFECTIVE CLINICAL TRIALS THROUGH PARTNERSHIPS AND EFFICIENT USE OF RESOURCES

**8:25 Chairperson's Remarks**
*Peter Ronco, CEO, Emmes*

**8:30 Thinking of Going Smaller? What to Expect When Transitioning from a Large Pharma Company to a Small Biotech**
*Susan G. Mullin, Vice President, Clinical Operations, Ventyx Biosciences, Inc.*
This presentation will focus on the differences between the work experience at a large pharma vs. a small biotech, what to expect during the transition, and how to plan for success. Topics will include: infrastructure, choosing a CRO, relationships, technology and culture, recruitment, training, and development of team members.

**9:00 Why Following the Status Quo for a Pediatric Rare Disease Clinical Study Was Not the Optimal Approach for a Small Biotech**
*Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.*
Clinical study success depends on three "C" or core elements: communication, collaboration, and cooperation from all participating individuals. When it comes to working on rare diseases, the chances of outsourcing to a CRO or vendor with prior experience in that particular indication are often nonexistent. This presentation will focus on how Rezolute took a more direct, hands-on approach to executing a rare pediatric pivotal Phase 3 Global Program.

**9:30 CO-PRESENTATION: Operationalizing a Virtual Site: Insights from Bayer and Science 37**

*Darcy Forman, Chief Delivery Officer, Science 37*

*Speaker II to be Announced*

The optimal clinical trial design is not a one-size-fits-all approach. Just as each clinical trial has its own unique characteristics, the elements of a virtual clinical trial require tailored integration to harmonize with specific protocol requirements. Explore insights from Bayer and Science 37 as they discuss their journey, the importance of collaboration in fostering innovation and explore perspectives on virtual trial execution.

**9:45 CO-PRESENTATION:**

*Brandie Jonas*

*Courtney Maguire, Senior Director Clinical Program Management, Geron Corporation*

*Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical*

**10:15 Decentralized Approaches—Especially in Rare Disease/Oncology—Into Trials That Require Centers Well-Versed in Clinical Research**

*Caro Unger, Senior Director, Clinical Operations*

Running trials nimbly—utilizing in-house talent and managing a trial without a CRO. How to evaluate if this is the right model for you and look at the pros and cons for your team/organization. Which vendors and consultants will you need and which resources can be used from the company? Which processes and plans will need to be developed and which lessons learned?

**10:45 Networking Coffee Break**

## OPERATIONALIZING DEI EFFORTS THROUGH OUTSOURCING AND PARTNERSHIPS

**11:05 Chairperson's Remarks**

*Diana Foster, Vice President, Strategy and Special Projects & Diversity Awareness Program Lead, Society for Clinical Research Sites*

**11:10 Recruitment Planning to Ensure Diverse Clinical Trial Participation**

*Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics*

Discover strategies for diverse clinical trial participation by developing inclusive protocol designs, applying data-driven site identification, and proactively customizing outreach and support for diverse populations. Attendees will learn strategies for determining trial-specific benchmarks and measuring success to enhance their ability to contribute to equitable and representative clinical trials.

**11:30 Forging Inclusive Alliances: Collaborative Partnerships in Operationalizing DEI Initiatives**

*Janaka Karunaratne, Consultant, Individual Consultant*

**11:40 PANEL DISCUSSION: Breaking Barriers, Bridging Gaps: Strategies for Creating and Outsourcing Clinical Trial Diversity Plans**

*Moderator: Susan Erondo, Founder and COO, Uncharted Access/Uncharted Advocates*

The implementation of robust clinical trials diversity plans is critical for fostering inclusivity and advancing biomedical research that benefits diverse populations. By embracing innovative and collaborative strategies and outsourcing partnerships, CliniOps can enhance participant representation and embark on equitable access to biomedical solutions. This presentation aims to equip the audience with the knowledge and tools to develop effective diversity plans that drive impactful and inclusive clinical trials.

*Panelists:*

*Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics*

*Dinorah Villanueva, Associate Director, Diversity, Equity, & Inclusion on Clinical trials (DEICT) Processes, The Janssen Pharmaceutical Companies of Johnson & Johnson*

*Janaka Karunaratne, Consultant, Individual Consultant*

*Naomi Orebiyi, Uncharted Access/Uncharted Advocates*

*Karen Patterson, CEO and Executive Director, KPE Research Solutions*

**12:40 pm Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Digital Innovations for Patient-Centered Clinical Trials Using Real-World Data**

*Karina D'Angelo, PhD, Director, Scientific Real World Data Strategy, Parexel*

*Denis McMillan, Vice President, Global Feasibility, Parexel*

*Camilla Ramdeen, PhD, Executive Director, Strategic Feasibility, Parexel*

*Russell Robbins, MD, MBA, Chief Medical Information Officer, PurpleLab*

Supporting inclusion of underrepresented populations in clinical trials and real-world data studies requires a multi-faceted approach – access to real world data sources supports decision making to ensure diverse populations are considered proactively throughout research study phases. This presentation highlights ways to ensure studies have DEI in patient populations to meet FDA expectations and innovative ways of using healthcare data linked with deidentified SDOH attributes.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 5th Annual

# Building New Clinical Programs, Teams and Strategies in Small Biopharma

**FEBRUARY 11-13, 2024**
All Times EST

Program Development and Implementation Strategies for Your Clinical Trials Portfolio

Cambridge Healthtech Institute's 7th Annual

# Managing Your Clinical Trials to Succeed in Small Biopharma

**FEBRUARY 13-14, 2024**

Unlocking Success in Clinical Trials: Empowering Small Biopharma with Effective Management Strategies

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## ENHANCING CLINICAL TRIAL IMPLEMENTATION THROUGH TECHNOLOGY AND STRATEGIC OPERATIONAL APPROACHES

**10:45 Chairperson's Remarks**
*Antoinette Torres Frankum King, Vice President, Head of Clinical Development North America, Clinical Development, ClinChoice*

**10:50 How Do You Stay Nimble and Agile While You Grow?**
*Peter Ronco, CEO, Emmes*
Your biotech portfolio is growing—congratulations! But what clinical operations capabilities, systems, and external providers do you need to prioritize first to support this growth? What are the best parts of big pharma that you can adopt, but without the bureaucracy, big prices, and lack of flexibility? And how do you project and strengthen the culture that made your company successful?

**11:05 Optimal Resource Utilization, Vendor Management, Data Metrics, and Tech in Small Biopharma Clinical Operations**
*Salam Ammus, Executive Director, Clinical Data Management, Mural Oncology*
Regardless, if a small biopharma has an outsourcing operational model or not, they will need a conscientious strategic operational plan. They will need to either have internal staff or leverage a service provider that will assist in overseeing the CRO or study activities. Small bioPharma may need to rely on external professional services to staff quickly with the appropriate profiles to adjust workload around study needs.

**11:20 Talk Title to be Announced**
*Patrick McCarthy, Esq., Chief Executive Officer, Validcare*

**11:35 Mastering Clinical Trials: Navigating Success in Small Biopharma**
*Ed Tumaian, Vice President, Clinical Operations, Cyclo Therapeutics, Inc.*
Discover strategies for managing clinical trials effectively in small biopharmaceutical companies. Learn to foster transparency and oversight with integrated project teams, define your role in ensuring trial success, and make informed decisions about in-house expertise and technology integration. Navigate challenges for a successful trial journey.

**11:55 PANEL DISCUSSION: Scaling-Up Your Organization: What Expertise Do You Develop In-House, and What Technology Do You Build vs. Buy?**
*Moderator: Lorenzo Balsamo, Director, Clinical Informatics & Innovation, Tango Therapeutics*
As you grow as a small biopharma, your portfolio is getting more complex—more countries, more indications, more sites, and more headaches! Learn from industry experts as they outline their experiences and mistakes so you can chart your own path forward with confidence.
*Panelists:*
*Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical*
*Ed Tumaian, Vice President, Clinical Operations, Cyclo Therapeutics, Inc.*
*Salam Ammus, Executive Director, Clinical Data Management, Mural Oncology*
*Peter Ronco, CEO, Emmes*

**12:20 pm Solving Small Biopharma's Big Challenges: What IRT Has to Offer**
*Tiffany Sox, Group Leader, Project Manager, CPS, Almac Clinical Technologies, Almac Group*
Small biopharma does not have the same resources and timelines to run their clinical trials as big players do, and yet they need the same best-in-class technology solutions to ensure safety and efficacy. The good news is, it's possible. Join us to discuss how.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Making Rare Connections in Rare Conditions: Forecasting Study Performance with AI to Find Patients & Investigators**
*Rohit Nambisan, CEO & Founder, Lokavant*
Approaching the new frontier of clinical research, rare diseases, niche indications & limited resources for small study teams will become normal. As challenges increase, AI will reduce burden & improve efficiency by helping pinpoint suitable patients & investigators for specific studies from RWD w/ remarkable speed. We'll share how AI emerges as a tool, and an engine of opportunity, enabling smaller teams to compete on the global stage with limited resources

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## OPTIMIZING PROVIDER SELECTION AND VENDOR OVERSITE

**2:20 Chairperson's Remarks**
*Julie Nolte, Executive Director, Clinical Operations, Arcutis Biotherapeutics, Inc.*

**2:25 ClinEco as Your Strategic Outsourcing Ally**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:30 PANEL DISCUSSION: How Do You Choose a CRO?**
*Moderator: Kathleen Harper Wisemandle, Founder and Executive Coach, Aspire to Grow Coaching & Consulting LLC*
Our panelists will discuss the key learnings and best practices for choosing and managing a CRO relationship toward successful study completion, ongoing risk management and optimal partnership. In addition, they will provide insights on how they chose the best CRO for their unique needs.
*Panelists:*
*Dawn Buchanan, Vice President, Clinical Operations, AffyImmune Therapeutics, Inc.*
*Richard L. Polgar, Senior Advisor, Danforth Advisors*

**2:55 Getting the Job Done—Keys to Successful Selection, Partnership, and Management of Clinical Trial Vendors**
*Camisha Harge, Vice President, Clinical Development & Operations, ASLAN Pharmaceuticals*
For small biotechnology companies, ensuring that the appropriate vendor partners are engaged is of particular importance, as not only is there a greater dependence on the success of each of the clinical trials, but the viability of the company itself is at stake. This presentation will provide a framework for successful selection, partnership, and management of the various vendors toward successful set-up and execution of clinical program trials.

**3:25 Challenges and Successes of Bringing Trial Activities In-House While Partnering with a CRO**
*Jamie Spencer Christensen, Director, Clinical Operations, Kodiak Sciences, Inc.*
Expanding the internal Clinical Operations team while partnering with a CRO can be successful, but choosing the right roles at the right time while adequately developing a CRO oversight process/plan that fosters teamwork, partnership, and collaboration can have its challenges. This session will provide an overview of how one company worked through this internal growth while running six global Phase III trials that successfully met each study's critical milestones.

**3:50 Ensuring Operational Success and Maintaining Quality When Outsourcing for Clinical Trials**
*Julie Nolte, Executive Director, Clinical Operations, Arcutis Biotherapeutics, Inc.*
The topic includes strategies and key considerations to implement operational success for clinical studies with outsourced teams. Operational success in clinical trials is attributed to robust study planning and diligent oversight when outsourcing. We will review study planning strategies: highlighting resources, processes, and systems to adequately support study activities and identify risks. We will also review best practices for study oversight: highlighting quality and milestone management to ensure operational success.

**4:10 Sponsor Oversight Requirements: A Risk-Based Approach**
*Preeti Baweja, Director, Clinical Operations, Ventyx Biosciences, Inc.*
With multiple vendor partners, a requirement for sponsor oversight, and a burden to maintain quality pose an immediate need to identify an oversight approach that is feasible, flexible, and manageable. What should the sponsor oversee & how to document the oversight are some of the questions many sponsors are asked to address. This presentation will focus on a risk-based approach to oversee vendor partners.

**4:25 CO-PRESENTATION: Automating Trial Data Journeys from the Point-of-Care** flatiron
*Ariel Bourla, Senior Director, Data Science and Digital Health, Johnson & Johnson R&D*
*Mariel Boyd, Senior Product Manager, Clinical Research, Flatiron Health*
Acceleration of data availability within a study is critical when possible and if there's a way to achieve speed without sacrificing data quality, or burdening internal resources—that could be the difference between success and failure for smaller, leaner biopharma sponsors. In this talk, we will show how technology and technology-enabled abstraction within the EHR can enable the capture and transfer of 100% of study data while preserving data quality. We'll show how smaller sponsor teams can rely on new processes to transfer intentionally collected data like adverse events or medical history and unstructured data, like cancer history, smoking status, or survival status. Small and lean teams alike, can achieve study speed and efficiency, alleviating manual efforts and creating the best possible study experience.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment** Medable
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?** trialbee
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## GROWING YOUR CLINICAL OPERATIONS

**9:10 Chairperson's Remarks**
*Doug A. Schantz, Senior Vice President, Clinical Operations, Asklepios BioPharmaceutical, Inc.*

**9:15 PANEL DISCUSSION: So You're Growing Up?**
*Moderator: Valerie Reynaert, Vice President, Global Clinical Operations, Immunocore*
How are you scaling your ops organization to the next level? Which roles and core competencies do you need to build? What roles do you decide to move in-house and which ones do you insource or outsource? Centered on talent, staffing, and sourcing elements, this panel will exchange their expertise, recount hurdles confronted, and elucidate acquired insights to educate small to mid-size biopharma leaders.
*Panelists:*
*Ann-Marie Hulstine, Senior Director, Clinical Operations, TriSalus Life Sciences*
*Kristine Koontz, PhD, Vice President, Global Clinical Operations, Daiichi Sankyo, Inc.*
*Anne Marie L. Inglis, PhD, Senior Director & Asset Lead, Clinical Operations, GSK*
*Doug A. Schantz, Senior Vice President, Clinical Operations, Asklepios BioPharmaceutical, Inc.*

**9:45 Successful Clinical Outsourcing Strategies in Small Biotech—The Whys and Hows**
*Anastasia Gutierrez, Vice President, Clinical Operations, Immuneering Corp.*
This presentation will be focused on how to evaluate the outsourcing needs and select "fit for purpose" outsourcing model to complement small biotech infrastructure. Speaker will share best practices and considerations for assessing and selecting clinical vendors, as well as understanding the budget and scope before contract is signed. Special focus will be given to building successful partnership with the CROs from the start and building A-team for the trial.

**10:00 Addressing Clinical Development Costs & Challenges: A Small Biopharma Perspective**
*Maribelle Guloy, PhD, Director Clinical Development, Daiichi Sankyo Company*
One of the challenges of a small biopharma is linked to high clinical development costs. To circumvent these barriers, small biopharma companies tend to seek partnerships outside the U.S., e.g., Eastern Europe or India, to manage their clinical trials. Balancing the cost efficiency of running trials in the region(s) with the extra work needed to ensure compliance will be discussed.

**10:15 Lean Enrollment: Getting Full Studies on a Resource Diet**
*Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth*
Recruitment Strategies that drive efficiency: Prototyping study design & I/E in market to validate feasibility assumptions; Avoiding one-size-fits-all approach for Patient-Facing communications; Building for optimization — enabling A/B testing in a regulated environment; Risk mitigation by stage + metrics to track; Adaptive forecasting.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

## FOSTERING DYNAMIC PROJECT TEAMS: UNLEASHING POTENTIAL WITH LEAN RESOURCES

**11:40 Chairperson's Remarks**
*Tommy Jackson, CEO, Prelude*

**11:45 It's Time to Get REAL: Is Your Team Ready to Navigate the Rapid Changes You Are Facing?**
*Jason Gubb, Co-Founder, ClinOpsClarity and Emergent Teams*
Teams are facing white-water change. Too slow to adapt, you risk getting stuck on the rocks; or worse, ceasing to be relevant. Teams must evolve at pace, continuously experimenting and growing their capabilities. To succeed, teams must discard old ways of thinking and form more useful mindsets and sustainable habits. In other words, to navigate constant change and accelerate performance in today's fast-moving world, teams need to be emergent.

**12:00 pm Building Teams That Rise to the Occasion in Small Biopharma/Biotech**
*Jennifer J. Gaskin, Senior Director, Clinical Operations, Celldex Therapeutics, Inc.*
In the competitive world of biotechnology, small companies need to be able to build successful teams to succeed. This is no easy task, as small companies often have limited resources, budgets, and a tight timeframe. However, there are several things that small biotech companies can do to build successful teams. This talk will take you through the special considerations and critical factors in creating teams that rise to the occasion.

**12:15 PANEL DISCUSSION: Building High-Performing Teams That Can Navigate Rapid Changes**
*Moderator: Jason Gubb, Co-Founder, ClinOpsClarity and Emergent Teams*
Small biopharma face continuous disruption from external forces and within their organization, which often leads to misalignment within teams. With increased complexity in drug development and study designs, new leadership qualities are required of teams to understand and maximize the intersection of technology and collaboration with agility. Our session will explore approaches for building high-performing teams that can emerge, adapt, and achieve superior performance in such a dynamic environment.
*Panelists:*
*Kunal Sampat, Host, Clinical Trial Podcast*
*Allison Kemner, Vice President, Clinical Sciences and Operations, Tyra Biosciences*
*Jennifer J. Gaskin, Senior Director, Clinical Operations, Celldex Therapeutics, Inc.*
*Chuck Bradley, Former Senior Vice President, Global Development Operations, Annexon Biosciences*

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Doing More with Less – Prioritizing Technology for Better Site Performance**
*Stuart Cotter, Vice President, Technology Strategy and Innovation, Advarra*
Clinical trial designs and study teams are continually asked to do more with less: requests for more metrics, expanded regions, faster recruitment results, and more complexity across a finite workforce. Despite each stakeholder's best efforts, there are persistent challenges that regularly throw studies off track and result in costly workarounds. Learn how prioritizing the site technology experience produces the best outcomes for your study.

**1:20 Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)***. Best of Show Winner to be Announced.**

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## UNLOCKING CLINICAL TRIAL TRIUMPH: REGULATORY AND FEASIBILITY GUIDANCE THAT ENCOMPASSES ALL STAKEHOLDERS

**4:30 Chairperson's Remarks**
*Anthony Vigliotti, Chief Product Officer, Adlib Software*

**4:35 ICH Guidelines for Designing Quality into Clinical Trials**
*Kathleen Harper Wisemandle, Founder and Executive Coach, Aspire to Grow Coaching & Consulting LLC*
Recently updated regulatory guidance for clinical trial planning has become more complex. We will discuss an overview of ICH E8 (R1) and ICH E6 (R3), including the proactive planning of clinical studies using Quality by Design and

Critical to Quality Factors Assessments. The aim is to ensure trial operational feasibility, subject safety, and quality data for submissions from a multi-stakeholder lens.

**4:55 Bridging the Gap: Navigating Clinical Trial Feasibility for Strategic Success**
*Anthony Ciliberto*
*Donna Hanson, Vice President, Strategy & Optimization, Advanced Clinical*
*Jennifer Weaver, Director, Study Delivery Shared Services and Analytics, CSL Behring*
As the landscape of healthcare evolves, the importance of efficient and well-executed clinical trials becomes paramount. This discussion aims to delve into the intricacies of clinical trial feasibility, exploring its critical role in shaping strategic outcomes. We will navigate the journey from the initial assessment of trial viability to the realization of stakeholder benefits that ultimately contribute to strategic feasibility.

**5:15 Genetically Modified Biologics & Implications for Feasibility & Study Start-Up**
*Christopher L. Jenkins, Founder, Principal Partner & Chief Gene Therapy Biosafety Officer, Clinical Biosafety Service*
With the FDA accelerating pathways in rare disease, oncology, infectious disease and other indications using gene therapy, implications on study start-up and feasibility for sites exist to conduct these trials. This discussion will highlight regulatory and practical feasibility questions.

**5:35 Training AI/ML to Auto-Classify eTMF Documentation: Here is What We Learned**
*Anthony Vigliotti, Chief Product Officer, Adlib Software*
Clinical trials have multiplied in the past 20 years, escalating documentation needs. Managing the immense data against evolving TMF standards leads to operational inefficiencies and FDA rejection risks. Join our session as we demonstrate key learnings from training a machine learning model for eTMF auto-classification. We'll cover how AI/ML overcomes persistent documentation challenges and ensures GMP, CDISC, and FDA compliance, offering your organization a competitive edge in clinical trials.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

### BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*
Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

### SCALING ORGANIZATIONAL CAPACITY FOR EFFECTIVE CLINICAL TRIALS THROUGH PARTNERSHIPS AND EFFICIENT USE OF RESOURCES

**8:25 Chairperson's Remarks**
*Peter Ronco, CEO, Emmes*

**8:30 Thinking of Going Smaller? What to Expect When Transitioning from a Large Pharma Company to a Small Biotech**
*Susan G. Mullin, Vice President, Clinical Operations, Ventyx Biosciences, Inc.*
This presentation will focus on the differences between the work experience at a large pharma vs. a small biotech, what to expect during the transition, and how to plan for success. Topics will include: infrastructure, choosing a CRO, relationships, technology and culture, recruitment, training, and development of team members.

**9:00 Why Following the Status Quo for a Pediatric Rare Disease Clinical Study Was Not the Optimal Approach for a Small Biotech**
*Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.*
Clinical study success depends on three "C" or core elements: communication, collaboration, and cooperation from all participating individuals. When it comes to working on rare diseases, the chances of outsourcing to a CRO or vendor with prior experience in that particular indication are often nonexistent. This presentation will focus on how Rezolute took a more direct, hands-on approach to executing a rare pediatric pivotal Phase 3 Global Program.

**9:30 CO-PRESENTATION: Operationalizing a Virtual Site: Insights from Bayer and Science 37**
*Darcy Forman, Chief Delivery Officer, Science 37*
*Speaker II to be Announced*
The optimal clinical trial design is not a one-size-fits-all approach. Just as each clinical trial has its own unique characteristics, the elements of a virtual clinical trial require tailored integration to harmonize with specific protocol requirements. Explore insights from Bayer and Science 37 as they discuss their journey, the importance of collaboration in fostering innovation and explore perspectives on virtual trial execution.

**9:45 CO-PRESENTATION:**
*Brandie Jonas*
*Courtney Maguire, Senior Director Clinical Program Management, Geron Corporation*
*Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical*

**10:15 Decentralized Approaches—Especially in Rare Disease/Oncology—Into Trials That Require Centers Well-Versed in Clinical Research**
*Caro Unger, Senior Director, Clinical Operations*
Running trials nimbly—utilizing in-house talent and managing a trial without a CRO. How to evaluate if this is the right model for you and look at the pros and cons for your team/organization. Which vendors and consultants will you need and which resources can be used from the company? Which processes and plans will need to be developed and which lessons learned?

**10:45 Networking Coffee Break**

### OPERATIONALIZING DEI EFFORTS THROUGH OUTSOURCING AND PARTNERSHIPS

**11:05 Chairperson's Remarks**
*Diana Foster, Vice President, Strategy and Special Projects & Diversity Awareness Program Lead, Society for Clinical Research Sites*

**11:10 Recruitment Planning to Ensure Diverse Clinical Trial Participation**
*Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics*
Discover strategies for diverse clinical trial participation by developing inclusive protocol designs, applying data-driven site identification, and proactively customizing outreach and support for diverse populations. Attendees will learn strategies for determining trial-specific benchmarks and measuring success to enhance their ability to contribute to equitable and representative clinical trials.

