FINAL AGENDA

14th Annual

SCOPE

FEBRUARY 6-9, 2023

SUMMIT FOR CLINICAL OPS EXECUTIVES

Rosen Shingle Creek • Orlando, FL

IN-PERSON + VIRTUAL

REGISTER BY JANUARY 6 & SAVE UP TO $200

Driving Innovation in Clinical Trials & Digital Health

CONFERENCE PROGRAMS:

- FEASIBILITY & STUDY START-UP
- RECRUITMENT & ENGAGEMENT
- BUDGETING & RESOURCES
- OUTSOURCING
- CLINICAL SUPPLY
- DATA
- DECENTRALIZED & HYBRID
- DIGITAL MEASUREMENTS
- REAL WORLD EVIDENCE
- BIOMARKERS & BIOSPECIMENS
- QUALITY & MONITORING
- MED DEVICE TRIALS
- LEAN CLIN OPS FOR SMALL BIOPHARMA
- TRAINING & DEVELOPMENT
- INVESTOR CONFERENCE

Keynote Speakers:

Amy Abernethy, MD, PhD
Verily/FDA

Adrelia Allen
Merck

Christopher Boone, PhD
AbbVie

Kimberly Fookes
Novartis

Naikia Byrd-Atkinson
Sanofi

Vicky DiBiaso, MPH, BScN
Sanofi

Balazs Flink, MD
Daiichi Sankyo, Inc.

Darren Weston
Janssen Clinical Innovation

Deborah Profit, PhD
Otsuka

Marisa Rackley
Takeda

Virginia Nido
Genentech

Demetris Zambas
Pfizer

Signature Sponsors

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EVENT AT-A-GLANCE

February 6-9, 2023 | All Times EST
Rosen Shingle Creek | Orlando, FL + Virtual

Monday, February 6
AM & PM

8:00 am – 1:00 pm
SCOPE's 2nd Annual *Masters of Clinical Research Golf Tournament**

2:00 – 5:00 pm
Monday Afternoon Pre-Con User Group Meetings & Hosted Workshops

5:00 – 6:30 pm
Evening Kick-Off Plenary Keynote and 7th *Annual Participant Engagement Awards*

6:30 – 7:45 pm
SCOPE's Kick-Off Networking Happy Hour

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

	Tuesday, February 7 AM & PM	Wednesday, February 8 AM	Wednesday, February 8 PM	Thursday, February 9 AM & PM
C1: FEASIBILITY & STUDY START-UP	Protocol Development, Feasibility, and Global Site Selection		Study Start-up in Multi-Center and Decentralized Trials	
C2: RECRUITMENT & ENGAGEMENT	Enrollment Planning and Patient Recruitment		Patient Engagement and Retention through Communities and Technology	
C3: BUDGETING & RESOURCES	Clinical Trial Forecasting, Budgeting and Contracting		Resource Management and Capacity Planning for Clinical Trials	
C4: OUTSOURCING	Mastering an Outsourcing Strategy		Relationship and Alliance Management in Outsourced Clinical Trials	
C5: CLINICAL SUPPLY	Data Technology for End-to-End Clinical Supply Management		Clinical Supply Management to Align Process, Products and Patients	
C6: DATA	Clinical Data Strategy and Analytics		Artificial Intelligence in Clinical Research	
C7: DECENTRALIZED & HYBRID	Decentralized and Hybrid Trials		Decentralized Trials and Clinical Innovation	
C8: DIGITAL MEASUREMENTS	Sensors, Wearables and Digital Biomarkers in Clinical Trials			
C9: REAL WORLD EVIDENCE	Accessing and Generating RWD		Leveraging RWD for Clinical and Observational Research	
C10: BIOMARKERS & BIOSPECIMENS	Biomarker Technology and Innovation		Biospecimen Operations and Vendor Partnerships	
C11: QUALITY & MONITORING	Risk-Based Quality Management		Central and Remote Monitoring	
C12: MED DEVICE TRIALS	Medical Device Clinical Trial Design and Operations		Device Trial Regulations, Quality, and Data Management	
C13: LEAN CLIN OPS FOR SMALL BIOPHARMA	Building New Clinical Programs, Teams, and Ops in Small Biopharma		Clinical Ops for Novel Modalities	
C14: TRAINING & DEVELOPMENT	Clinical Research Training Forum			
PC1: INVESTOR CONFERENCE	SCOPE Venture, Innovation, & Partnering Conference			

2023 SPONSORS

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Plenary Keynote Presentations

MONDAY, FEBRUARY 6, 2023

GOLF TOURNAMENT & PRE-CONFERENCE USER GROUP MEETINGS

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the Masters of Clinical Research page.
SCOPEsummit.com/sponsor-exhibitor/masters-of-clinical-research
**Limited space available. Separate registration and fee required for Golf.*

2:00 pm Pre-Conference User Group Meeting & Hosted Workshops
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! Learn more on the SCOPE Summit website. SCOPEsummit.com/pre_conference_user_group_meetings

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

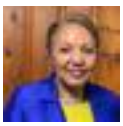
5:00 pm Organizer's Welcome Remarks & 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education






Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi
Launched in July 2021 as a $33.7M commitment from Novartis and the Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to high-quality education and promising jobs; address inherent bias in the data standards; and find actionable solutions to environmental and climate issues that disproportionately affect health among communities of color. This session brings together leaders from collaborating partner companies Novartis, Sanofi and Merck and one of the participating HBCUs to discuss how Beacon of Hope aims to improve the quality and inclusivity of clinical trials.

5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards
Now in its 7th 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 2023 Participant Engagement Award program is brought to you by Cambridge Healthtech Institute (CHI)'s SCOPE and is **accepting submissions at**:
SCOPEsummit.com/participant-engagement-award

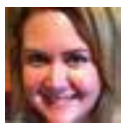
EVENT HOSTS & JUDGES

CO-MODERATORS: 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, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate
Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics

6:30 SCOPE's Kick-Off Happy Hour

Plenary Keynote Presentations

TUESDAY, FEBRUARY 7, 2023

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 am Organizer's Welcome Remarks


Marina Filshtinsky, MD, Executive Director, Cambridge Healthtech Institute (CHI)
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:35 Chairperson's Introduction
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 Would I Want My Mother to Be Part of a Clinical Trial?
Virginia Nido, Global Head, Product Dev Industry Collaborations, Genentech, a member of the Roche Group
For many years, our industry has been talking about becoming more patient centric and innovative in our approach to clinical trials and all the great things we are doing to make clinical trials more convenient for participants. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you really want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working. But we still have so far to go and together we must continue to drive an uncomfortable level of change.

9:05 INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It





Moderator: Balazs Flink, MD, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Debbie Profit, PhD, Vice President, Clinical Management and Applied Innovation, Otsuka
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals Inc
Ken Getz, MBA, Founder, CISCRP; Deputy Director, Center for the Study of Drug Development, Tufts University School of Medicine
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources and a never-ending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. The advent of DCTs, novel tech and data sources and then the pandemic put us all to the test. However, we are now facing supply chain disruptions and other human/material resource challenges that make everything even more complicated. What is a clinical ops leader to do?

9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

WEDNESDAY, FEBRUARY 8, 2023

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

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

2:20 Chairperson's Introduction
Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real World Evidence in Informing Regulatory Pathways
Christopher Boone, PhD, Vice President, Global Head of HEOR, Abbvie
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilizing RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms, Verily, Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms, Verily, former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Vice President, Global Head of HEOR, Abbvie

2:55 Fireside Chat: Future Ready Operations; Building a Multi-Year Roadmap


Demetris Zambas, VP and Global Head, Data Monitoring and Management, Pfizer
Darren Weston, Senior Vice President, Integrated Data Analytics & Reporting, Janssen Clinical Innovation at Johnson & Johnson
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorships Available)***. Last Chance for Exhibit Viewing**

Cambridge Healthtech Institute's 13th Annual

Protocol Development, Feasibility, and Global Site Selection

Improving Outcomes through Patient-Centric Trial Design, Digital Innovations, Data and Modeling

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 10th Annual

Improving Study Start-up and Performance in Multi-Center and Decentralized Trials

Strategically Implementing Process, Tech and Systems for Rapid Study Start-up and Execution of Trials

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
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9:00 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

2:00 User Group Meetings
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 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! Learn more on the SCOPE Summit website.

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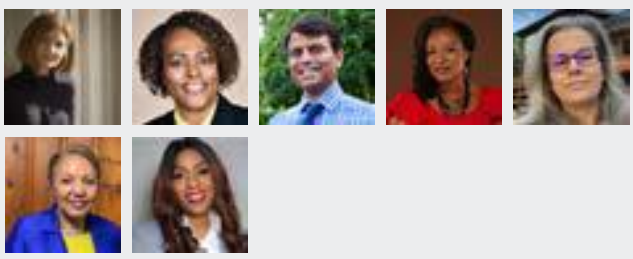

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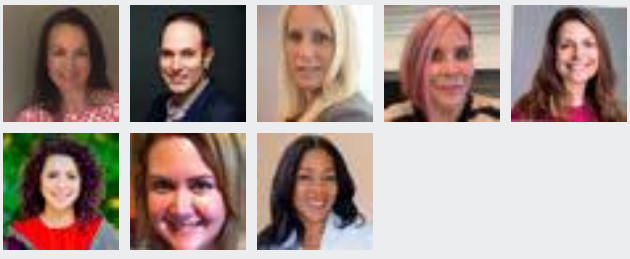

Co-Moderators:
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Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
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8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
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Panelists:
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Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

TRIAL FEASIBILITY AND PLANNING: NEW METHODS FOR PREDICTING AND MEASURING SITE PERFORMANCE AND TRIAL COST

10:35 **Chairperson's Remarks**
Speaker to be Announced, CMIC Group

10:40 **Trial Cost as an Emerging Driver of Trade-off Decisions in Trial Feasibility and Execution Planning**
Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Traditional feasibility assessments at program or study level historically concentrated on key operational performance and quality metrics. In the past years, there has been a significant increase in per-patient costs and trade-off decisions include cost besides speed and quality much more than ever before. This presentation will highlight some of the key trends, and root causes and will show some examples of decision-making at program or study level.

11:10 **High Stakes Start-up: How to Come in First in the Feasibility Game**
Tamara J. O'Black, Vice President of Compliance, Quality, & Regulatory, Minneapolis Heart Institute Foundation
Lisa Tindell, Vice President, Clinical Research Operations, Sponsored Clinical Trials, Minneapolis Heart Institute Foundation
The stakes are never higher for site-sponsor partnerships than during feasibility assessment and start-up. Roll the dice and take a side-by-side look at two fictional sites working hard to put it all together. With a combined operations-compliance approach and tips, tricks, and tools for everyone, you'll come away with a better approach and understanding of what it takes to come in first from a site that does it frequently.

11:40 **How Implementing a Dialogue around Performance Can Increase Overall Study Delivery**
Ellyn Getz, Director, Patient Parthership, CSL Behring
Saartje Vansteenkiste, Director, Global Clincial Operations, CSL Behring
We as clinops leaders, all know the saying, "if it's not documented, it didn't happen." What if we follow that same line of thinking when talking about our study performance? How well did we deliver our actual recruitment target versus the one we planned when we had our final protocol signed off? Let's talk performance, folks, and see how it can help improve our study delivery.

12:10 pm **Talk Title to be Announced**
Jef Benbanaste, VP of Product, Intelligent Trials, Medidata, a Dassault Systèmes company

12:40 **Transition to Lunch**

12:45 **Site Initiation in Asia & Tips for Japan Market Entry**
Tomoko Umeda, Senior Project Manager, Project Management Division, CMIC Group
This presentation will give an in-depth perspective into the differences between Asia and other countries related to site initiation; including regulatory regulations. The presentation will also look at the challenges and opportunities for sponsors looking to enter the Japan Pharmaceutical Market and how selecting the right partner can lead to great success.

1:15 **Coffee & Dessert Break in the Exhibit Hall**
(Sponsorship Opportunities Available)

PERSPECTIVES ON PROTOCOL DEVELOPMENT, CYCLE TIME IMPROVEMENTS, AND STUDY DESIGN OPTIMIZATION

2:10 **Chairperson's Remarks**
Melissa Easy, VP and General Manager, Clinical Technologies, IQVIA

2:15 **Accelerating Clinical Trial Feasibility with Data Science**
Corey Jones, Senior Manager, Data Visualization and Design, Janssen R&D Data Science, Johnson & Johnson

This presentation will explore how the feasibility process can be enhanced with data science & technology. The talk will share the journey of developing applications and insights to move an organization relying on Excel and other offline, fragmented solutions to a connected, efficient solution generating real-time insights for better site selection.

2:45 Human-enabled AI with Interactive RWD and Technology: How Innovating Today's Feasibility Becomes Tomorrow's Success

Alexandra Charge, Head of Clinical Planning and Patient Engagement & Recruitment, Clinical, Citeline

Speaker II to be Announced

The evolution & fusion of RWD and AI is key to the modern clinical trial feasibility. What are today's RWD and predictive tech? How are they being utilized? What's next? But why has putting this into practice been so slow? Learn how to break the curse of 80% of clinical trials being delayed or not meeting target, and how this approach will set the stage for long-term, sustainable success.

3:15 Streamlining Protocol Design with Machine Learning and Artificial Intelligence: Where It's Added the Most Value

Gabriela Feldberg, Practice Leader, Applied Analytics & Artificial Intelligence, AstraZeneca

3:45 Charting a Course: Sailing into the Future of Strategic Feasibility

Kevin Marsh, Vice President, Global Head, Patient-Centered Research, Evidera
Timothy Mudric, VP Head, Operational Strategy Leads & Strategic Feasibility, PPD, part of Thermo Fisher Scientific

Strategic feasibility is charting a new course. Pandemics, regulation changes, patient centricity, diversity/inclusion, real-world data, predictive analytics, digital and decentralized site and patient partnership models challenge historical feasibility methodologies. Utilizing data science to gain trial insights is a burgeoning area of development. How organizations encapsulate these challenges, leverage performance analytics, and bring forth enterprise feasibility solutions that were once thought of as consulting will now be mainstream feasibility.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

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

Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.

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

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program

Caroline Jackson, Executive Vice President, Patient Services, mdgroup

Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced

Speaker to be Announced

9:00 Session Break

OPTIMIZING PROCESS & TECHNOLOGY FOR TRIAL FEASIBILITY AND STUDY START-UP

9:10 Chairperson's Remarks

9:15 From Feasibility to Start-up Simplicity

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

This presentation focuses on the feasibility and study start-up process and will meet the following learning objectives by identifying the site's "pain points" and what solutions exist to support the site in this process, simplifying staff onboarding to new trials by organizing the unruly disparate tech and document, and improving your metrics and best practices, not to mention, investigator and staff morale.

9:45 Talk Title to be Announced

Speaker TBD, TBD, Advarra

10:15 The Feeling is Mutual: Building Stronger Site-Sponsor Relationships Through Good Feasibility Practices

Matt Jones, Feasibility Product Leader, IQVIA Technologies

Inflationary pressures and resource constraints are putting study timelines and budgets at risk, frustrating sites and sponsors alike.

In this session, we'll introduce Good Feasibility Practices as the only way to build healthy long-term sponsor-site relationships:

- Start early in the planning phase
- Use feasibility assessments to gain mutual understanding and respect
- Develop a company-wide feasibility program that captures and connects feasibility assessments at the portfolio, study, and site level

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

SITE SELECTION AND SITE ENGAGEMENT DURING THE FEASIBILITY PROCESS & IMPROVING START-UP TIMELINES

11:40 Chairperson's Remarks

11:45 PANEL DISCUSSION: Sponsor and Site Interactions in Phase I Trials: Feasibility, Start-up, and Contracting.

Moderator: Kristi Womack, Senior Director, Clinical Pharmacology Operations, Intra-Cellular Therapies, Inc.

Early-phase studies differ from late-phase studies in many ways. Studies are shorter in duration with fewer subjects and often have expedited start-up requirements. The intricacies of these studies aren't discussed frequently. This panel will focus on how the sponsor and site collaborate to enroll studies on time and within budget; what's important during feasibility assessment; maintaining open lines of communication; and expediting the contracting process.

Panelists:

Patrick McLaughlin, CEO, Anaheim Clinical Trials

Christina Greene, PhD, Director, Global Site Agreements, Merck

12:15 pm Better Site Selection: How AbbVie Is Improving Its Site Selection Process with Machine Learning Capabilities

Bardia Akbari, Vice President, Development Operations, Oncology, Abbvie, Inc.

In the competitive world of clinical research, selection of right sites is a critical success factor for on-time delivery of any study. Interdependencies in clinical research environment including investigator interest, novelty of approach, choice of comparator, etc., all play a role in performance of the site. A multi-dimension approach to site selection starting from protocol concept sheet will help teams with selection of sites best fit for any study.

12:45 Transition to Lunch

12:50 Talk Title to be Announced

Speaker to be Announced

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction
Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

INCORPORATE PATIENT INSIGHTS, ENROLLMENT FORECASTS, AND RESOURCE CONSIDERATIONS FOR STUDY START-UP

4:25 Chairperson's Remarks
Jade Dennis, Senior Director, Design Hub, Eli Lilly & Company

4:30 Patient Burden – Designing Trials that Lighten the Load
Hugh Dai, Associate Director, Design Hub, Eli Lilly & Company
Jade Dennis, Senior Director, Design Hub, Eli Lilly & Company
Clinical trials inevitably place burden on patients in a variety of ways. The ability to measure the burden a trial will place on a patient provides a quantitative way to assess the burden different study designs have and equips clinical development teams with data to optimize SoA designs, leading to more patient-friendly designs with reduced cost and lower patient discontinuation rates.

5:00 Predictive Modeling for Feasibility and Patient Enrollment: Advanced Modeling for Enrollment Prediction to Facilitate Portfolio Planning
Li Wang, PhD, Senior Director & Head, Statistical Innovation, AbbVie, Inc.
Accurate forecast of a clinical trial enrollment timeline at the planning stage is of great importance to both corporate strategic planning and trial operational excellence. We propose a new statistical framework based on generalized linear mixed-effects models (GLMM) and non-homogeneous Poisson processes to model the country initiation, site activation, and subject enrollment sequentially in a systematic fashion. Substantial improvement in prediction accuracy is observed when applied to 30 real studies.

5:30 Training and Technology: Challenges around Continuous Education and Site Engagement
Philip Bedrin, Director of Learning & Technology Solutions, ScienceMedia, Inc.
Malachi Bierstein, Vice President of Sales, ScienceMedia
Speaker II to be announced
We must recognize the impact of training sites throughout the life of a clinical trial, ensuring site compliance, patient safety and minimizing risk. ScienceMedia has supported studies which accelerated trial timelines up to 20%. But what are the challenges that come with continuous education and maintaining site engagement? How are role-based systems and patient-facing mechanisms impacting clinical trial startup and conduct, and how can we make them more accessible to all?

6:00 Building an Unknown Global Clinical Program in an Under-Resourced World
Morgen Alexander-Young, Associate Director Global Trial Optimization, Global Clinical Trial Operations, Merck & Co.
Adrienne Walstrum, Program Director, Merck & Co.
Building a global clinical trials program in an indication where the sponsor has had limited presence is a daunting challenge. Emphasizing the need for truly collaborative engagement with experts in the field cannot be overlooked. Through a real-world, ongoing example we share our setbacks and successes, and build a road map for clinical program growth.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

STREAMLINING THE STUDY START-UP PROCESS WITH DIGITAL PROTOCOLS AND BUILT-FOR-PURPOSE SYSTEMS

8:25 Chairperson's Remarks
Lorena Gomez, Global Head, Study Start Up, COA, and Digital Implementation, AbbVie, Inc.

8:30 Building a Start-up Team from the Ground up
Lorena Gomez, Global Head, Study Start Up, COA, and Digital Implementation, AbbVie, Inc.
Lorena Gomez will share how one sponsor company went from a decentralized, monitor-driven start-up model to a dedicated study start-up team with streamlined processes and built-for-purpose systems. This presentation will cover the discovery process, deployment, and change management for the implementation of a new, global Study Start-Up function and share early data onsite activation cycle time improvements.

9:00 PANEL DISCUSSION: Digital Protocols and Automation Platforms for Accuracy in Feasibility
Moderator: Joseph Kim, Chief Strategy Officer, ProofPilot
Feasibility sometimes feels like a progressive game of bait and switch. Sponsors attribute this to unforeseeable decisions and last-minute changes. But most would agree that the final protocol and accompanying documents should tell the whole story – they don't. Learn how digital protocols and automation ensure sites/sponsors confidently establish a "what you see is what you get" level of trust in feasibility, to ensure high-quality execution and fair site compensation.
Panelists:
Nadia Aldhalimy, BS, Regional Manager, Circuit Clinical
Katherine Broecker, Senior Director, Design Hub Data Insights, Eli Lilly & Co.
Kylie Scheideler, Director of Operational Strategy, Javara

9:30 How Reducing the Burden of Technology Unlocks Higher Performing Sites and Expedites Study Startup
Kenny Kong, Director, Life Sciences & Health IT, Exostar LLC
As the global Life Sciences industry modernizes its' approach to clinical trials, we've seen incredible growth in clinical study technology. Activating sites and granting them access to your systems can be time consuming often delaying study timelines. Come learn how Exostar transforms access management by providing a connected ecosystem of sites, CROs and sponsors which expedites timelines while enabling frictionless access for sites and users.

9:45 Talk Title to be Announced
Speaker to be Announced

10:15 Talk Title to be Announced
Speaker to be Announced

10:45 Networking Coffee Break

IT TAKES A LITTLE HELP FROM FRIENDS: PATHWAYS TO PATIENT ENGAGEMENT

11:05 Chairperson's Remarks
Marlene Peters-Lawrence, Clinical Research Project, NIH, NINDS

11:10 CASE STUDY: The Role of Patient Advocacy in Ensuring a Representative Patient Population – Gilead's Science/Patient Engagement Studies
Emily Freeman, PhD, Senior Director, Patient Engagement, Global Medical Strategy and Operations, Gilead

11:40 eConsent? Yes. How About Flexible Consent?
Ian Greenfield, Chief Strategy Officer, Patient Engagement, YPrime
No matter what method is used, the goal of informed consent remains the same – to properly inform patients as efficiently and effectively as possible. In this session, we'll explore how to use technology to improve the consent experience for sites as well as participants, regardless of whether it's in the clinic, living room, or both.

12:10 pm CASE STUDY: Pathways to Engagement – A Framework for Engaging Diverse Populations in Clinical Research
Marlene Peters-Lawrence, Clinical Research Project, NIH, NINDS
Tiffany Powell-Wiley, MD, Physician-Scientist, National Institutes of Health
Recruitment methods for engaging underrepresented populations into clinical research incorporating digital health technology are limited. In this case study presentation, we will describe how the Communication, Awareness, Relationships, and Empowerment research recruitment model helped to reduce challenges in recruiting predominately African American Washington, D.C communities into a National Institutes of Health community engagement, technology enable research study.

12:40 Transition to Lunch

12:45 SCOPE Send Off Luncheon Presentation
Speaker to be Announced

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Cambridge Healthtech Institute's 15th Annual

Enrollment Planning and Patient Recruitment

Tools and Strategies to Improve Diversity and Achieve Enrollment Goals

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 10th Annual

Patient Engagement and Retention through Communities and Technology

Patient-Centric Approaches and Technologies to Engage and Retain Diverse Populations

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

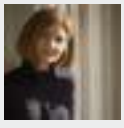
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education





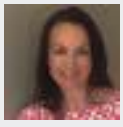


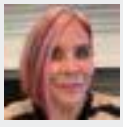
Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

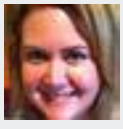
Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards




Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

BUILDING DIVERSITY, EQUITY, AND INCLUSION (DE&I) INTO CLINICAL TRIAL ENROLLMENT

10:35 **Chairperson's Remarks**
Neil Weisman, President, Continuum Clinical

10:40 **Strategizing to Achieve Diversity in Clinical Research – A Regulatory Perspective**
Jamie Brewer, MD, Clinical Team Lead, Division of Oncology 3, Office of Oncologic Diseases, FDA
Presentation will discuss FDA's recommended approach to developing a strategy to enroll diverse populations in clinical trials that support approval of FDA regulated medical products; and will provide an overview of currently implemented strategies that may drive success.

11:10 **Transforming Clinical Trial Diversity Equity & Inclusion Goals into Action**
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Neha Londono, Director, Clinical Trial Diversity & Inclusion, Seagen, Inc.
This session will explore foundational elements of Seagen's approach to clinical trial diversity equity and inclusion. Key components will include devising a personalized strategy founded in epidemiology, and centered in inclusive trial design, patient centric solutions, strategic site selection, site focused services, and collaboration with patient advocacy and trusted messengers.

11:40 **PANEL DISCUSSION: Operationalizing Diversity in Clinical Trials: Cross-Functional Capabilities Needed to Recruit, Track, & Adapt for Meaningful Change**
Moderator: Jason Gubb, Clinical Operations Consultant and Co-Founder of Emergent Teams
Efforts to improve DE&I have focused on trial entry criteria to ensure diverse populations; however, we need to go beyond intent and get real about *how* we can make a meaningful difference to ensure clinical trials better reflect the population most likely to use the drug if approved. Our esteemed panel will share insights and discuss strategies and examples on how we can proactively ensure our industry is truly future-ready.

Panelists:
Jamie Brewer, MD, Clinical Team Lead, Division of Oncology 3, Office of Oncologic Diseases, FDA
Alekhya Pochiraju, Senior Product Development Lead, Clinical Operations, Genentech
LaShell Robinson, MS, Director Diversity, Equity & Inclusion in Clinical Research, Takeda
Sheila Rocchio, Digital Growth & Education, eClinical Solutions

12:10 pm **Make DEI Part of the Plan: Strategies for the Successful Enrollment of Diverse and Inclusive Patient Populations**
Gaby Grekin, Senior Director, Global Strategy, BBK Worldwide
Any meaningful commitment to diversity, equity, and inclusion (DEI) must be considered in the planning stage — not tacked on as an afterthought. Only an intentional and integrated approach will succeed. We will discuss making DEI a priority at the beginning of a trial; barriers to recruiting racially, ethnically, and socio-economically diverse populations; and share strategies for overcoming those challenges to ensure your trial includes and reflects populations that will ultimately benefit from them.

12:40 **Transition to Lunch**

12:45 **Addressing Enrollment Challenges in Rare Disease and Oncology Research Studies**
Robert Loll, SVP, Business Development & Strategic Planning, Praxis Communications, LLC
Creating unique, customized programs is essential to clinical trial recruitment and retention especially in the fields of rare disease and oncology. Join us for a fireside chat with industry experts where we explore the nuances of tailoring an approach designed to meet these unique patient populations where they are in their journey in order to bring trial awareness and opportunities to them in a relatable and accessible way.

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

NEW APPROACHES TO SUPPORT ENROLLMENT GOALS

2:10 Chairperson's Remarks
George Dorsett, Vice President, Business Development, Clariness

2:15 Geo-Mapping to Support DCT and Diversity in Clinical Trials
Katherine Broecker, Senior Director, Design Hub Data Insights, Eli Lilly & Co.
The Geo-mapping visualization tool has been developed to allow recruitment and engagement teams to combine multiple data sources visually to identify target patients, investigators, and decentralized capabilities that can expand enrollment reach. Data layers include DCT vendor locations, disease prevalence, demographic segments, and investigator locations. These elements viewed together can guide the user in their enrollment efforts to maximize reach and eliminate gaps in clinical trial recruitment and diverse representation.

2:45 Impact of Socioeconomic Status on Clinical Trial Diversity
Ivor Clarke, CEO, SubjectWell
As an industry, we strive for a diverse, representative population for every trial, seeking to increase patient participation by offsetting burdens with medical value. Yet these barriers to participation are not experienced equally by all socioeconomic groups. Using data from recent patient surveys, this session explores the correlation between socioeconomic status (education, social class, and income), barriers to participation, and patient diversity.

3:15 PANEL DISCUSSION: Overcoming Recruitment Challenges of Global Studies
Moderator: Amy Froment, Head, Global Trial Optimization, Regeneron
There is no single patient – they are all individuals with different needs and perspectives. How can we ensure messaging and information is inclusive but cost effective in a global study across multiple languages and cultures. How can we achieve diversity goals? How can we ensure that we can focus sites on utilizing recruitment tools fully where they can be overwhelmed with novel technologies, platforms and their clinical workload?
Panelists:
Nanci Eannucci, Director, Clinical Trial Recruitment Strategy, Bristol Myers Squibb
Gwenn Oakes, Director, Global Trial Optimization, Merck
Cory Potts, Senior Manager, Site Engagement, Diversity Lead, Bayer

3:45 Improving Trial Recruitment & Engagement with Effective Use of Lab Data
Parag More, Executive Director, Quest Healthcare Analytics Solutions, Quest Diagnostics
Attend this session to learn how Quest Diagnostics Clinical Trials Solutions works with pharmaceutical organizations to provide data- and infrastructure-based solutions for site and investigator validation and identification, patient recruitment outreach, HCP outreach, DCTs, cohort profiling and analytics, patient-initiated screening (pre-testing), and more.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
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On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced
Speaker to be Announced

9:00 Session Break

LEVERAGING DATA AND TECHNOLOGY TO IMPROVE OUTREACH AND ENGAGEMENT

9:10 Chairperson's Remarks
Speaker to be Announced, Trialbee

9:15 CASE STUDY: How Otsuka Leveraged Data to Address Recruitment and Engagement during (and after) the Pandemic
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Unprecedented times – unprecedented approaches. The struggle with assessing and monitoring the impact of COVID on studies (ex. site activations/enrollment) was a challenge for industry. A creative team at Otsuka leveraged internal and external data (e.g., CDC and open data sources) to develop visualizations that informed near/real time modeling, as well as storyboards for long term narratives of the what, why and when of COVID; then applied same, to RUS/UKN war.

9:45 Adaptive Experiences in Clinical Trials - Why Providing Choice Drives Patient Compliance and Retention
Andrea Valente, CEO, ClinOne
Andrea Valente, CEO of ClinOne, will host an informative presentation examining the role of Adaptive Experiences in clinical trials and how they can provide choice to drive patient compliance and retention. Whether that means using technology at the site, paper at home, or anything in between, it is essential to trust all trial participants (patients, caregivers, sites, and study teams) and empower them to take control of their experience.

10:15 Using Data and Analytics to Identify and Solve Site Enrollment Challenges
Neil Weisman, President, Continuum Clinical
Site activation delays, an increase in competitive trials, and study coordinator labor shortages are a few of today's challenges that are resulting in never-before-seen enrollment bottlenecks at study sites, leading sponsors and recruitment partners to think differently to achieve success. This presentation will help sponsors maximize their enrollment efforts by identifying and mitigating commonly overlooked metrics in the recruitment funnel that lead to longer enrollment and lower ROI when left unattended.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

CREATIVITY AND ENGAGEMENT IN RECRUITMENT AND RETENTION

11:40 Chairperson's Remarks
Dawn Anderson, Managing Director, Life Sciences, Deloitte

11:45 Come for the Cure, Stay for the Community: Retention Strategies Centered around Participants and Results
Maggie Kuhl, Vice President, Research Engagement, Michael J Fox Foundation for Parkinsons Research
The ongoing Parkinson's Progression Markers Initiative study enrolled more than 1,000 participants between 2010 and 2018 at 33 sites in 10 countries in a longitudinal, observational study involving repeat biological sampling, imaging scans and clinical assessments. The audience will hear pillars of retention/ engagement strategy and examples of varied approaches (e.g., in-person events, "share your story" forms, newsletters, conference calls, participant profiles) to consider in building their own study retention strategies.

12:05 pm Strategies for Patient Recruitment by Therapeutic Area
Melanie Goodwin, Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer Inc.
Many sponsors have been diligent about increasing the focus on enrollment planning, but is it truly proactive or are we still being reactive? This presentation will focus on how the industry needs to move to a more programmatic and even a therapeutic area approach to recruitment planning. It will explore how pulling the enrollment focus even earlier will not only benefit each study and site, but also our participants.

12:25 Rare Disease versus Chronic Conditions: Compare and Contrast Recruitment and Engagement Strategies
Deborah Howe, Director, Global Patient Recruitment and Engagement, Alexion, AZ Rare Disease
Michele Teufel, Site Management & Monitoring Therapy Area Strategy & Portfolio Delivery, Development Operations, AstraZeneca Pharmaceuticals, Inc.
Internet campaign for rare disease? Grassroots efforts for chronic conditions? Or is it really vice versa? This session will explore the similarities and differences in recruitment and engagement strategies for rare diseases and chronic conditions. A variety of approaches will be discussed including patient centricity and insights, protocol feasibility, centralized and localized patient recruitment and retention tactics, support services, and much more.

12:45 Transition to Lunch

12:50 Talk Title to be Announced
Speaker to be Announced

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction
Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

ENHANCING PATIENT CENTRICITY TO IMPROVE ENGAGEMENT AND RETENTION

4:25 Chairperson's Remarks
Speaker to be Announced, Scout Clinical

4:30 One Year in: Creating an Internal Global Development Patient Engagement Team: Remit, Resourcing, & Relationships
Amy Froment, Head, Global Trial Optimization, Regeneron
Tara Gipp, Associate Director, Clinical Trial Optimization, Recruitment & Retention, Regeneron Pharmaceuticals
Regeneron has created an internal patient engagement capability to support clinical trials. One year in, we have learned how to connect multiple stakeholders across the organization and partner with external vendors and CROs to deliver meaningful change for patients, sites and study teams. We will share how we defined our remit, how we maximized resource through internal and external partnerships and relationships by sharing real life examples and challenges.

4:50 Innovating Patient Recruitment through Pharmacy Channel Outreach
Omar Abdelsamad, Executive Director, Patient Recruitment, Clinical Trial Services, CVS Health
Victoria Reid, Vice President, Freenome
The CVS Health pharmacy channel enables innovative clinical trial engagement via100M+ patient connections. The pharmacist is the most trusted healthcare provider and the pharmacy is the most visited healthcare site among patients. Using case studies, this presentation demonstrates how this relationship with patients coupled with innovative outreach tactics enrolls referrals at 2x-3x the rate of traditional channels. Stakeholders will speak to these case studies and innovations.

5:10 The Value of Incorporating Patient Voice, Obtaining Patient Feedback, and Demonstrating Gratitude throughout the Clinical Trial Journey
Kandria Harry, BSN, Manager, Patient Engagement and Clinical Strategy, Astellas Pharma Inc.
This session will focus on TransCelerate's work to provide more effective ways to engage with and embed the voice of patients in the design and execution of clinical studies. In addition to highlighting the impact and value of TransCelerate's existing Patient Experience Resources: The Patient

Protocol Engagement Toolkit (P-PET) and the Study Participation Feedback Questionnaire (SPFQ) Toolkit, there will be an introduction to the newly developed Gratitude Toolkit.

5:30 Talk Title to be Announced
Speaker to be Announced

6:00 Boosting Comprehension with Augmented Reality, AI and Avatars for an Interactive Consent Process
Daniella Frisoli, Study Start-Up Specialist, Country Clinical Operations (CCO) UK, Roche
Studies show that potential benefits of interactive interfaces are empirically proven to improve comprehension and information retention. In an effort to improve comprehension, engagement and trial retention, Roche has developed an interactive Consent process that incorporates augmented reality, audio touchpoints, customized avatars, and a completely reinvented consent form.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

ADVANCING CLINICAL INNOVATION AND PATIENT CENTRICITY THROUGH TECHNOLOGY AND PARTNERING

8:25 Chairperson's Remarks
Speaker to be Announced, Care Access

8:30 Is There Technology Overload? Finding the Right Balance for Patients and Sites
Moderator: Michelle Shogren, CEO & Owner, Innovate in What You Do!
With the proliferation of digital health technologies, how can we determine the right mix to improve clinical research without overloading patients and/or sites? How do we lessen the technology adoption burden on sites? What's the future of finding patients? Facebook? Databases? Scanning EMRs? Physician engagement?
Panelists:
Tom Julian, Senior Consultant, Gilead
Amir Lahav, Head of Strategic R&D, Digital Healthcare Innovation, Mitsubishi Tanabe Pharma America
Gayna Whitaker, Director, Strategic Feasibility, AstraZeneca

9:00 Patient-Centric Sampling at Merck: How the Patient Voice Shaped Our Sampling Strategy
Melanie Anderson, Principal Scientist, Translational Medicine, Merck
Jennifer Campbell, Principal Scientist, Preclinical Development, Merck
Over the past decade, Merck has conducted numerous trials involving patient-centric sampling, an enabling technology for decentralized trials. Patient preference questionnaires were included in multiple trials. Patients preferred at-home sampling with novel collection devices that were painless, simple, and minimized sample volume. Participant feedback has shaped our company's patient-centric sampling strategy and has enabled us to implement sampling approaches that are truly patient-centric.

9:30 When does a Clinical Trial Start Being Just a Clinical Trial: A Path to the New Normal
Alison Holland, Executive General Manager, Digital and Decentralized Solutions, Medable
The industry is heading towards a place where digital elements (DCT's) start to become standard as we operate trials. To achieve scale, and give patients a true choice, digital strategies need to be embedded early into drug development and embraced by sites, patients and sponsors. Join us as we discuss the path to the new normal for everyone in the clinical trials ecosystem.

9:45 Detecting Changes in Patients' Conditions with Virtual Waiting Rooms
Ivor Clarke, CEO, SubjectWell
SubjectWell shares a virtual waiting room (VWR) that simplifies the difficult process of enrolling for conditions that must be tested when symptoms are active. This session examines the VWR as an effective patient engagement tool, including best practices learned across multiple case studies and a blueprint for future applications.

10:15 The Next-Gen of Community-Based Clinical Trial Site Networks: Location & Trust Can Improve Recruitment & Diversity
Dawn Anderson, Managing Director, Life Sciences, Deloitte
The industry is looking to new site network models focused on community-based clinics. By being embedded in the community, new site networks may be able to increase patient recruitment & convenience, improve retention, & enhance diversity in clinical trials. We will discuss strategies and ways non-traditional site networks could transform the clinical trial delivery model.

10:45 Networking Coffee Break

IT TAKES A LITTLE HELP FROM FRIENDS: PATHWAYS TO PATIENT ENGAGEMENT

11:05 Chairperson's Remarks
Marlene Peters-Lawrence, Clinical Research Project, NIH, NINDS

11:10 CASE STUDY: The Role of Patient Advocacy in Ensuring a Representative Patient Population – Gilead's Science/Patient Engagement Studies
Emily Freeman, PhD, Senior Director, Patient Engagement, Global Medical Strategy and Operations, Gilead

11:40 eConsent? Yes. How About Flexible Consent?
Ian Greenfield, Chief Strategy Officer, Patient Engagement, YPrime
No matter what method is used, the goal of informed consent remains the same – to properly inform patients as efficiently and effectively as possible. In this session, we'll explore how to use technology to improve the consent experience for sites as well as participants, regardless of whether it's in the clinic, living room, or both.

12:10 pm CASE STUDY: Pathways to Engagement – A Framework for Engaging Diverse Populations in Clinical Research
Marlene Peters-Lawrence, Clinical Research Project, NIH, NINDS
Tiffany Powell-Wiley, MD, Physician-Scientist, National Institutes of Health
Recruitment methods for engaging underrepresented populations into clinical research incorporating digital health technology are limited. In this case study presentation, we will describe how the Communication, Awareness, Relationships, and Empowerment research recruitment model helped to reduce challenges in recruiting predominately African American Washington, D.C communities into a National Institutes of Health community engagement, technology enable research study.

12:40 Transition to Lunch

12:45 SCOPE Send Off Luncheon Presentation
Speaker to be Announced

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Cambridge Healthtech Institute's 13th Annual

Clinical Trial Forecasting, Budgeting and Contracting

Innovative Strategies for Cost-Efficient Trials

FEBRUARY 6-8, 2023
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 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

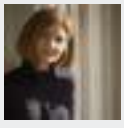
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

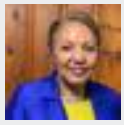
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education





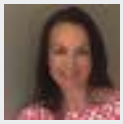




Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

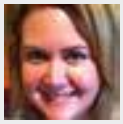
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

A DEEP DIVE ON BUDGETING: COLLABORATIVE APPROACHES, STRATEGY, & TOOLS

10:35 **Chairperson's Remarks**
Anca Copaescu, CEO, Strategikon Pharma

10:40 **FIRESIDE CHAT: Collaborating across Functions to Improve the Forecasting, Budgeting, and Accruals Process**
Carrie Lewis, Executive Director, Clinical Program Optimization, Endo Pharmaceuticals
Richard O'Hara, Director, Clinical Business Operations, Endo Pharmaceuticals
This fireside chat will focus on the accrual/forecasting process for Clinical trial budgets. Specifically, the processes for working with vendors to obtain current accruals and forecasts. We will also discuss coordination with the internal functions at the Sponsor to ascertain the most accurate and current timelines, enrollment rates, screen failure and drop out rates. Aligning all expectations with both the operations teams as well as Finance and Senior Management.

11:10 **Budgeting in Financially Uncertain Times: Planning around Massive Inflation**
Kenneth Olovich, Director, Sourcing and Finance, Chorus Division, Eli Lilly and Company
Uncertain financial times, shifting labor markets, and inflation at record-high levels have put intense pressure on operating expenses and cash flow for pharma companies. Now more than ever, accurate trial forecasts and predictive cost models are necessary that build in inflationary risks and other tolerances. CROs who help their sponsors do this well will be favored and will appear as partners who are good stewards of money.

11:40 **Presentation to be Announced**

12:10 pm **Talk Title to be Announced**
Speaker to be Announced

12:40 **Transition to Lunch**

12:45 **Talk Title to be Announced**
Speaker to be Announced

1:15 **Coffee & Dessert Break in the Exhibit Hall**
(Sponsorship Opportunities Available)

SITE BUDGETING, CONTRACTING, AND PAYMENTS: GIVING SITES A SEAT AT THE TABLE

2:10 **Sponsored Chairperson's Remarks** *(Opportunity Available)*

2:15 **Mutually Supportive Site Budgeting & Contracting: Simple Ways for Sponsors to Optimize a Positive Financial Relationship with Their Investigator Sites (or "Six Simple Steps Sponsors Should Speedily Systematize so Sites Smile Serenely")**
Christopher Chan, Vice President, FP&A, IGM Biosciences, Inc.
When it comes to budgeting, contracting, and payments, the sponsor-investigator site relationship has long been characterized by significant difficulties and contention. That these challenges have proven so enduring over time underscores their inherently persistent nature. Using multiple real-world anecdotes, this presentation will explore some of the more common issues and analyze potential effective ways these challenges can be alleviated and even subdued.

2:45 **Clinical Trial Budgets: A Perfect Storm Challenging Study Delivery**
Karen Lodigiani, Senior Director, Head, Site Contracts & Budget Management, Daiichi Sankyo
Site contract and budget negotiations have contributed to significant delays to study start-up for years. The impact of the pandemic, inflation, and staffing shortages has significantly increased site burden. While a site-centric approach by Sponsors that incorporates FMV principles and aligns with Site expanded needs can be an effective strategy for efficient site contract and budget negotiation in this environment, implementation requires Site and Sponsor collaboration.

3:15 Optimizing Clinical Trial Agreements and Budgets in the New Regulatory Landscape and Evolving Challenges

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

In order to successfully deliver innovative therapies to patients with unmet medical needs the trial management regulatory guidelines need to be standardized further, and robust methods of evaluation of study protocol complexity developed in conjunction with risk management strategies, adequate provisions in clinical trials agreements and accurate budgeting are needed.

3:45 Improving trade-off decisions through cost transparency

Divya Gupta, Knowledge Management Consultant, ZS

Chelsea Gallagher to be Announced, Director of Innovation in R&D Analytics, BMS

Have you ever wondered what the impact to your trial will be if you add an assessment? Or Cycle? Or endpoint? BMS's Innovation & Digital Health team has developed a solution to support study teams, during the trial design process, in making decisions based on expected impact – including budgets. This solution:

- Empowers study teams to understand study cost drivers
- Increases the visibility into various components of cost (fixed vs. variable)
- Enables the right level of transparency
- Improves teams' ability to make trade-off decisions before protocol approval, enabling streamlined downstream processes

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

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

Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.

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

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program

Caroline Jackson, Executive Vice President, Patient Services, mdgroup

Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced

Speaker to be Announced

9:00 Session Break

THE FINANCIAL IMPACT OF DECENTRALIZED CLINICAL TRIALS ACROSS SPONSORS, SITES, AND CROs

9:10 Chairperson's Remarks

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

9:15 PANEL DISCUSSION: The Truth behind the Financial Impact of Decentralized Clinical Trials

Moderator: Meghan Harrington, Vice President Clinical Trial Financial Management, Medidata

The impacts of decentralized trials on clinical financial management are becoming clearer as more sites, sponsors, and CROs execute virtual and hybrid trials. Data is key to understanding the impacts but does the industry have enough cost benchmarking data to make conclusions and respond accordingly? Measuring data to understand the difference between perception and reality when it comes to the impact of DCTs is crucial. Join this panel session as a site, sponsor, and CRO share notes on the effects of remote monitoring and the shift from SDV to SDR, hidden costs on DCTs that we all may not be accounting for, and the extra time that sites may spend supporting the patients with technology.

In this session, you will learn:

- How algorithms in the industry around costing benchmarks take into account remote/ virtual visits
- Unique financial challenges sites are facing that could affect the patient experience
- How to reimagine financial stability and planning for decentralized clinical trials

Panelists:

James Brazeal, Vice President, Research Operations, Circuit Clinical

10:15 Study Budget Negotiations

Cassidy Duffany, Manager, Operations Finance, Elligo Health Research®

Lori Rich, Vice President, Financial Operations, Elligo Health Research®

Join Elligo Health Research as they discuss the steps needed to build a study budget and the negotiation process, including:

- Protocol review
- Study budget build
- Negotiations process
- Determining study feasibility
- Finalizing the budget

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

INFLATION, CLIMATE CHANGE, & WAR: IMPACT ON BUDGETS AND OUTSOURCING

11:40 Chairperson's Remarks

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

11:45 Promoting/Working/Accelerating Climate Mitigation in Trial Design

Jason Lanier, Global Program Leader, Director, Janssen

Jason LaRoche, Director and Focus Area Leader, Janssen Clinical Innovation

Governments, healthcare providers, and other stakeholders are calling for action on climate change. We'll discuss the climate footprint of clinical research and propose an activity-based approach for future measurement. We will discuss how this approach can be applied to estimating the climate footprint of future trials and co-inform trial design as well as how we as an industry can come together to collectively measure and reduce the emissions from clinical research.

12:15 pm **PANEL DISCUSSION: Managing the Downstream Impact of World Events in Clinical Trials from a Clinical Sourcing and Operations Perspective**

Moderator: Scott Sawicki, MA, Senior Director, Strategic Sourcing & Vendor Management, ADC Therapeutics

Panelists:

Daniella Ajib, Executive Director, Vendor Outsourcing, Gilead Global

Hansu Dong, Executive Director, Clinical Outsourcing & Business Operations, Clinical Operations, Novavax

Rene Stephens, MSHS, Independent Consultant

Mary Frances Sassaman, Vice President, Project Delivery, ICON

12:45 **Transition to Lunch**

12:50 **The New Age of R&D Procurement: Strengthen Vendor Performance Management & Oversight with Technology**

Anca Copaescu, CEO, Strategikon Pharma

Over $50B are spent annually in R&D outsourcing across multiple service categories, supporting increasingly more complex studies with fewer resources. Core activities (RFP management, strategic partner governance and category sourcing) are painfully manual and lacking data driven analytics. Learn how technology increases business scalability in a resource-constrained environment, strengthening vendor oversight, minimizing compliance risks and reducing the overall cost of outsourcing execution.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 **Plenary Keynote Introduction**

Ivor Clarke, CEO, SubjectWell

2:25 **Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways**

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 **Advancing Evidence Generation of the Future**

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 **Fireside Chat: Next-Generation Data Sources**


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 **Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap**



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs

Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck

Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.

With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 **Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

ALGORITHMS AND TOOLS FOR RESOURCE MANAGEMENT

4:25 **Chairperson's Remarks**

4:30 **Resource Management Algorithms for Site Management: Process and Impact**

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

Resource estimation algorithms are key for clinical operations, especially for site management. We will sketch our algorithm approaches and how they evolved over time driven by application of RBQM, reflecting feasibility efforts, etc. Further, we will highlight our approach to be consistent between early estimation on study level and breakdown on country level. Finally, we will touch validation with time tracking.

5:00 **Balancing a Programming Resourcing Portfolio**

Francis Kendall, MBA, BSC, Executive Director Statistical Programming, Biometrics, AstraZeneca

The presentation will present a case study on how to evolve a group to maximize resource usage together with new processes and technology to have an operational impact on the business.

5:30 **Digital Diversity: Foundational Data Science to Build Equitable and Inclusive Trials**

Alexandra Moens, PharmD, Director, Product Marketing, H1

6:00 **CO-PRESENTATION: Forecasting Development Resource Requirements for a Complex Cell-Therapy Clinical Pipeline: Utilizing a Predictive Productivity-Based Resource Tool to Estimate Future Role-Specific Headcount Requirements**

Catherine Allen, Executive Director, Development Strategic Operations, Kite Pharma

Grant A Morgan, PhD, Founder, CamAlex Castle Consulting

Kite Pharma, a Gilead Company, is dedicated to achieving one of the most ambitious goals in medicine, to cure cancer. Our engineered T cell therapy Development programs require unique resource requirements. Kite Development partnered with CamAlex Castle Consulting to create a reporting tool utilizing role-based productivity algorithms to estimate Development resources. We will discuss goals, design, implementation, and lessons learned as a pilot tool for resource planning and budgeting.

6:30 **Close of Day**

6:30 **SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)**

*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

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Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

BUILDING RELATIONSHIPS AND MANAGING RESOURCES IN A DIVERSE CLINICAL SUPPLY CHAIN AND PARTNER NETWORK

8:25 Chairperson's Remarks
Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

8:30 FEATURED PRESENTATION: Trends & Challenges in Pharma Sourcing and Procurement – Managing Relationships With The Modern Supplier
Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA
This presentation covers how Bayer's External Relationship Governance model adds value to the business ensuring a reliable partnership and complements the Sourcing & Procurement Functions, sharing current trends on procurement roles and the necessity to have an operational perspective in sight, with different approaches from different business necessities and how to best manage CMOs, 3PLs and Clinical Trials partners.

9:00 PANEL DISCUSSION: How Small Biotechs Develop, Manage, and Maintain Relationships with CROs
Moderator: Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences
This panel will discuss the key considerations for smaller biotechs in selecting CROs to work with, how small biotechs can position themselves as valuable partners to CROs, and strategies for managing and maintaining relationships with CROs.
Panelists:
Hansu Dong, Executive Director, Clinical Outsourcing & Business Operations, Clinical Operations, Novavax
Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.
Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.

10:00 Talk Title to be Announced
Speaker to be Announced

10:15 Impact of FDA's Guidance on Diversity and Inclusion on Post Marketing Research
Sean Kennedy, MPH, Executive Director, Therapeutic Strategy Lead, Real World Evidence, Worldwide Clinical Trials
Aman Khera, MBA, FRAPS, FTOPRA, Vice President, Global Head of Regulatory Strategy, Scientific Solutions, Worldwide Clinical Trials
Daniel Perez, CCRP, Director and Global Head of Patient Experience, Patient Experience, Diversity & Inclusion, Worldwide Clinical Trials

10:45 Networking Coffee Break

MITIGATING THE IMPACT OF STAFF TURNOVER ON RESOURCES AND OUTSOURCING THROUGH TALENT RETENTION AND DEVELOPMENT

11:05 Chairperson's Remarks
Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson

11:10 PANEL DISCUSSION: Strategies to Attract, Engage, and Retain Talent During Times of Change
Moderator: Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson
This panel will discuss the impact staff turnover has on clinical trial operations and outsourcing, working with CROs and sites to mitigate staffing changes, insights on returning to the office, DE&I efforts, and meaningful changes that impact employees, and how to develop talent and grow people into careers.
Panelists:
Eileen Doherty, Vice President, Enabling Business Information Solutions (EBIS), The Janssen Pharmaceutical Companies of Johnson & Johnson
Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Endo Pharmaceuticals
Valerie Balosso, Director, Data Management, Infectious Diseases, GSK

12:10 pm The Tempus TIME Network
Matthew Cooney, Vice President, Therapeutic Development, Oncology, Medical Science, Tempus Labs
The TIME Network screens hundreds of thousands of patients daily using a combination of technology and nursing review to find potential trial subjects. Once an appropriate patient is identified, the trial site is rapidly opened using a pre-approved clinical trials agreement, regulatory process, central IRB, and uniform contracting. This streamlined process has empowered the TIME Network to activate hundreds of trials in an average of 10 days.