**11:30 Forging Inclusive Alliances: Collaborative Partnerships in Operationalizing DEI Initiatives**
*Janaka Karunaratne, Consultant, Individual Consultant*

**11:40 PANEL DISCUSSION: Breaking Barriers, Bridging Gaps: Strategies for Creating and Outsourcing Clinical Trial Diversity Plans**
*Moderator: Susan Erondo, Founder and COO, Uncharted Access/Uncharted Advocates*
The implementation of robust clinical trials diversity plans is critical for fostering inclusivity and advancing biomedical research that benefits diverse populations. By embracing innovative and collaborative strategies and outsourcing partnerships, CliniOps can enhance participant representation

and embark on equitable access to biomedical solutions. This presentation aims to equip the audience with the knowledge and tools to develop effective diversity plans that drive impactful and inclusive clinical trials.

***Panelists:***

***Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics***

***Dinorah Villanueva, Associate Director, Diversity, Equity, & Inclusion on Clinical trials (DEICT) Processes, The Janssen Pharmaceutical Companies of Johnson & Johnson***

***Janaka Karunaratne, Consultant, Individual Consultant***

***Naomi Orebiyi, Uncharted Access/Uncharted Advocates***

***Karen Patterson, CEO and Executive Director, KPE Research Solutions***

**12:40 pm Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Digital Innovations for Patient-Centered Clinical Trials Using Real-World Data**

***Karina D'Angelo, PhD, Director, Scientific Real World Data Strategy, Parexel***

***Denis McMillan, Vice President, Global Feasibility, Parexel***

***Camilla Ramdeen, PhD, Executive Director, Strategic Feasibility, Parexel***

***Russell Robbins, MD, MBA, Chief Medical Information Officer, PurpleLab***

Supporting inclusion of underrepresented populations in clinical trials and real-world data studies requires a multi-faceted approach – access to real world data sources supports decision making to ensure diverse populations are considered proactively throughout research study phases. This presentation highlights ways to ensure studies have DEI in patient populations to meet FDA expectations and innovative ways of using healthcare data linked with deidentified SDOH attributes.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 16th Annual

# Clinical Data Strategy and Analytics

Data Management in Digital and Hybrid Trials

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 7th Annual

# Artificial Intelligence in Clinical Research

AI to Lead Clinical Trial Modernization

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## TRANSFORMING TOOLS AND APPROACHES

**10:45 Chairperson's Remarks**
*Speaker to be Announced*

**10:50 Advanced Data Monitoring to Prevent Clinical Trial Fraud**
*Demetris Zambas, Vice President & Global Head, Clinical Data Sciences, Pfizer Inc.*
Can centralized monitoring boost data quality? This presentation will share the efforts to answer this question and more.

**11:20 CO-PRESENTATION: Technology Masterclass: Leveraging AI and Data Intelligence to Accelerate Clinical Trials**
*Silvio Galea, Chief Data and Analytics Officer, WCG*
*Paul J. Mancinelli, PhD, CTO, WCG*
Improving the safety, efficacy and efficiency across the clinical trial lifecycle is critical. Buzzwords aside, artificial intelligence, data analytics and technology have the power to connect stakeholders and applications and enhance protocol design, study feasibility, and patient identification and recruitment. In this session, WCG will discuss how we're applying artificial intelligence to optimize trial execution and harnessing the power of data in one unified platform to improve and accelerate research.

**11:50 Building a Capability to Enable Data-Driven Decision-Making in Clinical Research**
*Disa Lee Choun, Head of Integrated Clinical and Operational Analytics (ICOA), Johnson & Johnson*
Elevating data-driven organizations to new heights involves constructing a robust data infrastructure, harnessing cutting-edge technologies, adhering to privacy and data security regulations, and enforcing data governance principles. Enabling data innovation can transcend internal and external barriers, effectively overcoming silos.

**12:20 pm CO-PRESENTATION: Driving Efficiencies in Trial Strategy Generation and Trial Overnight with Generative AI**
*Wendy Morahan, Senior Director, Clinical Data Analytics, Clinical Technologies, IQVIA Technologies*
*Wing Lon Ng, Director, AI Engineering, Analytics Center of Excellence, IQVIA*
Automation in clinical trials is essential to help improve accuracy and streamline complex processes, and the recent explosion of innovation with generative AI is delivering promising advances. Join us to discuss how automation with Large Language Models can reduce clinical trial strategy generation from days to minutes and how dynamic trial oversight dashboards are generated with natural language, conversational analytics requests.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Digitalized Clinical Development: Driving Meaningful Change Through Innovation**
*Matteo di Tommaso, Vice President, Digital Technology, Bristol Myers Squibb*
*Maria Perkinson, Senior Vice President, Process & Tech Optimization, Nurocor*
*Kailash Swarna, Managing Director, Accenture*
Biopharma Companies are moving toward full automation and harmonization of business processes across the clinical development lifecycle, beginning with digitalized protocol through regulatory approval. This digital automation leads to efficiencies, which will significantly reduce the time and cost of drug development. Key industry organizations and thought leaders will share their experiences in realizing full digitalized clinical development.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## DATA MANAGEMENT IN DIGITAL AND FLEXIBLE TRIALS

**2:20 Chairperson's Remarks**
*Denise Ferraiolo, Senior Vice President, Clinical Operations, Imaging Services, Invicro*

**2:25 CO-PRESENTATION: Status Update of the DATA4YOU Data Review Platform—Bringing Different Personas Together for Near Real-Time Access to Clinical Trial Data**
*Ward Lemaire, Head of Data Management, Integrated Data Analytics & Reporting, Janssen Pharmaceutical Companies of Johnson & Johnson*
Bringing key roles together in a next-generation data review platform that facilitates near real-time access to clinical trial data allows for early decision-making and cross-functional risk-based data review methodologies (medical review, clinical data review, central monitoring). Building on a platform that can further develop machine learning capabilities prepares us for the future evolution of data becoming bigger and increasingly complex.

**2:50 Digital Data Flow: Digitalizing Clinical Protocol Information to Accelerate Clinical Research and Pharma to Healthcare Interoperability**
*William Illis, Global Head, Collaboration & Technology Strategy Clinical Development, Novartis Pharmaceuticals*
Digitizing clinical protocol information can streamline system configuration during study start-up, enable analytics-assisted study design feasibility, and support routine use of point-of-care data for research. TransCelerate's DDF initiative and CDISC have delivered a foundational data model, exchange standard, and open-source reference implementation aimed at supporting use of digital protocols across industry. This presentation will highlight current capabilities, demonstrated use cases, and a future roadmap for multi-stakeholder collabs to achieve interoperability.

**3:15 Application of AI/ML to Digital Measurement to Inform Early-to-Late-Stage Clinical Development Lifecycle of Therapeutics**
*Subha Madhaven, Vice President and Head, AI/ML, Quantitative and Digital Sciences, Global Metrics and Data Management, Pfizer Inc.*
AI/ML technologies, including the latest Generative AI capabilities, play a transformative role in accelerating drug candidate identification, predicting safety and efficacy, optimizing patient recruitment, and enabling personalized medicine approaches. These technologies leverage clinical trials, RWE, wearables, and molecular data to inform drug safety and efficacy as well as to help meet patients where they are.

**3:40 CO-PRESENTATION: Next-Generation EDC Systems**
*Kapil Gombar, Director CDM, Clinical Technology Innovation & Support, AbbVie*
*Lance Kupka, Director, Clinical Data Systems, Abbive*
Electronic Data Capture (EDC) has traveled a long road to acceptance within the pharmaceutical industry. As technology advanced rapidly over the past 3+ years, the use of an EDC tool within the industry has lagged behind the innovation.

**4:10 Update from Vulcan**
*Amy Cramer, Focus Area Leader: Capitalizing on Data Assets, The Janssen Pharmaceutical Companies of Johnson & Johnson*
The biopharmaceutical industry strives to ensure patient wellness and safety by producing new drug candidates that have undergone rigorous testing and approval by global health authorities. However, R&D inefficiencies around approaches and processes for drug development have caused roadblocks for successfully starting, recruiting, executing, and completing a clinical research study, ultimately delaying development of needed medications for patients.

**4:25 Unlocking AI's Potential in Clinical Trials: Navigating Bias, Misconceptions, and Future Opportunities**
*Todd Rudo, MD, CMO, Clario*
This session will explore the transformative role of AI in clinical trials: where we are today, common misconceptions in leveraging AI, proactively tackling the potential for bias, and navigating the current regulatory landscape. Participants will gain an understanding of the responsible application of AI-enabled algorithms in clinical trial endpoint collection and data analysis.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## DATA GOVERNANCE AND DATA STANDARDS

**9:10 Chairperson's Remarks**
*Brett Kleger, CEO, Datacubed Health*

**9:15 Clinical Data "Sciencing" the Data Quality and Data Integrity Validation Approach to ECOA Data**
*John Finn, Executive Director and Inflammation & Immunology-RAE TA Lead, Clinical Data Sciencest, Pfizer Inc.*
Historically data validation for ECOA modules focused on "within form/ within visit" checks that were skewed to a focus on Data Quality - but allowed very easily identifiable data integrity matters to be overlooked – such as implausible changes from visit to visit within an assessment, or cross-assessment dis-correlations. This presentation will provide approaches to ensure DQ and DI and unleash the true value that CDS brings to ensuring both.

**9:35 Data Governance and Data Integration from Various Sources**
*Victoria A. Gamerman, PhD, Global Head of Data Governance, Boehringer Ingelheim Pharmaceuticals, Inc.*
Data governance is the set of policies, procedures, and roles that define how your data is collected, stored, processed, and shared. This concept is critically important for clinical trials data management.

**9:55 CO-PRESENTATION: The Future of SD™ Transformation: AI and HITL**
*Sanjay Bhardwaj, Executive Director, Head of Clinical Data Technologies, AbbVie, Inc.*
*Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.*
The session discusses the challenges of SD transformation, the traditional approach to SD transformation, and the AI + HITL approach. It also discusses the lessons from AbbVie's implementation of an AI-powered SD transformation solution.

**10:15 Building a Capability to Enable Data-Driven Decision-Making in Clinical Research**
*Stacy Eckstein, Manager, Trial Informatics, Incyte Corporation*
*Luke Moyer, Head, Global Clinical Supply Chain, Incyte Corporation*
*Elke Ydens, Associate Director of Business Solutions, Data Division, Anju Software*
Focuses on establishing a robust capability to facilitate data-driven decision-making in clinical research. The research aims to develop and implement strategies that enhance the integration, analysis, and interpretation of clinical data. By leveraging advanced technologies and methodologies to empower healthcare professionals and researchers with the tools and process to ask the right questions early and obtain the data necessary to derive meaningful insights from complex clinical datasets.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

**11:40 Chairperson's Remarks**
*Todd Rudo, MD, Chief Medical Officer, Clario*

**11:45 CO-PRESENTATION: Clinical Data Management Advancements: Focus on Integration, Interoperability, Integrity—I-ELEVATE—Integrated Platform for Efficient Data Linkage, Effortless and Versatile Access for Transparency and Effectiveness in Daily Data Management Activities**
*Mary Koularmanis, Director, Oncology Data Management Operations, Bayer U.S. LLC*
*Anita Kratchmarov, Global TA Head, Data Management & Oncology Development Operations, Bayer HealthCare*
Creating a one-stop shop integrated platform (I-ELEVATE) with focus on enabling efficiency and interoperability via versatile, streamlined access to study clinical, operational, and metadata will lead to transparency of resource

estimation, efficient management of timelines, data deliverables, and outliers/risks, and will help close the gap between traditional data management practices and evolving technology.

**12:15 pm CO-PRESENTATION: Automation: From Protocol Definition through Submission**
*Brian Hermann, Senior Director, Reporting, Archiving & Mapping—Global Clinical Data Integration, Merck*
*Narayanarao Pavuluri, Senior Director & Global Head, Clinical Database Services, Merck*
*Donald Thampy, Executive Director, Merck*
Currently, there are a lot of handoffs between tasks and functions from protocol definition, collector build, data transformations, SD, ADaM, Tables, Listings, Figures, and Submissions. How can we automate these functions end-to-end by flowing the data and metadata, including the data into submissions to make it easier for the reviewers for easy access of the data they need to verify instead of searching multiple places? Consider ways to achieve this.

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Stop Exploring Your Data — Action It**
*Lisa Moneymaker, CTO/CPO, Saama*
Join this exciting session to learn about how to stop exploring your data and instead spend your time actioning it with Saama's ground-breaking AI-driven platform.
You'll learn how: to ask questions of your data with generative AI chat, create custom listings without programmers, let AI direct you to critical insights, and accelerate timelines by automating key processes.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## AI-POWERED DATA MANAGEMENT SOLUTIONS

**4:30 Chairperson's Remarks**

**4:35 CO-PRESENTATION: Supercharging Data Engineering in R&D to Scale Advanced Analytics and Machine Learning**
*Gian Prakash, Director, Data Engineering, Information Research, AbbVie, Inc.*
*Chris Sinclair, PhD, Senior Director, Information Research Operations Network, AbbVie, Inc.*
The pharmaceutical R&D industry is investing heavily in harnessing the power of advanced analytics and machine learning. However, data engineering in the pharma R&D industry presents unique challenges, such as data silos, managing diverse data sources while adhering to strict regulatory requirements, and protecting patient privacy. This presentation will discuss how AbbVie is re-imagining the data engineering capabilities to scale and expedite advanced analytics and machine learning.

**5:05 CO-PRESENTATION: Enhancing Clinical Data Review: Leveraging AI for Efficient and Insightful Analysis**
*Abhijit Parab, Executive Director, Global Clinical Data Management and Data Service Delivery, Bristol Myers Squibb Co.*
*Rishitha Sajja, Senior Manager, Clinical Data Management*
Technological progress like AI/ML enhances clinical data review. Robust AI/ML learns from patient data, offers AI traceability for issue analysis, and deploys methods like NLP to automate review. This aids data managers in automatic query generation, focusing on key discrepancies and predicting query trends.

**5:35 CO-PRESENTATION: Engaging Patients in Clinical Trial Design Improves Enrollment, Retention, and Trial Data**
*Kathleen Beusterien, Senior Research Scientist, Oracle Life Sciences*
*Rebecca Nash, PhD, Principal RWE, Oracle Life Sciences*
Proactive patient engagement in the design of clinical trials, including the endpoints used in data collection, can positively impact trial optimization, and feasibility assessments. A patient-centric approach meets with growing expectations by regulators and combined with a data driven approach to understanding of patient behaviours can accelerate study recruitment and aid in ongoing retention, as well as promoting inclusiveness and diversity, and ultimately overall quality of data.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## AI HYPE AND HOW TO RIDE IT

**8:25 Chairperson's Remarks**
*Todd Sanger, Vice President, Advanced Analytics and Data Sciences, Eli Lilly and Co.*

**8:30 Using AI to Optimize Clinical Trial Design**
*Jade Dennis, Executive Director, Clinical Trial Design Capabilities, Eli Lilly and Company*
*Todd Sanger, Vice President, Advanced Analytics and Data Sciences, Eli Lilly and Co.*
Using AI & analytics through a web-based design tool, study development teams can optimize their study design in real-time. Built on extracting protocol elements, data standardization, and development of predictive models to understand how different design features impact operational metrics, the tool surfaces data for users to draw insights, identify trends, and make data-informed decisions to accelerate timelines and reduce patient burden and cost.

**8:50 CO-PRESENTATION: Adopting and Integrating AI/ML in Clinical Operations: Change Strategies for Data-Driven Platforms**
*Kelly Gregory, Manager, R&D Data Science, Data Science Solutions, Privacy & Ethics, Janssen Pharmaceuticals, Inc.*
*Phuong Clare Vo-Schneider, Director, R&D Data Science, Data Science Solutions, Privacy & Ethics, Janssen Pharmaceuticals, Inc.*
Change management for artificial intelligence adoption is imperative for successful clinical trial operations. Strategies for how we enable change with clinical teams, helping them to navigate machine learning transformation, will be covered. We will walk through one of our use cases illustrating how we successfully overcame challenges and gained user adoption for one of our data-driven, AI/ML-enabled platforms.

**9:15 Embracing the Next-Generation of Clinical Data: Pioneering Innovation in the Clinical Research Ecosystem**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*
Advances in clinical research over the last five years have given rise to an intricate patient data ecosystem, presenting both challenges and opportunities for clinical research professionals. This keynote will explore the convergence of three key innovation themes that are shaping the future of the clinical research ecosystem.

**9:30 Enhancing EDC Efficiency: Leveraging AI for Automated Site Data Integration**
*Tai Xie, PhD, CIMS Global*
In clinical trials, Electronic Data Capture (EDC) systems are vital, managing trial operations, eCRFs, and study flow per protocol. Sites often use site-specific data forms (SSDFs) during patient visits, transcribing to EDC later. This risks transcription errors, prompting onsite Source Data Verification (SDV). A new AI-driven method streamlines data entry, shifting to remote SDV, enhancing data quality and trial efficiency. This method succeeded in two clinical trials, promising transformative results.

**9:45 Embracing Generative AI in Clinical Development: The LLM Breakthrough**
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*
This presentation focuses on the rapid advancements in Generative AI, particularly highlighting GPT-4's unprecedented capabilities. As the latest iteration in AI technology, GPT-4 emerges as a pivotal tool in clinical research, adept at diverse tasks including data generation, summarization, translation, extraction, and comprehensive analysis. This session underscores the significance of accessible, varied data sources as the backbone for successful Generative AI applications in life sciences.

**10:15 PANEL DISCUSSION: Generative AI in Clinical Research: Technology and Data Challenges**
*Moderator: Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**10:45 Networking Coffee Break**

## SYNTHETIC DATA IN CLINICAL TRIALS

**11:05 Chairperson's Remarks**
*Dorothee B. Bartels, PhD, Chief Digital Officer, AETION*

**11:10 Using Machine Learning to Augment and Inform Clinical Trial Design: Use-Cases from Multiple Therapeutic Areas**
*Khaled Sarsour, PhD, Vice President, Data Science and Digital Health; Real World Evidence & Advanced Analytics, Janssen Pharmaceuticals*
This presentation will share several case studies in various therapeutic areas of challenges and solutions of AI and ML implementation in clinical trial design.

**11:35 Driving Drug Development with Synthetic Data**
*Dooti Roy, PhD, Director, Global Biostatistics and Data Sciences, Boehringer Ingelheim Pharmaceuticals, Inc.*
Using artificial patients for drug development or medical device development is a promising field, only if the models can reach the required complexity and can be truly representative of the human population.

**12:00 pm PANEL DISCUSSION: AI in Clinical Research and RWE: Synthetic Data and Beyond**
*Moderator: Dorothee B. Bartels, PhD, Chief Digital Officer, AETION*
*Panelists:*
*Zhaoling Meng, PhD, Associate Vice President & Global Head, Clinical Modeling & Evidence Integration, Sanofi*
*Lucy Mosquera, Research Associate, Electronic Health Information Lab at Children's Hospital of Eastern Ontario; Sr Director of Data Science at Replica Analytics an Aetion Company*
*Khaled Sarsour, PhD, Vice President, Data Science and Digital Health; Real World Evidence & Advanced Analytics, Janssen Pharmaceuticals*
*Dooti Roy, PhD, Director, Global Biostatistics and Data Sciences, Boehringer Ingelheim Pharmaceuticals, Inc.*

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Enabling a Clinical Information Highway**
*Kim Walpole, Associate Principal, ZS*
Explore the transformative potential in drug development. We'll share how technology can facilitate a seamless flow of clinical information, connect stakeholders and stream data-driven decision-making. By harnessing cutting-edge technology, the industry will be able to accelerate medical research, enhance patient care and revolutionize the way clinical trials are conducted. Join us to discover the future of a clinical information highway, where data-driven insights drive healthcare forward.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 3rd Annual

# Decentralized and Hybrid Trials

Best DCT Practices and Case Studies

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 13th Annual

# Decentralized Trials and Clinical Innovation

Flexible Trials and Patient-Driven Choices

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth
7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## IMPLEMENTING DCT ELEMENTS INTO MAINSTREAM OPERATIONS

**10:45 Chairperson's Remarks**
*Ryan Jones, Co-Founder & CEO, Florence Healthcare*

**10:50 Once Upon a Time: Thinking of Trial Flexibility During Protocol Development**
*Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck*
Once upon a time....is a great beginning for a story, but not for a clinical trial protocol. With high complexity, numerous procedures, and other factors, study sites and participants complain about the burden of clinical trials. Can there be a happy ending? Merck's approach to protocol development aims to find that balance.

**11:20 Transforming Clinical Trials of the Future**
*Hassan Kadhim, Head of Clinical Operations and Development Business Capabilities, Vertex Pharmaceuticals*
This session will focus on the work to transform clinical trials of the future to be more patient-centric, including introduction of a scenario-planning methodology to explore the potential drivers influencing the future of clinical trials and considerations for enabling participant data return.

**11:50 Enabling Greater Flexibility in Conducting Clinical Trials—Lessons Learned**
*Joachim Lovin, DCT Specialist, Novo Nordisk*
The need to evolve clinical trials to include broad adoption of technologies and solutions, as appropriate, is highly important to enable greater flexibility, patient choice, and diversity in clinical trial populations. Join us to learn more about important and helpful tools developed to modernize clinical trials and explore the value demonstrated by their use to date.

**12:20 pm Decentralized Clinical Trials: The Next Phase**
*Darlene Ellenor, Director, Project Operations, eClinical Development and Delivery, ICON*
The evolution of clinical trials continues with a steady increase in demand for decentralised components, but what will be the tipping point when decentralised clinical trials are considered business as usual? This presentation will explore the status quo – where key stakeholders (patients, sites, and sponsors) are in this journey, where the gaps are, what works and what doesn't, and how we are showing the value of DCTs.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Are Decentralized Clinical Trials Dead? Leveraging Insights to Deliver More Patient-Centric Trials in the Future**
*Drew Bustos, Chief Marketing Officer, Executive Leadership, YPrime*
This presentation explores the evolving landscape of decentralized clinical trials (DCTs). By integrating fresh insights from patients and sponsors on key aspects like informed consent, Interactive Response Technology (IRT), Electronic Clinical Outcome Assessments (eCOA), and wearable technologies, we aim to redefine what patient-centric trials look like. We'll delve into how these elements can be effectively leveraged to enhance patient engagement and experience and streamline trial operations.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## TRANSFORMING LANDSCAPE OF CLINICAL TRIAL LOCATIONS

**2:20 Chairperson's Remarks**
*Melissa Nezos, Executive Vice President, Clinical Operations, Firma Clinical Research*

**2:25 Implementing Hybrid Approaches**
*John Campbell, Head of Decentralized Trials, Walgreens Co.*
The unprecedented increase in the volume of data from digital technologies is an opportunity to address long-standing challenges in clinical research. To ensure equitable outcomes from clinical trial innovation requires an initial acknowledgment and sustainable plan. During this session, we will highlight recent activities to showcase the impact on patients, providers, and other key stakeholders.

**2:55 Leveraging Independent Pharmacies to Use DHTs in Decentralized Trials**
*Katherine Williams, PharmD, MSM, RPh, Associate Principal Scientist, Regulatory Affairs, Merck & Co., Inc.*

The audience will gain insight in the independent pharmacies' community outreach and the impact they make in a community. The pharmaceutical industry will gain key points on how to leverage independent pharmacies in clinical trials to improve recruitment, retention, and diversity in clinical trials.