12:40 Transition to Lunch

12:45 SCOPE Send off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

> " Great amount of innovation around digitizing and decentralizing trials"
>
> – Patrycja M., VP Products, ConcertAI

Cambridge Healthtech Institute's 7th Annual

Mastering an Outsourcing Strategy

Innovative Outsourcing Models and Determining Success Through Metrics and Governance

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 9th Annual

Relationship and Alliance Management in Outsourced Clinical Trials

Strategies for Building Successful Partnerships and Alliances in a Competitive Landscape

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

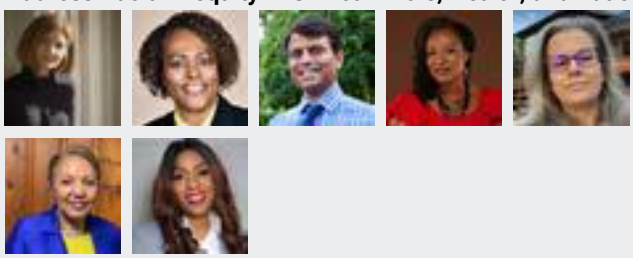
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education

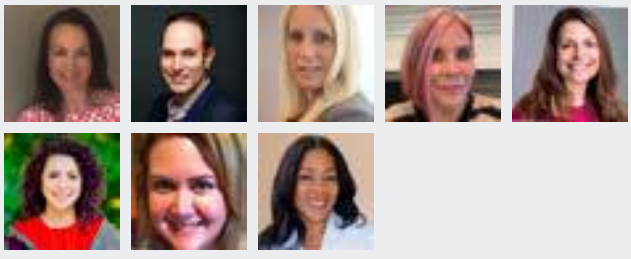


Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards



Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 **Grand Opening Coffee and Refreshment Break in the Exhibit Hall**

OUTSOURCING TO TECHNOLOGY VENDORS: KEY CONSIDERATIONS

10:35 **Chairperson's Remarks**
Neil Berger, VP, FSP Commercial and Operational Strategy, Parexel

10:40 **Key Considerations for Evaluating and Selecting Technology Suppliers for Digital Health Technologies (DHT)**
Sonali Bhatnagar, Associate Director, Clinical Innovation & Digital Health, R&D Sourcing & Procurement, Merck
Learn about the challenges, key questions, and considerations by big pharma when considering, selecting, and onboarding new suppliers to help prepare for subsequent clinical trials supporting various therapeutic areas in the Digital Health Technologies space.

11:10 **Outsourcing to Technology Vendors: Contracts, Metrics, and Challenges**
Nick Lewis, Head, PRO Development Strategic Sourcing, Bayer
With decentralized clinical trials and patient centricity being accelerated in the light of the COVID-19 pandemic, there are a plethora of suppliers offering wearable, biosensors, devices, and app services. With the shift from traditional suppliers to technology vendors, how do we ensure the solution is fit for purpose, the supplier can meet sponsor expectations, and the clinical trial proceeds as per the plan?

11:10 **Presentation to be Announced**

11:10 **Outsourcing to Technology Vendors: Contracts, Metrics, and Challenges**
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11:40 **Talk Title to be Announced**
Speaker to be Announced

12:10 pm **Talk Title to be Announced**
Speaker to be Announced

12:40 **Transition to Lunch**

12:45 **Avoiding Outsourcing Strategies that No Longer Work**
Neil Berger, Vice President, FSP Commercial and Operational Strategy, Parexel
Don't change your outsourcing model for the wrong reason
Outsourcing models and trends
Emerging models and metrics to consider

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

EXPLORING OUTSOURCING MODELS

2:10 **Chairperson's Remarks**
Speaker to be Announced, KPS Life

2:15 **Growing Pains: Anticipating the Impact of a Biotech's Evolution on Outsourcing Strategy**
Richard Scaife, Vice President, Strategic Outsourcing & Vendor Management, VectivBio AG, PCMG Committee Member
The strategy for Phase II/III trial outsourcing is well tested, identifying and implementing third-party resources to fulfill tasks, coverage, and timescale that cannot be met with internal capacity. But, what happens when a small biotech sponsor evolves and expands? Where are the most likely changes to OS strategy and implementation likely to occur and require future-proofing? Can growing pains be mitigated?

2:45 **When CULTURE and STRATEGY Sit Down To Breakfast: Exploring Outsourcing Models Through a Partnership Lens**
Debbie Gilmore, Vice President, Strategic Alliance Management, ICON
Kelly Simcox, Global Head, Clinical Operations R&D, Sanofi

Sponsors continue to evolve both outsourcing strategies and operating models to improve clinical trial performance. In this session, Sanofi and ICON discuss how they created a shared partnership / alliance culture, which evolved both the outsourcing strategy and operating model. The result leverages the best of both organizations and aims at shaping a more efficient environment.

3:15 From Pharma to Biotech: Differences in Sourcing Approaches
Richard L Polgar, Sr Advisor, Danforth Advisors
Big pharma and biotech each have their unique attributes that play out quite differently during sourcing events. Learn the differences and similarities while capturing skills to improve your sourcing event and supplier governance. Walk away with the knowledge to be more successful, plan better and think about the long-term value that can be captured. Learn from veterans in the industry while having fun.

3:45 Ecosystem Collaboration: Partnering for More Accessible Clinical Trials that Support Sponsors, Patients, and Providers Lightship
Samantha Eells, Co-Founder, Lightship
Clinical trial design and conduct are multifaceted with collaboration across organizations, supply chains, and health systems. Ensuring patient safety, quality, and data integrity across programs is key for success. To create clinical trials that offer more access and choice, seamless integration of processes and patient and provider preferences are required. We'll discuss best practices for clinical trials that incorporate the spectrum of decentralized to in-person approaches for a successful study.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall ALMAC prime

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
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WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program mdgroup
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced tomorrows
Speaker to be Announced

9:00 Session Break

METRICS AND KPIs FOR CROs AND THIRD-PARTY PROVIDERS

9:10 Chairperson's Remarks
David MacMurchy, CEO, Lightship

9:15 Building a Relationship Health Program and the Impact on Partnerships
Keith Dorricott, Director, Dorricott Metrics & Process Improvement Ltd.
Dennis Salotti, Senior Director & Head, Strategic Outsourcing & Clinical Innovation, Jazz Pharmaceuticals
This presentation will focus on the key elements of clinical vendor governance and oversight from the perspective of a mid-size pharma; and using holistic vendor relationship management as a vehicle to support effective partnership. The presentation will cover the following key points: overall framework for effective governance; performance management and differentiating relationship vs. delivery metrics; and implementing a relationship health program within a partnership.

9:45 PANEL DISCUSSION: Approaches and Best Practices for Assessing CRO Performance
Moderator: Yusuf Ghadiali, Executive Director & Head, Clinical Trial Business Operations, Daiichi Sankyo, Inc.
With many companies in some form of CRO outsourcing model, including FSP arrangements, it is increasingly important to have effective performance measures that help assess the overall relationship and performance not only at an individual study level but also at a portfolio level. This panel will discuss what approaches have worked well, and what haven't worked well including incentive models (bonus, earn-backs, etc.).
Panelists:
Debbie Gilmore, Vice President, Strategic Alliance Management, ICON
Randy Krauss, Executive Director, Metrics, Analytics, & Performance, Merck
Dennis Salotti, Senior Director & Head, Strategic Outsourcing & Clinical Innovation, Jazz Pharmaceuticals
Keith Dorricott, Director, Dorricott Metrics & Process Improvement Ltd.

10:15 The importance of Expertise in IRT CALYX
Craig Mooney, Vice President, Scientific E-tech Enabled Services, Calyx

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)* PHILIPS

INFLATION, CLIMATE CHANGE, & WAR: IMPACT ON BUDGETS AND OUTSOURCING

11:40 Chairperson's Remarks
Marina Malikova, PhD, Executive Director, Surgical Translational Research, Operations and Compliance, Boston University School of Medicine

11:45 Promoting/Working/Accelerating Climate Mitigation in Trial Design
Jason Lanier, Global Program Leader, Director, Janssen
Jason LaRoche, Director and Focus Area Leader, Janssen Clinical Innovation
Governments, healthcare providers, and other stakeholders are calling for action on climate change. We'll discuss the climate footprint of clinical research and propose an activity-based approach for future measurement. We will discuss how this approach can be applied to estimating the climate footprint of future trials and co-inform trial design as well as how we as an industry can come together to collectively measure and reduce the emissions from clinical research.

12:15 pm PANEL DISCUSSION: Managing the Downstream Impact of World Events in Clinical Trials from a Clinical Sourcing and Operations Perspective

Moderator: Scott Sawicki, MA, Senior Director, Strategic Sourcing & Vendor Management, ADC Therapeutics

Panelists:

Daniella Ajib, Executive Director, Vendor Outsourcing, Gilead Global

Hansu Dong, Executive Director, Clinical Outsourcing & Business Operations, Clinical Operations, Novavax

Rene Stephens, MSHS, Independent Consultant

Mary Frances Sassaman, Vice President, Project Delivery, ICON

12:45 Transition to Lunch

12:50 The New Age of R&D Procurement: Strengthen Vendor Performance Management & Oversight with Technology

Anca Copaescu, CEO, Strategikon Pharma

Over $50B are spent annually in R&D outsourcing across multiple service categories, supporting increasingly more complex studies with fewer resources. Core activities (RFP management, strategic partner governance and category sourcing) are painfully manual and lacking data driven analytics. Learn how technology increases business scalability in a resource-constrained environment, strengthening vendor oversight, minimizing compliance risks and reducing the overall cost of outsourcing execution.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction

Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap

Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs

Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck

Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.

With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

OUT WITH THE OLD, IN WITH THE NEW: IMPROVING ALLIANCES AND RELATIONSHIPS WITH NEW STRATEGIES

4:25 Chairperson's Remarks

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

4:30 Alliance Management in the Clinical Space: Strategies for Becoming a Partner of Choice

Brigid McTague, Vice President, Global Head, Planning, Resourcing and Partnerships Management, Janssen R&D

5:00 Throwing out the Alliance Playbook: Exploring a Site-Centric Approach

Noelle Gaskill, Head, Clinical Research Operations, Mirati Therapeutics

In a competitive landscape, what does a successful site organization alliance/collaboration look like? What is the latest in these models and how do you actually measure success? I look forward to covering at a high-level how the alliance space has evolved over my tenure in working with CROs and sponsors in a competitive landscape and how I use that knowledge to make a difference today.

5:30 User Support: The Intersection Between eClinical Software and a Site Centric Mindset

Bob Weney, Director, Global Client Services, Clinical Project Services, Almac Group

The success of your clinical trial in part relies on a positive experience for your sites and patients. As clinical trials become more intricate and run longer, sites are experiencing higher turnover rates than ever before. Join us as we discuss evolving trends in daily user support needs/requests.

6:00 Partnering for Success, a Modern Solution to Outsourcing

Laurie Callen, Senior Director, Clinical Data Management, Moderna Therapeutics

David Geismer, Senior Vice President, Professional Services, Medidata

Sponsors rely on technology companies to support their clinical trials. So how do Sponsors get the most value out of their vendors in order to effectively and efficiently run their trials? In this session, Moderna and Medidata discuss how they moved from the traditional sponsor/vendor relationship into a partnership that drove the successful completion of their COVID trials in record time. They will also showcase how this partnership is changing the way both companies operate today and into the future.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

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Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

BUILDING RELATIONSHIPS AND MANAGING RESOURCES IN A DIVERSE CLINICAL SUPPLY CHAIN AND PARTNER NETWORK

8:25 Chairperson's Remarks
Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

8:30 FEATURED PRESENTATION: Trends & Challenges in Pharma Sourcing and Procurement – Managing Relationships With The Modern Supplier
Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA
This presentation covers how Bayer's External Relationship Governance model adds value to the business ensuring a reliable partnership and complements the Sourcing & Procurement Functions, sharing current trends on procurement roles and the necessity to have an operational perspective in sight, with different approaches from different business necessities and how to best manage CMOs, 3PLs and Clinical Trials partners.

9:00 PANEL DISCUSSION: How Small Biotechs Develop, Manage, and Maintain Relationships with CROs
Moderator: Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences
This panel will discuss the key considerations for smaller biotechs in selecting CROs to work with, how small biotechs can position themselves as valuable partners to CROs, and strategies for managing and maintaining relationships with CROs.
Panelists:
Hansu Dong, Executive Director, Clinical Outsourcing & Business Operations, Clinical Operations, Novavax
Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.
Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.

10:00 Talk Title to be Announced
Speaker to be Announced

10:15 Impact of FDA's Guidance on Diversity and Inclusion on Post Marketing Research
Sean Kennedy, MPH, Executive Director, Therapeutic Strategy Lead, Real World Evidence, Worldwide Clinical Trials
Aman Khera, MBA, FRAPS, FTOPRA, Vice President, Global Head of Regulatory Strategy, Scientific Solutions, Worldwide Clinical Trials
Daniel Perez, CCRP, Director and Global Head of Patient Experience, Patient Experience, Diversity & Inclusion, Worldwide Clinical Trials

10:45 Networking Coffee Break

MITIGATING THE IMPACT OF STAFF TURNOVER ON RESOURCES AND OUTSOURCING THROUGH TALENT RETENTION AND DEVELOPMENT

11:05 Chairperson's Remarks
Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson

11:10 PANEL DISCUSSION: Strategies to Attract, Engage, and Retain Talent During Times of Change
Moderator: Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson
This panel will discuss the impact staff turnover has on clinical trial operations and outsourcing, working with CROs and sites to mitigate staffing changes, insights on returning to the office, DE&I efforts, and meaningful changes that impact employees, and how to develop talent and grow people into careers.
Panelists:
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Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Endo Pharmaceuticals
Valerie Balosso, Director, Data Management, Infectious Diseases, GSK

12:10 pm The Tempus TIME Network
Matthew Cooney, Vice President, Therapeutic Development, Oncology, Medical Science, Tempus Labs
The TIME Network screens hundreds of thousands of patients daily using a combination of technology and nursing review to find potential trial subjects. Once an appropriate patient is identified, the trial site is rapidly opened using a pre-approved clinical trials agreement, regulatory process, central IRB, and uniform contracting. This streamlined process has empowered the TIME Network to activate hundreds of trials in an average of 10 days.

12:40 Transition to Lunch

12:45 SCOPE Send off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Cambridge Healthtech Institute's 4th Annual

Data Technology for End-to-End Clinical Supply Management

Controlling the Complexity of Clinical Supply Chain Forecasting and Contingency Planning

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 6th Annual

Clinical Supply Management to Align Process, Products, and Patients

Managing the Supply Chain and Maintaining Resiliency in a Complex Ecosystem

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

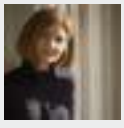
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

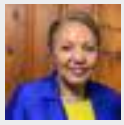
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education



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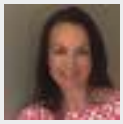
Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

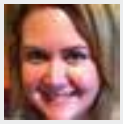
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 SCOPE's Kick-Off Happy Hour

7:45 Close of Day

TUESDAY, FEBRUARY 7

7:00 am Registration Open

7:30 Morning Brew & Pastries to Jumpstart Your Day *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 Chairperson's Remarks


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 Chairperson's Plenary Keynote Introduction
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 Would I Want My Mother to Be Part of a Clinical Trial?
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 Grand Opening Coffee and Refreshment Break in the Exhibit Hall

TOOLS FOR TRACKING, MONITORING, MANAGING, AND ANALYZING COMPLEX SUPPLY

10:35 Chairperson's Remarks
Todd Kole, Vice President, Clinical Project Services, Clinical Technologies, Almac Group

10:40 How Real-Time Monitoring of IP Can Reduce Site Burden while Reducing Excursions
Evan Hahn, Vice President North America, North America, TSS AB
Advances in monitoring technology present opportunities to track temperature in real-time. This allows sponsors the best of both worlds – the ability to significantly reduce temperature excursions, while also reducing the work required from site staff. This presentation will cover how these technologies are being applied and provide real-world metrics that illustrate the positive outcomes in clinical settings.

11:10 Outsourcing to Technology Vendors: Contracts, Metrics, and Challenges
Nick Lewis, Head, PRO Development Strategic Sourcing, Bayer
With decentralized clinical trials and patient centricity being accelerated in the light of the COVID-19 pandemic, there are a plethora of suppliers offering wearable, biosensors, devices, and app services. With the shift from traditional suppliers to technology vendors, how do we ensure the solution is fit for purpose, the supplier can meet sponsor expectations, and the clinical trial proceeds as per the plan?

11:40 Clinical Supply: Reducing Risk and Cost through Simulations and Machine Learning
Leslie Taylor, Director, Global Clinical Supply Chain Technologies, Incyte Corp.

12:10 pm Using Low-Code Automation to Manage the Clinical Supply Chain
Lisa Cannarella, Global Life Sciences Industry Lead, Appian
Carla Galdos, Assoc. Dir, Master Planning and Scheduling, Merck
Amaury Ginart, Assoc. Dir, New Technologies, Merck
Pramod Sachdeva, Founder and Managing Director, Princeton Blue
The Merck Global Clinical Supply Chain demand has been increasing, exceeding everyone's expectations. Now more than ever, it's imperative that we find ways to get clinical supplies to patients. Merck in partnership with Appian and Princeton Blue, used an Agile methodology to develop the Clinical Supply Scheduling Tool and Clinical Supply Release Tool which drive significant value. Join us to learn about Clinical Supply Chain tracking using process workflow and automation.

12:40 Transition to Lunch

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Coffee and Dessert Break in the Exhibit Hall

IRT – HOW TO EFFECTIVELY MANAGE VENDORS AND SYSTEM STANDARDS

2:10 Chairperson's Remarks
Maria Napoliello Humagain, Director, Clinical Supply Technologies, Arcus Biosciences

2:15 IRT Success in Challenges
Alminaz Noorani, Senior Manager Clinical Systems, Global Development Operations, Ultragenyx Pharmaceutical, Inc.
A deep dive into identifying and working with stakeholders in the lifecycle of IRT system development and beyond. Navigating challenges along the way to ensure a robust and successful study build and documentation.

2:45 Setting up IRT Standards, Preferred Vendors, and Governance
Maria Napoliello Humagain, Director, Clinical Supply Technologies, Arcus Biosciences
Creating and maintaining a relationship with the IRT vendor is very important. In order to establish this, the sponsor should set up preferred standards and governance with the IRT vendors. Part of this is working together as

a team and creating a standard that is vendor agnostic and simple. Using a governance plan and KPIs to keep track of trends and issues will help maintain quality and performance.

3:15 Collaborative RTSM Delivery Driving Quality & Time Savings
Brian Dunton, Head, Client Services, Atreo.io
In this session we will discuss strategies for success, including: pre-kickoff and kickoff preparation, common challenges/pitfalls during system design, standards, configuration vs. customization pros and cons, integration implementation(s), UAT, and post go-live change management.

3:45 Talk Title to be Announced
Speaker to be Announced

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
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WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced
Speaker to be Announced

9:00 Session Break

MANAGING THE DIVERSE ECOSYSTEM OF A CLINICAL SUPPLY CHAIN NETWORK

9:10 Chairperson's Remarks
Kevin R. Collier, Vice President, RTSM Product Management, Medidata

9:15 Global Resource Planning Tool for Clinical Supplies Project Management
Michael Wichtendahl, Director, Clinical Drug Supply Management, AbbVie
This presentation covers the development of a Global Resource Planning Tool to manage the Clinical Supply Project Manager resources across all clinical trial packaging projects. The tool utilizes study start/end data from Clinical Planning and is used in combination with pre-defined study metrics and project complexity data to define resource requirements and forecast staffing needs.

9:45 Presentation to be Announced

10:15 The Race with Changing Supply Management Regulations: How Your IRT Can Help You Stop Playing Catch-up and Get Ahead
Matthew Lowrie, Quality Assurance Manager, Clinical Technologies, Almac Group
Being the #1 IRT vendor gives some great insight into the current regulatory landscape. We want to give a peek behind our curtain into what WE see in supporting our clients. This discussion will highlight successes and failures that we've seen when it comes to eClinical systems and inspector's inquiries on Labelling, Direct to Patient, Supply Strategies, Expiry, and more! Join Us.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

SUPPLY, CAPACITY PLANNING, AND RESOURCE MANAGEMENT FOR COMPLEX CLINICAL TRIALS

11:40 Sponsored Presentation *(Opportunity Available)*

11:45 Presentation to be Announced

12:15 pm Presentation to be Announced

12:45 Transition to Lunch

12:50 Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction
Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

MAINTAINING MOMENTUM FOR EXTENDING USEFUL LIFE OF UNUSED CLINICAL TRIAL SUPPLIES – SUCCESSFUL REVERSE LOGISTICS

4:25 Chairperson's Remarks
Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer

4:30 Optimizing Clinical Supply Chain Management
Hope Meely, Chief Clinical Officer, Slope
In this session, clinical operations teams, project managers, and clinical research coordinators will learn best practices to optimize clinical supply chain management, including facilitating collaboration between sponsors, CROs, sites, labs, vendors, and biorepositories; obtaining real-time visibility into the location and status of IP, lab kits, samples, and supplies; gaining traceable chain-of-custody for biological samples, IP, lab kits, and supplies; and ensuring compliance through protocol adherence and amendment harmonization.

4:45 Sponsored Presentation *(Opportunity Available)*

5:00 Bayer Update on Full Kits4Life Program Implementation, Impact, & Moving on with Expanded Partnerships and Scope
Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer
Bayer will share how they created the pilot for their clinical trial sites to donate unused clinical trial supplies for humanitarian aid with the help of Kits4Life program coordinators. And Bayer's efforts in implementing, scaling and expanding the initiative with other partners. A panel discussion will follow with other sponsors who will share their recent pilot experiences. Come learn about the toolkit and how you can incorporate Kits4Life into your organization.

5:30 Presentation to be Announced

6:00 PANEL DISCUSSION: Reimagining Reverse Supply Chain Logistics to Make a Meaningful Impact on Global Health
Moderator: Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer
Panelists:
Greg Folz, CCRP, Founder, Kits4Life
Josh Kravitz, Kits4Life Program Coordinator, MedSurplus Alliance

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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

BUILDING RELATIONSHIPS AND MANAGING RESOURCES IN A DIVERSE CLINICAL SUPPLY CHAIN AND PARTNER NETWORK

8:25 Chairperson's Remarks
Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

8:30 FEATURED PRESENTATION: Trends & Challenges in Pharma Sourcing and Procurement – Managing Relationships With The Modern Supplier
Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA
This presentation covers how Bayer's External Relationship Governance model adds value to the business ensuring a reliable partnership and complements the Sourcing & Procurement Functions, sharing current trends on procurement roles and the necessity to have an operational perspective in sight, with different approaches from different business necessities and how to best manage CMOs, 3PLs and Clinical Trials partners.

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Daniel Perez, CCRP, Director and Global Head of Patient Experience, Patient Experience, Diversity & Inclusion, Worldwide Clinical Trials

10:45 Networking Coffee Break

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

Valerie Balosso, Director, Data Management, Infectious Diseases, GSK

12:10 pm **The Tempus TIME Network**

Matthew Cooney, Vice President, Therapeutic Development, Oncology, Medical Science, Tempus Labs

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12:40 **Transition to Lunch**

12:45 **SCOPE Send off Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 **Closing Remarks**

1:20 **Scope Summit 2023 Adjourns**

Cambridge Healthtech Institute's 15th Annual

Clinical Data Strategy and Analytics

Data to Empower Digital and Hybrid Trials

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 6th Annual

Artificial Intelligence in Clinical Research

AI to Support Clinical Trial Transformation

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
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1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
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2:00 User Group Meetings
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 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! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

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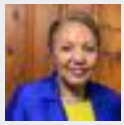


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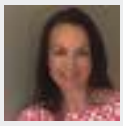
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

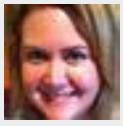
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 SCOPE's Kick-Off Happy Hour

7:45 Close of Day

TUESDAY, FEBRUARY 7

7:00 am Registration Open

7:30 Morning Brew & Pastries to Jumpstart Your Day *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 Chairperson's Remarks


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 Chairperson's Plenary Keynote Introduction
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 Would I Want My Mother to Be Part of a Clinical Trial?
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 Grand Opening Coffee and Refreshment Break in the Exhibit Hall

NEW TOOLS AND APPROACHES

10:35 Chairperson's Remarks
Ralph Russo, Senior Director & Global Head, Clinical Database Management, Pfizer Inc.

10:40 Methods for Automating Clinical Database Build – How to Leverage Metadata to Reduce Cycle Times
Ralph Russo, Senior Director & Global Head, Clinical Database Management, Pfizer Inc.
This session will showcase methods to minimize the cycle time for database build. The session will highlight a simple method to leverage standard metadata to iteratively prototype the clinical database while the protocol matures. We'll explore emerging methods that build upon this concept to further reduce cycle times and increase quality.

11:05 Status Update of a next generation platform to optimize transformation and review of increasingly complex clinical trial data
Ward Lemaire, Head of Data Management, Integrated Data Analytics & Reporting, Janssen, J&J
With the accelerated increase and complexity of clinical data sources, we need to modernize our digital environments to take full advantage of automation, near real-time access to data, and provide the capability for integrated review processes and collaboration across departments. The future platform will facilitate significant cost and time efficiencies and prepare for future capabilities driving risk-based medical and clinical data review with Artificial Intelligence and Machine Learning capabilities.

11:30 Building Next-Generation Systems for Clinical Development
Narayanarao Pavuluri, Senior Director & Global Head, Clinical Database Services, Merck
How can we build the next-generation of interconnected systems to alleviate siloed data, and streamline processes to have a smooth flow of data with proper controls while providing enhanced functionality, user experience, and flexibility to individual functional areas?

11:50 Debunking the Myths with the Application of Advanced Analytics in Clinical Development
Nareen Katta, Head of Data Science & Analytics, AbbVie, Inc.
The data and analytics space continues to evolve rapidly, and leaders often get overwhelmed by the technical jargon like Big Data, Machine Learning, Artificial Intelligence, etc. This talk explores different case studies that highlight the successes and challenges of enabling advanced analytics in clinical development.

12:10 pm Artificial Intelligence Can Improve Patient Experience in Decentralized Clinical Trials
Łukasz Kidziński, PhD, Director of Artificial Intelligence, Research & Development - Imaging, Clario
Kevin Thomas, PhD, Director of Artificial Intelligence, Research & Development, Clario
The clinical trial industry is undergoing a rapid transition toward decentralization, where some or all health assessments are performed remotely in participants' homes instead of in medical centers. Adopting artificial intelligence in this setting can empower more patients to enroll in trials, successfully complete them without burden, and submit high-fidelity assessments of their health. In this talk we will discuss insights from our recent article in Nature Medicine on this topic.

12:40 Transition to Lunch

12:45 Using AI to Drive Clinical Data Automation
Suman Kumar, Senior Manager, Life Sciences, Deloitte
Girish Rajeev, Global Head, Clinical Data Standards, Takeda Pharmaceuticals
The traditional flow of data across the clinical trial life cycle can become a complicated maze of manual effort, rework, and inefficiency—contributing to trial time and cost. Companies should harness AI to streamline the clinical trial data lifecycle, and open new opportunities. We'll discuss: Challenges with traditional approaches to managing clinical study data and potential for AI to deliver faster, more efficient, and significantly less expensive clinical trials.

1:15 Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

ADVANCED ANALYTICS FOR CLINICAL OPERATIONS TRANSFORMATION

2:10 Chairperson's Remarks
Ubong Peters, PhD, Operations Insights Analyst, Product Development Global Clinical Operations, Genentech

2:20 Accelerating Clinical Trial Enrollment viaMed.ai – Site Intelligence Hub
Xiaoying Wu, Vice President, Data Platforms & Privacy, Janssen Pharmaceuticals, Inc.
Site selection is one of the known bottlenecks for clinical trials. We created Site Intelligence Hub to overcome some of the challenges and to accelerate the process of study start-up.

2:45 Moving Clinical Research into the Digital Era with Autonomous Clinical Data
Julie Smiley, Senior Director Life Sciences Product Strategy, Oracle
With the exponential growth and complexity of clinical trial data sources, traditional study setup and conduct processes are becoming unsustainable. Hear how Oracle has leveraged the TransCelerate DDF toolkit to automate study setup and data flow to help sponsors and CROs significantly streamline processes, while reducing costs and timelines.

3:15 Hypevs Reality – How to Operationalize Data Science Approaches for Trial Operations
Taylor Uttley, Senior Director, Head of Strategy and Operations, Data Strategy & Solutions, Vertex Pharmaceuticals, Inc.
Lily Xu, PhD, Senior Principal Data Scientist, Data Science, Vertex Pharmaceuticals, Inc.
We have experimented over the years with using public and private data sources to help study teams select sites and PIs, which is very important but sometimes challenging for rare disease clinical development. It's critical to work with the business to optimize the right questions for AI/ML applications to get the most value from large-scale RWD datasets. Lessons learned from the data science point of view will be shared.

3:45 Using In-Trial Analytics to Drive DCT Endpoint Quality
Alan Kott, Clinical Vice President, Practice Lead, Data Analytics, Signant Health
In this session we will present examples and use cases for applying advanced data analytics tools and principles to optimize endpoint quality in decentralized trials.

DATA REQUIREMENTS FOR AI – POWERED SOLUTIONS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
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WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced
Speaker to be Announced

9:00 Session Break

DATA MANAGEMENT FOR DIGITAL TRIALS

9:10 Chairperson's Remarks
Rakesh Maniar, Head of eClinical Technologies, Global Data Management & Standards, Merck & Co.; Co-Lead, TransCelerate eSource Initiative; Immediate Past Co-Chair/Co-Founder, SCDM eSource Implementation Consortium

9:15 Towards a Digital Data Platform for Connected Clinical Trials
Hui Zhang, PhD, Senior Director, Digital Office, Eli Lilly & Co.
While digital health technology promotes the ability to collect wearable sensor data, what matters more than that is how some of these most complex digital data can be efficiently visualized, extracted, and analyzed for digital measures development. We would like to present Lilly's example of what a digital data platform should (and can) do to ensure dBM research is done efficiently and rigorously.

9:45 Digitalized Clinical Development: The Future of Pharmaceutical Drug Development
Gregg Dearhammer, Senior Vice President, Data Sciences, Safety & Medical Services, IQVIA
Barrie Nelson, Founder & Executive Vice President, Clinical Innovation, Nurocor
Mike Sullivan, Executive Director, Global Clinical Development IT, Bristol Myers Squibb
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.

10:15 Talk Title to be Announced
Speaker to be Announced

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

NOVEL INTEGRATIVE SOLUTIONS

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

11:45 AI Usage in Clinical Data
Christopher P. Lamplugh, Associate Vice President & Head, Global Data Management & Standards, Merck & Co., Inc.
Rakesh Maniar, Head of eClinical Technologies, Global Data Management & Standards, Merck & Co.; Co-Lead, TransCelerate eSource Initiative; Immediate Past Co-Chair/Co-Founder, SCDM eSource Implementation Consortium
Exploration of AI training, accuracy, and the precision of outputs in the validation of clinical data.

12:15 pm Talk Title to be Announced
Speaker to be Announced

12:45 Transition to Lunch

12:50 Optimize Data Acquisition in a Data-Rich World
Walker Bradham, Product Leader, Clinical Development, Product Management, Merative
Amanda Cross, Vice President, Biometrics, Worldwide Clinical Trials
Jennifer Duff, General Manager, Clinical Development Solutions, Product Management, Merative

Whether you ride atop the wave of data in your next clinical trial, or swim hard against it depends on this: getting data management right. The first time. For all the data you harness during decentralized trails, learn about action-oriented tools that make it easier to collect, access and ensure data integrity and traceability. Employ quick configurations and built-in validation, then use that ocean of valuable data to deliver measurable results.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 **Plenary Keynote Introduction**
Ivor Clarke, CEO, SubjectWell

2:25 **Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways**
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 **Advancing Evidence Generation of the Future**
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 **Fireside Chat: Next-Generation Data Sources**


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 **Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap**



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 **Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

AI TO TRANSFORM CLINCAL DEVELOPMENT

4:25 **Chairperson's Remarks**
Speaker to be Announced, Objective Health

4:30 **AI for Clinical Operations Solutions**
Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
This session will describe Pfizer's AI journey through the lens of clinical data, use cases, implementation, and key to success. Clinical Data Management for the Vaccine Study presented an opportunity for ML/NLP to assist in saving valuable time reconciling data. The foundation for a Smart Data Quality strategy was expanded to other TAs thanks to the solution's Pattern Recognition and Clinical Inference capabilities that will be explained in detail.

4:50 **Natural Language Generation in Clinical Research**
Brian Martin, Head of AI, R&D Information Research, Research Fellow, AbbVie, Inc.
NLP is a conventional approach. We are moving forward with natural language generation as the next step. It will be a game-changing solution once it moves to the mainstream.

5:20 **Graph Machine Learning Meets Clinical Ops: The Lessons Learned and Best Practices from Building TrialGraph**
Shameer Khader, PhD, Senior Director AI & Machine Learning & Data Science, Digital Health & Bioinformatics, AstraZeneca Pharmaceuticals, Inc.
Pharmaceutical companies can leverage systematic analyses of the data streams generated during clinical trials to improve future clinical trials. However, traditional analytical approaches cannot handle variables' sparsity or high-dimensional relationships. We have been developing TrialGraph – a technology solution to intelligently optimize tasks, including side effect prediction. During this session, I will share our lessons learned and best practice recommendation in building enterprise-scale analytic solutions to accelerate clinical development.

5:30 **Connected Intelligence from Enrollment Planning to Trial Conduct**
West Barnes, Senior Director, Product Analytics Center of Excellence, R&D Solutions, IQVIA
Wendy Morahan, Senior Director, Clinical Data Analytics, IQVIA Technologies
In this session you will learn how IQVIA is using real-world data and connected intelligence to build decision support technologies that can optimize clinical trial strategies based on sponsor constraints such as cost, risk, and time. West Barnes and Wendy Morahan will provide a closer look at how AI powered technologies can enable you to uncover deeper insights, make better decisions, and improve outcomes.

6:00 **What to build an AI model? Start with a data strategy first.**
Victoria A. Gamerman, PhD, Global Head of Data Governance, Boehringer Ingelheim Pharmaceuticals, Inc.
Accelerating speed of delivering medicines to the people who need them starts with understanding the end to end data flow. This includes organizational models that have capabilities to describe data with its biases and leverage metadata to support the speed of finding necessary information contained in the data. The solution starts with a holistic Data Strategy that lives at the intersection of Clinical Strategy and Digital Strategy.

6:30 **Close of Day**

6:30 **SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)**
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On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

CASE STUDIES AND ETHICAL USE DISCUSSION

8:20 Chairperson's Remarks
Speaker to be Announced, Saama

8:25 AI-Enabled Endpoints and Decision-Making in Clinical Development
Gregory V. Goldmacher, MD, PhD, MBA, Head of Clinical Imaging, Merck & Co.
One of the most powerful applications of AI is a form of pattern recognition that can operate at scale, using inputs that humans find difficult/impossible to evaluate. This allows measurement of safety and efficacy in clinical trials using fewer subjects, with greater confidence in the result than is possible with traditional methods. We will discuss the opportunities for sponsors to improve their trials using AI tools, with illustrative examples.

8:40 How much uncertainty can AI eliminate in recruitment rate prediction?
Lucas Glass, Vice President, Analytics Center of Excellence, IQVIA
Estimating enrollment rates accurately is a critical function of portfolio and study planning but accurate estimations are notoriously difficult. Artificial intelligence can be used to generate recruitment rate predictions that mitigate risk and uncertainty. This presentation outlines methods, approaches, experimental results, and practical considerations for using machine learning to predict enrollment rates for clinical trials.

8:55 Leveraging AI and Machine Learning to Assemble Documents for Clinical Events Adjudication
Kris Ulstad, Staff Clinical Software Engineer, Clinical Data Operations, Abbott
We have made major enhancements to automate workflow and reduce event prep time. We have incorporated our Document Redaction Tool which uses Machine Learning to identify and redact PHI and other confidential information. With a new dashboard to help prioritize tasks, the CSA's improved functionality will help users spend less time browsing screens and more time managing events so they can get adjudicated on time.

9:15 Utilization of Artificial Intelligence and Lessons Learned from the Ph3 VISION Trial
Phillip Kuo, M.D., Ph.D., Senior Medical Director, Scientific and Medical Services, Invicro
During this talk, we will discuss:
• Overview of the key obstacles and successes of the VISION trial
• Rationale underpinning the novel read criteria for the VISION trial
• Use of artificial intelligence in the quantification of PET imaging
• Combining quantification and personalized dosimetry to potentially improve outcomes.

9:40 AI-Enabled Endpoint – A Case Study
Kenneth Broos, Clinical Innovation Leader, Digital Measurement Solutions, Johnson & Johnson Pharmaceutical R&D
Scoring imaging is difficult for humans to perform and yet forms the basis for critical endpoints in trials. AI provides a perfect supplement to increase accuracy and has the potential to decrease sample size. Large past trials and their data form the ideal catalyst to expedite progress. A case study in the field of RA/PSA.

10:00 Talk Title to be Announced
Speaker to be Announced

10:15 PANEL DISCUSSION: Ethical Use of AI: GMLP in Clinical Trials
Moderator: Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
Panelists:
Brian Martin, Head of AI, R&D Information Research, Research Fellow, AbbVie, Inc.
Matthew Studney, Vice President, MRL IT, Merck & Co.
Lucas Glass, Vice President, Analytics Center of Excellence, IQVIA

10:45 Networking Coffee Break

STRATEGY LEVEL DATA SOLUTIONS

11:05 Chairperson's Remarks
Speaker to be Announced, Median Technologies

11:10 Novo Nordisk on Launching a New Data Science and Innovation Group
Adama Ibrahim, Vice President, Digital Strategy & Change Management, Novo Nordisk
Showcase this new group dedicated to ultimately unlocking a future without chronic diseases. We will share a case study of how we work to harness disruptive innovation from disease understanding to molecular design, and portfolio management through cutting-edge analysis of high-quality scientific and patient data. Specialist areas this group covers include automation, AI/ML, external intelligence, data strategy, and infrastructure.

11:40 Talk Title to be Announced
Speaker to be Announced

12:10 pm Merck's Strategic IT Approach to AI Use in Clinical Development
Matthew Studney, Vice President, MRL IT, Merck & Co.
This presentation will explain the strategic approach and various use cases for the application of AI throughout the Clinical Development environment at Merck.

12:40 Transition to Lunch

12:45 Using Technology to Streamline Study Conduct in a Scalable, Efficient Manner
David Blackman, Executive Director Digital Trials Strategy, Oracle
Greg Jones, Life Sciences & Healthcare Chief Technology Officer, Oracle
Learn how a consistent foundation spanning governance to provenance of data, automated pipelines for consolidation and aggregation of data, and democratization to the generation of insights through the development of AI/ML models can help streamline your study and provide unprecedented insights into the clinical continuum.

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Cambridge Healthtech Institute's 2nd Annual

Decentralized and Hybrid Trials

Best Practices and Winning Strategies for DCTs

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 12th Annual

Decentralized Trials and Clinical Innovation

Technology and Infrastructure for DCTs

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

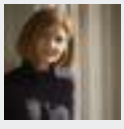
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

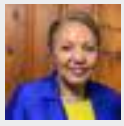
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education






Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
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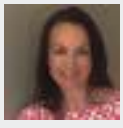


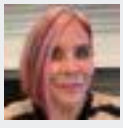


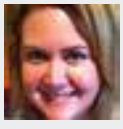


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Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 SCOPE's Kick-Off Happy Hour

7:45 Close of Day

TUESDAY, FEBRUARY 7

7:00 am Registration Open

7:30 Morning Brew & Pastries to Jumpstart Your Day *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 Chairperson's Remarks


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 Chairperson's Plenary Keynote Introduction
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 Would I Want My Mother to Be Part of a Clinical Trial?
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 Grand Opening Coffee and Refreshment Break in the Exhibit Hall

DCTs ARE HERE TO STAY. ARE WE READY?

10:35 Chairperson's Remarks
Mark Maietta, President, Sales and Marketing/Commercial Ops, YPrime

10:40 Transforming Clinical Trials of the Future: A Look into Clinical Trials 2031 and beyond
Hassan Kadhim, Director & Head, Clinical Trial Business Capabilities, Bristol Myers Squibb Co.
This session will focus on TransCelerate's 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.

11:00 Implementing Disruptive DCT Approaches
Isaac R. Rodriguez-Chavez, PhD, Vice Chair, IEEE-SA-DCT Program
Multiple deficiencies have historically impacted traditional trials with recruitment and enrollment challenges, difficulties to retain trial participants, lack of inclusion and diversity, and difficulties with data quality. Traditional trials are now disrupted with DCTs which represent a multi-dimensional and multi-functional enterprise that combines scientific, medical, clinical research, operational, regulatory, legal, quality control, and quality assurance expertise.

11:20 Decentralized Trials Are Here to Stay – Do the Industry, Investigators, and Patients All Have the Same Understanding of the Concept?
Roland Barge, Associate Director, User Experience Research, Regeneron Pharmaceuticals, Inc.
Patrick A. Floody, Executive Director, Global Clinicl Trial Services, Regeneron Pharmaceuticals, Inc.
Advances in technology and changes in expectations due to COVID-19 have reportedly increased adoption of decentralized trials. Regeneron conducted two U.S.-focused surveys to determine the current perception and awareness of decentralized clinical trials from two non-industry perspectives. The first focused on clinical trial site perceptions of decentralized trials, and the second focused on clinical trial patients and healthy subjects. We also compared our results to recent industry data.

11:45 Clinical Trial Conduct across More USA Zip Codes – A Decentralized Approach
Conor Kane, Head, Process Data Integration EBIS, Janssen Pharmaceuticals, Inc.
Rachel Soon, Director, Janssen Clinical Innovation
Armed with the knowledge that 50% of FDA trials are conducted in 1-2% of zip codes in the US today, Janssen are exploring multiple, innovative options to expand into the remaining zip codes and enhance participant representation in our trials. We will aim to share lessons learned to date from our experience in providing more localized options to clinical trial participants.

12:10 pm Defining a Digital and Connected Future for Clinical Trials
Jim Reilly, Vice President, Development Cloud Strategy, Veeva
Richard Young, Vice President, Vault CDMS Strategy, Veeva
The industry is accelerating technology adoption under a decentralized umbrella. However, stakeholder collaboration remains a challenge. How can we deliver efficient practices that connect sites, patients, and researchers in a sustainable manner? We must continue the momentum toward patient- and site-centric trials with a digital model that is paperless, connected, and harmonizes data for a complete and concurrent view of studies. Join Veeva to discuss best practices driving digital trial transformation.

12:40 Transition to Lunch

12:45 Push & Pull: The Duality of Modern Clinical Trials
Derk Arts, MD, PhD, Founder & CEO, Castor
During this panel, Castor's Derk Arts will moderate a discussion on how to solve design and interoperability challenges that should be imperative in modern trials, and how we can break the shackles that still hold us back.

1:15 Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

EXPANDING ZIP CODE COVERAGE

2:10 Chairperson's Remarks *(Opportunity Available)*

2:15 The Transforming Landscape of Clinical Trial Locations: Community-Based, Home, Traditional, Retail, and Virtual

Josh Rose, Clinical Trial Innovation and Drug Development Executive, CVS Health

The traditional dedicated clinical trial site approach model has served its purpose well for years as the gold standard for clinical research. However, the industry is still plagued with low patient enrollment, imbalance in participant diversity, elongated timelines, and increasing study costs. It's time for the industry to embrace more current and evolved approach to clinical trial locations.

2:45 Designing for decentralization: An evidence driven approach to optimize protocols to realize the promises of DCTs

Amit Mudgal, Associate Principal, ZS

Arnab Roy, Decision Analytics Manager, ZS

Which assessments & visits can we feasibly decentralize? What are the risks and benefits to patients and sites if we were to decentralize specific assessments? Creating an analytical ecosystem to enable data & evidence based decision is critical for fit-for-purpose DCT study design and for upfront operational planning & risk mitigation.

3:15 Trust Is a Two-Way Street: How Industry Can Lead and Maintain Patient Engagement in DCTs

John Campbell, Head of Decentralized Trials, Walgreen Co.

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

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.

3:45 Talk Title to be Announced

Speaker to be Announced

4:00 Talk Title to be Announced

Speaker to be Announced

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

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

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

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program

Caroline Jackson, Executive Vice President, Patient Services, mdgroup

Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced

Speaker to be Announced

9:00 Session Break

STUDY DESIGN FOR DCT

9:10 Chairperson's Remarks

David Hadden, President and Founder, Pro-ficiency

9:15 DCT by Design – Using a Design Studio to Optimize SoA and DCT

Jade Dennis, Senior Director, Design Hub, Eli Lilly & Company

Sara Doshi, PhD, Senior Director, Decentralized Design & Delivery Integration, Eli Lilly & Co.

The Schedule of Activities (SoA) requires strong cross-functional collaboration to achieve an optimal design. A web-based design studio, backed by an SoA taxonomy, enables exploration of SoA designs that streamline trial delivery and support decentralization opportunities. As the digital design library grows and more studies deploy DCT capabilities, frequency of DCT utilization and impact to downstream operational metrics will be critical to future study success.

9:45 DCT Fireside Chat with Industry Leaders

Anthony Costello, CEO, Patient Cloud, Medidata, a Dassault Systèmes company

Designing and executing successful DCTs requires leadership, vision, and operational excellence. Join this session to hear from senior leaders in the industry on how to successfully implement DCT programs and why optimizing patient, site, and sponsor experiences is essential to running global clinical trials.

10:15 Improving the Patient Experience Through User-Focused Design

Karl McEvoy, Product Director, Decentralized Trial Technology, eCOA Product Innovation, YPrime

Expanding global reach and the move towards decentralized trial models means that we must evolve our technology to improve study experience for patients and sponsors. Software will be more heavily relied upon to keep patients connected, informed, and engaged. Let's explore the importance of utilizing user-focused research on software design and implementation in clinical trials.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

DCTs TO CHANGE SPONSOR-CRO DYNAMIC

11:40 Chairperson's Remarks

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

11:45 The Impact of Decentralized and Hybrid Trials on Sponsor-CRO Collaborations

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

The presentation will assess the impact of decentralized and hybrid clinical trials on sponsor-CRO relationships based on the results of a global survey. Current and planned usage of specific DCT solutions and technologies by organizations will be discussed. The role of CROs in DCT adoption and implementation will also be examined as well as those technologies and outsourcing approaches that are viewed as most effective by organizations.

12:05 pm Lessons Learned that Transform the Sponsor-CRO Relationship for Hybrid Decentralized Trials

Trinette Mitchell, Head, Emerging Priorities & Innovation, Takeda Pharmaceuticals, Inc.

A pilot DCT program evaluates how eTools for remote data capture and remote visits impact a collaborative operating model between the sponsor and CRO for study start-up. Lessons learned during the pilot program, further evolve the sponsor-CRO relationship in areas like protocol design and eTools feasibility.

12:25 **DCTs: Driving a New Paradigm of Partnering**
Tina Caruana, Subject Matter Expert, eClinical Solutions, Digital & Decentralized Trials, Medrio
DCTs offer a plethora of decentralized options, however, novel and often unproven approaches can be costly and complex for Sponsors and CROs to operationalize. At times, these new models have created unwanted burdens on clinical trial sites, a key stakeholder in the research continuum, and one that DCTs are meant to serve and empower. Attendees will learn the strategies Medrio used to effectively guide sites through uncharted waters of DCTs.

12:45 **Transition to Lunch**

12:50 **Clinical Outcome Assessments (COAs): Applying Scientific Rigor and Good Instrument Design**
Lindsay Hughes, PhD, Director, eCOA Science & Consulting, eCOA Science, Clario
Jowita Marszewska, PhD, Scientific Advisor, eCOA Science & Consulting, Clario
The bedrock of a successful trial is a well-designed protocol with reliable measurements of biomedical and health-related outcomes to satisfy regulatory standards. This session examines how scientific rigor can be applied to clinical outcome assessments (COAs) even though they are subjective. We will synthesize the scientific practices underpinning good instrument design and COA data collection methods and recommend next steps for addressing data collection challenges.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 **Plenary Keynote Introduction**
Ivor Clarke, CEO, SubjectWell

2:25 **Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways**
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 **Advancing Evidence Generation of the Future**
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 **Fireside Chat: Next-Generation Data Sources**


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 **Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap**



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 **Booth Crawl & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

DCT LEGO BLOCKS: WEARABLES, DATA, QUALITY

4:25 **Chairperson's Remarks**
Lindsay Hughes, PhD, Director, eCOA Science & Consulting, eCOA Science, Clario

4:30 **PANEL DISCUSSION: Digital Technologies to Enable Decentralized and Hybrid Clinical Trials**
Moderator: Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Hui Zhang, PhD, Senior Director, Digital Office, Eli Lilly & Co.

5:00 **Future Direction of Decentralized Clinical Trial Capabilities within a Quality Framework**
Teri Breedlove, Advisor Clinical Services and Capabilities, Eli Lily and Company
Joanne Dourado, Senior Director, Medicines Quality Organization
Since the COVID pandemic, the implementation of clinical trials utilizing Decentralized Trial (DCT) capabilities has become a priority for pharmaceutical companies. Trials that incorporate DCT capabilities include new complexities, often around remote patient visits. Here at Lilly, we have discovered new approaches for remote trial activities, while concurrently remaining focused on patient safety and data integrity. This proposal shares a path forward to address these complexities, including shared best practices.

5:30 **A Digital Device Case Study: Deploy, Connect, and Send Digital Data in Clinical Trials**
Erika Moree, Head of Learning and Development, ProofPilot
For decades, clinical research has been mostly centered on an "entered data" orientation. As clinical research becomes more remote and more digital, the challenges to collect this sort of data faithfully and responsibly has far exceeded our conventional capabilities. ProofPilot is proud to present a case study along with best practices on what it takes to efficiently deploy devices, connect them, send digital data, and return them.

6:00 **Data-Driven Approaches to Re-Design Clinical Trials to Enable Decentralization**
Shivani Mehta, Associate Director Data Science, Janssen R&D
This presentation will focus on the strategy and approach for decentralized clinical trials using a data-driven AI/ML approach. Key highlights of the presentation will include developing our vision and strategy, and more specifically our suite of tools that focus on protocol optimization by reimagining Schedule of Activities.

6:30 **Close of Day**

6:30 **SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)**
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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

SCALING DECENTRALIZATION WITH NEW STANDARDS AND APPROACHES

8:25 Chairperson's Remarks
Melissa Nezos, Executive VP, Clinical Operations, Firma Clinical Research

8:30 Developing Industry Guidelines and Standards for DCTs Enabled by Digital Health Technologies
Isaac R. Rodriguez-Chavez, PhD, Vice Chair, IEEE-SA-DCT Program
Mathew Rose, MD, Co-Chair, IEEE, Founder and CEO, SAAVHA, Inc.
Historical limitations of traditional trials have led the industry to find better solutions – DCTs enabled by technology whose value proposition includes optimized efficiencies in all steps of trials while enhancing diversity, inclusivity, and participant-centric approaches. Despite fast DCT adoption, there is confusion. The IEEE-SA-DCT program is set up to develop the industry DCT guidelines and standards to harmonize best practices. This program will be discussed in this presentation.

9:00 The Role of the Community Pharmacist in Decentralized and Hybrid Trials
Jake, Galdo, PharmD, MBA, BCPS, BCGP ESPhA Pharmacy Quality Advisory and Consultant
Tina Schlecht, PharmD, MBA, Chief Pharmacy Officer at RxE2
Norris G. Turner, PharmD, PhD, resident & CEO, Turner Healthcare Quality Consulting, Inc.
Community pharmacists play a key role in the future of clinical trials. This session presents the current ways community pharmacists are supporting clinical trials in their communities and the future opportunities as more trials move to hybrid and decentralized conduct. Hear from pharmacists engaged in the process about the success of patient recruitment via local pharmacies and the next steps for addressing patient diversity and patient retention.

9:30 Increasing Patient Engagement and Retention through Patient-First Digital Trial Solutions
Mohamed "Mo" Ali, Chief Domain Expert, Medable
Access to clinical trials is a human right and participation should be easy yet lack of diverse patient populations and high drop-out rates remain persistent challenges for sponsors alike. In this discussion, Mohammed Ali will share how Medable is dramatically broadening the reach of research to increase trial diversity while easing patient and site burden through the use of Patient-first digital trial tools designed to improve engagement, retention and data quality.