**3:25 Evidence-Based Digital Health in Pharma Industry**
***Ramya S. Palacholla, Director Digital Science, Digital Health & AI, AstraZeneca Pharmaceuticals***
This talk is based on a decade of experience working in some of the leading and largest hospital systems in the country (including Harvard, Johns Hopkins, Tufts) leading their Innovation hubs while actively collaborating with big pharma to build and implement digital health solutions that benefit patients. The audience can hear a unique perspective from a doctor who is passionate about building digital health solutions that can greatly impact patients.

**3:50 PANEL DISCUSSION: Enabling Clinical Research In Provider-Based Settings: What Works, and What Work Needs to Be Done?**
***Moderator: Tony Clapsis, General Manager, Senior Vice President, CVS Health Clinical Trial Services***
The session will explore the performance of embedded programs to date, explore provider challenges in building or partnering, and case studies from enabling companies that have built research capabilities. The session will also provide perspective on how sponsors have worked with such programs, and how expectations about their role differ from dedicated trial sites.
***Panelists:***
***Irfan Khan, CEO, Circuit Clinical***
***Aaron S. Weinberg, MD, MPhil, National Director of Clinical Research, Carbon Health***
***Brandon Cormier, CCO, Elligo Health Research***
***Henry Wei, MD, Executive Director, Development Innovation, Regeneron***
***Jonathan Feldstein, Co-Founder, Profound Research***

**4:25 CO-PRESENTATION: Bridging the Worlds of Clinical Trial and Healthcare Data**
***Daniel Braga, Vice President, Product Management - Patient Cloud, Medidata***
***Kelly McKee, Vice President, DCTs and Patient Registries, Medidata***
Clinical trial sites use many systems across the lifespan of a program to capture health data on trial participants, increasingly collected remotely as sponsors cater to patients with decentralized capabilities. These data represent critical points for the success of new therapies; however, they also represent important health information for individual patients and broader patient populations. Join this session with Medidata's Dan Braga and Kelly McKee as they discuss the problem of transferring healthcare data into clinical trial systems and where there are opportunities to use existing technology to turn healthcare data into trial data.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
***Colin Weller, General Manager, Evidence Generation Platform, Product, Medable***
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
***Matt Walz, CEO, Business Operations, Trialbee***

**9:00 Transition to Sessions**

## OVERCOMING IMPLEMENTATION CHALLENGES: IT TAKES A VILLAGE

**9:10 Chairperson's Remarks**
***Donna Mongiello, RN, BSN, Senior Vice President, Strategic Solutions, Commercial, YPrime***

**9:15 State of the State of Decentralized Clinical Trials**
***Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative***
Recommendations, guidance, and tools exist to implement decentralized clinical trial approaches. But how is the clinical trial enterprise doing with DCT implementation? This presentation will provide a state of the state of decentralized clinical trials, discuss the gaps that remain to advance the uptake of DCT approaches, and identify areas of progress or potential solutions to address those gaps.

**9:30 CO-PRESENTATION: Creating a Framework for Excellence: Technology and Global Standards in Decentralized Clinical Trials**
***Isaac R. Rodriguez-Chavez, PhD, MHSc, MSc, Scientific & Clinical Affairs, IEEE***
***Mathew Rose, MD, Co-Chair, IEEE; Founder and CEO, SAAVHA, Inc.***
We will delve into the advantages of integrating digital health technologies in DCTs and discuss the pressing need for standardized practices to overcome associated challenges along with the IEEE standards being developed. Additionally, we will emphasize how the implementation of global standards can establish a framework for excellence in DCTs, enhancing data integrity, patient safety, and regulatory compliance, while also fostering increased patient participation and engagement.

**9:45 Sponsored Presentation** *(Opportunity Available)*

**10:00 Talk Title to be Announced**
***Todd McGrath, Chief Operating Officer and General Manager - Home Trial Support, MRN***

**10:15 Walking before running: right-sizing hybrid trials for patients, sites, and sponsors**
***Andrés Escallón, Vice President, eCOA Strategy, Suvoda***
- Revisit the drive towards an "all virtual" approach to DCT, and the increasing shift to hybrid designs
- Explore learning from Suvoda case studies on how to implement hybrid trials successfully, focusing on right-sized approaches that meet patient, site, and trial needs
- Discuss how learning from DCT and hybrid trials can apply to future innovations, including AI, and strategies to use technology tools thoughtfully to drive overall trial success

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

**11:40 Chairperson's Remarks** *(Sponsorship Opportunity Available)*

**11:45 CO-PRESENTATION: Creating the DTRA DCT Playbook: Collaboration and Partnering to Support DCT Adoption**
***Dylan Bechtle, Associate Director, Regulatory Policy and Intelligence, The Janssen Pharmaceutical Companies***
***Jane Myles, Co-Lead, Priority Initiative 3B, DCT Playbook, Decentralized Trials & Research Alliance (DTRA)***
DTRA's member organizations, including pharma sponsors, site networks, technology, and service providers, have collaborated on 12 initiatives to address challenges related to designing and implementing decentralized trials. DTRA partners with cross-industry consortia, such as ACRO, ACRP, CTTI. SCRS and Transcelerate to align on key areas of focus and need. Panelists will share a playbook that includes tools, processes, and frameworks from this cross-collaboration to support the strategic, fit-for-purpose DCT adoption.

**12:00 pm PANEL DISCUSSION: Implementation Challenges for Decentralized and Hybrid Trials**
***Moderator: Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.***

COVID gave a push for the decentralization of clinical trials. FDA granted support and green light for DCT, and companies have. Does it mean we are ready?

*Panelists:*
*Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative*
*Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites (SCRS)*
*Robert DiCicco, Vice President, Portfolio Management, TransCelerate BioPharma Inc.*
*David Evans, President & CEO, CDISC*
*Craig Lipset, Founder, Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)*
*Isaac R. Rodriguez-Chavez, PhD, MHSc, MSc, Scientific & Clinical Affairs, IEEE*

12:45 **Transition to Lunch**

12:50 **LUNCHEON PRESENTATION: Crafting Site-Centric Strategies to Execute Better Trials**
*Natalie Blake, Director, Global Clinical Trials Organization - Project Management, Merck*
*Ken Getz, Executive Director, Research Professor (PHCM), Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems*
Clinical research sites play a pivotal role in the success of trials and the development of new treatments. However, the evolving research landscape, driven by changing technology, regulations, and patient expectations, presents challenges and opportunities. Join Natalie Blake of Merck and Ken Getz of Tufts University as they discuss strategies to improve trial performance and experience for sites by centralizing information, simplifying technology, and improving site engagement.

1:20 **Coffee & Dessert Break in the Exhibit Hall 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!

1:25 **Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

2:20 **Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

2:25 **Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

2:30 **PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

3:00 **CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

3:30 **Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## CLINICAL INNOVATION STRATEGIES AND FLEXIBLE TRIALS

4:30 **Chairperson's Remarks**
*Adam Halbridge, Exec. Director, Tokenization, ICON plc*

4:35 **Avoiding Muddy Pigs in Change Management When It Comes to DCTs and New Ways of Working**
*Sylvie Kruyner, Director, DCT Operations, Bayer Pharmaceuticals*
*Michelle Shogren, CEO & Owner, Innovate in What You Do!; Senior Director of Innovation, Pharma R&D Clinical Operations, Bayer*
Many solution provider companies have entered the world of DCTs and are attempting to revolutionize clinical trials. However, we have seen mixed results when it comes to adoption by Pharma, CROs, and Sites. Let's have a look at where we are on the adoption train and what may be stalling us.

5:05 **Building a Village for Modern Clinical Research: Foundational Technology to Enable Successful Decentralized Clinical Trials**
*Krista L. Russell, Head Digital Health Solutions, Data Sciences Institute, Takeda Pharmaceuticals*
Biopharmaceutical sponsors, clinical research organizations (CROs), and clinical sites require consistent approaches to deploy technology solutions for use in clinical trials. This presentation will evaluate the essential elements of a "village" of providers aligned on the value through strategic cross-functional alignment and understanding of solutions aimed at trial design, innovation, and connected services.

5:35 **What Are We Doing? New Challenges for Decentralized Trials in the Post-COVID Era**
*Anthony Everhart, MD, Clinical Vice President, Internal Medicine, Signant Health*
Efforts to continue clinical research during the COVID pandemic contributed to the rapid acceleration of decentralized methodologies. However, new data suggests that the intense focus on reducing participant burden may have shifted burden to other key functions rather than removing burden from the system. Addressing these new challenges will be necessary to further the growth of decentralized trials.

6:05 **Close of Day**

## WEDNESDAY, FEBRUARY 14

7:15 am **Registration Open**

## BREAKFAST PRESENTATION

7:45 **BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*
Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype

from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## LEGO BLOCKS OR CORNERSTONES? PATIENTS, SITES, DEVICES, DATA

**8:25 Chairperson's Remarks**
*Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Co.*

**8:30 Patient-Focused Technology for Real Diversity in Hybrid Trials**
*Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Co.*
Sponsors, sites, and patients have unique motivations and challenges in the conduct of clinical trials. Aligning the interests of stakeholders requires a thorough understanding of the goals and respective journey that each takes. Community-based clinical trials are an emerging option to level the playing field, position patients at the center of the end-to-end experience, and address long-standing inequities that result in gaps in scientific evidence applied to care.

**8:50 PANEL DISCUSSION: Challenges and Opportunities of Utilizing Global and Local Home Health Suppliers**
*Moderator: RoseAnn Price, Procurement Director Clinical Trial Specialty Services, R&D Sourcing & Procurement, Merck & Co., Inc.*
A panel including Clinical Ops, Clinical Development, Suppliers, Patient, Clinical Site, and Procurement to discuss the challenges and value of utilizing home health services. The panel will be selected, once the idea is selected.
*Panelists:*
*Deborah A. Guattery, Standards & Process Lead, Decentralized Clinical Trials, Pfizer Inc.*
*Linda Vineski, Director, Senior Clinical Quality Operations Manager, Merck & Co.*
*Ronnie Sharpe, Co-Founder & COO, Savvy Cooperative*
*Robin Marcus, RN, BSN, Head of Global Decentralized Trial Market Development, Marken*
*Christina Brennan, MD, MBA, Senior Vice President, Clinical Research, Northwell Health*

**9:30 Going Beyond ROI: Necessary Criteria for Impactful Innovation with Decentralized Clinical Trials**
*Rupi Bancil, Senior Vice President, Global Study Operations & Expansion, Care Access*

## CASE STUDIES AND DATA SOLUTIONS

**10:00 Lessons from a Fully Decentralized Trial in Dermatology**
*Candice Estes, MPH, Clinical Trial Manager, Development Operations, Incyte*
The audience will gain a deeper understanding of the operationalization of a completely decentralized trial. Audience members will leave with the knowledge of our key lessons learned including protocol designing to align with a DCT, screening and enrollment process management, remote clinical and ePRO assessment, direct-to-patient drug supplying, and proactive risk identification and mitigation.

**10:15 Decentralized Clinical Trials in Nutritional Studies**
*Pamela Sun, PhD, Head, Clinical Innovation Lab, Nestle SA*
In the setting for clinical studies for nutrition, health and wellness, we are embracing the revolution of decentralized clinical trial and digital health technologies. We can share our experience in digitalization of clinical studies across lifespan from babies to adults, and across categories from food, beverages, infant and maternal nutrition to medical nutrition and supplements.

**10:30 The Integrated Clinical Data Platform: Undisrupting Clinical Trials with a New Data Architecture Paradigm**
*Ching Tian, Chief Innovation Officer, Emmes Corp.*
We've witnessed an explosion of technology solutions offerings for clinical trials. There is mounting evidence, however, that the fragmented nature of these solutions may be causing significant disruption and preventing meaningful efficiency improvements in trials. The community needs to embrace a new concept of an integrated clinical data platform to address the growing multi-source data complexity challenge of modern clinical trials to finally solve some of these persistent issues.

**10:45 Networking Coffee Break**

## CONNECTED HEALTH AND DATA SOLUTIONS FOR FLEXIBLE TRIALS

**11:05 Chairperson's Remarks**
*Ching Tian, Chief Innovation Officer, Emmes Corp.*

**11:10 How Connected Devices Enable Decentralized Trials**
*Jian Yang, Vice President, Digital Health, Eli Lilly Company*
DCTs leverage "virtual" tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, patient-driven virtual health care interfaces, and direct delivery of study drugs and materials to patients' homes. This talk will discuss the post-COVID strategies for connected devices implementation in hybrid trials.

**11:40 Using Digital Technologies to Accelerate Behavioral Health Assessments and Interventions—Learnings from Real-World Studies**
*Abhishek Pratap, PhD, Senior Clinical Program Leader, Central Nervous System, Boehringer Ingelheim*
This talk will focus on the use of digital health technologies(DHTs) to advance medical product development—from assessment to interventions in real-world settings. I will share learnings from clinical research studies to help inform the development of robust digital endpoints and interventions focusing on improving behavioral outcomes.

**12:10 pm Validation of Digital Health Technologies for Clinical Trials: The NIH Framework**
*Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)*
This presentation will share the NIH Framework for digital technologies' validation in clinical trials.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Revolutionizing Research: Navigating the Spectrum with a Fully Hybrid Approach**
*Thad Wolfram, President, EmVenio*
This track will explore the methodology of a fully hybrid clinical trial approach. We will discuss how the combination of mobile Clinical Research Sites, personalized home visits, and convenient virtual visits are not only on the rise, but also effectively bridging the gap to bring clinical trials to previously underrepresented and diverse populations.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 7th Annual

# Digital Biomarkers and Endpoints in Clinical Trials

Digital Measurements and Endpoints in Registration Trials

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 13th Annual

# Digital Health Technologies in Clinical Research

Data, Regulatory and Infrastructure Support for Digital Solutions

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## DIGITAL BIOMARKERS AND ENDPOINTS IN REGISTRATION TRIALS

**10:45 Chairperson's Remarks**
*Dave Hanaman, President, Chief Commercial Officer, Curavit Clinical Research*

**10:50 Remaining and New Challenges for Digital Endpoints Implementation**
*Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.*
Novel digital endpoint, if used as the prespecified ranked endpoint in the registrational studies, may enhance labels and enable market access. Many pharmaceuticals are developing novel digital measures of health and disease to accelerate drug development and support product differentiation.

**11:15 Developing an Evaluative Framework for Digital Health Technology Diligence**
*Daniel Sanchez, Associate Director, Data Science & Digital Health, Oncology, Janssen Pharmaceuticals, Inc.*
The presentation will provide an overview of our digital health solution diligence process and the construction of an evaluative framework for novel endpoint development in oncology—focusing on a case example surrounding actigraphy sensor deployment in prostate cancer. We will also address the many hurdles associated with clinical trial implementation and the importance of a broader tech development vision within the context of an individual drug program.

**11:40 Digital Respiratory Endpoints with Continuous Wearable Sensors: Cough and Beyond**
*Shuai Steve Xu, Assistant Professor of Dermatology & Medical Director, Querrey Simpson Institute for Bioelectronics, Northwestern Memorial Hospital*
There has been a growing interest in novel respiratory digital measurements, specifically cough. This presentation will discuss the relevance of cough as a novel respiratory endpoint, introduce novel technologies including wearables and AI solutions that measure cough, and discuss challenges and opportunities for the future.

**12:05 pm A New Framework for Assessing Clinical Sites and Participants' Experience in Clinical Trials**
*Francesca Properzi, PhD, Director Research, Thought Leadership, DT Consulting*
Interactions between participants, clinical research staff and pharma companies are crucial to the success of drug development, as they affect research quality and the recruitment and retention of participants. Research staff and patients have certain expectations about conducting trials, and it's important for pharma firms to assess and manage these. We used a novel framework to assess these expectations and the current state of the industry globally.

**12:20 Today's Trends Influencing Tomorrow's Change**
*Natasha Massias, Senior Solution Architect, Datacubed Health*
This presentation addresses the integration of digital health technologies, such as wearables and sensors, in healthcare. It will highlight their role in advancing medical research and patient care by predicting and preventing health ailments. We'll also emphasize the benefits of these technologies in reducing patient burden in clinical trials, leading to more efficient and patient-friendly research methods, and envision their future impact on streamlining clinical trials.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: The Evolving Landscape of Digital Measures in Pharma**
*Jaydev Thakkar, Chief Operating Officer, Biofourmis*
Digital measures, the cornerstone of digital biomarkers, hold immense promise for revolutionizing drug development and propelling our understanding of treatment efficacy. Yet despite their transformative potential, their full utilization remains hindered by standardization hurdles, regulatory ambiguity, and limited awareness among patients and healthcare providers. We surveyed experts in pharma to uncover the benefits and challenges associated with integrating digital measures into drug development, and outline strategic approaches for their widespread adoption.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## CASE STUDIES

**2:20 Chairperson's Remarks**
*Sandra L. Goss, Director, Digital Health Strategy, AbbVie, Inc.*

**2:25 PANEL DISCUSSION: Alzheimer's in Focus: The Promise of Speech and Video in Cognitive Evaluation**

*Moderator: Stephen Ruhmel, Associate Director, Janssen Clinical Innovation, Johnson & Johnson Pharmaceutical R&D*

This session explores a cutting-edge study on the use of digital biomarkers to assess cognitive impairment as related to Alzheimer's disease. The panel delves into recent results, revealing how innovative speech and video analysis technologies can revolutionize remote cognitive assessments. The discussion will underscore the significance of these non-invasive, promising methods for early detection and continuous monitoring, offering a new dawn in Alzheimer's research.

*Panelists:*

*Amir Lahav, ScD, Founder and CEO, SkyMed Digital; Advisor, Pharma & MedTech*

*David Suendermann-Oeft, Founder and CEO, Modality.AI*

*Jacklynn Wong, Associate Director, Investigator and Patient Engagement, Johnson & Johnson*

**3:10 Impact of Upadacitinib on Wearable Device-Measured Physical Activity in Patients with Ankylosing Spondylitis from the SELECT-AXIS 2 Trial**

*Dan Webster, PhD, Director, Digital Strategy, AbbVie*

Physical activity (PA) is associated with improved mobility, pain, and function in people with Ankylosing Spondylitis (AS); however, the impact of pharmacologic interventions on PA is rarely measured in clinical research. Wearable technology provides an objective method to passively collect PA data. Here, we describe the effect of upadacitinib (an oral JAK inhibitor) on PA in 400 AS patients, over 14 weeks in the Phase 3 SELECT AXIS-2 study.

**3:35 Improving Objectivity of Facial Vitiligo Area Assessments Using 3-Dimensional Imaging**

*Sandra L. Goss, Director, Digital Health Strategy, AbbVie, Inc.*

This presentation will share a case study of using digital biomarkers in a dermatology study.

**4:00 Implementing and Operationalizing Digital Biomarkers**

*Vasanth Thirugnanam, Associate Director Data Science, Janssen Pharma*

An automated, scalable platform integrating, transforming, and delivering near real-time and concurrent digital health data from diverse sets of wearables, mobile applications, and AI/ML models.

**4:25 Digital Biomarkers and the Shift to More Participant-Centered Evidence Generation — Practical Advice for New Approaches**

*Lauren Sutton, Head of Product, Clinical Trial Recruitment, Verily*

Sponsors are integrating the use of digital biomarkers (DBMs) to make research more participant-centered and longitudinal. This talk will explore examples from neurology, cardiovascular, mental health, and more, looking at how digital measures can be used to generate high quality real-world data. We'll discuss how this capability can be combined with other novel research approaches to power continuous evidence generation, and share practical advice from a regulatory and operational perspective.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

### BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**

*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*

Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**

*Matt Walz, CEO, Business Operations, Trialbee*

**9:05 Transition to Sessions**

### DHT IN CLINICAL TRIALS: HOW AND WHY

**9:10 Chairperson's Remarks**

*Sarah Valentine, Partnerships Lead, Life Sciences, Digital Medicine Society (DiMe)*

**9:15 Digital Health Technologies in Clinical Trials: The Genentech Perspective**

*Thomas W. Switzer, Head Digital Health, gRED Early Clinical Development, Genentech, Inc.*

This presentation will share case studies of leveraging digital biomarkers for internal decisions as well as for modernizing endpoints.

**9:45 PANEL DISCUSSION: Quantifying the Net Financial Impact of Digital Endpoints in Clinical Trials**

*Moderator: Sarah Valentine, Partnerships Lead, Life Sciences, Digital Medicine Society (DiMe)*

Four years ago, the Digital Medicine Society launched the Library of Digital Endpoints. Since then, the number of sponsors collecting digital endpoints has increased tremendously. But with that rapid evolution in adoption, do these new digital modalities live up to the promise of reducing trial size and cycle times in clinical trials? Join us as we share findings from a recent collaboration to quantify the net financial impact of digital endpoints.

*Panelists:*

*Dan Karlin, CMO, MindMed*

*Marissa Dockendorf, Executive Director, Head of Digital Clinical Measures, Merck*

*Lada Leyens, PhD, PD Regulatory, Personalized Healthcare, Digital Health Regulatory Shaping Lead, Clinical Trial Innovation, F. Hoffmann-La Roche Ltd.*

**10:15 Reinventing the Six-Minute Walk Test with Sensors for In-Home Measurement of Functional Capacity**

*Melissa Ceruolo, Vice President, Engineering & Biomarker Analytics, Medidata*

Medidata is developing capabilities to perform clinical assessments in the home using advanced sensor technologies and patient-facing applications. Through a partnership with the University of Rochester Medical Center, we have conducted a study evaluating 100 patients with pulmonary hypertension and heart failure during 6-minute walk tests. We have shown that combining motion from the accelerometer and cardiac signal not only correlates with the gold standard of distance walked but is a more repeatable measure and can be collected at home, alleviating the burden of site visits. By investigating the sensor signal features, we derive an objective assessment of functional endurance where we can classify patients into disease cohorts with more specificity and have better and earlier prediction of outcomes. This work is revolutionizing how home functional assessments will occur and can ultimately be used as a standard of care.

This session will focus on how Medidata is using wearable sensors to reinvent the six-minute walk test and how accelerometer and cardiac sensor data equips researchers to predict outcomes better and sooner. Additionally, it will consider how at-home functional capacity assessments would improve patient experiences.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**

*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

### DIGITAL BIOMARKERS IN ONCOLOGY TRIALS

**11:40 Chairperson's Remarks**

*Lada Leyens, PhD, PD Regulatory, Personalized Healthcare, Digital Health Regulatory Shaping Lead, Clinical Trial Innovation, F. Hoffmann-La Roche Ltd.*

**11:45 The Value of the Digital Measures of Physical Activity and Performance in Cancer Cachexia**

*Carrie A. Northcott, PhD, Senior Director & Project Lead, Digital Medicine & Translational Imaging, Pfizer Inc.*

Cancer cachexia is characterized by unintentional weight loss, due to a loss in muscle mass that physically manifests as fatigue, functional impairment, weakness, and increased mortality. We will share evidence on the importance of, as well as how digital measures of physical activity and gait, derived from wearable sensors, can be used to quantitatively and passively assess changes in physical function and support clinical studies in a home environment.