9:45 Talk Title to be Announced
Speaker to be Announced

10:15 Talk Title to be Announced
Speaker to be Announced

10:45 Networking Coffee Break

SCALING DCT EFFORTS BEYOND ZIP CODE AND COMPANY LIMITS

11:05 Chairperson's Remarks
Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

11:10 Talk Title to be Announced
Speaker to be Announced

11:40 Real-World Results from Ongoing DCT Collaboration between Moderna, CVS, and Centricity Research
Ricardo De Lemos, Exec Dir Project Mgmt, Clinical Trial Svcs, CVS Health
Jeff Kingsley, Founder & CEO, IACT Health
Jessica Perry, Director, Patient Centricity, Clinical Innovation, Moderna
DCT design requires more complexity than brick-and-mortar research. Despite your best intentions, items can get overlooked. Our real-world experience can help guide you to success by demonstrating what we overlooked or dismissed and what we learned.

12:10 pm Cross Industry Initiatives to Ease DCT Adoption: Updates from DTRA
Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
The Decentralized Trials & Research Alliance enables collaboration of stakeholders to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research.

12:40 Transition to Lunch

12:45 Luncheon Presentation to be Announced
Speaker to be Announced

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Cambridge Healthtech Institute's 6th Annual

Sensors, Wearables and Digital Biomarkers in Clinical Trials

Digital Measurements and Endpoints in Hybrid and Conventional Trials

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 12th Annual

Decentralized Trials and Clinical Innovation

Technology and Infrastructure for DCTs

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

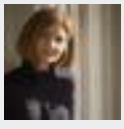
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

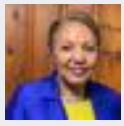
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education





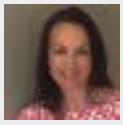




Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

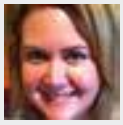
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 SCOPE's Kick-Off Happy Hour

7:45 Close of Day

TUESDAY, FEBRUARY 7

7:00 am Registration Open

7:30 Morning Brew & Pastries to Jumpstart Your Day *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 Chairperson's Remarks


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 Chairperson's Plenary Keynote Introduction
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 Would I Want My Mother to Be Part of a Clinical Trial?
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 Grand Opening Coffee and Refreshment Break in the Exhibit Hall

DIGITAL BIOMARKERS IN CNS, SLEEP AND DERMATOLOGY TRIALS

10:35 Chairperson's Remarks
Speaker to be Announced, Clinical Ink

10:40 Precompetitive Development of Digital Measures in Parkinson's Disease
Jie Shen, PhD, Director, Digital Science, AbbVie
Measurement of the signs and symptoms of Parkinson's Disease using objective tools has a long history. This talk will cover the progress made by the precompetitive Digital Drug Development Tools (3DT) consortium led by the Critical Path for Parkinson's and its members to advance the scientific, operational, and regulatory maturity of DHTs for use in PD research and therapeutic development.

11:05 Novel AI-Enabled Sensors for Quantifying Itch By Measuring Scratch
Shuai Steve Xu, Asst Prof Dermatology & Medical Dir, Querrey Simpson Institute for Bioelectronics, Northwestern Memorial Hospital
As evidenced by a recent multi-pharma consortium with the Digital Medicine Society, there is strong interest in nocturnal scratch as a clinical endpoint. I am a board-certified dermatologist and biomedical engineer who has developed a novel wearable that quantifies scratch with an AI algorithm. We have validated this in children and adults with AD - with our papers being covered widely by the media.

11:20 Leveraging Clinical and Real-World Studies to Develop and Validate Nocturnal Scratch and Sleep Measurements
Sandra L. Goss, Director, Digital Health Strategy, AbbVie, Inc.
Measuring nocturnal scratch and sleep as digital endpoints in the clinic and real-world studies can generate insightful data, including feasibility, validation of digital tool and endpoint, and confirmation. Each study type and population bring its own set of benefits and challenges, and there are multiple ways to use studies throughout development to optimize the development of novel digital endpoints.

11:35 Validation and Application of the Novel Digital Endpoints of Nocturnal Scratch and Sleep
Carrie A. Northcott, PhD, Senior Director & Project Lead, Digital Medicine & Translational Imaging, Pfizer Inc.
Nocturnal scratching and sleep disruptions are key aspects of Atopic Dermatitis that until recently have been challenging to measure, especially in a quantitative manner. The use of digital health technology tools, viaaccelerometry, provides the opportunity to passively, quantitatively, and continuously measure these symptoms. A key aspect to provide value in these assessments is that they are validated and can detect clinically relevant changes.

11:55 Scratching Detection Algorithm and Digital Endpoints Development for Atopic Dermatitis Patients
Ju Ji, PhD, Senior Research Scientist, Eli Lilly & Co.
We developed algorithms to detect scratch and restless motions based on wrist-worn actigraphy signal data. The algorithm is used to extract digital endpoints to quantify and evaluate itch and sleep disturbance in an objective way. The validity and clinical relevance of the novel digital endpoints is demonstrated through 2 phase 3 compound studies.

12:10 pm The Value of Passive Data Collection: Tying Active Assessments to Passive Measurements in Clinical Research
Joan Severson, Chief Innovation Officer, Clinical ink

12:40 Transition to Lunch

12:45 Reinventing the Six Minute Walk Test: Medidata and Labcorp's Approach to Novel Digital Therapies
Ben Schlatka, VP, Digital Biomarker Solutions, Medidata, a Dassault Systèmes company
Traditional functional measures like the six minute walk test are status quo despite the widely held perception that they are imperfect and subjective. Sensors offer the promise of frequent and objective quantitation in real world

environments with low patient burden. Attend this talk to learn about our cutting edge approach to reinvent the most commonly used functional test in life science research. Validation and regulatory pathways will be discussed.

1:15 Coffee and Dessert Break in the Exhibit Hall

DHT EVOLVING REGULATIONS

2:10 Chairperson's Remarks
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.

2:15 A Learning Regulatory Ecosystem: Advances in Regulatory Thinking in the Use of DHTs in Clinical Trials (EMA, FDA and ICH guidance)
Lada Leyens, PhD, PD Regulatory, Personalized Healthcare, Digital Health Regulatory Shaping Lead, Clinical Trial Innovation, F. Hoffmann-La Roche Ltd.
There are different regulatory pathways available for digital endpoint development teams to get health authority advice on the validation of novel digital measures and their acceptability as label enabling endpoint in pivotal clinical trials. This presentation will cover examples of digital endpoint developments that used different regulatory pathways, their challenges and opportunities and considerations for regulatory strategies

2:45 How to improve clinical trial data with Continuous Glucose Monitoring (CGM)
Robert Sala, Director of External Research and CRO Integration, Research, Dexcom
Join Robert Sala, Director of External Research and CRO Integration at Dexcom, and Michael Brown, Executive VP of Global Commercial Operations at Woodley Trial Solutions. We discuss the significance of real-time data collection from a world-leading wearable CGM device innovation, and how this is utilized in hybrid clinical trials. We'll also make time for a Q&A session, so please don't miss your chance to ask your burning questions to the experts.

3:15 Regulatory Update on Digital Endpoints
Michael Benecky, Senior Director, Regulatory Affairs, UCB
The presentation will discuss the evolving regulatory guidelines for use of Digital Health Technology (DHT) within pharmaceutical clinical development programs. Good regulatory practice is based on the mitigation of potential patient risks mitigation prior to implementation that may arise from DHT use within a pharmaceutical clinical trial. DHT risks that require mitigation include errors in patient management due to DHT malfunction, patient data privacy/ cybersecurity, electrical safety, and material biocompatibility.

3:45 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
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WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced
Speaker to be Announced

9:00 Session Break

REGULATORY UPDATE

9:10 Chairperson's Remarks
Sandra L. Goss, Director, Digital Health Strategy, AbbVie, Inc.

9:15 PANEL DISCUSSION: Novel Evidence for Regulatory Decisions: The Key Factors for Success
Moderator: Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
We define the scope of novel evidence, including RWE, Digital Biomarkers, and Novel Digital Endpoints. There has been a proliferation and adoption of RWE and DHT in the life cycle of drug development to improve outcome measurements and accelerate medicine development. The Panelists will discuss lessons learned and dissect successful cases to identify key "must haves" on how to use novel evidence to support regulatory decisions.
Panelists:
Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

9:45 Disruptive and Patient-Focused: Innovation to Meet Digital Endpoints
Furat Shawki, Head, Product and Operations, Clinical Trials, NuvoAir
This session explores the value of integrating clinical trials as part of patients' daily lives. Topics include: performing complex data collection outside the traditional model; innovative, patient-centric solutions integrating medical devices, wearables, and activity trackers; and the role of AI and machine learning in disrupting clinical trials. Hear the benefits of capturing digital endpoints in both home and clinic—from the points of view of patients, study personnel, and sponsors alike.

10:15 Remote Symptom Monitoring: Combining Active and Passive Digital Measures
Nathan Cashdollar, PhD, Director of Digital Neuroscience, Operations, Cambridge Cognition
Many innovative approaches for remote symptom monitoring of patients have recently emerged to optimize the metrics captured in decentralized clinical trials. One of these techniques is deploying high frequency active assessments to enhance the contextual insight of measures captured via passive physiological sensors. Combining active and passive data capture allows for a more comprehensive characterization of patients' fluctuating symptoms and thereby provides a higher fidelity to detect therapeutic interventions.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

DIGITAL TRIALS: PATIENTS AND DATA SOLUTIONS

11:40 Chairperson's Remarks
Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.

11:45 UX Testing for Wearables in DCTs
Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron

12:15 pm The Anatomy of Connected Digital Health Platform
Gian Prakash, Associate Director, Data Engineering, Information Research, AbbVie Inc.
Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.
Clinical trials have been collecting different sources of digital data (wearables, sensors, apps, images, etc.). These digital data sources have created opportunities for sponsors to develop drugs for unmet needs and acquire quality patient data. To manage these data sources, sponsors are developing modern platforms. This session will provide an overview of the capabilities required to develop a Digital Health Platform and prepare data for review and submission.

12:45 Transition to Lunch

12:50 Luncheon Presentation to be Announced
Speaker to be Announced

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction
Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.
An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

DCT LEGO BLOCKS: WEARABLES, DATA, QUALITY

4:25 Chairperson's Remarks
Lindsay Hughes, PhD, Director, eCOA Science & Consulting, eCOA Science, Clario

4:30 PANEL DISCUSSION: Digital Technologies to Enable Decentralized and Hybrid Clinical Trials
Moderator: Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Hui Zhang, PhD, Senior Director, Digital Office, Eli Lilly & Co.

5:00 Future Direction of Decentralized Clinical Trial Capabilities within a Quality Framework
Teri Breedlove, Advisor Clinical Services and Capabilities, Eli Lily and Company
Joanne Dourado, Senior Director, Medicines Quality Organization
Since the COVID pandemic, the implementation of clinical trials utilizing Decentralized Trial (DCT) capabilities has become a priority for pharmaceutical companies. Trials that incorporate DCT capabilities include new complexities, often around remote patient visits. Here at Lilly, we have discovered new approaches for remote trial activities, while concurrently remaining focused on patient safety and data integrity. This proposal shares a path forward to address these complexities, including shared best practices.

5:30 A Digital Device Case Study: Deploy, Connect, and Send Digital Data in Clinical Trials
Erika Moree, Head of Learning and Development, ProofPilot
For decades, clinical research has been mostly centered on an "entered data" orientation. As clinical research becomes more remote and more digital, the challenges to collect this sort of data faithfully and responsibly has far exceeded our conventional capabilities. ProofPilot is proud to present a case study along with best practices on what it takes to efficiently deploy devices, connect them, send digital data, and return them.

6:00 Data-Driven Approaches to Re-Design Clinical Trials to Enable Decentralization
Shivani Mehta, Associate Director Data Science, Janssen R&D
This presentation will focus on the strategy and approach for decentralized clinical trials using a data-driven AI/ML approach. Key highlights of the presentation will include developing our vision and strategy, and more specifically our suite of tools that focus on protocol optimization by reimagining Schedule of Activities.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

SCALING DECENTRALIZATION WITH NEW STANDARDS AND APPROACHES

8:25 Chairperson's Remarks
Melissa Nezos, Executive VP, Clinical Operations, Firma Clinical Research

8:30 Developing Industry Guidelines and Standards for DCTs Enabled by Digital Health Technologies
Isaac R. Rodriguez-Chavez, PhD, Vice Chair, IEEE-SA-DCT Program
Mathew Rose, MD, Co-Chair, IEEE, Founder and CEO, SAAVHA, Inc.
Historical limitations of traditional trials have led the industry to find better solutions – DCTs enabled by technology whose value proposition includes optimized efficiencies in all steps of trials while enhancing diversity, inclusivity, and participant-centric approaches. Despite fast DCT adoption, there is confusion. The IEEE-SA-DCT program is set up to develop the industry DCT guidelines and standards to harmonize best practices. This program will be discussed in this presentation.

9:00 The Role of the Community Pharmacist in Decentralized and Hybrid Trials
Jake, Galdo, PharmD, MBA, BCPS, BCGP ESPhA Pharmacy Quality Advisory and Consultant
Tina Schlecht, PharmD, MBA, Chief Pharmacy Officer at RxE2
Norris G. Turner, PharmD, PhD, resident & CEO, Turner Healthcare Quality Consulting, Inc.
Community pharmacists play a key role in the future of clinical trials. This session presents the current ways community pharmacists are supporting clinical trials in their communities and the future opportunities as more trials move to hybrid and decentralized conduct. Hear from pharmacists engaged in the process about the success of patient recruitment via local pharmacies and the next steps for addressing patient diversity and patient retention.

9:30 Increasing Patient Engagement and Retention through Patient-First Digital Trial Solutions
Mohamed "Mo" Ali, Chief Domain Expert, Medable
Access to clinical trials is a human right and participation should be easy yet lack of diverse patient populations and high drop-out rates remain persistent challenges for sponsors alike. In this discussion, Mohammed Ali will share how Medable is dramatically broadening the reach of research to increase trial diversity while easing patient and site burden through the use of Patient-first digital trial tools designed to improve engagement, retention and data quality.

9:45 Talk Title to be Announced
Speaker to be Announced

10:15 Talk Title to be Announced
Speaker to be Announced

10:45 Networking Coffee Break

SCALING DCT EFFORTS BEYOND ZIP CODE AND COMPANY LIMITS

11:05 Chairperson's Remarks
Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

11:10 Talk Title to be Announced
Speaker to be Announced

11:40 Real-World Results from Ongoing DCT Collaboration between Moderna, CVS, and Centricity Research
Ricardo De Lemos, Exec Dir Project Mgmt, Clinical Trial Svcs, CVS Health
Jeff Kingsley, Founder & CEO, IACT Health
Jessica Perry, Director, Patient Centricity, Clinical Innovation, Moderna
DCT design requires more complexity than brick-and-mortar research. Despite your best intentions, items can get overlooked. Our real-world experience can help guide you to success by demonstrating what we overlooked or dismissed and what we learned.

12:10 pm Cross Industry Initiatives to Ease DCT Adoption: Updates from DTRA
Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
The Decentralized Trials & Research Alliance enables collaboration of stakeholders to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research.

12:40 Transition to Lunch

12:45 Luncheon Presentation to be Announced
Speaker to be Announced

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Your Safety Is Our Top Priority

To ensure maximum safety, CHI has instituted mandatory health and safety protocols for all attendees, exhibitors, speakers, and staff who attend in person. Attendees who cannot participate because of this policy, or due to travel restrictions, are encouraged to participate using our highly praised virtual event platform. Our virtual events are designed to provide you with an in-person experience at your convenience, anywhere, anytime. We are actively following news and recommendations around COVID-19 and the Omicron variant. These protocols are subject to change as we continue to learn more. All in-person attendees must: Have a negative COVID-19 test result from an FDA-authorized over-the-counter antigen test within 24 hours prior to arriving at the event. You will be asked about your results at registration. CHI recommends all attendees: Have an updated COVID-19 vaccination and wear a mask in public spaces at the event.

SCOPE 7th Annual

PARTICIPANT ENGAGEMENT AWARD

IN MEMORY OF JERRY MATCZAK
#BELIKEJERRY #SCOPE2023

February 6 at 5:00pm

WHAT IS IT?

Now in its 7th 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 2023 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, CRO's, e-Patient Advisors, Agencies, Start-Ups, and Sponsors and invite you to submit your best work in the Patient Recruitment and Retention communications field.

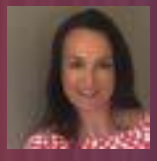
HOW TO WIN?

Your submission must truly be designed to engage potential, current, or alumni study participants and/or their influencers and show marked improvements in the status quo.

Submit your proposal by October 7, 2022

EVENT HOSTS & JUDGES

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



Kelly McKee
Vice President, Patient Recruitment and Registries, Medidata; Co-Creator of the SCOPE Participant Engagement Award

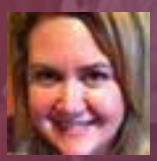
Micah Lieberman
Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

Gretchen Goller
Sr. Director, Head of Patient Recruitment, Clinical Development Operations, Seagen

Anne Marie Mercurio
Clinical Trial Volunteer and Patient Advocate

Marisa Rackley
Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda

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



Kelly White
Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co

Irena Webster
Vice President, Head of Development Operations, Forma Therapeutics

Learn more at: SCOPEsummit.com/participant-engagement-award

Cambridge Healthtech Institute's 12th Annual

Accessing and Generating RWD

Regulatory Grade RWD Sources and Strategies

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 8th Annual

Leveraging RWD for Clinical and Observational Research

Real-World Data for Next-Generation Studies

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

2:00 User Group Meetings
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 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! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

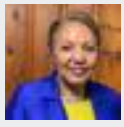
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education





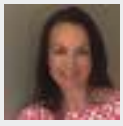




Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

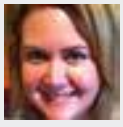
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

RWD GENERATION: TOOLS AND APPROACHES

10:35 **Chairperson's Remarks**
Rob Kalesnik-Orszulak, Regulatory Innovation Lead, RWE & Data Science, Global Regulatory Sciences, Bristol Myers Squibb Co.

10:40 **Recent Developments in Causal Inference and Real-World Evidence Generation**
Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.
With the growing interest in augmenting traditional randomized trials with data from other sources, there has been tremendous progress in the methodological and regulatory areas. We provide a review of emerging themes in the literature and address strengths and weaknesses of the trending approaches. Special emphasis will be given to current approaches around the issue of bias control, robustness of inferential validity, and use of modern analytics.

11:10 **RWE and AI Are Growing Together**
Dorothee B. Bartels, PhD, Global Head of RWE and Digital Sciences, UCB
The real-world data hype caused high expectations, including RCTs, might only play a minor role in future drug development. But they are rather complementary to RCT data and cannot replace them. Artificial intelligence may change drug development and time to market significantly, but will not replace past knowledge and experience. Real-World Evidence generation can be enhanced by AI and is key for public health.

11:40 **Practical Tools Available to Advance Fit-for-Purpose Use of Real-World Data (RWD) in Regulatory Decision-Making**
Rob Kalesnik-Orszulak, Regulatory Innovation Lead, RWE & Data Science, Global Regulatory Sciences, Bristol Myers Squibb Co.
Two recently developed tools, now publicly available, aim to increase fit-for-purpose use of RWE/RWD in regulatory decision-making will be presented, including proposals for reducing barriers and building trust with health authorities.

12:10 pm **Real World Evidence in Clinical Trials**
Sidd Bhattacharya, Partner, Cloud & Digital Transformation, PwC

12:40 **Transition to Lunch**

12:45 **A Meaningful Trial Diversity and Engagement Strategy**
Warren Whyte, Vice President, RWE Sciences, ERACE Lead, ConcertAI
The FDA recognizes the need for diversified clinical trials, yet traditional approaches to doing so may increase cost & time to market for new therapeutics. Proposing a diversity and engagement strategy using real-world data & AI-enabled technologies to measure differences in cancer care across regions/ population groups for improved regionalized engagement; reassesses study protocols identifying enrollment barriers; locate community-based organizations & other advocacy groups to foster greater trust strengthening physician-patient interactions.

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

DEFINITIONS AND DATA NEEDS

2:10 **Chairperson's Remarks**
Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC

2:15 **Clear, Consistent, and Computable Operational Definitions: Defining the Purpose and Data Needs for Real-World Evidence Generation**
Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC
Recent guidance call for establishing data-specific operational definitions in protocols for real-world research. What are operational definitions, what do they consist of, and how can we maximize their usefulness? In this presentation, I propose a standards-based structure and method for generating clear and consistent operational definitions for study design elements that can be displayed in a human-readable format, as well as leveraged in computable ways across multiple RWD use cases.

2:45 **Talk Title to be Announced**
Speaker to be Announced

3:15 Mechanisms for Transferring Structured and Unstructured Data from the EHR at the Point-of-Care into Study EDC Systems
Hugh Levaux, PhD, Vice President of Growth Strategy, Flatiron Health
Lauren Sutton, Senior Director, Product Management, Clinical Research, Flatiron Health
This session will focus on sharing outcomes of real studies that are using EHR to EDC applications to transfer data from EHR systems into EDC systems. We'll discuss how novel workflows, machine learning, and NLP can be implemented to augment the data available within the EHR that is eligible for transfer into EDC systems resulting in faster availability of high-quality study data.

3:45 Bridging the Gap between Patients, Health Care Providers, and Life Science Organisations
Andrew Taylor, Director, Head of Business Development, Life Sciences, Dedalus

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
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On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced
Speaker to be Announced

9:00 Session Break

DATA SOURCES AND INTEGRATION STRATEGIES

9:10 Chairperson's Remarks
Rachel E. Sobel, PhD, Executive Director & Head, Pharmacoepidemiology, Regeneron Pharmaceuticals, Inc.

9:15 Registries for RWE: Challenges and Opportunities
Rachel E. Sobel, PhD, Executive Director & Head, Pharmacoepidemiology, Regeneron Pharmaceuticals, Inc.
This presentation will review the recent RWE guidance from FDA and EMA on registries, and describe some of the challenges and opportunities in using registries to support safety and effectiveness evaluations, with a focus on rare disease, pediatric, and pregnancy registries, including some practical examples. I will discuss future directions and areas for improvement.

9:45 'Faster and Better': Automating Data between Electronic Health Records and Electronic Data Capture Systems at Hospitals
Dan Hydes, CEO & Co-Founder, IgniteData
Mats Sundgren, PhD, Senior Industry Scientific Director, i-HD (European Institute for Innovation through Health Data)
Nearly 50% of clinical trial data is duplicated between (EHRs) and (EDCs), wasting time and valuable resources. IgniteData's cloud-based Archer technology transports regulatory grade, clinically validated patient data from EHRs to sponsors' EDCs using HL7® FHIR and SMART on FHIR. Archer has the potential to fundamentally improve the delivery of clinical trials in hospital settings, that ultimately could lead to industry wide transformational change.

10:15 Talk Title to be Announced
Kwame Marfo, Market Strategy and Innovation Lead, Clinical Development, Komodo Health, Inc.
We live in a world with a plethora of health data available allowing us to get an accurate view of what the actual patient experience is and where there is truly unmet need. With patient tokenization, we can connect longitudinal real-world patient data in a privacy-preserving way. Explore how RWD can drive insights before, during and after clinical trials to accelerate trial timelines without compromising quality.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

THE FDA RWD FRAMEWORK

11:40 Chairperson's Remarks
Dorothee B. Bartels, PhD, Global Head of RWE and Digital Sciences, UCB

11:45 PANEL DISCUSSION: The FDA Real-World Evidence (RWE) Framework: How It Impacts Clinical and Observational Research
Moderator: Dorothee B. Bartels, PhD, Global Head of RWE and Digital Sciences, UCB
Panelists:
John Cai, MD, PhD, Executive Director, Real-World Data Analytics and Innovation, Merck
Manish Khatri, Director & Scientific Lead Data 42, Global Drug Development, Novartis Pharma AG
Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC
Marjorie Zettler, PhD, MPH, Executive Director, Clinical Science, Regor Pharmaceuticals, Inc.

12:45 pm Transition to Lunch

12:50 Getting the Most out of Structured and Unstructured Real-World Data for Evidence Generation
Jessica Paulus, ScD, VP of Research, OM1
Structured data, what's found in an electronic medical record, and unstructured data, what's found in clinician notes, real-world data (RWD) provide valuable insights into treatment effectiveness and safety, gaps in care, reasons for discontinuation, and more. Yet, understanding how these data complement each other and how to choose appropriate data sources based on different evidence needs is critical to success.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction
Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

RWE FOR TRIAL OPTIMIZATION

4:25 Sponsored Chairperson's Remarks *(Opportunity Available)*

4:30 Applying Quantitative Approaches in the Use of RWE in Clinical Development and Life-Cycle Management
Weili He, PhD, Distinguished Research Fellow, Head of Department, Medical Affairs and Health Technology Assessment Statistics, AbbVie, Inc.
While there are numerous publications in RWD and RWE areas, strategic planning and tactical execution perspectives from an end-to-end process are still lacking, including the use of RWEs not only in regulatory settings but also in non-regulatory settings along with organizational infrastructure considerations. We attempt to fill this void by providing thoughts on addressing the key considerations.

5:00 Pragmatic Trials: Building the Bridge between Clinical Trials and Real-World Clinical Practice
Helene Nordahl, PhD, Director, Real World Data Science & Innovation, Novo Nordisk, Inc.
Pragmatic trial designs can build the bridge between clinical trials and clinical practice, providing valuable real-world evidence, with the rigor of randomized clinical trials, to inform treatment decisions of payers, clinicians, employers, patients, and for regulatory purposes moving forward. Leveraging real-world healthcare data and linkage to claims data offers the opportunity to address novel endpoints. Operational lessons learned from conducting pragmatic trials will be shared along with case examples.

5:30 Evaluating QoL data for a cardiovascular study using an in-home digital smart hub
Thomas Rhoads, CEO, Spencer Health Solutions

6:00 Diversity in Clinical Trial Populations: How Using Real-World Evidence Can Help Achieve It
Marjorie Zettler, PhD, MPH, Executive Director, Clinical Science, Regor Pharmaceuticals, Inc.
In 2022 the FDA issued a guidance document recommending the prospective development of clinical trial diversity plans to address the inclusion of representative numbers of patients from racial and ethnic subgroups. Real-world evidence can be used to better understand differences in disease prevalence, diagnosis and treatment patterns among marginalized populations. Real-world evidence informs trial eligibility criteria, guide site selection, and assist with planning for post-marketing data collection to ensure diversity.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

RWD SOLUTIONS WITH PATIENTS IN MIND

8:25 Chairperson's Remarks
Manish Khatri, Director & Scientific Lead Data 42, Global Drug Development, Novartis Pharma AG

8:30 How Do Patients Benefit by Reuse of Data (RCT and RWD) across Clinical Development?
Manish Khatri, Director & Scientific Lead Data 42, Global Drug Development, Novartis Pharma AG
Traditionally clinical development process always relied on bespoke evidence generation specific to the development phase. Rapidly growing volumes of individual patient-level data and the pace of technology enabling advanced analytics, is the pharmaceutical industry duplicating parts of clinical research? What is the value of data and evidence that already exists? This presentation will cover the many lives a patient's data can and should have.