**12:15 pm AI/ML Biomarker Deployment to Accelerate Enrollment in Precision Oncology Trials**
*Oscar Carrasco-Zevallos, PhD, Associate Director, Data Science Platforms, Janssen R&D*
Precision oncology trials rely on biomarkers to identify and enroll likely responders to experimental therapies. Machine learning is enabling development of novel biomarkers that can be widely deployed and have superior performance compared to standard biomarkers. This presentation will describe a framework and case studies on ML-based biomarker deployment in global clinical trials, focusing on key requirements for translating research-grade algorithms to deployable, regulatory-grade ML products.

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Who Else is Sick of Lasagna's Law? New Approaches to Patient Finding and Retention**
*V. Scott Morris, Vice President and General Manager, Clinical Trial Solutions, Optum Life Sciences, Optum*
*Alexa Richie, DHSc, National Executive Director, Research, Optum Health, Optum*
With today's technology, the days of overestimating patient eligibility and submitting patients to unnecessary inconvenience should be over. Scott Morris, from Optum Life Sciences, and Alexa Richie, from Optum Health, will show how tapping into digital resources, real-world data and a nationwide network can usher in a new era for clinical trials.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## NOVEL EVIDENCE FOR REGULATORY TRIALS

**4:30 Chairperson's Remarks**
*Jeremy Wyatt, CEO, ActiGraph*

**4:35 CO-PRESENTATION: A Preliminary Analyses Exploring Factors That Affect Daily Diary Compliance Rates for Patients in Clinical Trial**
*Joseph Im, Head of Digital Health Technolgies Operations, Regeneron Pharmaceuticals, Inc.*
*Quang Nguyen, PhD, Principal Biostatistician, Regeneron Pharmaceuticals, Inc.*
A wide range of factors are thought to impact patient daily diary completion compliance based on anecdotal evidence. Key variables such as patient demographics and study design were analyzed for associations to compliance. This preliminary analysis paves the way to explore potential factors that can inform of ways to improve existing diary collection operating methods in clinical trials.

**5:05 PANEL DISCUSSION: Incorporating Digitally Derived Endpoints Within Clinical Development Programs By Leveraging Prior Work**
*Moderator: Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron*
Digital health technologies (DHTs) enable remote data collection, support a patient-centric approach to drug development, and provide real-time data in real-world settings. With increasing use of DHTs in clinical care and development, we expect a growing body of evidence supporting use of DHTs to capture endpoint data in clinical trials.
*Panelists:*
*Amy Abernethy, PhD, President, Product Development & CMO, Verily Life Sciences*
*Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.*
*Rasika Kalamegham, PhD, Head, US Regulatory Policy, Genentech*
*Jeremy Wyatt, CEO, ActiGraph*

**5:35 GLUCOSEREADY: A Digital Platform for Assessing Behavior, Glucose, Symptoms and Biometrics in Cardiometabolic Disease**
*David Anderson, PhD, Principal Scientist, Data Sciences, Clinical ink*
Clinical ink's GLUCOSEREADY digital health platform integrates consumer wearables and numerous validated tools, including CGM with event-based ePRO triggering, actigraphy, connected weight scales, a full suite of relevant eCOAs, and personality assessments to predict adherence, behavior modification and lifestyle standardization. All digital data are stored in a study-dedicated data warehouse with automated AI/ML tools to support near real-time data integrity, visualization, and monitoring.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**

***Scott Chetham, CEO & Co-Founder, Faro Health, Inc.***

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## DIGITAL DATA FLOW MANAGEMENT AND VISUALIZATION

**8:25 Chairperson's Remarks**

**8:30 Magnol.AI—Engineering Large Wearable Sensor Data towards Digital Measures**

***Hui Zhang, PhD, Senior Director, Digital Office, Eli Lilly and Company***

While many industry players promote the ability to collect wearable sensor data, what matters more than that is how we can uncover data insights and turn 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.

**9:00 CO-PRESENTATION: Strategies and Considerations in Handling and Analyzing Digital Health Technology Data Streams**

***Sarthak Chatterjee, PhD, Postdoctoral Fellow, Merck & Co., Inc.***

***Jie Ren, PhD, Director, Data Science, Global Digital Analytics & Technologies, Merck & Co., Inc.***

The large volume and high complexity of DHT data presents unique challenges for data handling and analysis. Here, we present systematic capability build to address such challenges and enable handling and analysis of DHT data in a robust and scalable manner. We'll discuss efforts on cloud-computing infrastructure build, data/algorithm organization, and algorithm literacy development. Such analytical capabilities around DHT data could support broader adoption of DHT-enabled measures in clinical trials.

**9:30 Sponsored Presentation** *(Opportunity Available)*

## DIGITAL BIOMARKERS INFRASTRUCTURE; NOVEL PATIENTS DATA SOURCES

**9:45 Harnessing Multimodal Data Analytics in Clinical Research: ORBIT, Multimodal Data Hub for Precision Medicine**

***Alex Li, Director, Data Science Platform, Janssen R&D LLC***

Janssen Data Science and the Oncology Biomarker and Diagnostic teams are partnering to develop new data platforms, processes, and advanced analysis pipelines to generate close to real-time insights. Access to multiple modal data for precision oncology studies will enable rapid decision-making to support trial execution and reverse translation of clinical findings back into the drug discovery pipeline.

**10:10 Does Your Drug Have an App? The Role of Digital Biomarkers in Shaping Digital Drug Solutions across Therapeutics Areas**

***Amir Lahav, ScD, Founder and CEO, SkyMed Digital; Advisor, Pharma & MedTech***

Emerging trends in Digital Biomarkers and ( SaMD) enabled the development of companion apps for commercial drugs. This approach allows pharma companies to remotely track medication side effects and monitor disease symptoms based on real-time digital measures otherwise not accessible using traditional RWE studies. What makes digital drug solutions successful? How are they regulated? What is the role of AI in empowering patients to make healthier choices?

**10:30 Patient Community Networks for Crowd-sourced RWD**

***Yael Elish, Founder & CEO, StuffThatWorks***

***Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical***

***Matt Veatch, Managing Director, Revesight Consulting***

**10:45 Networking Coffee Break**

## CONNECTED HEALTH AND DATA SOLUTIONS FOR FLEXIBLE TRIALS

**11:05 Chairperson's Remarks**

***Ching Tian, Chief Innovation Officer, Emmes Corp.***

**11:10 How Connected Devices Enable Decentralized Trials**

***Jian Yang, Vice President, Digital Health, Eli Lilly Company***

DCTs leverage "virtual" tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, patient-driven virtual health care interfaces, and direct delivery of study drugs and materials to patients' homes. This talk will discuss the post-COVID strategies for connected devices implementation in hybrid trials.

**11:40 Using Digital Technologies to Accelerate Behavioral Health Assessments and Interventions—Learnings from Real-World Studies**

***Abhishek Pratap, PhD, Senior Clinical Program Leader, Central Nervous System, Boehringer Ingelheim***

This talk will focus on the use of digital health technologies(DHTs) to advance medical product development—from assessment to interventions in real-world settings. I will share learnings from clinical research studies to help inform the development of robust digital endpoints and interventions focusing on improving behavioral outcomes.

**12:10 pm Validation of Digital Health Technologies for Clinical Trials: The NIH Framework**

***Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)***

This presentation will share the NIH Framework for digital technologies' validation in clinical trials.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Revolutionizing Research: Navigating the Spectrum with a Fully Hybrid Approach**

***Thad Wolfram, President, EmVenio***

This track will explore the methodology of a fully hybrid clinical trial approach. We will discuss how the combination of mobile Clinical Research Sites, personalized home visits, and convenient virtual visits are not only on the rise, but also effectively bridging the gap to bring clinical trials to previously underrepresented and diverse populations.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 13th Annual

# Accessing and Generating RWD

Regulatory Grade RWD Sources and Strategies

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 9th Annual

# Leveraging RWD for Clinical and Observational Research

Real World Data for Next-Generation Studies

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## LEARNING FROM PARTNERS

**10:45 Chairperson's Remarks**
*Craig Serra, Head of Clinical Research Scientific & Technical Engagement, Flatiron Health*

**10:50 Real-World Evidence: Leveraging RWD for Clinical and Observational Research**
*Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.*
In certain areas of unmet medical need, RWD may be used to generate evidence for regulatory and related purposes. Oftentimes, data may need to be pooled from disparate sources. In such cases, it is essential to assess combinability of the different data sources. We review existing approaches and suggest recommendations. In addition, we highlight other relevant topics relating to RWE analysis and reporting, including mitigation of bias from residual confounding.

**11:15 CO-PRESENTATION: Health Systems as Key Partners for RWD Research**
*John D. Chelico, MD, System Vice President & Chief Medical Information Officer, CommonSpirit Health*
*Eirini Scholosser, Founder & CEO, Dyania Health*
This presentation will share a perspective of a large and modern health system on medical information in general, and on possibilities of partnership with pharmaceutical companies to move forward medical and clinical research.

**11:40 Better Utilizing Real-World Data to Drive Clinical Research Success at AMCs (Phenotypes, Ontologies, Enclaves, and more)**
*Christopher Herrick, Vice President, Research Technology, Mass General Brigham*
The MGB Hospital Integrated Research Organization (HIRO) empowers industry sponsors, sites, and clinicians to accelerate AMC-based research by streamlining study startup, fostering collaborative workflows, and harnessing data-driven insights for patient-centric study designs. Our robust multi-modal real-world data platform combined with our unique approach to working with outside organizations enables us to better identify, engage, and recruit patients and successfully support sponsors from feasibility to trial performance.

**11:55 Transforming Healthcare Using Deep Data and Remote Monitoring**
*Michael Snyder, PhD, Stanford W. Ascherman Professor & Chair, Department of Genetics, Director, Center for Genomics & Personalized Medicine, Stanford University*
Following 109 individuals for over 13 years revealed numerous health discoveries covering cardiovascular disease, oncology, metabolic health, and infectious disease. We also found that individuals have distinct aging patterns that can be measured in an actionable period of time. Finally, we used wearable devices for early detection of infectious disease, including COVID-19, and microsampling for monitoring and improving lifestyle. We believe that advanced technologies have the potential to transform healthcare.

**12:20 pm First-in-Class AI JIT and RWE for Clinical Development**
*Ryan Kennedy, Senior Vice President, General Manager – Digital Trial Solutions, ConcertAI*
*Caroline Merilat, Director of Research Operations, QCCA and Exigent Network*
Historically trials have fallen behind on the originally predicted schedule and often under-accrued the targeted number of enrolled patients. As the focus of biopharma innovations has become increasingly precise, hence narrower in the targeted patient characteristic, these issues are even more acute. This presentation addresses why JIT study designs, working within JIT-capable research networks, with JIT-optimized AI technologies, offer an alternative that operates at scale and increasingly represents a new standard.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Learning Faster from EHR Data: How Life Sciences-Health System Partnerships Are Changing Evidence Generation**
*Ryan Ahern, MD, MPH, CMO, Life Sciences, Truveta*
Discover how life sciences companies and health systems are collaborating to unlock clinical insights from EHRs at scale. We'll discuss how ongoing collaboration can prevent or quickly resolve research roadblocks, highlight innovative methods for identifying patient cohorts, optimize trial design, improve clinical care, and outline the practical implications of real-world evidence generated through partnerships.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**

*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## TRIAL TOKENIZATION CHALLENGES

**2:20 Chairperson's Remarks**
***Michael Fronstin, Global Head of Client Partnerships and Commercialization, Oracle Life Sciences***

**2:25 What Is Trial Tokenization and What Are the Benefits?**
***Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC***
This presentation is designed to set the tone for the trial tokenization discussion and it will emphasize the role of various stakeholders involved in decision-making and process development around trial tokenization.

**2:35 Fit-for-Purpose Use of Various Types of Tokens**
***Thomas Dougherty, Director, RWE Partnerships and Innovation, RWE Center of Excellence, Pfizer Inc.***
This presentation will elaborate on how clinical trial teams decide on which trials to tokenize and why.

**2:45 Various Methods of Tokenization & Selecting a Token Strategy**
***Akshay Vashist, Head of Medical and Real-World Data Analytics, Otsuka Pharmaceutical Co.***
There are several methods of tokenization available on the market. Which one is the right fit for your goals? This talk will summarize existing approaches and point out strengths and weaknesses of each of them.

**2:55 Collaboration between RCT & RWD/RWE Teams**
***Lucinda Orsini, Vice President, Value and Outcomes Research, COMPASS Pathways***
How can we bring together clinical trials and RWD teams? Organizations that solve this problem will definitely win a competitive advantage in the near future.

**3:05 Implementation of Trial Tokenization within a Pragmatic Randomized Trial: Learnings & Challenges**
***Emily Zacherle, Associate Director, Real-World Evidence, Novo Nordisk, Inc.***
This presentation will provide an overview of key learnings and challenges from implementation of trial tokenization and data linkage within a pragmatic randomized clinical trial, such as driving efficiencies with early collaborative engagement and operationalizing tokenization at a single versus multi-site level.

**3:15 PANEL DISCUSSION: Clinical Trial Tokenization: Bringing RCT & RWD Together**
***Moderator: Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC***
Clinical Trial Tokenization: Bringing RCT & RWD Together. What is clinical trial tokenization, why is it beneficial to clinical research, and how do you implement these novel solutions effectively in your research and drug development programs? Come learn from experts in the field. Hear why these methods were important for their programs, the challenges they faced bringing RWD & RCTs together, and effective approaches to overcoming those challenges.
***Panelists:***
***Emily Zacherle, Associate Director, Real-World Evidence, Novo Nordisk, Inc.***
***Akshay Vashist, Head of Medical and Real-World Data Analytics, Otsuka Pharmaceutical Co.***
***Lucinda Orsini, Vice President, Value and Outcomes Research, COMPASS Pathways***
***Thomas Dougherty, Director, RWE Partnerships and Innovation, RWE Center of Excellence, Pfizer Inc.***

**3:45 Development of a Site-and-Study Agnostic Patient Referral Model Based on Patient Matching Learnings**
***Alyssa Beckwith, Director, Strategic Program Leader, The Janssen Pharmaceutical Companies of Johnson & Johnson***
***Ariel Bourla, MD, PhD, Senior Director, Data Science and Digital Health, Johnson & Johnson R&D***
As clinical trials become more complex, patients in US community-based settings have even less access to clinical research. We have captured insights from various patient-matching solutions, including key elements that enhance outcomes. We will discuss our current efforts directed towards our goal of improving timely identification of trial-eligible patients and successfully referring them to trial sites where they can access valuable study opportunities and contribute to future learnings.

**4:10 Case Studies on AI-Driven Patient Recruitment**
***Wout Brusselaers, CEO, Deep 6 AI***
The promise of AI in clinical research is here. It can contextualize patient journeys from unruly electronic medical record (EMR) data with unprecedented speed and precision. Through real-world examples, we will explore how AI is precisely matching patients to complex inclusion and exclusion criteria and surfacing hard-to-recruit patient populations. Attendees will hear the tangible impact AI has on optimizing study design, improving feasibility, and accelerating recruitment.

**4:25 CO-PRESENTATION: RWD Enrichment Studies: Leveraging Tokenization in the Pre- and Post-Trial Periods to Inform Product Strategy**
***Irene Cosmatos, MSc, Senior Director, Epidemiology & Real-World Evidence, UBC***
***Jeff Lowry, Senior Director, Technology Solutions Services, UBC***
Capturing data on the patient's healthcare journey prior to and following participation in a research study builds a more complete understanding of their healthcare journey and increases the overall evidence yield. This presentation explores the use of tokenization and linkage to secondary healthcare data for generating insights on long-term treatment effectiveness and safety to enrich the learnings from the core study.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
***Colin Weller, General Manager, Evidence Generation Platform, Product, Medable***
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
***Matt Walz, CEO, Business Operations, Trialbee***

**9:00 Transition to Sessions**

## RWE—SUPPORTED REGISTRATION STUDIES

**9:10 Chairperson's Remarks**
***Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC***

**9:15 eSource to EDC: Applying an Innovation-To-Scale**
***Paul Jacobs, Associate Director, Development Innovation, Regeneron Pharmaceuticals***
Using ongoing innovation-to-scale to drive an approach for eSource to EDC that embraces the learnings, challenges, and failures as a key part of the process.

**9:35 PANEL DISCUSSION: Using RWD to Increase Patient Diversity in Clinical Trials**
***Moderator: Marjorie Zettler, PhD, MPH, Senior Director, Clinical Science, Accutar Biotech***
Recent FDA guidance recommends that sponsors develop a diversity plan for pivotal clinical trials, with enrollment goals for participants of different racial or ethnic backgrounds, as well as operational measures to achieve

those goals. How can RWD/RWE be leveraged to help prepare diversity plans and improve diversity in clinical trial participation? This panel discussion will explore opportunities, success stories, and challenges in using RWD/RWE to promote more representative clinical trials.

*Panelists:*
***Dyan Bryson, Patient Engagement Strategist and Patient Advocate, Inspired Health Strategies***
***Jen Banks, Director, Project Management, Project Management, WEP Clinical***
***Wout Brusselaers, CEO, Deep 6 AI***
***Barry Leybovich, Senior Product Manager, Clinical Research, Flatiron Health, Inc.***
***Susan Zelt, RWE and Clinical Scientist, Yale University***

**10:15 20% of Surveyed Patients are Not Satisfied with Their Medications: Collecting Meaningful RWD from Challenging Patients**
***Erica Smith, PhD, Senior Vice President, Business Development and Marketing, Spencer Health Solutions***
Psychiatric patients are extremely difficult to engage, as they historically have low adherence (50%) and high dropout rates (48-55%) in clinical trials. In this study, patient experience and satisfaction were evaluated in patients taking atypical anti-psychotics using spencer®, an in-home dispensing & RWD collection platform. Nearly 20% of patients were dissatisfied with treatment. Remarkably, these complex patients were 95% adherent and 92% compliant to daily surveys via spencer®.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

## INTERNAL COLLABORATION TO ADVANCE RWE AND CLINICAL TRIALS TEAMS

**11:40 Chairperson's Remarks**
***Christopher Heckman, VP, Global Project Delivery, Global Head, Real World Intelligence, Fortrea***

**11:45 Regulatory Environment Update for RWD Application in Clinical Trials**
***Simon Dagenais, RWE Lead, Internal Medicine, Pfizer Inc.***
Biopharma companies are investing in real-world data (RWD) for a variety of uses. The potential to transform RWD into real-world evidence (RWE) to support regulatory decisions, including new product approvals or label expansions, is a key factor in the development of the RWD/RWE industry. This presentation will provide an overview of FDA regulations related to RWD and RWE and describe how the regulatory environment can influence this field.

**12:10 pm Trial Success Starts with Real-World Data**
***Alexander Deyle, Vice President, Life Sciences, Clinical Research, Flatiron Health, Inc.***
Currently, the data used to design clinical trial protocols are sourced from prior trials, key opinion leaders, and published data. During this presentation, we will discuss details on how real-world data can be used to design study protocols and present a specific example in which this has been done. We will also highlight the outcomes seen in both protocol optimization and patient matching.

**12:30 Nordic Data on the Globa Stage**
***Kirk Geale, PhD, CEO, Quantify Research***
This talk will help stakeholders understand and utilise one of the world's most important data regions outside of the US, the Nordics. Many practitioners and decision-makers know that these data are world-class, but few have the necessary information and tools to make informed decisions about where, when, why, and how to use these data. This talk will add a valuable resource to stakeholders' tool belts.

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Patient Perspectives on Clinical Trial Recruitment and Participation**
***Ria Westergaard, Director, Product Strategy for Clinical Trial Solutions, Intelligence Solutions, Evernorth Health Services***
Listening to and incorporating insights from patients is key to simplifying study designs for improved study enrollment, health equity, and outcomes. This session focuses on combining patient feedback with real world evidence including:
• Understanding unmet needs and which outcomes matter most to real patients
• Identifying challenges to enrollment and building solutions into study design
• Coupling data with patient engagement and feedback from study planning through recruitment

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
***Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco***
***Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco***

**2:25 Chairperson's Remarks**
***Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.***

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
***Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine***
*Panelists:*
***Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)***
***Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA***

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
***Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics***
*Panelists:*
***Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda***
***Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners***
***Michelle Longmire, Co-Founder & CEO, Medable, Inc.***
***Sam Srivastava, CEO, WCG***

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## RWD-POWERED CLINICAL TRIAL DESIGN AND EXECUTION

**4:30 Chairperson's Remarks**
***Speaker to be Announced***

**4:35 PANEL DISCUSSION: RWD-Informed Trial Design and Operations**
*Moderator: John Cai, MD, PhD, Executive Director, Real-World Data Analytics and Innovation, Merck*
Efforts in real-world data (RWD) and real-world evidence (RWE) to expedite and enrich the development of new biopharmaceutical products have accelerated in the last several years. This panel discussion will cover opportunities and challenges using real-world case studies of RWD-based trial design and operations.
*Panelists:*
*Zhaoling Meng, PhD, Associate Vice President & Global Head, Clinical Modeling & Evidence Integration, Sanofi*
*Laszlo Vasko, Senior Director, Clinical Innovation R&D IT, Janssen Pharmaceuticals, Inc.*
*Edwin A. White, Director, Trial Optimization, Metrics Analytics & Performance, Merck*
*Xiaoyan Wang, PhD, Senior Vice President, Life Science Solutions, Intelligent Medical Objects Inc.*

**5:15 Deriving External Control Arms from RWD to Enhance the Value of Phase 1 Trials**
*Ding Jiang, PhD, Senior Manager Biostatistics, Global Biometrics & Data Sciences, Bristol Myers Squibb Co.*
The study investigates deriving external control arms (ECA) from real-world data (RWD) to enhance the value of single-arm Phase 1 trials. It applied various methods such as G-computation, digital twins, propensity score matching, and inverse probability treatment weighting. All methods reduced bias in projecting treatment effects in Phase 3 trials compared to no adjustment, with digital twins offering the least biased estimates.

**5:35 Revolutionizing Patient Identification with Clinical AI that Decodes Vast Datasets in Milliseconds** MENDEL
*Karim Galil, MD, CEO, Mendel*
Discover how life sciences companies are leveraging clinical AI to interpret vast datasets at an unprecedented pace, finding the right trial participants more efficiently than ever. This session will share data demonstrating that industry-specific clinical AI outperforms LLMs like ChatGPT and Llama2 and explore the science behind creating true, physician-like intelligence where other deep learning-centric approaches have fallen short.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

### BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes** faro
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*
Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

### DIGITAL DATA FLOW MANAGEMENT AND VISUALIZATION

**8:25 Chairperson's Remarks**

**8:30 Magnol.AI—Engineering Large Wearable Sensor Data towards Digital Measures**
*Hui Zhang, PhD, Senior Director, Digital Office, Eli Lilly and Company*
While many industry players promote the ability to collect wearable sensor data, what matters more than that is how we can uncover data insights and turn 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.

**9:00 CO-PRESENTATION: Strategies and Considerations in Handling and Analyzing Digital Health Technology Data Streams**
*Sarthak Chatterjee, PhD, Postdoctoral Fellow, Merck & Co., Inc.*
*Jie Ren, PhD, Director, Data Science, Global Digital Analytics & Technologies, Merck & Co., Inc.*
The large volume and high complexity of DHT data presents unique challenges for data handling and analysis. Here, we present systematic capability build to address such challenges and enable handling and analysis of DHT data in a robust and scalable manner. We'll discuss efforts on cloud-computing infrastructure build, data/algorithm organization, and algorithm literacy development. Such analytical capabilities around DHT data could support broader adoption of DHT-enabled measures in clinical trials.