9:00 Sponsored Presentation *(Opportunity Available)*

10:15 PANEL DISCUSSION: Ethical Use of AI: GMLP in Clinical Trials
Moderator: Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
Panelists:
Brian Martin, Head of AI, R&D Information Research, Research Fellow, AbbVie, Inc.
Matthew Studney, Vice President, MRL IT, Merck & Co.
Lucas Glass, Vice President, Analytics Center of Excellence, IQVIA

10:45 Networking Coffee Break

STRATEGY LEVEL DATA SOLUTIONS

11:05 Chairperson's Remarks
Speaker to be Announced, Median Technologies

11:10 Novo Nordisk on Launching a New Data Science and Innovation Group
Adama Ibrahim, Vice President, Digital Strategy & Change Management, Novo Nordisk
Showcase this new group dedicated to ultimately unlocking a future without chronic diseases. We will share a case study of how we work to harness disruptive innovation from disease understanding to molecular design, and portfolio management through cutting-edge analysis of high-quality scientific and patient data. Specialist areas this group covers include automation, AI/ML, external intelligence, data strategy, and infrastructure.

11:40 Talk Title to be Announced
Speaker to be Announced

12:10 pm Merck's Strategic IT Approach to AI Use in Clinical Development
Matthew Studney, Vice President, MRL IT, Merck & Co.
This presentation will explain the strategic approach and various use cases for the application of AI throughout the Clinical Development environment at Merck.

12:40 Transition to Lunch

12:45 SCOPE Send Off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

2023 Interactive Breakout Discussions

TUESDAY, FEBRUARY 7

See page 70 for more info and discussion topics »

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. For a full list of topics and moderators, please visit SCOPEsummit.com/breakouts

Cambridge Healthtech Institute's 8th Annual

Biomarker Technology and Innovation

Guiding Policies and Frameworks to Operate Biomarker-Driven Trials

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 8th Annual

Biospecimen Operations and Vendor Partnerships

Technologies and Patient-Centric Operations to Deliver Biospecimens for Clinical Research

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

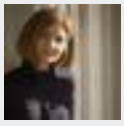
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

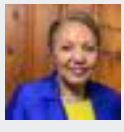
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education





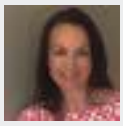




Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

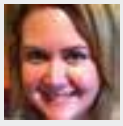
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.

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

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

POLICY & GOVERNANCE IN AN EVOLVING HEALTH TECHNOLOGY LANDSCAPE

10:35 **Chairperson's Remarks**
Karina Bienfait, PhD, Executive Director and Head, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol Myers Squibb Co.

10:40 **Novel Scientific Technologies and the Future of Evidence Generation, a Policy Perspective**
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Novel scientific techniques and technologies, including cell and gene therapies, mRNA, and AI/ML, offer exciting promise, but require new thinking about regulatory and evidence generation frameworks. This talk will explore the policy perspective, looking at recent FDA moves and areas for policy innovation. It will include lessons learned on how stakeholders can engage with regulators to advance novel evidence generation methods and the breakthrough technologies that can improve patient care.

11:10 **Human Tissue Policies: A Critical Prerequisite for Digital Transformation**
Brenda Yanak, Founder, Clinical Transformation Partners
As the industry hurtles down the path of digital transformation, much discussion has been on new tools and technologies and how data produced from them can be analyzed, with occasional discussion of the need to develop data governance models. This presentation examines the critical need for development of policies governing the use of human tissue and recommended components of such a policy, to ensure that organizations position themselves for success.

11:40 **Data Privacy Issues in Biobanking**
Mark Barnes, Partner, Ropes & Gray LLP
When companies share biospecimens and associated data with external entities, issues emerge of the conditions under which the materials and data were collected, and the regulatory frameworks of privacy that apply to sharing and downstream secondary uses of the associated data. This session will explore the legal and ethical issues of provenance of human biospecimens and associated demographic phenotypic data, and how that provenance informs acceptable and ethical secondary use.

12:10 pm **Clinical Trial & Consent Management: Too Important to Leave to Chance**
David Kaye, Vice President & General Manager, BioFortis, BioFortis, a Q2 Solutions Company
Patient samples are the lifeblood of any clinical trial but many companies are risking their data by using antiquated data collection methods (e.g.: pen & paper, homemade spreadsheets) in their modern clinical trials. In our talk, "Clinical Trial & Consent Management: Too Important to Leave to Chance" we highlight how clinical trial sample and consent tracking (CTST) software can revolutionize specimen management for pharmaceutical companies.

12:40 **Transition to Lunch**

12:45 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

POLICY & GOVERNANCE IN AN EVOLVING HEALTH TECHNOLOGY LANDSCAPE (CONT.)

2:10 **Chairperson's Remarks**
Speaker to be Announced, RadMD

2:15 **Biospecimen Governance – Key Principles and Best Practices to Consider**
Rose Redfield, Head of Biospecimen Operations, Daiichi-Sankyo
What is next after carefully implementing all the operational mechanisms to collect, process, annotate and store biospecimens? How to ensure biospecimens are utilized with legal and ethical and best practices? Why would a governance structure for biospecimens be needed? When would

this be beneficial? Navigating global regulations and internal expectation for research projects can be made easier with a few key principles regarding governance of utilizing biospecimens.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Data & Specimen Governance

Karina Bienfait, PhD, Executive Director and Head, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol Myers Squibb Co.

Samar Noor, Vice President, Statistical Programming, Global Biometric Sciences, Bristol Myers Squibb Co.

Explore the data governance and specimen governance frameworks Bristol Myers Squibb has put in place to support collection and delivery of high-quality biological specimens and data for clinical research. Gain insight into key processes and technologies leveraged to ensure proper infrastructure for biospecimen collections and clinical data quality.

3:45 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

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WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program

Caroline Jackson, Executive Vice President, Patient Services, mdgroup

Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced

Speaker to be Announced

9:00 Session Break

DATA PRIVACY AND CONSENT

9:10 Chairperson's Remarks

Brenda Yanak, Founder, Clinical Transformation Partners

9:15 Consent in Genomics: *Quo Vadis*?

Ma'n H. Zawati, PhD, Associate Professor, Human Genetics, Experimental Medicine, McGill University

This presentation will discuss recent consent trends in the field of genomics in both the clinical and research settings. It will touch on lessons learned from the pandemic and look into the future when it comes to data sharing, interoperability, return of results and incidental findings and many more.

9:45 Sponsored Presentation *(Opportunity Available)*

10:15 Gaps in Sample Tracking, Learn What Technologies & Services Are Essential for End-to-End Clinical Trial Sample Tracking

Stephanie Weber, Vice President, SampleGISTICS, SampleGISTICS, LabConnect

The challenges of real-time and accurate data submission from sites requires site-centric technologies and services that all sites can easily adapt to. Topics include, obtaining day of collection data, leveraging, and integrating courier tracking, and tracking beyond the Central Lab. You will discover the options and tools available for tracking at every stage of a sample's life cycle and the impact this knowledge has on clinical trial management and patient care.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

BIOMARKER SERVICES IN CLINICAL TRIALS FOR NOVEL THERAPEUTICS

11:40 Sponsored Presentation *(Opportunity Available)*

11:45 Challenges with Patient Sampling in Cell Therapy Studies

Rebecca Blanchard, PhD, President, Blanchard Consulting

The Development path for cell therapies has distinct features as compared to historical therapies. Early drug development is often focused on characterizing the Clinical Pharmacology of a drug therapy. In the world of cell therapies, many of these traditional investigations are quite unique. This talk will address the challenges with adequate and flexible sampling to support the development of cell therapies.

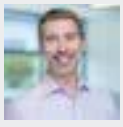
12:15 pm Presentation to be Announced

12:45 Transition to Lunch

12:50 Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION



2:20 Plenary Keynote Introduction

Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and

evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

DIGITIZATION AND INNOVATION IN BIOMARKER-DRIVEN TRIALS

4:25 Chairperson's Remarks
Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck

4:30 Patient-Centric Blood Collection Technologies That Will Minimize the Impact on the Subject/Patient and Align with the Changing Healthcare Consumer
Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck
Patient-centric blood sampling, or the self-collection of samples remotely from clinical sites, has been increasingly adopted. This approach not only reduces patient burden and allows for more diverse participation in clinical trials but increases the efficiency and breadth of the trials themselves. Technology drives this shift, but the voice of the healthcare consumer has evolved and demanded this shift to remote participation, digital health devices, and convenient participation options.

5:00 Biobanking and Biospecimen Operation in Precision Medicine
Lokesh Agrawal, PhD, Program Director, Biorepositories & Biospecimen Research, NIH NCI
The Cancer MoonshotSM Biobank (moonshotbiobank.cancer.gov) 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.

5:30 Sponsored Presentation *(Opportunity Available)*

6:00 PANEL DISCUSSION: Vendor Partnering Best Practices in a Changing Landscape: Considering Patient Centricity, DCTs, and Digitization in your Strategy
Moderator: Michael Tanen, Director, Head of Laboratory Operations and Logistics, Merck
Join this panel to explore the latest advancements in biospecimen collection technologies, patient-centric operational approaches, and IT solutions. And to discuss outsourcing and vendor management strategies to enable delivery of high-quality biological specimens, laboratory access, and diagnostics services necessary for biomarker-driven clinical trials.
Panelists:
Karina Bienfait, PhD, Executive Director and Head, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol Myers Squibb Co.
Rebecca Blanchard, PhD, President, Blanchard Consulting
Rose Redfield, Head of Biospecimen Operations, Daiichi-Sankyo
Brenda Yanak, Founder, Clinical Transformation Partners

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.

The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

ADVANCING CLINICAL INNOVATION AND PATIENT CENTRICITY THROUGH TECHNOLOGY AND PARTNERING

8:25 Chairperson's Remarks
Speaker to be Announced, Care Access

8:30 Is There Technology Overload? Finding the Right Balance for Patients and Sites
Moderator: Michelle Shogren, CEO & Owner, Innovate in What You Do!
With the proliferation of digital health technologies, how can we determine the right mix to improve clinical research without overloading patients and/or sites? How do we lessen the technology adoption burden on sites? What's the future of finding patients? Facebook? Databases? Scanning EMRs? Physician engagement?
Panelists:
Tom Julian, Senior Consultant, Gilead
Amir Lahav, Head of Strategic R&D, Digital Healthcare Innovation, Mitsubishi Tanabe Pharma America
Gayna Whitaker, Director, Strategic Feasibility, AstraZeneca

9:00 Patient-Centric Sampling at Merck: How the Patient Voice Shaped Our Sampling Strategy
Melanie Anderson, Principal Scientist, Translational Medicine, Merck
Jennifer Campbell, Principal Scientist, Preclinical Development, Merck
Over the past decade, Merck has conducted numerous trials involving patient-centric sampling, an enabling technology for decentralized trials. Patient preference questionnaires were included in multiple trials. Patients preferred at-home sampling with novel collection devices that were painless,

simple, and minimized sample volume. Participant feedback has shaped our company's patient-centric sampling strategy and has enabled us to implement sampling approaches that are truly patient-centric.

9:30 When does a Clinical Trial Start Being Just a Clinical Trial: A Path to the New Normal

Alison Holland, Executive General Manager, Digital and Decentralized Solutions, Medable

The industry is heading towards a place where digital elements (DCT's) start to become standard as we operate trials. To achieve scale, and give patients a true choice, digital strategies need to be embedded early into drug development and embraced by sites, patients and sponsors. Join us as we discuss the path to the new normal for everyone in the clinical trials ecosystem.

9:45 Detecting Changes in Patients' Conditions with Virtual Waiting Rooms

Ivor Clarke, CEO, SubjectWell

SubjectWell shares a virtual waiting room (VWR) that simplifies the difficult process of enrolling for conditions that must be tested when symptoms are active. This session examines the VWR as an effective patient engagement tool, including best practices learned across multiple case studies and a blueprint for future applications.

10:15 The Next-Gen of Community-Based Clinical Trial Site Networks: Location & Trust Can Improve Recruitment & Diversity

Dawn Anderson, Managing Director, Life Sciences, Deloitte

The industry is looking to new site network models focused on community-based clinics. By being embedded in the community, new site networks may be able to increase patient recruitment & convenience, improve retention, & enhance diversity in clinical trials. We will discuss strategies and ways non-traditional site networks could transform the clinical trial delivery model.

10:45 Networking Coffee Break

SCALING DCT EFFORTS BEYOND ZIP CODE AND COMPANY LIMITS

11:05 Chairperson's Remarks

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

11:10 Talk Title to be Announced

Speaker to be Announced

11:40 Real-World Results from Ongoing DCT Collaboration between Moderna, CVS, and Centricity Research

Ricardo De Lemos, Exec Dir Project Mgmt, Clinical Trial Svcs, CVS Health
Jeff Kingsley, Founder & CEO, IACT Health
Jessica Perry, Director, Patient Centricity, Clinical Innovation, Moderna

DCT design requires more complexity than brick-and-mortar research. Despite your best intentions, items can get overlooked. Our real-world experience can help guide you to success by demonstrating what we overlooked or dismissed and what we learned.

12:10 pm Cross Industry Initiatives to Ease DCT Adoption: Updates from DTRA

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

The Decentralized Trials & Research Alliance enables collaboration of stakeholders to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research.

12:40 Transition to Lunch

12:45 SCOPE Send Off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Media Partners

Official Event Publication

Clinical Research News

Lead Sponsoring Publications

Applied Clinical Trials · Clinical Leader · GEN Genetic Engineering & Biotechnology News · The Scientist

Sponsoring Publications

American Laboratory · American Pharmaceutical Review · DDN · Pharmaceutical Outsourcing

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Barnett International

Cambridge Healthtech Institute's 9th Annual

Risk-Based Quality Management

Best Practices to Implement and Advance Risk-Based Approaches in Clinical Trials

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 9th Annual

Central and Remote Monitoring

Monitoring and Analysis of Clinical Data – Tools to Effectively Detect and Manage Risk

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

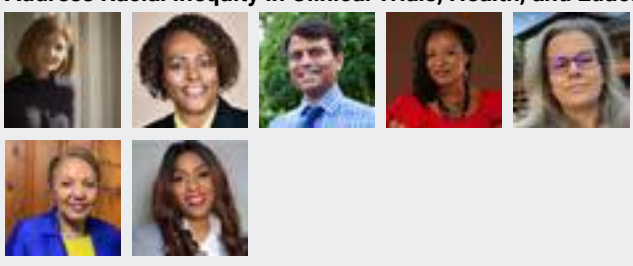
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education

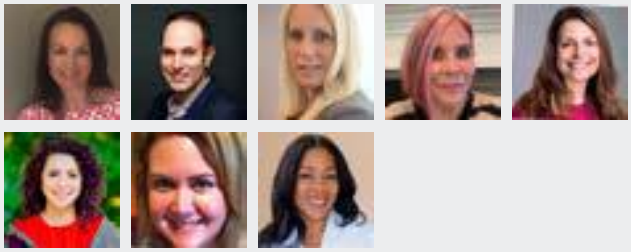


Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards



Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

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

Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate
Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.

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

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

REGULATORY UPDATE

10:35 **Chairperson's Remarks**
David Lacagnina, Chief Business Officer, Company Management, Cyntegrity Germany GmbH

10:40 **The Renovation of ICH Good Clinical Practice – TransCelerate Framework for ICH E8**
Melissa Suprin, Head, Quality Risk Management, Clinical Development, Pfizer Inc.
Madeleine Whitehead, Process Excellence Leader, Product Development Quality Solutions, Roche Products Ltd.
ICH's renovation of GCP achieved the first milestone with the release of ICH E8 General Considerations of Clinical Studies. The updated E8 represents a philosophical shift in the conduct of clinical research away from a one-size-fits-all application, promoting a proactive, risk-based approach. The TransCelerate framework focuses on the elements identified as essential for successful implementation and to prepare for the release of ICH E6 which sets the operational parameters required.

11:10 **Quality by Design, Why Risk Management is So Critical**
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
Quality by Design (QbD) is part of ICH E8 R1 and is coming to GCP with ICH E6 R3. This presentation will cover the main aspects of QbD, and go into detail on the role of risk management, and why it is such a critical aspect. Examples of measuring risk for both acceptance and management of risk will be explored.

11:40 **PANEL DISCUSSION: The Place of Quality Tolerance Limits in a Changing Regulatory Environment**
Moderator: Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck
While Quality Tolerance Limits are specifically called out in ICH E6 (R2), they are no longer in the revisions. Do QTLs still have a place in the Quality Management System? And if so, what are the recommendations on how to best implement QTLs to ensure regulatory compliance and ensure our clinical trials produce quality data that will answer the scientific questions of the trial, as well as trial participant safety?

Panelists:
Marcin Makowski, PhD, Head, Centralized Monitoring & Data Analytics, GlaxoSmithKline
Chris Wells, Study Statistician, Roche Pharmaceuticals
Marion Wolfs, Head, Senior Director, Risk Management & Central Monitoring, Janssen Pharmaceutical Companies of Johnson & Johnson

12:10 pm **Evolution of Risk-Based Monitoring — Shaped by Digital Transformation**
Jonathan Hill, Associate Director, Digital Strategy, Innovation & Analytics, IQVIA
Rajneesh Patil, Vice President, Clinical Operations Digital Strategy, Innovation, Analytics, IQVIA

12:40 **Transition to Lunch**

12:45 **Luncheon Presentation to be Announced**
Kristen Bennett, Director, Client Delivery, Client Services, WCG Avoca

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

CONSIDERATIONS AND BEST PRACTICES FOR IMPLIMENTING RISK-BASED APPROACHES IN CLINICAL TRIALS

2:10 **Presentation to be Announced**

2:15 **"DCT in Quality Track? Am I in the Right Session?" – Considerations for Imbedding Quality into DCT Approaches**
Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck
Yes, you are in the right session! We will discuss considerations to maintain quality and oversight of clinical trials while balancing new challenges and options associated with the wide variety of decentralized clinical trial approaches now available.

2:45 Improve Trial Experiences with Remote Monitoring and Technology
Kyle Hogan, President, Datacubed Health
In this presentation, we will discuss why improving the patient experience is critical to clinical trial success and the role remote patient monitoring and digital technologies play. We'll discuss how real-time data and transparency enable quicker decisions, patient safety, and an overall better experience for Sponsors, CROs, Sites, and patients.

3:15 Avoiding Duplication of Efforts in RbQM Implementation
Shawntel Swannack, Director, Central Monitoring & Data Analytics, GSK
As the industry adapts to new ways of working, RbQM processes are driving quality clinical trials. In evaluating your business' direction forward, reviewing the infrastructure and defining new responsibilities and accountabilities is key to ensuring efficient ways of working and reducing potential duplication of efforts in cross functional teams. Explore the different functions that have key accountabilities and offer insight into division of tasks, change management and effective implementation plans.

3:45 Harnessing Risk-Based Quality Management and Deep Learning to Improve Trial Knowledge and Drive Better Outcomes
Francois Torche, Co-Founder & CEO, CluePoints
In this session, Francois will share his depth of knowledge and experience as it relates to the challenges that our industry has been facing in adopting an RBM approach and are now facing in transitioning to RBQM following ICH E6 R2 (R3) recommendations. He will also present the opportunities offered by recent technologies and analytical techniques to help study teams get the most out of their data.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced
Speaker to be Announced

9:00 Session Break

ENABLING A CULTURE OF QUALITY IN ALL ASPECTS OF TRIAL EXECUTION

9:10 Chairperson's Remarks
Katherine Taylor, Head, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.

9:15 Meeting Disruption – Can an RBQM Implementation Journey Address Lack of Diversity in Clinical Trials?
Katherine Taylor, Head, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.
Implementing RBQM principles into existing clinical trial processes has proven to be challenging in supporting complex study designs. In addition, there is an impetus for the industry to explore whether RBQM can be leveraged in addressing the lack of clinical trial diversity. Can this be accomplished via industry-wide Key Risk Indicators?

9:45 Great Expectations: Harnessing Historical Insights to Accelerate RBQM Strategies
Olgica Klindworth, Senior Director, R&D, RBQM, Medidata, a Dassault Systèmes
As data collected in trials increases in volume and variety, it opens up new opportunities to harness insights across the trial lifecycle - from reducing protocol complexity (QbD), to improving site site selection with analytics, to executing better risk monitoring strategies with KRIs and QTLs. Learn how to take advantage of historical trial data and analytics to unlock powerful insights that improve risk-based oversight across the study.

10:15 Three Key Strategies to Successfully Implement Central Monitoring as Part of RBQM
Nicole Stansbury, Principal Consultant, BioTex Consulting LLC
Crystal Stone, Director, Customer Engagement, Remarque Systems
Central monitoring is a key component of a well-designed RBQM strategy yet it's still relatively new to the industry. This session will focus on the foundational components of central monitoring and will provide a roadmap for success including people, processes, and technology.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

ENABLING A CULTURE OF QUALITY IN ALL ASPECTS OF TRIAL EXECUTION, CONT.

11:40 Chairperson's Remarks
Marion Wolfs, Head, Senior Director, Risk Management & Central Monitoring, Janssen Pharmaceutical Companies of Johnson & Johnson

11:45 Beyond Trial Risk Analyses: Leveraging RBQM to Support Process Improvement and Educational Efforts
Marion Wolfs, Head, Senior Director, Risk Management & Central Monitoring, Janssen Pharmaceutical Companies of Johnson & Johnson
While RBM originally was focused on identifying site- and study-level risks, expanding our risk analyses beyond trial level gave us the opportunity to identify broader systemic issues that may be caused by external and internal processes. During the session, I will share examples of how we at Janssen – JnJ are using beyond trial level risk analyses to support process improvement and educational efforts.

12:15 pm AI for Identifying Patterns of Protocol Deviations in Clinical Trial
Haleh Valian, PhD, Associate Director, Quality Analytics, Biogen
Essential for establishing Good Clinical Practice and proper patient safety oversight is the competence to search for patterns and spot trends among protocol deviations. Typically, throughout clinical monitoring operations, all protocol deviations are logged continuously in the protocol deviations log, but the descriptions of the deviations are unstructured and nonuniform. The NLP-powered fuzzy text search technique lowers manual effort and enhances the healthcare team's accessibility and searchability of protocol deviations.

12:45 Transition to Lunch

12:50 Simulation-Based eLearning: Practical Application for Complex Trials

David Hadden, Founder & President, Innovation, Pro-ficiency

Come join Pro-ficiency's Founder & President, Dave Hadden, as he reviews a past Phase 3 case study, focusing how they addressed their unique challenges by adopting a simulation-based training approach. And both leaders and learners stand to benefit from a simulation training methodology, which pinpoints relevant site-based trends to guide targeted monitoring strategies. Objective of this presentation includes: Review of the study challenges and training needs; exploration of the training approach; discussion of outcomes, sample metrics and feedback from both the sites and study team; describe the differences between traditional and simulation-based eLearning; explain the benefits of simulation-based eLearning, list the three things sponsors must do differently to take advantage of this approach.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction

Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.

With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

EFFECTIVE OVERSIGHT AND MONITORING

4:25 Chairperson's Remarks

Michael A. Walega, Head, Centralized Monitoring, Bristol Myers Squibb Co.

4:30 Effective QMS Oversight and Governance – Focusing on the Risks That Matter

Jason Urban, PhD, Executive Director, R&D Quality Risk Management, Governance, & Analytics, Gilead Sciences

The Quality Management System provides a framework for defining and delivering quality outcomes across R&D. Hallmarks of an effective QMS are enhanced patient safety, assurance of data integrity, and minimized delays in trials and filings. Though the overall framework for an effective QMS may vary, it must contain these three elements: 1) achieving a state of control 2) active risk management, and 3) a culture where quality is everyone's responsibility.

4:50 Monitoring Clinical Trials – Identifying Trends, Patterns, and Unusual Data: Is Simple Better?

Michael A. Walega, Head, Centralized Monitoring, Bristol Myers Squibb Co.

As clinical trials become more complex, so has the technology that could identify realized risks. There is much value to be extracted and exploited from clinical and operational data repositories, utilizing analytics with incredibly nuanced capabilities. This presentation will touch on certain elements of monitoring where technology can be a help or a hindrance, to identifying realized risks and communicating their impact to protocol teams. Is simple better?

5:30 Talk Title to be Announced

Speaker to be Announced

5:45 Talk Title to be Announced

Speaker to be Announced
Speaker II to be Announced

6:00 Centralized and Medical Monitoring – A Marriage of Convenience or for Love?

Łukasz Bojarski, Head of Centralized Monitoring, AstraZeneca Pharmaceuticals, Inc.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced

Speaker to be Announced

8:15 Session Break

BEST PRACTICES IN MONITORING AND ERROR DETECTION

8:25 Chairperson's Remarks
Marcin Makowski, PhD, Head, Centralized Monitoring & Data Analytics, GlaxoSmithKline

8:30 Artificial Intelligence for Oversight of Monitoring Trip Reports
Laura Whitmore, Head, Clinical Operations, Cerevel Therapeutics LLC
Sponsors review monitoring trip reports as part of effective oversight, but the process can be very manual. Cerevel worked with two vendors to design and develop an Artificial Intelligence tool to scan reports for key data points, flag reports for review based on business criteria, and built a user interface that allows for quick insight into important report content.

9:00 INTERACTIVE EXERCISE: Breaking the Simplest Trial Ever
Marcin Makowski, PhD, Head, Centralized Monitoring & Data Analytics, GlaxoSmithKline
It is well recognized that errors in trial execution lead to audit, inspection findings. However, can a trial be done so badly that it produces a totally false answer to the scientific question? We will try to model such situation. Participants will conduct a simple trial checking if glasses improve vision. We will introduce errors to the trial execution and evaluate the impact on the answer to the scientific question.

9:45 Sponsored Presentation *(Opportunity Available)*

10:15 Sponsored Presentation *(Opportunity Available)*

10:45 Networking Coffee Break

SCALING DCT EFFORTS BEYOND ZIP CODE AND COMPANY LIMITS

11:05 Chairperson's Remarks
Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

11:10 Talk Title to be Announced
Speaker to be Announced

THREAD™

11:40 Real-World Results from Ongoing DCT Collaboration between Moderna, CVS, and Centricity Research
Ricardo De Lemos, Exec Dir Project Mgmt, Clinical Trial Svcs, CVS Health
Jeff Kingsley, Founder & CEO, IACT Health
Jessica Perry, Director, Patient Centricity, Clinical Innovation, Moderna
DCT design requires more complexity than brick-and-mortar research. Despite your best intentions, items can get overlooked. Our real-world experience can help guide you to success by demonstrating what we overlooked or dismissed and what we learned.