**9:30 Sponsored Presentation** *(Opportunity Available)*

### DIGITAL BIOMARKERS INFRASTRUCTURE; NOVEL PATIENTS DATA SOURCES

**9:45 Harnessing Multimodal Data Analytics in Clinical Research: ORBIT, Multimodal Data Hub for Precision Medicine**
*Alex Li, Director, Data Science Platform, Janssen R&D LLC*
Janssen Data Science and the Oncology Biomarker and Diagnostic teams are partnering to develop new data platforms, processes, and advanced analysis pipelines to generate close to real-time insights. Access to multiple modal data for precision oncology studies will enable rapid decision-making to support trial execution and reverse translation of clinical findings back into the drug discovery pipeline.

**10:10 Does Your Drug Have an App? The Role of Digital Biomarkers in Shaping Digital Drug Solutions across Therapeutics Areas**
*Amir Lahav, ScD, Founder and CEO, SkyMed Digital; Advisor, Pharma & MedTech*
Emerging trends in Digital Biomarkers and ( SaMD) enabled the development of companion apps for commercial drugs. This approach allows pharma companies to remotely track medication side effects and monitor disease symptoms based on real-time digital measures otherwise not accessible using traditional RWE studies. What makes digital drug solutions successful? How are they regulated? What is the role of AI in empowering patients to make healthier choices?

**10:30 Patient Community Networks for Crowd-sourced RWD**
*Yael Elish, Founder & CEO, StuffThatWorks*
*Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical*
*Matt Veatch, Managing Director, Revesight Consulting*

**10:45 Networking Coffee Break**

### SYNTHETIC DATA IN CLINICAL TRIALS

**11:05 Chairperson's Remarks**
*Dorothee B. Bartels, PhD, Chief Digital Officer, AETION*

**11:10 Using Machine Learning to Augment and Inform Clinical Trial Design: Use-Cases from Multiple Therapeutic Areas**
*Khaled Sarsour, PhD, Vice President, Data Science and Digital Health; Real World Evidence & Advanced Analytics, Janssen Pharmaceuticals*
This presentation will share several case studies in various therapeutic areas of challenges and solutions of AI and ML implementation in clinical trial design.

**11:35 Driving Drug Development with Synthetic Data**
*Dooti Roy, PhD, Director, Global Biostatistics and Data Sciences, Boehringer Ingelheim Pharmaceuticals, Inc.*
Using artificial patients for drug development or medical device development is a promising field, only if the models can reach the required complexity and can be truly representative of the human population.

12:00 pm **PANEL DISCUSSION: AI in Clinical Research and RWE: Synthetic Data and Beyond**

*Moderator: Dorothee B. Bartels, PhD, Chief Digital Officer, AETION*

*Panelists:*

*Zhaoling Meng, PhD, Associate Vice President & Global Head, Clinical Modeling & Evidence Integration, Sanofi*

*Lucy Mosquera, Research Associate, Electronic Health Information Lab at Children's Hospital of Eastern Ontario; Sr Director of Data Science at Replica Analytics an Aetion Company*

*Khaled Sarsour, PhD, Vice President, Data Science and Digital Health; Real World Evidence & Advanced Analytics, Janssen Pharmaceuticals*

*Dooti Roy, PhD, Director, Global Biostatistics and Data Sciences, Boehringer Ingelheim Pharmaceuticals, Inc.*

12:40 **Transition to Lunch**

12:45 **LUNCHEON PRESENTATION: Enabling a Clinical Information Highway**

*Kim Walpole, Associate Principal, ZS*

Explore the transformative potential in drug development. We'll share how technology can facilitate a seamless flow of clinical information, connect stakeholders and stream data-driven decision-making. By harnessing cutting-edge technology, the industry will be able to accelerate medical research, enhance patient care and revolutionize the way clinical trials are conducted. Join us to discover the future of a clinical information highway, where data-driven insights drive healthcare forward.

1:15 **SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 10th Annual

# Clinical Quality and Risk Management

Navigating Risk with High-Level Strategy and Best Practices

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 10th Annual

# Central and Remote Monitoring

Unlocking Study Insights through Centralized Monitoring

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## ENSURING AND EVALUATING CLINICAL QUALITY

**10:45 Chairperson's Remarks**
*Michelle Webb, Vice President, Avoca Quality Consortium, WCG*

**10:50 Does Quality Actually Improve with RBQM? A Review of New Evidence**
*Steve Young, CSO, CluePoints*
Risk-Based Quality Management (RBQM), including Quality by Design (QBD) and Risk-Based Monitoring (RBM), offers the promise of improve quality outcomes for clinical research along with greater efficiencies. It has been implemented increasingly over the past decade across our industry, and there is a growing comfort level that this new paradigm is achieving the promised benefits.

**11:20 What Do You Need to Be Inspection-Ready?**
*Sheri Lee, CEO, Principal Consultant, Premier Regulatory Consulting (PRC); Former National Program Expert, FDA*
Pharmaceutical companies must build inspection readiness strategies into their quality structure. If they are not ready, their application is at risk of being denied, and that can cost millions of dollars. To achieve inspection readiness, ensure the following: 1. Rights, safety, and welfare of subjects are protected; 2. Clinical trial data is accurate and reliable; 3. Compliant with health authority regulations and company's SOPs; 4. Compliance with good clinical practice.

**11:50 Ensuring Quality and Integrity of ePRO Data Using Central Monitoring and Analytical Techniques**
*Lynne Cesario, Executive Director, Global Lead Risk Based Monitoring Program, Pfizer Global R&D Groton Labs*
Data integrity is important to the success of a clinical trial, and modern data collection techniques require oversight and validation. This presentation will focus on ensuring quality and integrity of ePRO data in large, complex studies. ePRO data should be able to withstand scrutiny from regulators, and this talk will outline some of the challenges and methods of data surveillance and analysis to ensure quality and integrity.

**12:20 pm Proposed ICH E6 Updates to Quality Management—Will They Help or Hinder?**
*Keith Dorricott, Director, Dorricott Metrics & Process Improvement Ltd.*
Since ICH E6 was first introduced in 1996 there was no update until 2016. And we already have another draft update! ICH E6 R2 introduced the section on Quality Management. Will the proposed changes improve implementation of RBQM, make no real difference, or might they hinder? At this session you will hear a seasoned professional's view of the potential impact of the proposed changes and can join in the discussion.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Excellence Unveiled: Elevating Clinical Trials through Cutting-Edge Quality and Monitoring Strategies**
*Sheila Gwizdak, Head of Consulting, Halloran Consulting Group*
This session explores the dynamic landscape of clinical trials, focusing on innovative quality assurance and monitoring techniques. Attendees will learn their pivotal role in enhancing trial efficiency, reliability, and participant safety. The session will highlight the synergies between quality strategies, and monitoring protocols using evolving methodologies, technologies, and regulatory frameworks. By leveraging analytics and real-time tools, we will navigate their transformative potential to advance the pursuit of excellence in clinical trials.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## OPERATIONALIZATION OF RBQM

**2:20 Chairperson's Remarks**
*Bill Cooney, President and Chief Innovation Officer, MedPoint Digital, Inc.*

**2:25 Implementing RBQM across Departments: Putting the Pieces Together**
*Esther Huffman O'Keefe, Director Adaptive Monitoring Excellence, Takeda*
If 'quality' is everyone's responsibility, how do the pieces of risk-based quality management fit together? This presentation will consider the requirements for an end-to-end RBQM framework; discuss roles, responsibilities, and connections; and most importantly, review how clinical quality is the currency between all roles and deliverables in the RBQM methodology.

**2:55 COVID-19 Pandemic Impact on Risk-Based Quality Management**
*Mary Arnould, Senior Director, Monitoring Strategies, Clinical Operations, Astellas US, LLC*
The COVID-19 pandemic had numerous disruptive effects on clinical trial execution. It was especially disruptive to site monitoring practices and was the impetus for more widespread adoption of risk-based approaches. This session will review the impacts of the pandemic on RBQM implementation, including challenges and lasting positive trends.

**3:25 CO-PRESENTATION: Assessing Current Levels and Identifying Barriers to RBQM Adoption**

*Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*

*Linda Sullivan, MBA, Senior Fellow, Tufts Center for the Study of Drug Development; Founder, Metrics Champion Consortium*

Risk-based monitoring and risk-based quality management offer a compelling approach to drive clinical trial efficiency, speed, and quality by focusing on study risks most associated with essential safety and efficacy data. This session presents results of a study conducted by the Tufts Center for the Study of Drug Development to measure RBQM adoption. Adoption benchmarks for major, mid-size, and small biopharmaceutical companies and barriers to adoption will be presented.

**3:55 CO-PRESENTATION: Going Further, Together for the Sake of the Patient: RBQM Lessons Learned, Best Practices, and a Path Forward**

*Danilo Branco, Director, Central Monitoring Operations, Fortrea*

*Katherine Taylor, Head, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.*

*Alethea Wilson, Director, Merck*

This co-presentation will focus on a collaborative effort between Merck and Fortrea to establish functional, efficient, and patient-centric RBQM automation for clinical trials. Bringing new RBQM processes into cross-functional workflows can be tricky, and this case study will elucidate the lessons learned and best practices developed through the venture. The talk will then map the path forward and what RBQM automation looks like in an organization in the longer term.

**4:25 CO-PRESENTATION: The Journey to Trial Master File Excellence**

TRANSPERFECT

*Gillian Gittens, Director, eClinical Strategy & Solutions, Trial Interactive, TransPerfect Life Sciences*

*Elondo Roby, Project Manager, R&D Project/Program Management, Teva Pharmaceuticals*

Since 2021, Teva Pharmaceuticals has been working with their preferred supplier TransPerfect for TMF periodic reviews, to achieve TMF quality and demonstrate sponsor oversight of their CROs. With the ultimate goals being a program of TMF excellence and inspection readiness, this case study shows how the collaboration began and has progressed, the process refined and followed, and the key factors to what has become a successful partnership.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

### BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**

Medable

*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*

Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**

trialbee

*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

### RISK ASSESSMENT ACROSS FUNCTIONAL AREAS

**9:10 Chairperson's Remarks**

*Artem Andrianov, PhD, MBA, CEO, Company Management, Cyntegrity*

**9:15 PANEL DISCUSSION: Synergizing for Success: The Power of Cross-Functional Engagement in Risk Assessment**

*Moderator: Randy Holzberger, MS, Associate Director, Clinical Operations, Gilead*

A common theme in regulatory guidance includes sponsors' responsibility to identify risks "across the processes used in critical trials" (ICHE6(R3) Section 3.10.1.1 Risk Identification), which implies cross-functional contributions. Yet, one of the biggest challenges companies face is dedicated participation from team members in the study de-risking process. As an industry, how can we effectively empower our cross-functional colleagues to realize the risk assessment potential as a driving force behind RQBM?

*Panelists:*

*Kristin Stallcup, MS, Director, RBQM Operations, Takeda*

*Gosia Szczodrak, Associate Director, Clinical Operations, Gilead*

*Anne Smith, Director, Central Monitoring, Regeneron Pharmaceuticals, Inc.*

*Danilo Branco, Director, Central Monitoring Operations, Fortrea*

**10:15 CO-PRESENTATION: From Data Chaos to Real-Time Quality**

EDETEK LIFE SCIENCES

*Munther Baara, Vice President of Product Strategy and Innovation, EDETEK, Inc.*

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

*Speaker To Be Announced*

Velocity, variety, and volume of data in clinical trials can lead to chaos. Sponsors need tools to get from disarray to clarity, efficiency, and quality. This presentation showcases how CONFORM reduces cycle times, eliminating technical challenges in data ingestion and aggregation while providing quality management, real-time alerts, and risk assessment. It also introduces the power of AI with groundbreaking feature called Chat.IQ, an innovative tool that will revolutionize interactions with data.

**10:45 Coffee Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

**10:50 Special Book Signing**

*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

### LEVERAGING DATA TO ENHANCE RBQM

**11:40 Chairperson's Remarks**

*Esther Huffman O'Keefe, Director Adaptive Monitoring Excellence, Takeda*

**11:45 CO-PRESENTATION: Targeted Source Data Review/Verification Optimization and Data Change Analysis**

*Barton Damron, Associate Director, Risk Management-Central Monitoring, Johnson & Johnson*

*Daniyal Kamal, MS, Specialist CMM, Risk Management & Central Monitoring, Janssen*

Targeted SDR/SDV Optimization, shortened to tSDX, introduced the concept of subject sampling of enrolled subjects, and was operationalized in MAR2022, with current implementation on ~30 trials. Impact and KRI data will be shared, including numbers of subjects assigned to have no SDR or SDV. Adjacent to tSDX, data from a new dashboard in development, measuring overall query rates and corresponding data changes, will be summarized.

**12:15 pm Leveraging Metadata/Audit Trail Data for RBQM**

*Nechama Katan, Director of Data Science, Data Monitoring and Management, Pfizer Inc.*

Clinical Data Science meets Audit Trail and Meta Data and the result is higher quality and insight. This use-case shows how a team with strong coding skills is able to leverage Audit Trail and Meta Data for informing site process performance and site audits. We will review the business case and the tools that were developed to meet the needs of the study team.

**12:45 Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: RBQM: The Connective Tissue for Clinical Data Quality**

MEDIDATA

*Olgica Klindworth, Vice President, Data Quality and Risk Management Solutions, Medidata*

*Michael Mendoza, Executive Director, eClinical Technology Strategy and Biometrics, TFS*

Ensuring clinical data quality is a cross-functional responsibility that starts well before the first patient is enrolled. Why, then, do we still pigeonhole RBQM as a niche and often only a monitoring exercise? We think one reason is that the current implementation of RBQM in many organizations lacks one source of data truth, real time access to data and sophisticated tools to identify signals of risks sooner and make adequate decisions. In this session, we'll present a different view on how RBQM can be a connective tissue, helping break operational silos weaving data quality oversight into the DNA of the trial's lifecycle.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**

*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**

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

**2:25 Chairperson's Remarks**

*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**

*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**

*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**

Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## CLOSING THE LOOP ON CENTRAL MONITORING SIGNALS

**4:30 Chairperson's Remarks**

*Brook White, VP of Marketing & Commercial Operations, Sales and Marketing, CRIO*

**4:35 Managing Central Monitoring Action Fatigue**

*Olivia Feiro, Associate Director, Central Monitoring, CSL Behring*

One fundamental pillar of RBQM/central monitoring is identifying signals and potential issues at sites and assigning actions to the study team to address them. When a study is conducted over a long period time, study teams become fatigued with the RBQM process and show resistance to new actions. This talk will explore how the speaker researched central monitoring-related action rates and explored methods to revive actions on long running studies.

**5:05 RBQM+ End to End—Design to Launch and Continuously Improving**

*Miguel Valenzuela, Associate Director, Clinical Operations RBQM+, Alnylam UK Ltd.*

RBQM+ on paper seems like a straightforward activity. Carry out a risk assessment on the protocol, critical data and trial processes, document mitigations, and implement a monitoring strategy for the risks, including centralized monitoring. The reality, however, is that RBQM is a culture shift on how we conduct clinical trials. RBQM is not just about tools, it is about people and acceptance of a new way work on trials.

**5:35 Empowering RBQM by Standardizing Source Data at the Point-of-Care**

*Alex Bragat, Head, Data Management, N-Power Medicine*

This talk highlights a novel approach of equipping sites with infrastructure complemented by standardized processes to enable the collection of high-quality and semantically harmonized source data at the point-of-care. This approach allows programmatic trial cohort identification, electronic access to structured and real-time I/E information and enhanced protocol adherence while empowering downstream RBQM and central monitoring across all stages of the data journey, from pre-screening through clinical trial completion.

**5:50 Operationalizing RBQM**

*Duncan Hall, CEO, TRI*

The latest ACRO survey showed that the biggest blocker to RBQM adoption is operationalization. In this short but insightful presentation, Duncan will share some of the most common pitfalls, and a simple approach to successfully operationalize and embed RBQM in your organization. Finally, Duncan will show how successful RBQM adoption will lead to a happier and more effective monitoring team, better data quality, trial efficiency, and increased patient safety.

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**

*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## BEST PRACTICES IN CENTRAL MONITORING AND RBQM

**8:24 Chairperson's Remarks**

*Shawntel Swannack, Director, Central Monitoring & Data Analytics, GSK*

**8:25 Accelerating Open-Source Initiatives in Clinical Trials: The 30k Insights**

*Gosia Szczodrak, Associate Director, Clinical Operations, Gilead*

In recent years, collaboration within the biotech and pharma sectors has significantly surged. In this presentation, we'll examine the role of open-source tools in fostering collaboration, transparency, and standardization across industry. We'll also provide an overview of current open-source initiatives in

the clinical trial domain, including safety monitoring, data standardization, and a newly-released open source framework—containing 30k lines of code— for Risk-Based Quality Management (RBQM).

**8:50 Advancing Healthcare Equity by Promoting Diversity in Clinical Trials through Risk-Based Quality Management (RBQM) and Central Monitoring (CM)**

*Naveen KK, Vice President & Global Head, CMR, CM & Safety Services, Fortrea*

*Lydia Matombo, Director, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.*

*Alan Switzer, Director, Customer Success, Fortrea*

Leveraging Risk-Based Quality Management (RBQM) methods and Central Monitoring (CM) strategies to develop, execute, and oversee Diversity and Inclusion (D&I) in clinical trials fostering broader data sets and improvements in Health equity. The amalgamation of D&I with RBQM and CM ensure a more comprehensive understanding of healthcare outcomes along with fostering a more inclusive subject population that is representative of the real-world.

**9:15 CO-PRESENTATION: Harnessing The Power of Technology to Minimize Subjectivity in Clinical Research**

*Sofie Reynders, Associate Project Director, Neuroscience, Premier Research*

*Martin Strassnig, Consultant, Neuroscience, Premier Research*

*Speaker 111 to be Announced*

Centralized platforms for real-time access and management of clinical trial data are increasingly crucial, especially in trials with subjective endpoints prone to variability. This session focuses on technology's role in quickly identifying trends, expediting issue resolution, and driving informed decisions in clinical studies with subjective endpoints. Case studies will illustrate how real-time expert review of key study data improves signal detection, enhancing the likelihood of study success.

**9:45 Source Data Verification as a Last Resort, Rather than a Fundamental Activity, to Ensure Study Quality**

*Łukasz Bojarski, Executive Director, Centralized Monitoring & Risk Based Quality Management, AstraZeneca*

Source Data Verification (SDV, transcription check performed by Site Monitor) has been believed to be the fundamental quality ensuring activity in the era of paper Case Report Forms. I will present data on the effectiveness of Source Data Verification (SDV) in warranting quality of studies delivered according to the principles of Risk-Based Quality Management and discuss whether there's a place for SDV in a modern study monitoring framework.

**10:15 Change Is Our Only Constant: How to Provide Oversight and Evolve Your Process through Changing Times**

*Shawntel Swannack, Director, Central Monitoring & Data Analytics, GSK*

In times where change is rapid, let's explore ways to provide business management monitoring to ensure your process is robust and effective. Identify when it is time to evaluate a need for improvements or retraining. During this session, we explore key areas of oversight in your application of RbQM process and how to ensure highest quality within your clinical trials.

**10:45 Networking Coffee Break**

## CONNECTED HEALTH AND DATA SOLUTIONS FOR FLEXIBLE TRIALS

**11:05 Chairperson's Remarks**

*Ching Tian, Chief Innovation Officer, Emmes Corp.*

**11:10 How Connected Devices Enable Decentralized Trials**

*Jian Yang, Vice President, Digital Health, Eli Lilly Company*

DCTs leverage "virtual" tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, patient-driven virtual health care interfaces, and direct delivery of study drugs and materials to patients' homes. This talk will discuss the post-COVID strategies for connected devices implementation in hybrid trials.

**11:40 Using Digital Technologies to Accelerate Behavioral Health Assessments and Interventions—Learnings from Real-World Studies**

*Abhishek Pratap, PhD, Senior Clinical Program Leader, Central Nervous System, Boehringer Ingelheim*

This talk will focus on the use of digital health technologies(DHTs) to advance medical product development—from assessment to interventions in real-world settings. I will share learnings from clinical research studies to help inform the development of robust digital endpoints and interventions focusing on improving behavioral outcomes.

**12:10 pm Validation of Digital Health Technologies for Clinical Trials: The NIH Framework**

*Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)*

This presentation will share the NIH Framework for digital technologies' validation in clinical trials.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Revolutionizing Research: Navigating the Spectrum with a Fully Hybrid Approach**

*Thad Wolfram, President, EmVenio*

This track will explore the methodology of a fully hybrid clinical trial approach. We will discuss how the combination of mobile Clinical Research Sites, personalized home visits, and convenient virtual visits are not only on the rise, but also effectively bridging the gap to bring clinical trials to previously underrepresented and diverse populations.

**1:15 SCOPE Summit 2024 Adjourns**

## 2024 Partnering Organizations

SCOPEsummit.com/partnering-organizations

Cambridge Healthtech Institute's 9th Annual

# Operationalizing Biomarkers and Precision Medicine Clinical Trials

Biomarker-Driven Trial Design, Consent Management and Operations

**FEBRUARY 11-13, 2024**
All Times EST

Cambridge Healthtech Institute's 8th Annual

# Modernizing Lab, Biospecimens and Biobanking Operations

Patient-Centric Collection, Sample Tracking, Vendor Management, and Data Considerations

**FEBRUARY 13-14, 2024**

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## ENABLING BIOMARKER DRIVEN TRIALS

**10:45 Chairperson's Remarks**
*Derek Grimes, Senior Vice President, Clinical Operations, Frontage Laboratories, Inc.*

**10:50 Transforming Healthcare Using Deep Data and Remote Monitoring**
*Michael Snyder, PhD, Stanford W. Ascherman Professor & Chair, Department of Genetics, Director, Center for Genomics & Personalized Medicine, Stanford University*
Following 109 individuals for over 13 years revealed numerous health discoveries covering cardiovascular disease, oncology, metabolic health, and infectious disease. We also found that individuals have distinct aging patterns that can be measured in an actionable period of time. Finally, we used wearable devices for early detection of infectious disease, including COVID-19, and microsampling for monitoring and improving lifestyle. We believe that advanced technologies have the potential to transform healthcare.

**11:20 A New Clinical STAR (Sample Tracking and Reconciliation) Formation**
*Arkady I. Gusev, PhD, Head, Lab Excellence & Operations in Biomarker Development, Novartis Institutes for BioMedical Research, Inc.*
The end-to-end clinical sample management remains the area of focus and opportunity for improvements for many pharma/biotech companies. It directly impacts operational efficiency, data integrity/quality, and clinical trial speed. We will present a solution based on commercially available IT platforms covering sample collection planning, sample data ingestion, QC/clean up, and reconciliation. The system is also expected to work in concert with electronic sample requisition forms which will also be discussed.

**11:50 CO-PRESENTATION: Streamlining Biosample Information for Effective Clinical Trial Management**
*Elena Gogvadze, Senior Consultant, Roche*
*Magdalena Jodlowska, Biosample Operations Portfolio Lead, F. Hoffmann-La Roche Ltd.*
A fragmented and non-integrated landscape in biosample operations management poses a huge challenge for effective delivery of clinical studies. We are tackling this challenge by developing a centralized biosample planning and study conduct platform - a tool that (i) allows efficient study planning using standardized information, (ii) provides end-to-end oversight of study conduct and sample and data tracking, and (iii) ensures adherence to FAIR principles, enhanced data quality, and compliance.

**12:20 pm Tell Me What I Don't Know: AI-Enhanced Decisions in Biomarker-Informed Trials**
*Tobi Guennel, PhD, Senior Vice President Product & Chief Architect, Data Management, Systems Integration, Product Innovation, QuartzBio, part of Precision for Medicine*
Human drug development teams make data-driven decisions, but these decisions can be limited by prior experience, expertise, and inefficient collaboration. Deploying generative artificial intelligence (AI) in drug development disrupts the limits of human-structured queries. We demonstrate how conversational AI empowers users to extract sample and biomarker information at the speed of decisioning. Predictive features of GAI enable novel insights by proactively surfacing information instead of passively waiting for input.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: Bridging the Biospecimen Data Gap: Revolutionizing Clinical Trials through Streamlined Data Management**
*Mark Melton, Vice President of Scientific Operations and Development, Slope*
From fragmented processes to siloed stakeholders, serious shortcomings in sample tracking and data management practices risk compromising study timelines and data integrity. Join us as we explore best practices for enhancing your approach to data governance, data reconciliation, lab vendor relationships, and more. Discover how streamlining the collection and management of biospecimen data can improve collaboration and data integrity, thereby accelerating the pace of clinical research.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## OVERCOMING OPERATIONAL CHALLENGES OF BIOMARKER & BIOSPECIMEN MANAGEMENT

**2:20 Chairperson's Remarks**
*Karina Bienfait, PhD, Executive Director and Head, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol Myers Squibb Co.*

**2:25 CO-PRESENTATION: Real-Time Specimen Tracking at Bristol Myers Squibb**

*Victor Cardenas, Associate Director, Global Clinical Development IT, Bristol Myers Squibb Co.*

*Pritesh Patel, Associate Director, Global Biospecimen and Imaging Management, Bristol Myers Squibb Co.*

BMS has taken the approach of aligning both business and technology objectives to ensure we have full visibility for all clinical trial specimens. We will identify the long-term vision/aspiration and ways in which BMS has been taking a staged approach to achieve it. Multiple approaches have been tested. Our goal is to reduce patient and site burden and ensure the quality and integrity of precious specimens are maintained.

**2:55 Lifecycle Management: Utilizing Technology to Modernize at the Enterprise Level**

*Nancy DeFusco, Director, Specimen Lifecycle Management, Merck Sharp & Dohme LLC*

Explore MSD's process and technology to address enterprise-level inefficiencies and inconsistencies in reporting of biospecimens to enable real-time comparison, evaluation, and decisions. A cross-functional workstream was created to assess the biospecimen lifecycle process, from the protocol through metadata accumulated days, weeks, and years after physical collection. We developed a platform that harmonizes the data from multiple sources to one metadata stream allowing for enhanced real-time decisions and actions.

**3:25 Outsourcing Strategies to Improve Biomarker and Biospecimen Operations**

*Jarod Prince, Senior Manager, R&D Operations, Amgen*

Strategic outsourcing leveraging external resources is key to streamlining biospecimen operations. The push towards precision medicine has led to increased collection of biomarker specimens which can be tested as a study endpoint or stored until needed to enhance future scientific discovery. This presentation will highlight steps to strategically outsource components of biospecimen operations to enhance efficiency, maintain data integrity, ensure compliance, and achieve successful outcomes in research and development endeavors.

**3:55 CO-PRESENTATION: Building Clinical Sample Management Capability to Support Oncology and Cell Therapy Clinical Pipeline**

*Anna Kosenko, Team Lead, Sample Management & Data Operations, Takeda Pharmaceuticals, Inc.*

*Heather H. Shih, PhD, Head of Oncology Clinical Biomarker Operations, Oncology & Cell Therapy, Takeda Pharmaceuticals, Inc.*

Clinical PK, immunogenicity, and biomarker data derived from patient samples directly contribute to study endpoint and clinical decisions. A robust sample management capability is critical to oncology and cell therapy clinical studies due to the complex nature of biomarker design, the variety of sample types, and needs for fast data turnaround. We will share our success as well as challenges from our recent experience building an end-to-end sample management capability.

**4:25 Optimising Pathology Strategy and Workflows in Clinical Trials**

PathAI

*Saumya Pant, PhD, Vice President, Clinical Development Services, PathAI*

Dr. Saumya Pant will discuss approaches and considerations when planning central pathology protocols and workflows in clinical trials, especially in trials that heavily rely on pathology for patient enrollment and endpoint evaluation. Drawing from learnings in NASH and oncology, Dr. Pant will present data from AI digital pathology algorithms and their impact on improving endpoint accuracy and patient enrollment, and conclude with actionable strategies for clinical operations.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**

Medable

*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*

Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**

trialbee

*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## DATA MANAGEMENT AND INDUSTRY STANDARDIZATION

**9:10 Chairperson's Remarks**

*Deborah Shepard, PhD, Director Biomarker Clinical Assay Lead, Global Product Development & Oncology & Rare Disease, Pfizer Inc.*

**9:15 Aligning Biomarker Data with CDISC SD Biomarker Domains**

*Deborah Shepard, PhD, Director Biomarker Clinical Assay Lead, Global Product Development & Oncology & Rare Disease, Pfizer Inc.*

CDISC has introduced a number of Study Data Tabulation Model (SD) domains for biomarker data. There are distinct domains for data generated from genomic, cell phenotyping, proteomic, histopathology, microbiology, and immunogenicity assessments. Formatting biomarker data according to the CDISC domains is required for FDA and PMDA regulatory submissions. It also standardizes data from different laboratories and studies for analysis for internal decision-making and inclusion in publications and conference presentations.

**9:45 PANEL DISCUSSION: PANEL DISCUSSION: Industry Standardization to Accelerate Precision Medicine**

*Moderator: Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC*

Do you work with biomarker or pk samples? Are you frustrated with how long it takes to reconcile specimens and data from the multitude of testing labs and storage facilities in a clinical trial? Come hear from leaders from both industry and Central Labs - understand problem from both sides - and discuss the best ways of driving standardization to accelerate Precision Medicine operations.

*Panelists:*

*Dmitri Mikhailov, PhD, Director & Global Head, Biomarker Coordination, Novartis Institutes for BioMedical Research, Inc.*

*Tia Parker, Director, ATL Central Lab Operations, Q2 Solutions*

*Deborah Shepard, PhD, Director Biomarker Clinical Assay Lead, Global Product Development & Oncology & Rare Disease, Pfizer Inc.*

*Mary Zuniga, Senior Director, Translational Immunology, Eli Lilly & Co.*

*Mark Melton, Vice President of Scientific Operations and Development, Slope*

**10:15 How to Reach Clinical Trial Objectives Faster in the Complex World of Clinical Research**

LabConnect

*Cindy Markham, Chief Commercial Officer, LabConnect*

Today's higher complexity in clinical research translates to more work for the sites and more opportunities for errors in sample collection, processing, packaging, and shipping. One lost or non-viable sample can impact the ability to enroll a patient in a clinical trial or include data from an enrolled patient in the regulatory submission. We'll reflect on the complex challenges and provide innovative approaches to operate more efficiently and effectively.

**10:45 Coffee Break in the Exhibit Hall**

Assertia WorldCare Clinical

**10:50 Special Book Signing**

*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

## DIGITAL BIOMARKERS ARE STILL BIOMARKERS

**11:40 Chairperson's Remarks**
*Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC*

**11:45 Repurposing Cell Therapy Products for Research: Operational Considerations**
*Karina Bienfait, PhD, Executive Director and Head, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol Myers Squibb Co.*
The ability to repurpose investigational autologous cell therapy drug products (and intermediates) for research provides new opportunities for scientific exploration. However, complexity in the cell therapy space results in operational challenges for standard specimen management. This presentation will explore strategies to address these challenges and solutions to manage residual cell therapy materials as part of the standard biopharma biorepository infrastructure.

**12:05 pm Building Participant Engagement through the Return of Value**
*Scott Topper, PhD, Chief Clinical Operations Officer, Color Health, Inc.*
Research programs are successful when participants feel engaged and invested. A "return of results" program that provides meaningful personal information back to participants can be incredibly effective, driving gratitude and longitudinal engagement. One groundbreaking example is the NIH *All of Us Research Program*, which has enrolled over 500,000 individuals and is returning hereditary disease risk analysis, pharmacogenomics, and recreational genetics. This talk describes the process, principles and impact.

**12:25 Next-Generation Informed Consent**
*Sofiane Nacia, Associate Director, Strategic Trial Participant Liaison, Novartis*
Embark on a journey into the future of informed consent with the next-gen paradigm. This groundbreaking concept seamlessly automates and globally translates traditional documents, breaking language barriers while maintaining local relevance. Witness the transformative leap in patient communication, enhancing accessibility and specificity. Join us to explore the innovative features that mark a pivotal shift in healthcare and research, shaping the landscape of patient-centric communication practices.

**12:45 Transition to Lunch**

**12:50 Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## TUESDAY AFTERNOON PLENARY SESSION: MODERNIZING TRIALS WITH FDA & INTERSECTION OF INNOVATIVE DEVELOPMENT MODELS AND INVESTMENT APPROACHES

**2:20 Organizer's Welcome Remarks**
*Marina Filshtinsky, MD, Executive Director, Conferences, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**2:25 Chairperson's Remarks**
*Jie Wu, PhD, Co-Founder & CDO, Segmed, Inc.*

**2:30 PANEL DISCUSSION: Fireside Chat with FDA on Modernizing Clinical Trials**
*Moderator: Ken Getz, Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine*
*Panelists:*
*Kevin Bugin, PhD, Deputy Director, Operations, Office of New Drugs (OND), FDA Center for Drug Evaluation and Research (CDER)*
*Marsha Samson, PhD, Analyst, Office of Medical Policy, FDA*

**3:00 CROSS-INDUSTRY PANEL: Intersection of Innovative Development Models and Investment Approaches That Move the Needle at the Portfolio Level**
*Moderator: Jacob LaPorte, PhD, Co-Founder, Prisma Therapeutics*
*Panelists:*
*Angela DeLuca, Vice President, Head of Oncology & Cell Therapies Clinical Operations, Global Development Office, R&D, Takeda*
*Michael Greeley, Co-Founder & General Partner, Healthcare Technology, Flare Capital Partners*
*Michelle Longmire, Co-Founder & CEO, Medable, Inc.*
*Sam Srivastava, CEO, WCG*

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## ADVANCEMENTS IN BIOBANKING & BIOREPOSITORY OPERATIONS

**4:30 Chairperson's Remarks** *(Sponsorship Opportunity Available)*

**4:35 Intelligent AI/BI for Biomarker Labs and Biorepositories: Transforming Analysis to Insights**
*Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck*
Scientific organizations use business intelligence (BI) tools to develop dashboards that display and explain events that have happened (WHAT) to transform instincts into informed decisions. Integrated technologies have allowed the convergence of BI and Artificial Intelligence (AI) to allow for the understanding of causation in such events (WHY) by integrating powerful technologies like augmented analytics. This transformation, from the WHAT to understanding the WHY, facilitates transformation from analysis to insights.

**5:05 Best Biospecimen and Biobanking Practices to Accelerate Research Progress in Cancer**
*Lokesh Agrawal, PhD, Program Director, Biorepositories & Biospecimen Research, NIH NCI*
The Cancer Moonshot Biobank is a National Cancer Institute (NCI)-sponsored study that aims to accelerate cancer research through the collection of longitudinal blood and tissue biospecimens from cancer patients receiving standard-of-care therapy. The biospecimens, generally small biopsies, and accompanying medical data will be made available to accelerate research progress in cancer. Evidence-based, well-documented, and consistent procedures are used to collect specimens of known quality.

**5:35 Sponsored Presentation** *(Opportunity Available)*

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
*Scott Chetham, CEO & Co-Founder, Faro Health, Inc.*

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## TRANSFORMATIVE NEW TECHNOLOGIES TO REDUCE PATIENT BURDEN AND REACH BROADER POPULATIONS

**8:25 Chairperson's Remarks**
*Mike Martin, Principal, ZS*

**8:30 PANEL DISCUSSION: Hybrid Trials, DCTs, and Patient-Centricity: Where Are We Now and Where Are We Going?**
*Moderator: Ebony N. Dashiell-Aje, PhD, Executive Director & Head, Patient Centered Outcomes Science, BioMarin Pharmaceutical, Inc.*
Recently, clinical trial decentralization has held much promise – to increase operational efficiency, reduce patient burden, increase patient access, and enhance. In addition to enhancing data quality, patient-centricity has been a primary focus. However, challenges related to implementation remain. We will reflect on patient-centricity within the context of DCT adoption and discuss the future for model optimization to keep patients at the center of it all.
*Panelists:*
*Emily Epstein, LMSW, Trial Volunteer & Cancer Previvor, Research Coordinator, Genetic Social Worker, Division of Gynecologic Oncology , Genetics and Personalized Cancer Prevention, Weill Cornell Medicine*
*Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck*
*Alekhya Pochiraju, Senior Product Development Lead, Clinical Operations, Genentech*
*Isaac R. Rodriguez-Chavez, PhD, MHSc, MSc, Scientific & Clinical Affairs, IEEE*

**9:00 Microsampling and Shifting Paradigm of Decentralized Clinical Trials**
*Dmitri Mikhailov, PhD, Director & Global Head, Biomarker Coordination, Novartis Institutes for BioMedical Research, Inc.*
Microsampling technologies enable clinical trials to reach broader populations, collect additional samples during or post-study, and help reduce patient burden. This presentation will review various aspects for implementation in clinical trials and will cover several topics, including the main areas for microsampling impact on clinical trials, operational planning for microsampling implementation, and considerations for microsampling approach in relation to bioanalytical utility and data interpretation.

**9:30 A platform based approach to patient recruitment & enrolment: maximising patient & sponsor experience**
*Manuri Gunawardena, CEO, Executive, HealthMatch*
HealthMatch & Velocity Clinical Research have embarked on a pilot as part of a strategic partnership to trial platform wide recruitment across over 100 trials. By employing HealthMatch across over 100 trials simultaneously, significant gains in recruitment efficiency and patient experience have been achieved. The speakers, representing leadership of both organizations will share on the partnership, the benefits and how sponsors can likewise benefit from a broader based approach.

**10:00 PANEL DISCUSSION: Remote Blood Sampling Devices/Apps: The Next Transformative Approach to Optimizing Sample Data Collection—Are We There Yet?**
*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:*
*Kelli Aufderheide, Director, Decentralized Trial Solutions, Q2*
*Angela Tucker, Program Director, Decentralized Trials, Labcorp*
*Enaksha Wickremsinhe, PhD, Bioassay Development Lead, Bill & Melinda Gates Medical Research Institute*

**10:45 Networking Coffee Break**

## CONNECTED HEALTH AND DATA SOLUTIONS FOR FLEXIBLE TRIALS

**11:05 Chairperson's Remarks**
*Ching Tian, Chief Innovation Officer, Emmes Corp.*

**11:10 How Connected Devices Enable Decentralized Trials**
*Jian Yang, Vice President, Digital Health, Eli Lilly Company*
DCTs leverage "virtual" tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, patient-driven virtual health care interfaces, and direct delivery of study drugs and materials to patients' homes. This talk will discuss the post-COVID strategies for connected devices implementation in hybrid trials.

**11:40 Using Digital Technologies to Accelerate Behavioral Health Assessments and Interventions—Learnings from Real-World Studies**
*Abhishek Pratap, PhD, Senior Clinical Program Leader, Central Nervous System, Boehringer Ingelheim*
This talk will focus on the use of digital health technologies(DHTs) to advance medical product development—from assessment to interventions in real-world settings. I will share learnings from clinical research studies to help inform the development of robust digital endpoints and interventions focusing on improving behavioral outcomes.

**12:10 pm Validation of Digital Health Technologies for Clinical Trials: The NIH Framework**
*Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)*
This presentation will share the NIH Framework for digital technologies' validation in clinical trials.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Revolutionizing Research: Navigating the Spectrum with a Fully Hybrid Approach**
*Thad Wolfram, President, EmVenio*
This track will explore the methodology of a fully hybrid clinical trial approach. We will discuss how the combination of mobile Clinical Research Sites, personalized home visits, and convenient virtual visits are not only on the rise, but also effectively bridging the gap to bring clinical trials to previously underrepresented and diverse populations.

**1:15 SCOPE Summit 2024 Adjourns**

Cambridge Healthtech Institute's 5th Annual

# Data Technology for End-to-End Clinical Supply Management

**FEBRUARY 11-13, 2024**
All Times EST

Controlling the Complexity of Clinical Supply Chain Forecasting and Contingency Planning

Cambridge Healthtech Institute's 5th Annual

# Clinical Supply Chain Strategies to Align Process, Products and Patients

**FEBRUARY 13-14, 2024**

Ensuring a Safe, Stable and Secure Supply Chain in Constantly Shifting Dynamic Clinical Trials

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## CENTER STAGE SESSION: FDA AND EMA INSPECTIONS—ARE YOU PREPARED?

**8:30 Chairperson's Opening Remarks**
*Maria Napoliello Humagain, Director, Clinical Supply Technologies, Arcus Biosciences*

**8:35 Clinical Supplies & Systems: Inspection Readiness (FDA and EMA) Preparation and Request Management**
*Don Yeung, Director, Global Clinical Drug Supply, Genmab US, Inc.*
During any inspection (FDA/EMA), Interactive Response Technology (IRT)/Randomization and Trial Supply Management (RTSM) in the past has been an afterthought or of minimal focus. Come and find out how a sponsor responded to real-life inspection-related findings, while other sponsors are in preparation for upcoming inspections with regulatory agencies. This interactive presentation and panel will discuss the best practices on preparation and responses to inspection-related findings specific to IRT/RTSM.

**9:05 FIRESIDE CHAT: Experience and Insights from a Regulatory Inspection**
*Moderator: Maria Napoliello Humagain, Director, Clinical Supply Technologies, Arcus Biosciences*
Let's discuss recent inspection experiences regarding IRT and how to address findings and how to be prepared for next time.
*Panelists:*
*Kara Kaur, Senior IRT Manager, Global Clinical Drug Supply, IRT & Systems, Genmab US, Inc.*
*Don Yeung, Director, Global Clinical Drug Supply, Genmab US, Inc.*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## IRT INTEGRATION AND DATA FLOWS

**10:45 Chairperson's Remarks**
*Andrew Schachter, Founder/ CEO, Axiom Real-Time Metrics*

**10:50 Industry Demands: Sponsors Pushing IRT Vendors for Innovative Features and Solutions**
*Constantine Ward, Global Head, Clinical Supply & IRT Guru, Optimal Supply*
This presentation will focus on enhancing clinical site supply strategies. This session will delve into proposed IRT features, along with external concepts that sponsors can evaluate utilizing, and which IRT vendors can potentially incorporate into their development roadmaps. Together, we aim to address existing gaps by identifying necessary features to potentially pave the way for reliable artificial intelligence use.

**11:20 IRT: Past, Present & Future**
*Jason Williams, Senior Manager, Clinical Trial Tools & Technologies, Takeda*
What is IRT? Why are IRT systems important for successful clinical trials? What type of data should be recorded in an IRT? Come take a journey with me as I walk you through the history of Interactive Response Technology (IRT). Along this journey I will be discussing IRT data collection, complexities, integrations, temperature excursion documentation, and more.

**11:50 Case Study: Designing the Right IRT for Direct-to-Patient and Home Treatment Studies**
*Irina Grishina, Senior Project Manager, ACTT, eClinical Operations, CSL Behring*
*Kelsey Kern, Clinical Trial Supply Study Manager, CSL Behring*
Using case studies, they will explore the importance of a flexible IRT design in a DTP or home treatment study. They will share how the IRT design can be adapted to reduce waste and maintain line of sight to the clinical supply. They will offer some tips and tricks for ensuring a streamlined, user-friendly DTP experience at sites, and subsequently for patients.

**12:20 pm Tackling Trial Supply Shortages with Advanced IRT**
*Lee Bardy, Associate Business Excellence Director, Calyx*
In this session, we will review how a well-designed IRT system with expert support can address drug supply/shortage issues, via flexible, adaptable settings and advanced RTSM design
We will share what actions can be taken throughout the life of your trials to manage both known & unknown, expected and emergency drug shortages.

**12:50 Transition to Lunch**

**12:55 LUNCHEON PRESENTATION: IRT / Clinical Trial Supply Managed in Real-Time: Eliminate the Manual Work**
*Andrew Schachter, Founder/ CEO, Axiom Real-Time Metrics*
IRT and Clinical Trial supply are often the lifeblood of any study. They are fundamental to managing, enrolling and supplying subjects through the study. So why are so many of these done in a way that requires so much manual work in a dozen spreadsheets?

Join this session to discuss how IRT/Clinical Supply should work together across the landscape of your broader study requirements. Learn how to rapidly set-up IRT and Clinical Supply configurations to deliver real-time decision making data seamlessly.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## TOOLS FOR FORECASTING, TRACKING, AND REDUCING COSTS

**2:20 Chairperson's Remarks**
*Leslie Taylor, Director, Global Clinical Supply Chain Technologies, Incyte Corp.*

**2:25 Enhanced Drug Forecasting to Minimize Waste and Right-Size Supply Inventories with Lens for Environmental Sustainability**
*Kristel Rens, Director, Innovation and Strategy, Clinical Supply Chain, Janssen Pharmaceutical Companies of Johnson & Johnson*
In the realm of clinical trial drug supply forecasting, complexity has surged and the need for fast data decision making is growing. Leveraging interconnected systems and determining right input parameters is essential. This approach optimizes end-to-end supply strategies, reduces costs beyond inventory, while bolstering environmental sustainability. It guarantees efficient clinical supply chain throughout its entire operations, aligning with an industry evolution need.

**2:40 Reducing Clinical Supply Waste through Modeling and Integrations**
*Chelsea Gallagher, Senior Director, Drug Development Innovation & Digital Health, Bristol Myers Squibb Co.*
Clinical supply waste reduction and streamlined planning is achieved through a comprehensive innovation program driven by cross-functional collaboration, integration of processes, data ,and models between clinical supply, clinical operations, clinical trial analytics, innovation & digital health analytics, and IT. This program aimed to reduce clinical supply waste by 5% (valued at $15M/ year) through improved demand forecasting, improved supply optimization, automated data pipelines, and model performance monitoring.

**2:55 Talk Title to be Announced**
*Tola Olorunnsola, Vice President, Strategy, Innovation, Marketing and Digital, Avantor Services, Avantor*

**3:25 Beyond Simulations: Using Machine Learning to Optimize the Supply Chain**
*Eric Bitzegaio, Senior Director, Engineering, Medidata, a Dassault Systemes Co.*
Supply managers practice more art than science when optimizing trial supply chains. They might employ a simulation or forecasting tool to predict demand, or look at dashboards for monitoring, but they ultimately use trial and error. Machine learning techniques can analyze inventory data and provide guidance around meeting supply targets. This talk will address applications of machine learning techniques on inventory data to improve supply chain efficiencies.