12:10 pm Cross Industry Initiatives to Ease DCT Adoption: Updates from DTRA
Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
The Decentralized Trials & Research Alliance enables collaboration of stakeholders to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research.

12:40 Transition to Lunch

12:45 SCOPE Send Off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

"After 2 years of not seeing so many familiar faces, being back at SCOPE filled a void, and reconfirmed that human kindness and the desire to help others, still exists!"

– Erin O., VP Clinical Operations, Rezolute, Inc.

Cambridge Healthtech Institute's 4th Annual

Medical Device Clinical Trial Design and Operations

Best Practices for Site Selection, Patient Recruitment, Protocol Design, and Optimization

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's 4th Annual

Device Trial Regulations, Quality, and Data Management

Optimizing Clinical Data Strategy and Operations to Support Regulatory Approvals

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

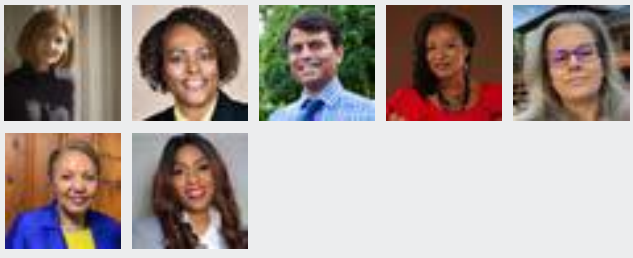
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education

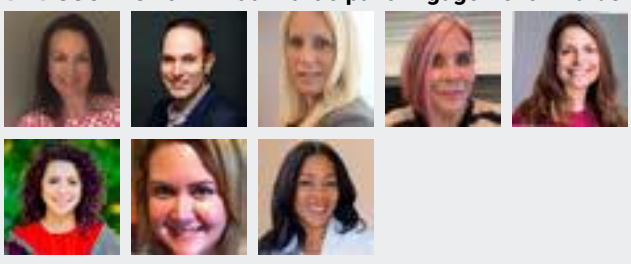


Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards



Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.

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

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

SITE SELECTION, ENROLLMENT, AND PROTOCOL DEVELOPMENT

10:35 **Chairperson's Remarks**
Speaker to be Announced, Medrio

10:40 **Site Success: How Sponsors Can Identify Sites with Great Potential and Help Them to Succeed**
David Sheleheda, Global Head, Clinical Operations, Integra LifeSciences Corp.
Identifying sites suited to your study can be challenging. There are misconceptions that site effectiveness relies upon a thought leader as an investigator or a study coordinator with eons of experience. Well-versed teams are important, but these foundational requirements fit within a broader set of parameters. Learn about barriers to site selection, developing partnerships to speed site identification, the importance of engagement and motivation, and the impact of patients' experiences.

11:10 **Considerations for Protocol Development and Study Implementation**
Anne Swearingen, Head, Medical Operations & Effectiveness, ConvaTec
Clinical study protocol development has become much more complicated, particularly with the notion of Decentralized Clinical Trials. Additional considerations, such as the use of apps, telemedicine and other digital tools such as eConsent add complexity. This session will discuss some of the recent trends and provide perspectives on considerations for protocol writing, and then study implementation.

11:40 **Medical Device Recruiting: The Chess Match of Infrastructure, Education, Population, and Resources**
Jenny Dean, Senior Project Manager, Clinical Research, ZOLL Medical Corp.
MeDev trials are historically deemed unyielding beasts which can make or break a company's bottom line or substantive growth. From regulatory policy to red tape, trials are an ocean of ebbs and flows. But there is a simple solution. In the words of Lou Holtz, Head Coach Notre Dame Football, Do right, Do everything to the best of your ability, and Show people you care.

12:10 pm **Device Trial Regulations, Quality, and Data Management**
Alethea Wieland, Managing Expert, Advarra
Device Trial Regulations, Quality, and Data Management will provide an in-depth understanding of the complex regulatory requirements and guidelines, examine clinical data strategy and use of RWD in pre- and post-market studies and offer best practices to operationalize regulatory mandates.

12:40 **Transition to Lunch**

12:45 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

OPERATIONALIZING REGULATORY MANDATES

2:10 **Sponsored Presentation** *(Opportunity Available)*

2:15 **The Link between Clinical Evaluation and Clinical Trials**
Inga Darville, MS, Cinical Evaluation Specialist, Boston Scientific
A clinical evaluation is a methodological method used to collect, appraise and analyze clinical data to support the safety and performance of a medical device when used as intended, and clinical investigations provide the highest level of clinical data of safety and performance for a medical device. While one may connect the two, how much of a benefit is this connection and how does one maximize it?

2:45 **How to Present Data for Regulatory Review**
Lucy Stone, Clinical Evaluation Specialist, Vascular Devices Team, BSI
The presentation will outline how to present clinical evidence for a regulatory review that will clearly support conformity to regulatory requirements, including defining the scope of evidence required, defining the state-of-the-art, defining safety and performance objectives, presentation of the clinical data, assessment of the clinical data, and quantitatively defining the benefits. Following these guidelines will allow timely review with minimal rounds of Q&A from the reviewer.

3:15 PANEL DISCUSSION: MDR 3-Year Anniversary: Where Are We Now? How Have Companies Fulfilled Their Evidence Gaps? What Other (Global) Regulations/Guidances Do You Need to Consider?

Moderator: Glenda Guest, President, Assured of Quality Consulting & Training

Compliance with the EU MDR requires medical device manufacturers to demonstrate that their device is designed, manufactured, and tracked according to the regulation's requirements. Join industry experts as they discuss, three years in, how they are addressing challenges with clinical evidence development, quality system management, post marketing surveillance tracking and risk management. Gain valuable insights from this discussion of MDR and related requirements such as ISO 13485 risk management principles.

Panelists:

Jen Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific

Lucy Stone, Clinical Evaluation Specialist, Vascular Devices Team, BSI

Anne Swearingen, Head, Medical Operations & Effectiveness, ConvaTec

Christina Villar, Head, Global Clinical Operations, Philips Healthcare

3:45 Sponsored Presentation *(Opportunity Available)*

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

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WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program

Caroline Jackson, Executive Vice President, Patient Services, mdgroup

Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced

Speaker to be Announced

9:00 Session Break

INNOVATIVE TECHNOLOGIES AND APPROACHES TO IMPROVE CLINICAL RESEARCH

9:10 Chairperson's Remarks

Amir Lahav, Head of Strategic R&D, Digital Healthcare Innovation, Mitsubishi Tanabe Pharma America

9:15 Clinical Trials for Kids: Designing Gamified Medical Devices and Digital Health Technologies in Pediatric Trials

Amir Lahav, Head of Strategic R&D, Digital Healthcare Innovation, Mitsubishi Tanabe Pharma America

Kids are not small adults. Developing a medical device or a mobile health app for children requires not only originality and creativity, but also extensive knowledge of developmental psychology and child behavior. There is much more we can do to improve the clinical trial experience, making it more friendly for both parents and children. This talk will explore new ways such as video animation, game-based software, augmented reality, and more.

9:45 Abbott's Custom CTMS Provides Enterprise Level Services to Accurately and Efficiently Conduct Clinical Studies from Start-up thru to Close Out

Jaime Altamirano, Jr., Staff Clinical Data Systems Analyst, Abbott Labs

Abbott has been managing clinical studies through integrated customized CTMS platforms to allow study execution, site management, and site operations teams to collaborate and drive clinical studies to completion. We recently re-designed the CTMS into a modern and intuitive enterprise-level application, merging key clinical study services into a single platform, providing new features to track and reconcile requirements and documents real-time, improving efficiencies and increasing productivity, and achieving audit readiness.

10:15 Sponsored Presentation *(Opportunity Available)*

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

NEW TECHNOLOGIES REDUCING PATIENT BURDEN AND SITE BURDEN

11:40 Chairperson's Remarks

Glenda Guest, President, Assured of Quality Consulting & Training

11:45 Decentralized Trials and Patient Centricity – Approaches for Expanding Clinical Trial Access and Representation

Adriann Kern, Director, Clinical Affairs, Thrive, an Exact Sciences Co.

The FDA draft guidance *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials* outlines new requirements for inclusion in IDE submissions. This talk will discuss how decentralized models can help expand geographic reach by leveraging technologies and local infrastructure to gain access to intended and underrepresented populations; and how innovative patient-centered trial approaches help broaden participation among underserved populations.

12:15 pm Site-Facing Technology: Overcoming Barriers to Adoption

Shah Fahad Moin, Senior Manager, Clinical Systems, Edwards Lifesciences

The barrage of technology has taken clinical trial operations by storm. Sites are being inundated with requests to adopt new technologies. What are the major pain points sites experience when dealing with new technologies? How can sponsors help ease sites' implementation and ongoing use of clinical systems? This presentation offers pointers on dealing with these questions and others in pursuit of reducing barriers and achieving a better site technology experience.

12:45 Transition to Lunch

12:50 Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction

Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

CLINICAL DATA STRATEGY

4:25 Chairperson's Remarks
Melinda Pautsch, Vice President, Med Device & Diagnostics, Medidata, a Dassault Systèmes company

4:30 Clinical Data: Considerations for Building an AI-Worthy Body of Evidence
Caitlyn Seidl, Vice President, Clinical Affairs, MotusGI
Building evidence strategies for AI-enabled devices can be a complex process; however, with the right understanding of the requirements, the process goes from complex to more straightforward. In this talk, we'll go over what to consider when building a data collection strategy, review what the FDA expects, and how to design studies that balance AI development needs, regulatory requirements, and company objectives.

5:00 Novel Diagnostics: Running Studies with Large Data Sets
Patti Connolly, COO, Verici Dx
The landscape is changing in the development of novel diagnostics. Many organizations developing advanced tests are leveraging large data sets to create more personalized tools in *in vitro* diagnostics. Such data sets require large studies, multi-center participation, inclusive study populations, and commitment to curation and maintenance of data in a platform that fosters research while protecting security and privacy. Driving innovation in diagnostics requires also becoming a data science company.

5:30 Enrollment Enablement for Medical Device Studies Using Direct-to-Patient Modalities
Dan Brenner, CEO, 1nHealth
Steve Wimmer, Director of Partnerships, 1nHealth
Patient enrollment is often a process that delays clinical trials, particularly when it comes to medical device studies. Many traditional recruitment methods create obstacles between patients and trials, resulting in costly delays. Direct-to-patient recruitment fills trials faster, and often reaches overlooked populations, resulting in more diverse and representative studies. 1nHealth offers a look at how to employ digital direct-to-patient recruitment to enroll patients faster and more smoothly in medical device trials.

6:00 Real-World Data: Pre- and Post-Market Uses
Jen Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific
There are multiple types of real-world data (RWD). This presentation will review requirements by study type and share how real-world data and experience (RWD/RWE) could be used in both the pre- and post-market settings. This presentation will highlight a case study in embedding post-market studies in a national registry.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)
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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

ADVANCING CLINICAL INNOVATION AND PATIENT CENTRICITY THROUGH TECHNOLOGY AND PARTNERING

8:25 Chairperson's Remarks
Speaker to be Announced, Care Access

8:30 Is There Technology Overload? Finding the Right Balance for Patients and Sites
Moderator: Michelle Shogren, CEO & Owner, Innovate in What You Do!
With the proliferation of digital health technologies, how can we determine the right mix to improve clinical research without overloading patients and/or sites? How do we lessen the technology adoption burden on sites? What's the future of finding patients? Facebook? Databases? Scanning EMRs? Physician engagement?
Panelists:
Tom Julian, Senior Consultant, Gilead
Amir Lahav, Head of Strategic R&D, Digital Healthcare Innovation, Mitsubishi Tanabe Pharma America
Gayna Whitaker, Director, Strategic Feasibility, AstraZeneca

9:00 Patient-Centric Sampling at Merck: How the Patient Voice Shaped Our Sampling Strategy

Melanie Anderson, Principal Scientist, Translational Medicine, Merck
Jennifer Campbell, Principal Scientist, Preclinical Development, Merck
Over the past decade, Merck has conducted numerous trials involving patient-centric sampling, an enabling technology for decentralized trials. Patient preference questionnaires were included in multiple trials. Patients preferred at-home sampling with novel collection devices that were painless, simple, and minimized sample volume. Participant feedback has shaped our company's patient-centric sampling strategy and has enabled us to implement sampling approaches that are truly patient-centric.

9:30 When does a Clinical Trial Start Being Just a Clinical Trial: A Path to the New Normal

Alison Holland, Executive General Manager, Digital and Decentralized Solutions, Medable
The industry is heading towards a place where digital elements (DCT's) start to become standard as we operate trials. To achieve scale, and give patients a true choice, digital strategies need to be embedded early into drug development and embraced by sites, patients and sponsors. Join us as we discuss the path to the new normal for everyone in the clinical trials ecosystem.

9:45 Detecting Changes in Patients' Conditions with Virtual Waiting Rooms

Ivor Clarke, CEO, SubjectWell
SubjectWell shares a virtual waiting room (VWR) that simplifies the difficult process of enrolling for conditions that must be tested when symptoms are active. This session examines the VWR as an effective patient engagement tool, including best practices learned across multiple case studies and a blueprint for future applications.

10:15 The Next-Gen of Community-Based Clinical Trial Site Networks: Location & Trust Can Improve Recruitment & Diversity

Dawn Anderson, Managing Director, Life Sciences, Deloitte
The industry is looking to new site network models focused on community-based clinics. By being embedded in the community, new site networks may be able to increase patient recruitment & convenience, improve retention, & enhance diversity in clinical trials. We will discuss strategies and ways non-traditional site networks could transform the clinical trial delivery model.

10:45 Networking Coffee Break

SCALING DCT EFFORTS BEYOND ZIP CODE AND COMPANY LIMITS

11:05 Chairperson's Remarks

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

11:10 Talk Title to be Announced

Speaker to be Announced

11:40 Real-World Results from Ongoing DCT Collaboration between Moderna, CVS, and Centricity Research

Ricardo De Lemos, Exec Dir Project Mgmt, Clinical Trial Svcs, CVS Health
Jeff Kingsley, Founder & CEO, IACT Health
Jessica Perry, Director, Patient Centricity, Clinical Innovation, Moderna
DCT design requires more complexity than brick-and-mortar research. Despite your best intentions, items can get overlooked. Our real-world experience can help guide you to success by demonstrating what we overlooked or dismissed and what we learned.

12:10 pm Cross Industry Initiatives to Ease DCT Adoption: Updates from DTRA

Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)
The Decentralized Trials & Research Alliance enables collaboration of stakeholders to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research.

12:40 Transition to Lunch

12:45 SCOPE Send Off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

2023 Partnering Organizations

SCOPEsummit.com/partnering-organizations

Cambridge Healthtech Institute's Inaugural

Building New Clinical Programs, Teams, and Ops in Small Biopharma

Innovative Approaches to Launching Lean Clinical Trials in Small Biopharma

FEBRUARY 6-8, 2023
All Times EST

Cambridge Healthtech Institute's Inaugural

Clinical Ops for Novel Modalities

Managing the Operational Complexities of Cell and Gene Therapy Clinical Trials

FEBRUARY 8-9, 2023

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
Connect with your peers and colleagues at SCOPE's 2nd 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 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

2:00 User Group Meetings
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 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! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

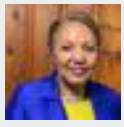
5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education





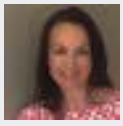




Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

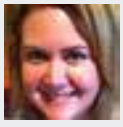
5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards










Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate

Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 **SCOPE's Kick-Off Happy Hour**

7:45 **Close of Day**

TUESDAY, FEBRUARY 7

7:00 am **Registration Open**

7:30 **Morning Brew & Pastries to Jumpstart Your Day** *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 **Chairperson's Remarks**


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 **Chairperson's Plenary Keynote Introduction**
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 **Would I Want My Mother to Be Part of a Clinical Trial?**
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 **INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It**





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 **Grand Opening Coffee & Refreshment Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

DEMONSTRATING VALUE FOR SMALL BIOPHARMA: INDUSTRY BENCHMARKS AND ACTIONABLE ADVICE FOR HIGH-PERFORMING TRIALS

10:35 **Chairperson's Remarks**
Kathleen Harper Wisemandle, Founder and Leadership Coach, Aspire to Grow Coaching & Consulting LLC

10:40 **Where Challenge and Innovation Collide: The Path to Success for Small Biopharma**
Murray L. Aitken, Senior Vice President & Executive Director, IQVIA Institute for Human Data Science
Small biopharma clinical trials have doubled in the past five years, with higher overall success rates than larger companies. They have sponsored more than 3,300 clinical trials since 2021. Even in the face of challenges, small biopharmas are embracing innovation, with shorter trial durations and greater 'white space' between research phases. The session will offer data and insights on clinical ops and the importance of innovation to small biopharma.

11:10 **Approaches and Principles for Clinical Trial Design: Use of Clinical Trial Modeling and Simulation to Optimize Trial Conduct and Success**
Charlie Barr, MD, MPH, CMO, Adaptic Health
Clinical trials face many challenges on the path to success. Scientific advances in disease biology and technology enable discovery of new targets and therapies but increase the complexity and number of choices, especially for smaller companies with limited resources. Study design is foundational for solving these challenges. We will identify principles and best practices for clinical trial design to optimize success, based on analysis of the literature and practical experience.

11:40 **Developing a High-Performance Virtual Clinical Research Operations Team: Maintaining Efficiency and Productivity While Minimizing Burnout in the Post-Pandemic Era**
Kathleen Harper Wisemandle, Founder and Leadership Coach, Aspire to Grow Coaching & Consulting LLC
Since 2019, our industry's work has shifted as a result of COVID-19 limitations. Teams are working in a hybrid structure to complete complex clinical trial execution impacting team dynamics. Current practices to support virtual teams will be summarized. Members of the clinical trial operations industry were surveyed for primary pain points and benefits of the new virtual working model, to inform how to sustain and support high-performance virtual teams.

12:10 pm **Talk Title to be Announced**
Speaker to be Announced

12:40 **Transition to Lunch**

12:45 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 **Coffee & Dessert Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

SELECTING AND MANAGING THE RIGHT VENDOR FOR CLINICAL TRIAL SUCCESS: ENSURING PROPER OVERSIGHT AND IMPROVING THE CONTRACT MANAGEMENT PROCESS

2:10 **Chairperson's Remarks** *(Sponsorship Opportunity Available)*

2:15 **Developing an Effective Vendor Oversight Plan: Keys to Success in Reaching Clinical Trial Milestones**
Tina Karunaratne, Vice President & Head, Global Clinical Operations, Orum Therapeutics
Remember, the buck stops with the sponsor! So, effective oversight, particularly for a lean organization, begins with the realization that vendor resources are an integral part of a clinical operations team. The ability to oversee vendor activities to ensure optimal performance and minimal risk requires a well-thought-out vendor oversight plan – one that is realistic and feasible. We need to maximize the return on outsourcing investment.

2:45 **Sponsored Presentation** *(Opportunity Available)*

3:00 **Presentation to be Announced**

3:15 **Building a Vendor Relationship Management Team for Biotech Clinical Ops**
Kara Titus, Head of Clinical Vendor Management, Sage Therapeutics
Building a vendor management capability within an operations organization can be puzzling in determining scope and right size. Kara will share some insight into her experience of building a vendor management process and team that is fit for purpose, serving the needs of the organization to provide proper oversight of vendor activities, while building a relationship that brings value to both parties.

3:45 **What Should You Expect (Demand) from Your Vendor Partners?**
Sonia Araujo, Head of Product Management, Clinical, ArisGlobal, Clinical Product Management, ArisGlobal
Establishing clear roles and responsibilities between sponsor and vendor is crucial to the success of that partnership. Sonia will share some insights on what sponsors should expect – more, demand – from their vendors, focusing on CTMS and eTMF software vendors. Understanding those expectations also helps sponsors, especially smaller organizations, in building a business case for investment with a clearer return on investment metrics.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 **Find Your Table and Meet Your Moderator**

4:20 **Interactive Breakout Discussion Groups**
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 **Welcome Reception in the Exhibit Hall**

6:30 **Close of Day**

6:30 **SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)**
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am **Registration Open**

8:30 **Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program**
Caroline Jackson, Executive Vice President, Patient Services, mdgroup
Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 **Breakfast Presentation Option #2 Talk Title to be Announced**
Speaker to be Announced

9:00 **Session Break**

MANAGING THE COMPLEX PROCESS OF SITE SELECTION AND SITE ACTIVATION AS A SMALL BIOPHARMA

9:10 **Chairperson's Remarks**
Charlie Barr, MD, MPH, CMO, Adaptic Health

9:15 **Clinical Trial Site Activation and Engagement Success in Small Biopharma: Lessons Learned**
Daniel Beal, RN, BSN, CCRP, Associate Director, Site Engagement, Dyne Therapeutics
Driven by a race to proof-of-concept and bogged down by resourcing hurdles from vendor partners, small biotechs are turning to innovative solutions to bolster their in-house clinical operations capabilities within study start-up as a means of getting to FPI on time. In this presentation, Daniel will demonstrate how sponsors of any size can reduce start-up timelines drastically, without hiring a team or procuring yet another vendor to manage.

9:45 **PANEL DISCUSSION: Optimizing Trial Performance through Data-Driven Site Selection Strategies**
Moderator: Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics
This panel will provide a candid discussion into the key issues related to site selection. Topics will include how to identify the relevant patient population, how to assess historical performance and competitive landscape, recommendations for engaging with investigators and staff best suited to your trial, and tips on how to leverage internal recommendations to supplement quantitative data.
Panelists:
Dennise Greensmith, Associate Director Clinical Operations, Orum Therapeutics
Charlie Barr, MD, MPH, CMO, Adaptic Health
Tina Karunaratne, Vice President & Head, Global Clinical Operations, Orum Therapeutics

10:15 **Sponsored Presentation** *(Opportunity Available)*

10:45 **Coffee Break in the Exhibit Hall** *(Sponsorship Opportunities Available)*

STRATEGIES FOR ACHIEVING AND VALIDATING TRIAL SUCCESS

11:40 **Chairperson's Remarks**
Charlie Barr, MD, MPH, CMO, Adaptic Health

11:45 **Validating Performance Benchmarks and Forecasting Clinical Trial Completion**
Ashley Wills, Senior Director, Clinical and Medical Data, Analytics, and Insights, Mirati Therapeutics
Small biopharma organizations running lean clinical trials, more than ever, need to ensure they are validating their performance benchmarks in order to more accurately forecast clinical trial completion. This session will highlight key steps to better estimate performance based on past analogues, how to leverage internal data assets, and approaches for choosing the best modeling method for your trial.

12:05 pm **How University-Based Incubators Can Assist Biotech Start-Up Companies in Clinical Programming**
Kathi G. Durdon, Executive Director, Central New York Biotech Accelerator, SUNY Upstate Medical University
University-based incubators assist start-up company access to CORE facilities, simulated test environments, clinical trial units, interns, and an array of experts to serve as advisory board members, protocol reviewers, and principal Investigators. Review how biotech incubators serve small businesses and faculty innovators with clinical program needs through resource matching, PI and site selection assistance, regulatory education, scoping of funding sources, mentorship alignment, coordinated use of university infrastructure, and workforce needs.

12:25 **Integrated Data Review Including Site and Patient Voice**
Caro Unger, Dir Clinical Operations, Clinical Operations, Kinnate Biopharma Inc
Allows small internal teams to review global data sets and maintain quality and oversight, as well as subjective quality indicators such as participant and site feedback gathered from our patient advocacy group.

12:45 **Transition to Lunch**

12:50 Transforming Patient Engagement: What it Takes to Operationalize a Seamless, Trustworthy Clinical Trial Experience

Shirisha Kanthala, Associate Director, Trial Transparency and Disclosures, Disclosure, Incyte

Christina Masturzo, Head of Product for Patient Engagement and Recruitment, Patient Enagement and Recruitment, Citeline

Emerging biopharma companies race to bring novel treatments to patients, often with lean operations managing multiple trial activities and with less resources. How can these companies meet the needs of patients/caregivers, HCPs, recruitment partners, and sites while ensuring operational efficiency, study success, and enterprise scale? Citeline partnered with Incyte to launch more ways to reach, engage and educate stakeholders while creating a seamless experience for protocol-matched patients to participate in trials.

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction

Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future

Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs

Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck

Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.

With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

EARLY ENGAGEMENT STRATEGIES AND REGULATORY CONSIDERATIONS FOR NOVEL MODALITIES

4:25 Chairperson's Remarks

Sunny Hoffman, MS, MPH(ABSA), Client Services Partner, Clinical Biosafety Services and Castle IRB

4:30 Regulatory Biosafety & IBC Challenges of Gene Therapy for Accelerated Study Start-Up

Christopher L. Jenkins, Founder, Principal Partner & Chief Gene Therapy Biosafety Officer, Clinical Biosafety Service

The growth of gene, cell, and RNA-based therapies place an increasing challenge on study start-up activities. This is due to additional complexities including regulatory site level requirements for Institutional Biosafety Committee (IBC) risk assessment reviews in the US, Canada, Australia, and GMO reviews in the United Kingdom. This talk will educate pharma on these additional regulatory requirements, the impact on study start-ups, and strategies to mitigate.

4:50 Nuances of Conducting Cell & Gene Therapy Clinical Trials

Daniel E Larson, Vice President, Clinical Operations, ElevateBio

As with any treatment modality, cell and gene therapy therapeutic clinical trials have several unique considerations, including the way that they are manufactured, stored, and administered. In addition, there are specific study design requirements to comply with regulations and manage safety. The purpose of this discussion is to review some of the differentiating characteristics of a cell and gene therapy trial.

5:10 Early Engagement with Site Staff and Patients for a Cell Therapy Trial with a Novel Treatment Target

Rachel Haines, Dir Clinical Operations, Clinical Operations, Rinri Therapeutics Ltd

This talk will share ideas of how to develop and implement a plan to engage site staff and patients, prior to regulatory submission, to positively impact trial timelines, recruitment, and retention.

5:30 Sponsored Presentation *(Opportunity Available)*

6:00 Clinical Site Selection – A Strategic Approach for Cell and Gene Therapy Trials

Alexander M. Milstein, MD, Executive Vice President, Clinical Development and Medical Affairs, Chief Clinical Officer, Paracrine, Inc.