**3:55 Technological Solutions for Clinical Supply Chain Threat Detection and Mitigation**
*Leslie Taylor, Director, Global Clinical Supply Chain Technologies, Incyte Corp.*
Forecasting software combined with machine learning empowers supply chain planners to prevent and manage future risk. Our planners supplement long-term forecasts with fit-for-purpose tools to mitigate short term risks. Harness the power of robotic process automation and micro-tools to focus resources and avoid patient impact.

**4:25 How to Accelerate Adoption and Lower TCO with a Configurable RTSM System**
*Sean Roy, PhD, Senior Consulting Practice Director, Oracle Life Sciences*
Configurable RTSM systems present new opportunities to accelerate adoption of clinical trial platforms, while lowering the total cost of ownership. As the industry continues to move away from cumbersome custom solutions, new questions arise about how to standardize approaches to RTSM ownership, manage platform adoption, conduct site and sponsor training, perform cross-study analytics and reporting, and achieve economies of scale.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

## TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

### BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

### LEVERAGING DATA TO SUPPORT THE CLINICAL SUPPLY CHAIN

**9:10 Chairperson's Remarks**
*Kevin Grygiel, Director, Americas Clinical Solution Sales, Sales, Loftware*

**9:15 FEATURED PRESENTATION: AI/ML in RTSM**
*Barry Moore, Head, RTSM, R&D, GSK*
This talk explores the integration of Machine Learning and Artificial Intelligence in optimizing clinical trial supply chains and patient randomization. It highlights how these technologies enhance forecasting, inventory management, study management, and logistics, showcasing case studies and advancements. Join us to discover how AI is starting to change clinical trials, promoting efficiency, and accelerating studies.

**9:45 Med.ai-CAR T—An Integrated CAR T Data and Analytic Platform for R&D**
*Alex Li, Director, Data Science Platform, Janssen R&D LLC*
*Lina Yang, PhD, Senior Scientist, Data Science and Digital Health, Johnson & Johnson Innovative Medicine*
As an R&D organization, Johnson & Johnson Innovative Medicine Data Science & Digital Health is collaborating with the Oncology teams to develop an integrated solution for advanced analysis across modalities and scales in CAR T research. Access to CAR T multimodality data will enable the utilization of advanced AI/ML technology to enhance our understanding of manufacturability, efficacy, and safety in cell therapy products.

**10:15 Case Study: Optimizing Clinical Supply Chain with Machine Learning Tools: Improving Quality while Reducing Cost and Risk**
*Sarosh Anjum, Associate Director, Informations and Systems Strategy, Astellas*
*Kevin Landells, Vice President & General Manager, IRT, IQVIA Technologies*
There are many domains in which innovation through artificial intelligence is being presented. Whether that's concerning clinical systems, tracking and tracing, direct-to-patient, advanced therapeutics, distribution, or cost savings via supply forecasting, there are numerous options. The questions we must answer first are how to advance technology to improve safety and accountability, while reducing cost and risk. Let's have an interactive discussion on real-world case studies and other practical applications for AI.

**10:45 Coffee Break in the Exhibit Hall**

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

### BUILDING THE SUPPLY INFRASTRUCTURE FOR CELL AND GENE THERAPIES

**11:40 Chairperson's Remarks**
*Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America*

**11:45 FEATURED PRESENTATION: The Patient as Part of the Supply Chain**
*Lee F. Clough, RN, HP, C&G Operations Cell Steward Lead, Global C&G PMO, Novartis Pharmaceuticals Corporation*
This presentation will provide an overview of the CAR T Supply Chain and how different it is compared to other medications. We will evaluate the starting material provided by the patient and creating an autologous finished product. Looking at challenges with collection and discuss fresh vs. cryopreserved options for transporting the starting material and close with continuous improvements even after collecting autologous material for commercial batches and clinical trials.

**12:15 pm Clinical Supply Chain: Onboarding a Clinical Site for Successful Starting Material**
*Andrea Carney, Associate Director, Global Patient Supply, Immatics*
At the heart of TCR-based cell therapy manufacturing lies the starting material: patient cells, which are collected at clinical sites where patients receive their cancer treatments. To ensure the success of this critical step, it's essential to establish a strong foundation with clinical sites. This requires upfront effort to create a seamless process that benefits both the clinical site and the company and, most importantly, the cancer patients.

**12:45 Transition to Lunch**

**12:50 Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**
*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

**2:20 Organizer's Remarks**

## CENTER STAGE SESSION: MANUFACTURING FOR CELL THERAPIES

**2:25 Chairperson's Remarks**
***George Tiger, Global Vice President, Business Development, Almac Clinical Technologies, Almac Group***

**2:30 Challenges, Solutions, and the Future of Autologous Therapies**
***Albert Ribickas, Assistant Director, Cell Therapy Facility (CTF) Operations, H. Lee Moffitt Cancer Center & Research Institute***
The use of autologous CAR T therapies has been a breakthrough in the treatment of several forms of cancer. What can be accomplished to get more patients collected by apheresis, the product manufactured, and administered to the patient? How can the process be optimized to allow for the most expedient treatment of patients? The challenges and possible solutions will be explored and discussed.

**3:00 The Cell Therapy Clinical Supply Paradigm Today vs. What We're Building for Tomorrow**
***Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America***
This presentation will provide a summary of the unique clinical supply infrastructure required for today's approved commercial cell therapies, compared to the vastly different infrastructure needed to meet the cell therapies of tomorrow (currently in development), which are anticipated to be much more allogeneic, and their production increasingly decentralized.

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**
Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

**4:35 Presentation to be Announced**

**5:05 PANEL DISCUSSION: Manufacturing Cell Therapies**
***Moderator: Michael Mehler, Strategy Insights & Planning Manager, Cell & Gene Therapy, ZS Associates***
Cell health and expansion are critical to manufacturing of immunotherapies and production bioprocesses vary widely, significantly impacting quantities, quality, and costs. This panel addresses the practical challenges in manufacturing autologous and allogeneic cell therapies at scale bringing these impactful medicines to more patients.
***Panelists:***
***Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America***
***Andrea Carney, Associate Director, Global Patient Supply, Immatics***
***Lee F. Clough, RN, HP, C&G Operations Cell Steward Lead, Global C&G PMO, Novartis Pharmaceuticals Corporation***
***Matthew Hewitt, Vice President, Technical Officer CGT & Biologics, Charles River Laboratories***

**6:05 Close of Day**

## WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**
***Scott Chetham, CEO & Co-Founder, Faro Health, Inc.***
Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## SCALING ORGANIZATIONAL CAPACITY FOR EFFECTIVE CLINICAL TRIALS THROUGH PARTNERSHIPS AND EFFICIENT USE OF RESOURCES

**8:25 Chairperson's Remarks**
***Peter Ronco, CEO, Emmes***

**8:30 Thinking of Going Smaller? What to Expect When Transitioning from a Large Pharma Company to a Small Biotech**
***Susan G. Mullin, Vice President, Clinical Operations, Ventyx Biosciences, Inc.***
This presentation will focus on the differences between the work experience at a large pharma vs. a small biotech, what to expect during the transition, and how to plan for success. Topics will include: infrastructure, choosing a CRO, relationships, technology and culture, recruitment, training, and development of team members.

**9:00 Why Following the Status Quo for a Pediatric Rare Disease Clinical Study Was Not the Optimal Approach for a Small Biotech**
***Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.***
Clinical study success depends on three "C" or core elements: communication, collaboration, and cooperation from all participating individuals. When it comes to working on rare diseases, the chances of outsourcing to a CRO or vendor with prior experience in that particular indication are often nonexistent. This presentation will focus on how Rezolute took a more direct, hands-on approach to executing a rare pediatric pivotal Phase 3 Global Program.

**9:30 CO-PRESENTATION: Operationalizing a Virtual Site: Insights from Bayer and Science 37**
***Darcy Forman, Chief Delivery Officer, Science 37***
***Speaker II to be Announced***
The optimal clinical trial design is not a one-size-fits-all approach. Just as each clinical trial has its own unique characteristics, the elements of a virtual clinical trial require tailored integration to harmonize with specific protocol requirements. Explore insights from Bayer and Science 37 as they discuss their journey, the importance of collaboration in fostering innovation and explore perspectives on virtual trial execution.

**9:45 CO-PRESENTATION:**
***Brandie Jonas***
***Courtney Maguire, Senior Director Clinical Program Management, Geron Corporation***
***Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical***

**10:15 Decentralized Approaches—Especially in Rare Disease/Oncology—Into Trials That Require Centers Well-Versed in Clinical Research**
***Caro Unger, Senior Director, Clinical Operations***
Running trials nimbly—utilizing in-house talent and managing a trial without a CRO. How to evaluate if this is the right model for you and look at the pros and cons for your team/organization. Which vendors and consultants will you need and which resources can be used from the company? Which processes and plans will need to be developed and which lessons learned?

**10:45 Networking Coffee Break**

## PATIENT BIOSPECIMEN SUPPLY CHAIN

**11:05 Chairperson's Remarks**
***Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC***

**11:10 Biospecimens Supply Chain—Considerations around the Importation of Samples to Support Clinical Trials**
***Thomas J. McDonald, MS, Associate Director, Strategic Biospecimen & Vendor Logistics Management, Bristol Myers Squibb Co.***

Today, more than ever, clinical trial strategy includes the importation of biospecimens acquired from global sites. This may be done to develop cell and gene therapy, for assay to support primary endpoints, or simply for exploratory use or storage. In any instance, the process can be a challenging one. This conversation will touch on the classification of samples for US import, the relevant CDC guidance, and the customs clearance process.

**11:40 Sponsored Presentation** *(Opportunity Available)*

**12:10 pm PANEL DISCUSSION: The Biospecimen Supply Chain: A Prism of Perspectives**

***Moderator: Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC***

Have you encountered confusion or churn around the supply chain for biospecimens? Are you familiar with how the classification of your samples can impact importation? This is your opportunity to hear from industry experts in global logistics, sample management, and customs clearance on a multitude of topics. Our discussion will help illuminate various approaches espoused in the collection and importation of clinical samples and special considerations relevant to each scenario.

***Panelists:***

***Nancy DeFusco, Director, Specimen Lifecycle Management, Merck Sharp & Dohme LLC***

***Thomas J. McDonald, MS, Associate Director, Strategic Biospecimen & Vendor Logistics Management, Bristol Myers Squibb Co.***

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Digital Innovations for Patient-Centered Clinical Trials Using Real-World Data**

***Karina D'Angelo, PhD, Director, Scientific Real World Data Strategy, Parexel***

***Denis McMillan, Vice President, Global Feasibility, Parexel***

***Camilla Ramdeen, PhD, Executive Director, Strategic Feasibility, Parexel***

***Russell Robbins, MD, MBA, Chief Medical Information Officer, PurpleLab***

Supporting inclusion of underrepresented populations in clinical trials and real-world data studies requires a multi-faceted approach – access to real world data sources supports decision making to ensure diverse populations are considered proactively throughout research study phases. This presentation highlights ways to ensure studies have DEI in patient populations to meet FDA expectations and innovative ways of using healthcare data linked with deidentified SDOH attributes.

**1:15 SCOPE Summit 2024 Adjourns**

## Media Partners

Official Event Publication

Lead Sponsoring Publications

Sponsoring Publications

Lead Media Partners

Lead Sponsoring Organization

Cambridge Healthtech Institute's 4th Annual

# Medical Device Clinical Trial Design and Operations

FEBRUARY 11-13, 2024
All Times EST

Realizing the Potential of Device Trials through Strategic Design and Process Improvements

Cambridge Healthtech Institute's 4th Annual

# Device Trial Regulations, Quality, and Data Management

FEBRUARY 13-14, 2024

Forging a Path to Successfully Bring Devices to Market

## SUNDAY, FEBRUARY 11

**8:00 am SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament*** *(Sponsorship Opportunities Available)*
**Limited space available. Separate registration and fee required for Golf.*

**9:00 Registration Open**

### PRE-CONFERENCE WORKSHOPS

**1:00 pm – 1:45 pm [In-Person ONLY] Open Workshop: Introducing ClinEco, SCOPE's B2B Clinical Trial Community and Marketplace**
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about and register for the new B2B clinical trial community and marketplace featuring 65+ companies. ClinEco unites sponsors, CROs, service providers, and sites to streamline partnering, vendor research, innovation, and learning. This year we are also introducing 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. Join the ClinEco community 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 – 2:30 pm [In-Person ONLY] The Path towards Sustainable Trials Workshop**
**Reducing the Environmental Impact of Global Clinical Trials**
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond positive environmental impacts, sustainable approaches are expected from stakeholders and can be a deciding factor for customer selection and attracting talent. This workshop will discuss the current hotspots of carbon emissions in clinical research and suggest introductory reduction strategies in relation to each. 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.
*Jason Lanier, Environmental Sustainability Focus Area, Director, Janssen Clinical Innovation (JCI)*
*David Lumby, Executive Director, EHS, Thermo Fisher Scientific*

### SUNDAY AFTERNOON PLENARY SESSION: KICK-OFF MULTI-STAKEHOLDER PLENARY KEYNOTE AND PARTICIPANT ENGAGEMENT AWARDS

**3:00 Organizer's Welcome Remarks & 3rd Annual Masters of Clinical Research Golf Tournament Awards**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:10 Plenary Keynote Introduction**
*Fareed Melhem, Senior Vice President, Head of Medidata AI, Medidata*

**3:15 CO-PRESENTATION: The Next Horizon of Clinical Research: A Multi-Stakeholder Panel on Integrating Research into the Care Continuum**
*Uli Broedl, Senior Vice President, Head of Global Clinical Development & Operations, Boehringer Ingelheim*
*Janice Chang, CEO, TransCelerate Biopharma, Inc.*
*Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer*
This presentation will foster discussion between a diverse set of biopharma leaders representing health authorities, sponsors, sites, and industry consortia on the current and future opportunities facing global R&D, clinical care, and patient satisfaction. Specific topics discussed will include opportunities and barriers to giving patients access to clinical research as part of the care continuum.

**3:45 SCOPE's 8th Annual Participant Engagement Awards Introduction**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**3:50 SCOPE's 8th Annual Participant Engagement Awards**
*Co-Moderators:*
*Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator or the SCOPE Participant Engagement Award*
*David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC*
*Panelists:*
*Tricia Buchheit, Associate Director, Patient Recruitment, Alnylam Pharmaceuticals*
*Greg Christie, Chief Product Officer, StudyKIK*
*Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.*
*Otis Johnson, PhD, MPA, Principal Consultant, Trial Equity*
*Sarah Krüg, Executive Director, CANCER101; CEO, Health Collaboratory*
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*
*Jeffrey Zucker, Principal Clinical Research Consultant*

**4:35 SCOPE's Big Game Tailgate**
Everyone who's been to SCOPE knows that the Kickoff Reception is NOT to be missed! This year, in honor of the Big Game, we'll host a tailgate party to get you pumped up for the game! Meet your old friends, make some new ones, and soak up the Florida vibes as you get ready for your watch parties and another amazing SCOPE conference experience.

**5:50 Close of Day**

## MONDAY, FEBRUARY 12

**7:00 am SCOPE's Monday Morning Fun Run!**
Join SCOPE's Coordinators on Monday, February 12 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. **Meet in front lobby near birdcage at 7 am sharp!**
*RUN COORDINATORS:*

Eileen Murphy, Associate Conference Producer, Production, Cambridge Healthtech Institute
Nate DePinto, Assistant Meeting Planner, Cambridge Healthtech Institute
Steve Wimmer, Vice President, Partnerships, Business Development, 1nHealth

7:30 Registration Open

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

## MONDAY MORNING PLENARY SESSION: TRANSFORMING THE DEVELOPMENT PARADIGM & GENERATIVE AI IN CLINICAL TRIALS

**8:30 Organizer's Welcome Remarks**
*Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco*

**8:35 Plenary Keynote Introduction**
*Chris Crucitti, Chief Revenue Officer, Citeline*

**8:40 PLENARY KEYNOTE PRESENTATION: Time Is Life: Pfizer's Approach to Accelerating Clinical Development**
*Robert Goodwin, Senior Vice President, Clinical Development and Operations, Pfizer Inc.*
Transforming the development paradigm for clinical trials is imperative for increased accessibility, convenience, cost-efficiency, and faster results. Pfizer, acknowledging the criticality of time for patients, aims to further reduce development timelines by three years after already achieving a two-year reduction since 2016. Rob Goodwin, Senior VP and Head of Clinical Development & Operations shares insights on accelerating development while maintaining quality, compliance, and patient safety.

**9:05 INTERACTIVE PANEL: Use Cases of Generative AI in Clinical Trials: Beyond Can We...Where and When Should We?**
*Moderator: Brian Martin, Head of AI, R&D Information Research; Research Fellow, AbbVie, Inc.*
*Panelists:*
*Neil Garrett, PhD, Head of Regulatory Medical Writing, Johnson & Johnson*
*Samar Noor, Vice President, Head of Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.*
*Hoifung Poon, PhD, General Manager, Health Futures, Microsoft Research*
*Prasanna Rao, Senior Director, Global Head of AI/ML, Global Biometrics and Data Management, Pfizer Research & Development*

**9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall Best of Show Voting Opens**
SCOPE's exhibit hall is a one-of-a-kind experience. With 240 leading clinical trial technology and services companies represented it's easy to find new, innovative companies to partner with, and don't forget to visit your existing partners to see their latest and greatest. Take a minute to vote for SCOPE's Best of Show, grab some refreshments, charge your devices, or ham it up in a photo booth, but above all, wear comfy shoes; you've got some miles to cover!

**10:30 Special Book Signing**
*Barnett's 2024/2025 Good Clinical Practice: A Question & Answer Reference Guide*
Edited By: *Donna Dorozinsky, RN, MSN, CCRC President and CEO, Just in Time GCP*

## LEVERAGING REAL-WORLD EVIDENCE (RWE) FOR DEVICE APPROVALS

**10:45 Chairperson's Remarks**
*Melinda Pautsch, Vice President, Med Device & Diagnostics, Medidata*

**10:50 CO-PRESENTATION: Applying RWD: Use Cases from Flatiron, Exact Sciences, and Johns Hopkins University**
*Josh Buddle, Director, Clinical Operations, Flatiron Health*
*Jonathan Helfgott, MS, Program Coordinator, Senior Lecturer, Regulatory Science, Johns Hopkins University*
*Tara Marti, Associate Director, Clinical Development, Exact Sciences*
This comprehensive review will delve into key aspects of using DCTs and RWD/RWE, incorporating case studies and addressing FDA compliance and inspection readiness. Topics covered include remote clinical site inspections, RBM applications, and the integration of Digital Health solutions.

**11:20 Presentation to be Announced**

**11:50 RWE to Support A New HPV-Device Indication For Cervical Cancer Screening**
*Jeff Andrews, Vice President, Global Medical Affairs, Integrated Diagnostic Solutions, BD Diagnostic Systems*
This large RWE study involved both a unique, population-based design and a rapid, cost-effective approach conducted to support a new FDA indication for the Onclarity HPV assay, using PreservCyt liquid-based cytology, during cervical cancer screening. We used retrospective evaluation of real-world cervical screening, diagnosis, and treatment data from the New Mexico HPV Pap Registry (NMHPVPR) and used associated, de-identified cervical specimens collected in PreservCyt.

**12:20 pm Time to Evolve—How to Better Support Medical Device Study Builds, Execution, and Data Acquisition**
*Walker Bradham, Product Mangement Lead, Product Management, Merative*
There must be a better way to solve today's—and tomorrow's—complex medical device research challenges, and we believe that it can be done through solutions that improve time to insights needed to streamline clinical operations. But this can only be done if we embrace change. See how Zelta's clinical trials platform is built to help organizations increase efficiency, allow for more flexibility, and speed up trial processes.

**12:50 Transition to Lunch**

## CLINICAL EVIDENCE FOR ESTABLISHED AND NOVEL DEVICES

**12:55 LUNCHEON PRESENTATION: Navigating the Future of Clinical Trials: Harnessing the Power of the Connected Medical Device Ecosystem**
*Kavitha Lokesh, Vice President, Head of Life Sciences R&D Industry Solutions & Products, Cognizant*
*Seema Sayani, PhD, Sr. Director Life Sciences, Cognizant*
Connected medical devices constitute a rapidly evolving ecosystem that demands its many components to work in harmony to facilitate a seamless flow of data. This connected ecosystem can be a significant game changer and facilitate more efficient trials, accelerate study outcomes, and streamline the deployment of medical devices. However, enabling this ecosystem requires overcoming challenges around ensuring patient safety, adhering to strict regulations and mitigating cybersecurity risks, as well as incorporating AI capabilities. Join this session to learn about leveraging the connected medical device ecosystem for clinical trials, explore implementation strategies and gain insights from real-world use cases.

**1:25 Coffee & Dessert Break in the Exhibit Hall**

**1:30 Special Book Signing**
*Digital Health and Patient Data: Empowering Patients in the Healthcare Ecosystem*
Authors: *Disa Lee Choun and Anca Petra*

## CLINICAL EVIDENCE FOR ESTABLISHED AND NOVEL DEVICES (CONT.)

**2:20 Chairperson's Remarks**
*Inga Darville, MS, Clinical Product Risk, Boston Scientific*

**2:25 EU MDR: Understanding Clinical Data and How Much Do We Need for Approval**
*Inga Darville, MS, Clinical Product Risk, Boston Scientific*
The question that still remains is how much clinical evidence is sufficient to acquire EU MDR approval? The answer is dependent on many factors. In this presentation we will discuss the factors and the approaches as well as overcoming the challenges in obtaining EU MDR approval.

**2:55 Clinical Evaluations for Medical Devices: Lessons Learned and Best Practices**
*Mausam Patel, MS, Clinical Evidence Manager, Stryker*

With EU MDR, the burden of clinical evaluations has increased substantially. In this presentation, we will share our experience and lessons learned in writing EU MDR complaint clinical evaluation reports (CERs) for different types of medical devices. How can we perform clinical evaluations in efficient ways that are sustainable? Can we leverage clinical evaluations to go beyond compliance needs?

**3:25 Sufficient Clinical Evidence: Experience with EU MDR Certification**
*Bassil Akra, PhD, CEO, Owner, AKRA Team*
The EU MDR 2017/745 was published approximately 6.5 years ago, and it remains unclear which level of evidence is sufficient to address notified body expectations for legacy devices, well-established devices, and new innovative technologies of the various risk classes. Knowledge gained since the implementation of the EU MDR will be shared and recommendations will be given to innovators and manufacturers to establish a good clinical evidence strategy for the EU.

## OPTIMIZING CLINICAL OPERATIONS AND SITE MANAGEMENT

**3:55 CO-PRESENTATION: Abbott Leverages Analytics and CTMS to Drive Site Management and Operations**
*Jaime Altamirano, Jr., Staff Clinical Data Systems Analyst, Abbott Labs*
*Krupa Rocks, Associate Director Clinical Data Systems, Medical Devices, Abbott Labs*
Project teams can maximize investments and minimize costs by efficiently identifying sites that can activate and enroll quickly, and provide clean and complete data, towards a smooth competent authority approval. Such scenarios typically don't exist without a few hazards on the road; however, project teams can drive closer towards that reality with the right data and systems in tow. Abbott's CTMS and BI dashboards can fill the gaps.

**4:25 From Diagnostics to Treatment: The Benefits of Central Oversight and Quality Control**
*Faith Holmes, MD, CMO, Elligo Health Research*
A centralized oversight structure facilitates the ability to prioritize access through incorporation of hybrid models, meeting potential study participants at the point of intersection of their disease journey and a clinical trial. From decentralized to healthcare-first sites, the central team enables consistency and quality of data, as well as safety. Supporting healthcare-first sites has the longer-term benefit of reduced timelines from approval to adoption within healthcare.

**4:55 Welcome Reception in the Exhibit Hall**

**6:15 Close of Day**

# TUESDAY, FEBRUARY 13

**8:00 am Registration Open**

## BREAKFAST PRESENTATIONS

**8:30 BREAKFAST PRESENTATION OPTION #1: The New Frontier: How Intelligent Automation is Transforming Clinical Deployment**
*Colin Weller, General Manager, Evidence Generation Platform, Product, Medable*
Join us as Colin Weller, GM, Evidence Generation Platform at Medable, unveils how intelligent automation technology reduces clinical trial deployment timelines and accelerates evidence generation at scale as shown in their latest results to reduce trial deployment timelines by 50%. Weller will discuss how Top-10 global pharmaceutical companies are benefiting from Medable's novel technology, and how the expanded use of digital measures and biomarkers will continue to accelerate clinical development timelines.

**8:30 BREAKFAST PRESENTATION OPTION #2: What is a Patient Recruitment Platform, Why Do You Need One, and How Do You Choose One?**
*Matt Walz, CEO, Business Operations, Trialbee*

**9:00 Transition to Sessions**

## PATIENT-CENTERED DEVICE TRIALS

**9:10 Chairperson's Remarks**
*Steve Gompertz, Partner, Operations and Resourcing, QRx Partners; Adjunct Instructor, St. Cloud State University*

**9:15 CO-PRESENTATION: A Flywheel of Innovation in Medical Device Development**
*Sonia Brodie, MSc, Vice President, Clinical Research, Center for Neurology Studies*
*Gabi Pawlowski, MSc, CCRC, Clinical Research and Data Specialist, HealthTech Connex*
Bringing a new medical device to market benefits from efficiencies not just at the site level, but in the interface among the sponsor/CRO, the site, and the clinicians who will eventually be adopting the new technology into their regular practice.

**9:45 CO-PRESENTATION: Embracing Diversity in IVD Clinical Trials: A Comprehensive Plan**
*Martha Dockery, MS, Senior Manager, Clinical Monitoring, Health Equity Committee Chair, Exact Sciences*
*Angana Kharge, PhD, Clinical Development Scientist II, Exact Sciences*
Embracing diversity in clinical trials is an essential step towards equitable healthcare. By including a wide range of participants from diverse backgrounds, clinical trials can yield insights that better represent the real-world patient population. This inclusivity ensures that medical treatments are safe and efficacious for everyone. Using the FDA's Diversity Plan as the backdrop, we will discuss actionable strategies that can be designed to enhance inclusivity in IVD clinical trials.

**10:15 How is ePRO Shaping Reimbursement Strategies in Medical Device Trials?**
*Nicole Latimer, CEO, Medrio*
Nicole Latimer, the CEO of Medrio, presents the findings from a recent industry survey about the utilization of patient-reported outcomes in Medical Device Trials and real-life examples highlighting the value ePRO data can provide in shaping your commercialization plans.

**10:45 Coffee Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

**10:50 Special Book Signing**
*The Patient Recruitment Conundrum*
Author: *Ross Jackson*

## MANAGING RISK AND QUALITY THROUGH DEVICE DEVELOPMENT

**11:45 CO-PRESENTATION: Integration and Application of Risk Management in Medical Device Trials**
*Joy Frestedt, PhD, President, CEO, Frestedt Incorporated; Co-CEO, CSO, Eva MedTec*
*Steve Gompertz, Partner, Operations and Resourcing, QRx Partners; Adjunct Instructor, St. Cloud State University*
Risk management is often confused with risk analysis and treated as a one-time event rather than an ongoing process. Risk management is intended to be integrated across quality, regulatory, and clinical activities, with continual feedback loops. The results of risk management activities within each of these areas establish the requirements and objectives of the other two, creating a web of interrelationships that is critical to effectively managing risk.

**12:45 pm Transition to Lunch**

**12:50 LUNCHEON PRESENTATION: Designing a Med Device Clinical Trial Journey to Completion. What You Absolutely NEED to Know ... Potholes and All**
*Matty Lynch, Chief Operations Officer, ObvioHealth*
*Steve Schaefer, CEO and President, Mi-Helper, Inc.*
Clinical trial journeys are often less linear in practice than they are "on paper." This is especially true for at-home device trials, where capturing subjective outcomes to achieve endpoints is rarely straightforward. Our experts will outline the challenges of designing and deploying a remote, adaptive migraine device trial, revealing how to navigate the bumpy road to completion through innovative study design technology, collaboration, and a virtual site team.

**1:20 Coffee & Dessert Break in the Exhibit Hall 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!

**1:25 Special Book SIgning**

*Quantum Kids Guardians of AI: Story Quest and Activity Book*
Author: *Angela Radcliffe*

## CENTER STAGE SESSION: Co-Organized with MDIC

## RESOURCE TOOLS & MATERIALS TO CONSIDER IN A CLINICAL TRIALS STRATEGY: Incorporating Early Feasibility, Computation Modeling & Simulation and Patient Preference in Clinical Trial Design

**2:20 Chairperson's Remarks**

***Kert Gunasekaran, Program Director, Science of Patient Input, Medical Device Innovation Consortium***

**2:25 Early Feasibility Studies (EFS) Program**

***Peter Weiss, MD, Cardiac Electrophysiologist, Banner Health***

Despite frequent medical device innovation in the US, early stage clinical studies are often performed overseas, driven largely by costly and time-inefficient processes. As a result, the goals of early patient access to novel devices and efficient technology development and regulatory approval remain incompletely realized. The EFS initiative of the Medical Device Innovation Consortium engages relevant stakeholders in an effort to shift this ecosystem back towards studies in the US.

**2:45 Computation Modeling and Simulation (CM&S)**

***Steven Levine, PhD, Senior Director, Virtual Human Modeling, Dassault Systemes Co.***

This session discusses the transformative potential of computational modeling and simulation in clinical trials, focusing on *in silico* clinical trials (ISCT) and synthetic populations. By integrating generative AI methodologies with computational modeling, these virtual trials offer an innovative approach to trial design, reducing risks and costs, and expediting device development timelines. The session presents compelling evidence and collaborative efforts with FDA, showcasing a groundbreaking blueprint for utilizing these advanced approaches.

**3:05 The Science of Patient Input and Engagement**

***Alissa Hanna, Director, Patient Engagement, Edwards Lifesciences***

**3:30 Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)* **Last Chance for Viewing**

Join your colleagues in the Exhibit Hall for one last visit. Enjoy SCOPE's "Booth Crawl," where sponsoring booths have a silent competition to see who can serve the most fun or fancy food and drink. Visit their booths to see for yourself! Take a final lap around the hall and enjoy time with your newfound friends and partners.

## CURRENT AND FUTURE LANDSCAPE OF DIGITAL HEALTH AND DEVICES

**4:30 Chairperson's Remarks**

***Nicole Baker, PhD, CEO, biologit***

**4:35 FDA's Digital Health Centers of Excellence Program (DHCoE)—Update and Resource Overview**

***Glenda Guest, President, Assured of Quality Consulting & Training***

A positive outcome of the COVID pandemic and public health emergency was more rapid adoption of digital health technologies in both research and healthcare settings. The broad scope of these digital technologies includes categories like mobile health (mHealth), health information technology (Health IT), wearable devices, and telemedicine. Learn about FDA's plans for Artificial Intelligence (AI), Machine Learning (ML), cybersecurity and more during this update and overview of FDA's new DHCoE.

**5:05 CO-PRESENTATION: Evolving Regulatory Landscape with Digital Health Technologies and the Impact to Patient Access and Health Equity**

***Jiibril Palmer, Assistant Director, Regulatory Affairs, Digital Health, Merck***
***Katherine Williams, PharmD, MSM, RPh, Associate Principal Scientist, Regulatory Affairs, Merck & Co., Inc.***

The growth of digital health technologies in the past decade has driven change to the regulatory landscape around the world. This evolution has made an impact on patient access to these technologies which has also highlighted the increasing need for health equity. Although there are challenges within the new regulatory landscape, bringing new technologies to the market ultimately benefits the patient.

**5:35 Sponsored Presentation** *(Opportunity Available)*

**6:05 Close of Day**

# WEDNESDAY, FEBRUARY 14

**7:15 am Registration Open**

## BREAKFAST PRESENTATION

**7:45 BREAKFAST PRESENTATION: Empowering Clinical Operations Professionals: Harnessing AI to Enhance Outcomes**

***Scott Chetham, CEO & Co-Founder, Faro Health, Inc.***

Generative AI, machine learning, and large language models are all over the news and have the potential to impact every aspect of Clinical Development. As Clinical Development professionals, how can we differentiate the hype from reality and have an educated voice to assess the risk and rewards of these rapidly evolving technologies? Join Faro to explore current, upcoming, and hyped trends. Understand the challenges in adopting these technologies in Clinical Development.

**8:15 Transition to Sessions**

## REGULATORY UPDATES AND ADAPTING FOR THE FUTURE

**8:25 Chairperson's Remarks**

***Norbert Clemens, MD, Immediate Past Chair, ACRP Academy Board of Trustees; Chair Faculty, Medical Devices/IVD, German Society of Pharmaceutical Medicine***

**8:30 ISO 14155/ICH E6 (GCP) Requirements and Ongoing Revisions**

***Norbert Clemens, MD, Immediate Past Chair, ACRP Academy Board of Trustees; Chair Faculty, Medical Devices/IVD, German Society of Pharmaceutical Medicine***

ICH E6(R3) draft GCP guideline has reached Step 3 of the ICH process in May 2023. Main edits are two annexes: Annex 1: 'established' interventional trials of unapproved or approved drugs in humans; Annex 2: novel designs like DCTs, pragmatic clinical trials, use of registries, (EHR), hospital data, and medical claims data. Simultaneously, the revision of ISO 14155(2020) has been started. The presentation will update on the current status.

**9:00 Clinical Investigations and CE Marking—What's Important to a Notified Body?**

***Lisa Colton, Clinical Regulatory Lead, Global Regulatory Compliance Team, BSI***

This session will provide attendees with an overview of the MDR requirements related to clinical investigations conducted in the EU, and more importantly, will provide the attendees with insight and knowledge of what a notified body needs to consider as part of its conformity assessment to gain CE marking.

**9:30 Sponsored Presentation** *(Opportunity Available)*

**9:45 Innovating in Evolving Regulatory Framework—Clinical Strategy**

***Nataliya Deych, Vice President, Regulatory Affairs EMEA, Latam, Canada, Edwards Lifesciences***

What does "clinical strategy" mean? "Clinical strategy" is defined as a general plan to generate sound evidence that a medical device is (clinically) safe and effective & performs as claimed during its lifecycle; for the purpose of product registration/approval/clearance in target markets; for marketing reasons to substantiate defined claims supporting economic success of the product; by economically viable means; and in a predictable manner.

## DATA SYSTEMS FOR TRIAL EFFICIENCY

**10:15 CO-PRESENTATION: Abiomed's CLEHR Vision for EHR to Sponsor Data Integration**

*Dawn Bardot, PhD, General Manager, Global Service and Cloud Product, Abiomed*

*Dan Housman, Co-Founder, CTO, Graticule; Co-Founder, Courage Therapeutics*

CLEHR (Clinical from EHR) was developed to achieve Abiomed's vision to expand access to EHRs beyond the limitations of EDC and reduce manual copy-paste entry of information into EDC systems. The team will present challenges encountered and solution approaches to establish eSourcing of EHR data across Abiomed sites. The team will share how the many-to-many model of CLEHR scales the network across studies, sponsors, and sites.

**10:45 Networking Coffee Break**

## CONNECTED HEALTH AND DATA SOLUTIONS FOR FLEXIBLE TRIALS

**11:05 Chairperson's Remarks**

*Ching Tian, Chief Innovation Officer, Emmes Corp.*

**11:10 How Connected Devices Enable Decentralized Trials**

*Jian Yang, Vice President, Digital Health, Eli Lilly Company*

DCTs leverage "virtual" tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, patient-driven virtual health care interfaces, and direct delivery of study drugs and materials to patients' homes. This talk will discuss the post-COVID strategies for connected devices implementation in hybrid trials.

**11:40 Using Digital Technologies to Accelerate Behavioral Health Assessments and Interventions—Learnings from Real-World Studies**

*Abhishek Pratap, PhD, Senior Clinical Program Leader, Central Nervous System, Boehringer Ingelheim*

This talk will focus on the use of digital health technologies(DHTs) to advance medical product development—from assessment to interventions in real-world settings. I will share learnings from clinical research studies to help inform the development of robust digital endpoints and interventions focusing on improving behavioral outcomes.

**12:10 pm Validation of Digital Health Technologies for Clinical Trials: The NIH Framework**

*Chris M. Hartshorn, PhD, Chief, Digital & Mobile Technologies Section—CTSA Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)*

This presentation will share the NIH Framework for digital technologies' validation in clinical trials.

**12:40 Transition to Lunch**

**12:45 LUNCHEON PRESENTATION: Revolutionizing Research: Navigating the Spectrum with a Fully Hybrid Approach**

*Thad Wolfram, President, EmVenio*

This track will explore the methodology of a fully hybrid clinical trial approach. We will discuss how the combination of mobile Clinical Research Sites, personalized home visits, and convenient virtual visits are not only on the rise, but also effectively bridging the gap to bring clinical trials to previously underrepresented and diverse populations.

**1:15 SCOPE Summit 2024 Adjourns**

# CLINICAL TRIAL TECH VENTURE, INNOVATION & PARTNERING

*Accelerating Innovation, Accessibility and Scale*

**February 12-13, 2024**
Rosen Shingle Creek
**Orlando, FL**

*Registration includes access to the entire SCOPE Summit event February 11-14*

PART OF: SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

## Join us for an exclusive gathering of the leading innovators, investors, and sponsors who are driving the future of clinical trials.

Through keynote interviews, lively panel discussions, and lots of time for networking, we plan to explore topics that are critical to advancing clinical trials over the next decade.

**SCOPE's Clinical Trial Tech: Venture, Innovation & Partnering** takes place February 12-13, 2024, in Orlando, FL. This premier boutique conference runs in parallel with the 15th annual SCOPE Summit (Summit for Clinical Ops Executives). Building upon the success of the inaugural event, the 2nd Annual **Clinical Trial Tech: Venture, Innovation & Partnering** brings together senior-level investors, corporate executives, entrepreneurs, and start-up leaders from the clinical trials space. This high-level networking event consists of thought-provoking industry-led panels, fireside chats, and numerous networking opportunities for start-ups, 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

**Eric Snyder**
Partner
Novo Ventures (US), Inc.

**Bridget A. Ross**
CEO
ChroniSense Medical

Learn more at SCOPEsummit.com/partnering

Eighth Annual

# PARTICIPANT ENGAGEMENT AWARD

SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

IN MEMORY OF JERRY MATCZAK
#BELIKEJERRY #SCOPEsummit

**Sunday, February 11, 2024 | 3:45 pm**

## 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—we also invite you to submit your best work in the Patient Recruitment and Retention Communications field.

## HOW TO WIN?

Your submission must truly be designed to engage potential, current, or alumni study participants and/or their influencers and to show marked improvements in the status quo.

**Deadline submissions are closed.**

## EVENT HOSTS & JUDGES

CHAIRPERSON:
David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award

Kelly McKee
Vice President, Decentralized Clinical Trials (DCT), Medidata; Co-Creator of the SCOPE Participant Engagement Award

Micah Lieberman
Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

Gretchen Goller
Senior Director, Head of Patient Recruitment, Clinical Development Operations, Seagen

Otis Johnson, PhD
Chief Diversity, Inclusion & Sustainability Officer, Clario

Jeff Zucker
Senior Vice President, Clinical Trial Optimization & DCT, Worldwide Clinical Trials

Tarra Shingler
Chief Commercial Officer, StudyKIK

Tricia Buchheit
Associate Director, Patient Recruitment, Alnylam Pharmaceuticals

Sarah Krüg
Patient Advocate, Executive Director, CANCER101; CEO, Health Collaboratory

**Learn more at**: SCOPEsummit.com/participant-engagement-award

*Inaugural*

# SITE INNOVATION AWARD

SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

**Tuesday, February 13, 2024 | 12:15 pm**

## 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.

## 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 11-14, 2024, in Orlando, Florida.

**Deadline submissions are closed.**

## EVENT HOSTS & JUDGES

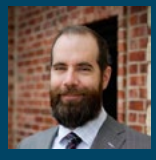
**Irfan Kahn**
CEO, Circuit Clinical

**Amanda Wright**
Co-Founder & COO, Javara

**Joe Dustin**
Vice President of Product Strategy, Medable, Inc.

**Bridget Kotelly**
Senior Conference Producer, Cambridge Healthtech Institute

**Sean Soth**
Senior Vice President, Strategy and Global Business Partnerships, SCRS



**Brad Hightower**
CEO, Hightower Clinical

**Marisa Rackley**
Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda

**Learn more at**: SCOPEsummit.com/participant-engagement-award

SUMMIT FOR CLINICAL OPS EXECUTIVES

# BEST of SHOW AWARD 2024


## 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.

**Submission Deadline: Friday, January 20**




**Learn more at**: SCOPEsummit.com/best-of-show-awards

# CLINICAL TRIAL TECH: Start Up Pitch CONTEST

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

**Monday, February 12, 2024 | 3:25pm**

## WHAT IS IT?

Join us at the inaugural Clinical Trial Tech Pitch Contest on February 12, 2024, in Orlando, FL, during the annual SCOPE Summit for Clinical Ops Executives. Pioneering start-ups with groundbreaking products and technologies in clinical trial innovation will present to a high-profile audience, including senior-level investors, corporate executives, and industry leaders. This boutique event provides a platform for emerging companies to showcase their strategic business models, connect with investors, and secure potential funding. Don't miss this opportunity to be part of the audience for this game-changing event.

## WHO IS IT FOR?

Are you a trailblazing start-up in the clinical trials space with $0 - $10 million and currently looking for further investment? Do you have a groundbreaking product that's poised to revolutionize the industry? Here's your chance to shine! Introducing the SVP Start-Up Competition at the upcoming conference in Orlando, FL, on February 12-13, 2024.

## HOW DOES IT WORK?

All submissions will be reviewed by a panel of industry experts representing perspectives from various sides of the clinical operations ecosystem. Six finalists will be selected to present their concepts in-person SCOPE's Clinical Trial Tech: Venture, Innovation & Partnering Conference taking place on February 12-13, 2024, in Orlando, FL.

## WHAT'S IN IT FOR YOU?

- **Showcase Your Innovation:** Present your cutting-edge product and technology to a high-profile audience, including senior-level investors, corporate executives, and industry leaders. Pitch your funding USPs to investors and separate your company from the competition.
- **Access to Capital:** Secure potential funding opportunities by connecting with investors actively seeking promising start-ups in clinical trials.
- **Expert Insights:** Gain invaluable strategic insights, honest perspectives, and practical business recommendations for collaboration and investment from industry experts.
- **Networking Galore:** Forge meaningful connections with start-ups, investors, and potential acquirers through thought-provoking panels, fireside chats, and extensive networking opportunities.
- **Market Visibility:** Exhibit your product in the conference hall, giving you the chance to connect with both emerging and established companies and understand the industry's direction.
- **Competitive Edge**: Compete head-to-head with other start-ups to win the prestigious SVP Start-Up Competition and gain recognition as an industry leader.
- **Be part of the future of clinical trials!** Don't miss this incredible opportunity to propel your start-up to new heights. Apply now for the SVP Start-Up Competition and make your mark in the clinical trials revolution.

**Submit your proposal by December 15, 2023**

**Learn more at**: SCOPEsummit.com/partnering/pitch-contest

# 2024 EVENT HIGHLIGHTS

## GOLF TOURNAMENT

Connect with your peers and colleagues at SCOPE's 3rd Annual Masters of Clinical Research Golf Tournament, starting at 8:00am on Sunday, February 11. 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 and Patty Rose.

**Interested in taking part in the 3rd Annual Golf Tournament? For complete event information, including registration* details visit the website.**

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

Masters of Clinical Research
SCOPE's 3rd Annual Golf Tournament

**February 11 at 8:00 am**

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

## 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 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-I

**Ilana Quigley**
Director, Sales
(+1) 781-972-5457
iquigley@healthtech.com

Companies J-Q

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

Companies R-Z

**Patty Rose**
Senior Director, 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...




## 2023 ATTENDEE DEMOGRAPHICS


- 62% Executive
- 15% Sales & Marketing
- 13% Manager
- 8% Scientist
- 2% Other


- 26% Biotech
- 20% Pharma
- 16% CRO
- 15% Healthcare
- 15% Services/Societies
- 3% Academic
- 5% Other

## For additional information, please contact:


Companies A-I

**Ilana Quigley**

Director, Sales
(+1) 781-972-5457
iquigley@healthtech.com

Companies J-Q

**Jon Stroup**

Sr. Manager, Business Development
(+1) 781-972-5483
jons@healthtech.com

Companies R-Z

**Patty Rose**

Senior Director, Sales
(+1) 781-972-1349
prose@healthtech.com

# CONFERENCE VENUE & HOTEL

## ROSEN SHINGLE CREEK

9939 Universal Boulevard
Orlando, FL 32819

Discounted Room Rate: $262 s/d

**Discounted Room Rate Cut-Off Date: January 11, 2024**

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

15th Annual SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES
February 11-14, 2024 | Orlando, Florida

| | Pharma-Biotech-Med Device/ Finance Company | CRO-Vendor-Tech Consultancy-Services Provider | VC/Investment Firm, Academic-Government-Site-Hospital |
|---|---|---|---|

## INDIVIDUAL EVENT PRICING

*Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Sunday, February 11 access to the following:*

- *Evening Kick-Off Plenary Keynote and 8th Annual Participant Engagement Awards*
- *SCOPE's Kick-Off Networking Happy Hour Big Game Tailgate*

*In addition, you will receive on-demand access to all presentations for one year.*

*If you wish to participate in SCOPE's Third Annual Masters of Clinical Research Golf Tournament, see the website registration page for further details (Separate registration required to golf, limited space available)*

| | | | |
|---|---|---|---|
| Standard Registration after January 5, 2024 and onsite | $2999 | $3099 | $1599 |

## GROUP EVENT PRICING

*Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Sunday, February 11 access to the following:*

- *Evening Kick-Off Plenary Keynote and 8th Annual Participant Engagement Awards*
- *SCOPE's Kick-Off Networking Happy Hour Big Game Tailgate*

*In addition, you will receive on-demand access to all presentations for one year.*

*If you wish to participate in SCOPE's Third Annual Masters of Clinical Research Golf Tournament, see the website registration page for further details (Separate registration required to golf, limited space available)*

| | | | |
|---|---|---|---|
| Standard Registration after January 5, 2024 and onsite | $2249 | $2299 | $1199 |

## ON-DEMAND CONFERENCE PRICING

*For those who cannot attend SCOPE on February 11-14, 2024, 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 | $2299 | $2449 | $1099 |

## 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!