There are thousands of publications, service offerings, and software solutions related to clinical site selection. Many of these solutions add tactical and operational value yet none address site selection strategy – a vitally important component of trial success and commercial adoption. We will discuss site selection strategy from a different perspective.

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

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THURSDAY, FEBRUARY 9

7:15 am Registration Open

BREAKFAST PRESENTATIONS

7:45 Breakfast Presentation to be Announced
Speaker to be Announced

8:15 Session Break

BUILDING RELATIONSHIPS AND MANAGING RESOURCES IN A DIVERSE CLINICAL SUPPLY CHAIN AND PARTNER NETWORK

8:25 Chairperson's Remarks
Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

8:30 FEATURED PRESENTATION: Trends & Challenges in Pharma Sourcing and Procurement – Managing Relationships With The Modern Supplier
Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA
This presentation covers how Bayer's External Relationship Governance model adds value to the business ensuring a reliable partnership and complements the Sourcing & Procurement Functions, sharing current trends on procurement roles and the necessity to have an operational perspective in sight, with different approaches from different business necessities and how to best manage CMOs, 3PLs and Clinical Trials partners.

9:00 PANEL DISCUSSION: How Small Biotechs Develop, Manage, and Maintain Relationships with CROs
Moderator: Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences
This panel will discuss the key considerations for smaller biotechs in selecting CROs to work with, how small biotechs can position themselves as valuable partners to CROs, and strategies for managing and maintaining relationships with CROs.
Panelists:
Hansu Dong, Executive Director, Clinical Outsourcing & Business Operations, Clinical Operations, Novavax
Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.
Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.

10:00 Talk Title to be Announced
Speaker to be Announced

10:15 Impact of FDA's Guidance on Diversity and Inclusion on Post Marketing Research
Sean Kennedy, MPH, Executive Director, Therapeutic Strategy Lead, Real World Evidence, Worldwide Clinical Trials
Aman Khera, MBA, FRAPS, FTOPRA, Vice President, Global Head of Regulatory Strategy, Scientific Solutions, Worldwide Clinical Trials
Daniel Perez, CCRP, Director and Global Head of Patient Experience, Patient Experience, Diversity & Inclusion, Worldwide Clinical Trials

10:45 Networking Coffee Break

MITIGATING THE IMPACT OF STAFF TURNOVER ON RESOURCES AND OUTSOURCING THROUGH TALENT RETENTION AND DEVELOPMENT

11:05 Chairperson's Remarks
Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson

11:10 PANEL DISCUSSION: Strategies to Attract, Engage, and Retain Talent During Times of Change
Moderator: Wanda Shoer, Head, Strategic Business Operations, Global Development, Johnson & Johnson
This panel will discuss the impact staff turnover has on clinical trial operations and outsourcing, working with CROs and sites to mitigate staffing changes, insights on returning to the office, DE&I efforts, and meaningful changes that impact employees, and how to develop talent and grow people into careers.
Panelists:
Eileen Doherty, Vice President, Enabling Business Information Solutions (EBIS), The Janssen Pharmaceutical Companies of Johnson & Johnson
Rosalie Filling, Vice President, Senior Global Head, R&D Operations, Endo Pharmaceuticals
Valerie Balosso, Director, Data Management, Infectious Diseases, GSK

12:10 pm The Tempus TIME Network
Matthew Cooney, Vice President, Therapeutic Development, Oncology, Medical Science, Tempus Labs
The TIME Network screens hundreds of thousands of patients daily using a combination of technology and nursing review to find potential trial subjects. Once an appropriate patient is identified, the trial site is rapidly opened using a pre-approved clinical trials agreement, regulatory process, central IRB, and uniform contracting. This streamlined process has empowered the TIME Network to activate hundreds of trials in an average of 10 days.

12:40 Transition to Lunch

12:45 SCOPE Send off Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Closing Remarks

1:20 Scope Summit 2023 Adjourns

Cambridge Healthtech Institute's & Barnett International's

Clinical Research Training Forum

Managing Quality and Minimizing Risk through Strategic Training Initiatives

FEBRUARY 6-8, 2023
All Times EST

MONDAY, FEBRUARY 6

8:00 am SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament* *(Sponsorship Opportunities Available)*
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9:00 Conference Registration Open

1:00 pm Open Workshop: Introducing ClinEco, the New B2B Clnical Trial Community and Marketplace
Sit down with a small cross-industry group for a 45-minute hands-on session to learn about, share feedback, and register for free for the new B2B clinical trial community and marketplace. ClinEco unites sponsors, CRO's, 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 for free at: https://clineco.io/register. Let us know if you are joining us at: bgallant@clineco.io. Walk-ins welcome. *Open to all SCOPE attendees*.

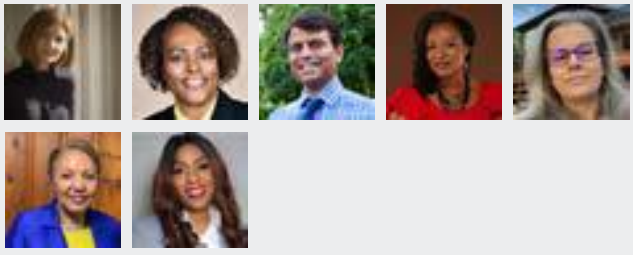
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks and 2nd Annual Masters of Clinical Research Golf Tournament Awards
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

5:05 Plenary Keynote Introduction
Brian Kay, CEO, StudyKIK

5:10 INTERACTIVE PANEL: Lighting a "Beacon of Hope" to Address Racial Inequity in Clinical Trials, Health, and Education



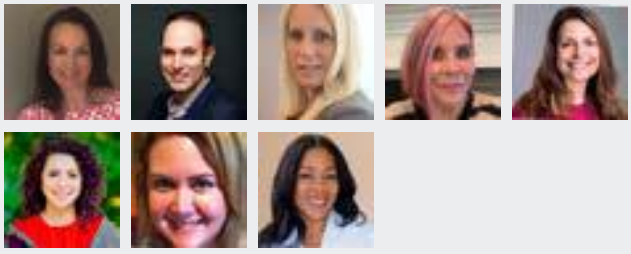
Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi

Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and investigators; improve access to education and jobs; and identify solutions to environmental/climate issues that disproportionately affect health among communities of color. Collaborating partner companies Novartis, Sanofi, Merck, and an HBCU discuss how this program aims to improve quality and inclusivity within clinical trials.

Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, M.D. Director of Clinical and Translational Research
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J Maxwell, M.D., Associate Dean for Research at Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Naikia Byrd-Atkinson, Director, US Clinical Trials Diversity and Inclusion, Sanofi

5:40 SCOPE's 7th Annual Participant Engagement Awards Introduction

5:45 SCOPE's 7th Annual Participant Engagement Awards



Co-Moderators:
Kelly McKee, Vice President, Decentralized Clinical Trials (DCT), Medidata
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
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.

Panelists:
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Anne Marie Mercurio, Clinical Trial Volunteer and Patient Advocate
Marisa Rackley, Vice President, Clinical Site Start Up, Site Engagement, Trial Optimization, Takeda
Irena Webster, Vice President, Head of Development Operations, Forma Therapeutics
Kelly White, Senior Director, Head, Global Trial Optimization, Oncology, Merck & Co.
Kendal Whitlock, Head, Digital Optimization, RWE Clinical Trials, Walgreens Boots Alliance

6:30 SCOPE's Kick-Off Happy Hour

7:45 Close of Day

TUESDAY, FEBRUARY 7

7:00 am Registration Open

7:30 Morning Brew & Pastries to Jumpstart Your Day *(Sponsorship Opportunities Available)* **or Morning Coffee**

THE REALITY OF A TRIAL EXPERIENCE & NAVIGATING A GLOBAL CRISIS

8:30 Chairperson's Remarks


Marina Filshtinsky, Conference Producer, Cambridge Healthtech Institute
Micah Lieberman, Executive Director, Cambridge Healthtech Institute

8:35 Chairperson's Plenary Keynote Introduction
Jim Reilly, Vice President, Development Cloud Strategy, Veeva Systems

8:40 Would I Want My Mother to Be Part of a Clinical Trial?
Virginia Nido, Global Head, Product Development Industry Collaborations, Genentech, a member of the Roche Group
Our industry has been talking about becoming more patient-centric in our approach to trials. But have we really changed the experience for patients or are we just continuing to admire the problem? Would you want YOUR mother to be part of one of your clinical trials? We need to get real. It should not take a pandemic to make changes to our protocols and processes and ways of working.

9:05 INTERACTIVE PANEL: Navigating a Global Crisis: Pandemic, War, Hyperinflation, Supply Chain Disruptions…You Name It





Moderator: Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.
Running a complex clinical trial involves a lot of moving pieces, forward planning, modeling, allocation of resources, and a neverending ability to adjust while maintaining the highest standards. It has never been easy, but many of us in the clinical research profession know how to do our part. With the advent of DCTs, a pandemic, supply chain disruptions, and talent shortages, what is a clinical ops leader to do?

Panelists:
Gaurav Sawhney, Vice President, Head, Clinical Partner Management, Takeda Pharmaceuticals, Inc.
Bryan O'Neill, Global Head, Clinical Supply Operations at Daiichi Sankyo, Inc.
Deborah Profit, PhD, Vice President, Clinical Management & Applied Innovation, Otsuka America Pharmaceutical, Inc.
Ken Getz, Executive Director, Tufts Center for the Study of Drug Development

9:35 Grand Opening Coffee & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

ALIGNING TRAINING CONTENT AND METHODS WITH OVERALL BUSINESS GOALS

10:35 Chairperson's Welcome and Opening Remarks

10:40 Taking the Uncertainty out of Aligning L&D Strategy with Organizational Goals
Dara Moore, M.Ed., Associate Director, Learning and Development, Clinical Development and Safety Quality, Center of Excellence, AstraZeneca, Alexion Rare Disease Unit
This presentation is an exploration of how to use brainstorming methods to align L&D strategy with organizational goals and frameworks, including Value/Vision/Promise statements. The discussion leverages a real use case, a Mural board template, and a strategy output format that articulates alignment to multiple company goals and frameworks, including an executive summary and tactical actions. Learners will take away tool templates for future use.

11:10 Developing an Inclusive Learning and Development Strategy for a Rapidly Changing Company: Building Knowledge and Capability in Support of Women's Health
Shawn Milheim, EdD, Director Learning & Development, Research & Development, Organon & Co.
This talk will focus on how the L&D leads from across Organon came together to develop a new agile and inclusive L&D strategy fit for a rapidly changing company and the marketplace, including how it can be scaled or applied in many settings.

11:40 Development of an Evolving Training Strategy
Amanda Gutierrez, LMHC-QS, PMP, Director of Learning & Development, Learning and Development, Quality, Biorasi
This presentation will feature the establishment and development of a training strategy while providing an understanding of how short-term and long-term initiative planning can be structured. The essential components of team and personnel development and its organizational impact are discussed, as well as how to maximize and interpret performance. A discussion about shifting your perspective on human capital management and development in alignment with personal and business strategy is included.

12:10 pm Building a Customized Life Sciences Training Model to Mitigate Attrition
Frances Gambino, MSLIS, Senior Director, Medidata Global Education, Medidata Solutions
A customized training model motivates and retains your research operations talent pool by providing a timely, structured path to best-in-class core proficiencies and demonstrated, customized applied skills and offers your organization a competitive advantage when attracting, growing, and retaining talent. Learn how to structure a training model to attract and retain talent for Clinical Operations roles across all stages – onboarding, foundational, advanced, certification, continuous learning, and community knowledge share.

12:40 Transition to Lunch

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Coffee & Dessert Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

INSPECTION READINESS AND REGULATORY UPDATES

2:10 Chairperson's Remarks

2:15 The Renovation of ICH Good Clinical Practice, the Framework for ICH E8: What Training Professionals Need to Know
Madeleine Whitehead, Process Excellence Leader, Product Development Quality Solutions, Roche Products Ltd.
The updated ICH E8 represents a philosophical shift in the conduct of clinical research away from a one-size-fits-all application, promoting a proactive, risk-based approach. The TransCelerate framework and tools focus on the elements identified as essential for successful implementation and can assist toward the goal of preparing teams for the release of ICH E6 R3, which sets the operational parameters required.

2:45 Keeping Inspection Readiness at the Forefront of Clinical Operations through Training Initiatives
Tracy Cannady, Manager, Training, United Therapeutics Corp.
The purpose of this presentation is to understand how our company leveraged an inspection readiness training program to further support the idea that inspection readiness starts at the beginning of the trial. Learn how our clinical operations teams collaborated to understand what individual departments are doing to be inspection ready and identify ways to support and motivate each other down the path of being inspection prepared.

MANAGING CHANGE THROUGH STRATEGIC TRAINING INITIATIVES

3:15 Enabling Change and Growth via a New Operating and Asset Team Model

Shawn Milheim, EdD, Director Learning & Development, Research & Development, Organon & Co.

Change is a part of every organization, and as Organon strengthens its pipeline strategy, the implementation of a new operating and asset team model is critical. This presentation will highlight the change management and training approach taken to help implement this new way of working while highlighting best practices in change management and training.

3:45 Teaching Effective Communication Strategies to Improve Diversity in Clinical Trials

Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

Our industry has spent over two years listening to the perspectives of patients of color and health equity experts to understand how to improve diversity in clinical research. This presentation will address effective engagement strategies that should be used by all site coordinators, including how those responsible for training initiatives can foster effective communication strategies that build trust with patients of color and improve systemic barriers in clinical trial participation.

INTERACTIVE BREAKOUT DISCUSSION GROUPS

4:15 Find Your Table and Meet Your Moderator

4:20 Interactive Breakout Discussion Groups

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. Please visit the Interactive Breakout Discussion Groups Page for more information.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

6:30 SCOPE out Pointe Orlando for an entertaining night out via our Courtesy Shuttle* (Sponsorship Opportunities Available)

*Courtesy shuttles will be available Tuesday and Wednesday 6:30-11:00pm, bringing you to and from The Pointe Orlando.
The Pointe Orlando is an open air-entertainment destination, featuring local and brand names restaurants, bars, nightclubs, 20-screen movie theater, comedy club and family attractions.
Shuttles will run a continuous loop 6:30-11:00pm between Rosen Shingle Creek, Hilton Orlando and Pointe Orlando.
On-site look for our courtesy shuttle signage directing you to pick up locations within the hotels.

WEDNESDAY, FEBRUARY 8

BREAKFAST PRESENTATIONS

8:00 am Registration Open

8:30 Breakfast Presentation Option #1 Achieving the Impossible: Maximizing Patient Experience and Data Quality in a Complex Rare Disease Program

Caroline Jackson, Executive Vice President, Patient Services, mdgroup

Mobile health has a significant impact on patient retention and experience in clinical trials. However,it's still under-utilized as there is a perception that more complex assessments and procedures cannot be conducted effectively in the home. This case study highlights how mdgroup worked with a client to implement complex sample collections in the homes of patients suffering from a rare disease, resulting in reduced travel burden and low dropout rates.

8:30 Breakfast Presentation Option #2 Talk Title to be Announced

Speaker to be Announced

9:00 Session Break

ASSESSING RETURN ON EFFORT AND INVESTMENT

9:10 Chairperson's Remarks

9:15 PANEL DISCUSSION: Strategies for Determining Return on Effort on Your Training Initiatives

Moderator: Tara McEvoy, Associate Director, Learning Center of Excellence, Development Services and Operational Excellence, Regeneron Pharmaceuticals, Inc.

In this interactive session, hear how our panelists have approached how they assess the value of their training initiatives, including how rubrics, metrics, and other tools are being utilized to measure training success. Come prepared to interact, share your ideas and strategies, and ask questions of our session panelists.

10:15 Level 3 Evaluations Made Simple, Credible, and Actionable

Ken Phillips, CPTD, CEO, Phillips Associates

By attending this session, participants will be able to: Use facts from a recent research study to benchmark the use of Level 3 evaluations in their organization. Conduct focus groups using three key questions to collect the data needed to conduct a credible Level 3 evaluation. Calculate the amount of training transfer associated with a training program using the estimation technique.

10:45 Coffee Break in the Exhibit Hall *(Sponsorship Opportunities Available)*

STRATEGIES FOR FOSTERING LEARNING ENGAGEMENT

11:40 Chairperson's Remarks

11:45 Programming Interactivity into Virtual Training Initiatives: What Does and Doesn't Work?

Naila Ganatra, MEd, General Manager, Barnett International
Lindsey Swank, MEd, Coordinator, Interactive Web Events, Barnett International

In many companies, virtual training has become the preferred method for training delivery, given the convenience and cost savings it provides. During this interactive session, we will explore engagement strategies that will help to ensure that your virtual initiatives achieve their desired outcomes and engage learners through a variety of virtual training delivery methods.

12:15 pm How Microlearning Can Be Used to Motivate Teams and Influence the Delivery of Results

Stacy Hubiak, Senior Director, Training & Learning Management, R&D Operations, Teva Pharmaceuticals

Compliance training can be very dry at times and hard to understand. In our fast-paced environment where colleagues face many daily interruptions, learning needs to be more concise and intentional. In this session we will discuss how microlearning can enhance complex topics while enhancing engagement and retention. By improving how we design and develop content, learners are able to leave learning experience feeling more comfortable and informed.

12:45 Close of Clinical Research Training Forum Program

12:50 Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

NEXT-GENERATION DATA SOURCES & BUILDING A ROADMAP FOR AN R&D ORGANIZATION

2:20 Plenary Keynote Introduction

Ivor Clarke, CEO, SubjectWell

2:25 Faster, Better, Cheaper: The Increasing Role and Opportunities for Real-World Evidence in Informing Regulatory Pathways

Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

An open dialogue on the facilitators, barriers, and open opportunities to effectively utilize RWE for informing regulatory pathways from a biopharma company perspective. Additionally, we will highlight some of the novel use cases and key lessons learned by biopharma companies in utilizing RWE for discovery and development purposes.

2:35 Advancing Evidence Generation of the Future
Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Clinical research is undergoing a major shift, as we move towards continuous evidence generation to support accelerated drug development and approvals. In this talk, Dr. Abernethy will share her firsthand experience with the evolving use of real-world data and evidence at FDA during COVID. She'll speak to the need for quality longitudinal data sets, the role of technology, and how new approaches are transforming the clinical research field.

2:45 Fireside Chat: Next-Generation Data Sources


Amy Abernethy, MD, PhD, President, Clinical Studies Platforms at Verily; Former Principal Deputy Commissioner, FDA
Christopher Boone, PhD, Global Head, Health Economics & Outcomes Research, AbbVie, Inc.

2:55 Fireside Chat: Future-Ready Operations: Building a Multi-Year Roadmap



Lynne M Cesario, Global Lead, Risk Based Monitoring Program, Pfizer Global R&D Groton Labs
Jane Hiatt, Executive Director, Site Management and Monitoring, Early-Stage Development, Merck
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
With increases in complexity and new trial modalities, organizations need to constantly assess what the future needs. This chat will focus on the strategic choices and approaches to be considered, and how to plan out such a multi-year roadmap.

3:25 Booth Crawl & Refreshment Break in the Exhibit Hall *(Sponsorship Opportunities Available)***. Last Chance for Viewing.**

4:25 Close of Day

CLINICAL TRIAL TECH
VENTURE, INNOVATION, & PARTNERING CONFERENCE

Accelerating Innovation, Accessibility and Scale

February 7, 2023
Welcome Reception: February 6

Rosen Shingle Creek
Orlando, FL & Virtual

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 Venture, Innovation, & Partnering Conference will take place in conjunction with the 14th annual SCOPE Summit (Summit for Clinical Ops Executives). We are excited to add this new conference to an already established and successful event of over 2,300 leaders in clinical operations and research. The Venture, Innovation, & Partnering Conference aims to bring together C-level executives from investment firms that support innovation in the clinical trial process, strategics from pharmaceutical and leading CROs, both venture and corporate arms who have a vested interested in driving this innovation, and also CEOs and innovators from industry, driving the technology in this space. This unique combination of events offers the opportunity to participate in a venture and partnering event featuring a very exciting and emerging tech space, while also offering the chance to visit the exhibit hall and meet companies and get a sense of where this industry is going.

Meet Our Co-Chairs

Jessica J. Federer
Partner, Boston Millennia Partners

Jodi J. Akin
CEO, Hawthorne Effect, Inc.

Konstantina Katcheves
Senior Vice President, Business Development, Bristol Myers Squibb

Learn more at SCOPEsummit.com/partnering

2023 Event Highlights

Masters of Clinical Research

SCOPE's 2nd Annual Golf Tournament

Connect with your peers and colleagues at SCOPE's 2nd Annual Masters of Clinical Research Golf Tournament, starting at 8:00am on Monday, February 6. 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.

February 6 at 8:00 am

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

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

Sponsors:

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

Attention Pharma!

25 for 25

If you are an employee of the following TOP 25 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.

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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!

CITELINE wcg

For Partnering and Sponsorship Information:

Companies A-K

Ilana Quigley
Senior Manager, Business Development
T: (+1) 781-972-5457
E: iquigley@healthtech.com

Companies L-Z

Patty Rose
Senior Manager, Business Development
T: (+1) 781-972-1349
E: prose@healthtech.com

2023 Interactive Breakout Discussions

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing. For a full list of topics and moderators, please visit SCOPEsummit.com/breakouts

TUESDAY, FEBRUARY 7
BREAKOUT DISCUSSION GROUPS

4:15 PM	Find Your Table and Meet Your Moderators
4:20 PM	Interactive Discussions
5:00 PM	Welcome Reception in the Exhibit Hall

Interactive Breakout Discussion Group Topics for SCOPE 2023

1. Integrating Early Patient and Site Insights in Protocol Development and Site Selection
2. Decentralized and Hybrid Trials: The New Ecosystem
3. Implementing a Data-Driven Site Selection Capability with RWD, Modelling, and Analytics
4. Building Diversity, Equity, and Inclusion (DE&I) into Trial Design and Ops
5. Strategies for Patient-Centric Trial Design and Patient Engagement
6. Budgeting for and Contracting with New Technology Companies: Strategies and Challenges
7. Establishing Metrics and Optimizing Governance for CROs and Third-Party Providers
8. Developing Tools for Speeding Study Start-Up: Contracting, Budgeting, Capacity Planning
9. RWD To Accelerate Design and Execution of Clinical Trials
10. Next-Gen Data Management for Next-Gen Trials... AI Including
11. Validating Digital Biomarkers and Endpoints
12. Clinical Data Strategies to Enable Decentralization
13. Risk-Based Approaches to Monitoring Hybrid/ Decentralized Trials
14. Integrating Biomarkers in Global Trials
15. Medical Device Clinical Trial Design, Operations, and Data Strategy
16. Adopting Supply Chain Predictive Analytics to Shift from Reactive to Proactive Decision-Making
17. Aligning Training Plans with Organizational Goals and Requirements
18. It's a Small, Small World: Environmental, Social, and Corporate Governance (ESG) and Sustainability in Clinical Research

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.

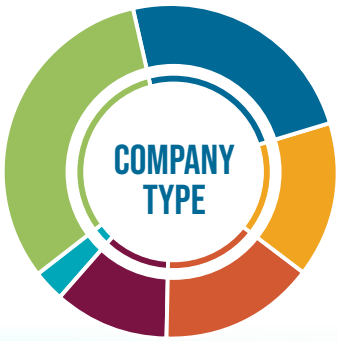
EXHIBIT

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
- Around the World Reception- Tuesday, February 7th
- Beverage carts, Swag bags, Golf Course hole Sponsorships
- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Conference Materials Advertisement
- Padfolios and More...

2022 ATTENDEE DEMOGRAPHICS



CRO	32%
Biotech	24%
Pharma	15%
Healthcare	15%
Services/Societies	11%
Other	3%

Executive	53%
Sales & Marketing	27%
Scientists	10%
Manager	9%
Other	1%

For additional information, please contact:

Companies A-K

Ilana Quigley
Senior Manager, Business Development
(+1) 781-972-5457
iquigley@healthtech.com

Companies L-Z

Patty Rose
Senior Manager, Business Development
(+1) 781-972-1349
prose@healthtech.com

Conference Venue & Hotel

ROSEN SHINGLE CREEK

9939 Universal Boulevard
Orlando, FL 32819

Discounted Room Rate: $251 s/d

Discounted Room Rate Cut-Off Date: January 6, 2023

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

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REGISTRATION

SUMMIT FOR CLINICAL OPS EXECUTIVES

FEBRUARY 6-9, 2023 | ORLANDO, FL
ROSEN SHINGLE CREEK + VIRTUAL

INDIVIDUAL EVENT PRICING

Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Monday, February 6 access to the following:

- *SCOPE's Second Annual Masters of Clinical Research Golf Tournament (Separate registration and fee required)*
- *Afternoon Pre-Con User Group Meetings & Hosted Workshops (opportunities available)*
- *Evening Kick-Off Plenary Keynote and 7th Annual Participant Engagement Awards*
- *SCOPE's Kick-Off Networking Happy Hour*

In addition, you will receive on-demand access to all presentations for one year.

	Pharma-Biotech-Med Device Company	CRO-Vendor-Tech Consultancy-Services Provider	Academic-Government-Site Hospital
Advance Registration Discount until January 6, 2023	$2699	$2749	$1399
Standard Registration after January 6, 2023 and Onsite	$2899	$2999	$1499

GROUP EVENT PRICING

Includes in-person or virtual access to the entire 3-day SCOPE conferences. Also includes Monday, February 6 access to the following:

- *SCOPE's Second Annual Masters of Clinical Research Golf Tournament (Separate registration and fee required)*
- *Afternoon Pre-Con User Group Meetings & Hosted Workshops (opportunities available)*
- *Evening Kick-Off Plenary Keynote and 7th Annual Participant Engagement Awards*
- *SCOPE's Kick-Off Networking Happy Hour*

In addition, you will receive on-demand access to all presentations for one year.

Advance Registration Discount until January 6, 2023	$1999	$2049	$1049
Standard Registration after January 6, 2023 and Onsite	$2149	$2249	$1149

ON-DEMAND CONFERENCE PRICING

For those who cannot attend SCOPE on February 6-9, 2023, whether in-person or virtual. After Event, will receive access to recordings of ALL presentations. Does not include Q&A or networking sessions.

Standard Registration and Onsite	$2199	$2349	$999

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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 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 2023 In-Person or Virtual.

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 781-972-5418.
mdolen@healthtech.com

Alumni Discount - SAVE 20%

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 20% off the registration rate.

**Alumni, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined.*

How to Register: SCOPEsummit.com

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Please use keycode **SCOPE PDFF** when registering!