FEBRUARY 6-9, 2023

MED DEVICE TRIALS

Part of:

14th Annual SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

Rosen Shingle Creek • Orlando, FL

IN-PERSON + VIRTUAL

PART 1 FEBRUARY 6-8 — Medical Device Clinical Trial Design and Operations

PART 2 FEBRUARY 8-9 — Device Trial Regulations, Quality, and Data Management

FEATURED SPEAKERS:

eClinical Ecosystems Engagement: Challenges in a Dynamic Med Tech Environment

Christina Villar, Head Global Clinical Operations, Global Clinical Operations, Philips Healthcare

Site Success: How Sponsors Can Identify Sites with Great Potential and Help Them to Succeed

David Sheleheda, Global Head, Clinical Operations, Integra LifeSciences Corp.

Novel Diagnostics: Running Studies with Large Data Sets

Patti Connolly, COO, Verici Dx

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

Clinical Data: Considerations for Building an AI-Worthy Body of Evidence

Caitlyn Seidl, Vice President, Clinical Affairs, MotusGI

Real-World Data: Pre- and Post-Market Uses

Jen Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific

REGISTER EARLY FOR MAXIMUM SAVINGS!

Signature Sponsors

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Organized by Cambridge Healthtech Institute

SCOPEsummit.com

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			

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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!

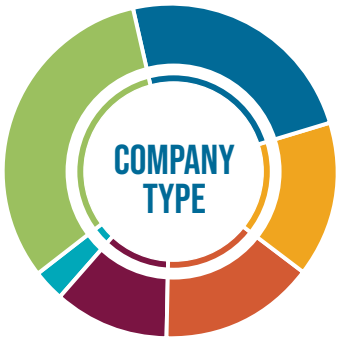
EXHIBIT

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)
- 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:

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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*.

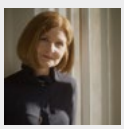
2:00 User Group Meetings
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are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

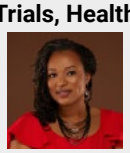
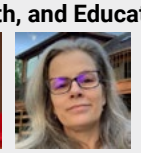
ADDRESSING RACIAL INEQUITIES IN CLINICAL TRIALS & PARTICIPANT ENGAGEMENT AWARDS

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





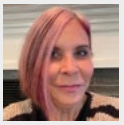
Moderator: Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Launched July 2021, a $33.7M commitment from Novartis and Novartis US Foundation, Beacon of Hope began as a 10-year collaboration to increase diversity among clinical trial participants and 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.

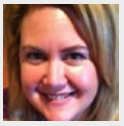
Panelists:
Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck
Rajbir Singh, MD, Executive Director of Precision Medicine and Health Equity Trials Design, Meharry Medical College
Priscilla Pemu, Doctorate, MBBS MS FACP, Associate Dean Clinical Research at Morehouse School of Medicine
Kimberly Fookes, Global Head, Diversity & Inclusion in Clinical Trials, Novartis
Celia J. Maxwell, MD, Associate Dean for Research, Howard University College of Medicine, Medicine & Health Affairs, Howard University Hospital
Jaydutt Vadgama, Prof & Exec VP Research & Health Affairs & Chief, Cancer Research & Training & Internal Medicine, Charles R Drew Univ of Medicine & Science
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

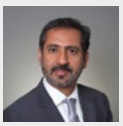
8:30 Chairperson's Remarks


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, 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

9:30 Help Us Set A World Record: Join Everyone For Group Photo At 9:25 Sharp In The Keynote to Make History!

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
Tina Caruana, Subject Matter Expert, eClinical Solutions, 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)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-10:30pm (last pick up), 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 6:30-10:30pm (last pick up) between Rosen Shingle Creek, Hilton Orlando, DoubleTree Orlando at SeaWorld, 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 Strategies for Biopharma Companies to Boost Clinical Trial Enrollment
Dennis Akkaya, Chief Commercial Officer, myTomorrows
We would like to invite you to join us for an informative event about overcoming obstacles in recruiting patients for BioPharma clinical trials. During this event, we will delve into barriers such as lack of awareness and financial considerations that can impede clinical trial recruitment success. Additionally, impactful strategies to increase clinical trial participation and recruitment success will be shared.

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.

9:35 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.

9:55 Clinical Trial Design Considerations in Digital Therapeutics (DTx): Spotlight on Comparison Groups
Acacia Parks, Fractional Chief Science Officer, Found
As relatively new entrants to the regulatory landscape, DTx products, many of which are classified as software as medical device (SAMD), are learning more from FDA about what types of study design features are needed to earn clearance. This talk will provide an overview of key design considerations for SAMD trials, including endpoints, safety considerations, and endpoint collection, with a deeper dive on choice and design of comparison group.

10:15 Making Medical Device Clinical Trials Future-Ready
Avi Kulkarni, Ph.D., SVP, Head of Life Sciences Strategic Business Unit, Cognizant
Seema Sayani, PhD, Senior Director, Life Sciences at Cognizant, Cognizant
While the last decade introduced significant advancements across clinical trial design, development and operations, we have also witnessed an increase in evidentiary needs for medical devices subject to clinical utility and safety reviews. This session explores evolving technology trends in clinical trials, with an emphasis on deploying the latest developments in observational, interventional and synthetic studies in the approval of novel diagnostics and devices.

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 with "Best of Show Award" Winner Announcement

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, Executive Director, 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)
*Courtesy shuttles will be available Tuesday and Wednesday 6:30-10:30pm (last pick up), 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 6:30-10:30pm (last pick up) between Rosen Shingle Creek, Hilton Orlando, DoubleTree Orlando at SeaWorld, 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 saama
Speaker to be Announced

8:15 Session Break

ADVANCING CLINICAL INNOVATION AND PATIENT CENTRICITY THROUGH TECHNOLOGY AND PARTNERING

8:25 Chairperson's Remarks
Jennifer Embury, Head of Customer Success, Business Development, 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, Innovation Integrator, 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 Medable
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 SubjectWell
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 Deloitte. ConvergeHEALTH™
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 THREAD
Kim Boericke, Chief Operating Officer, THREAD
Speaker II to be Announced

11:40 Real-World Results from Ongoing DCT Collaboration between Moderna, CVS, and Centricity Research
Ricardo De Lemos, Executive Director, Project Management, Clinical Trial Svcs, CVS Health
Jeff Kingsley, Founder & CEO, IACT Health
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.

12:00 pm PANEL DISCUSSION: Cross Industry Initiatives to Ease DCT Adoption: Updates from DTRA
Moderator: 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.
Panelists:
Jane E Myles, Co Lead, Priority Iniative 3B, DCT Playbook, Decentralized Trials & Research Alliance (DTRA)
Jonathan Andrus, MS, CQA, CCDM, President and COO, CRIO and Treasurer and Past Chair, Society for Clinical Data Management
Caroline Redeker, Senior Vice President, Corporate Development, Advanced Clinical

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

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

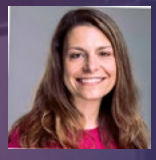
David Sall
President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award

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)

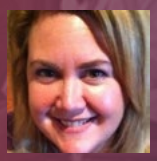
Gretchen Goller
Sr. Director, Head of Patient Recruitment, Clinical Development Operations, Seagen

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

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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- INTEGRATED SCHEDULER

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.

REGISTRATION

SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES
FEBRUARY 6-9, 2023 | ORLANDO, FL
ROSEN SHINGLE CREEK + VIRTUAL

INDIVIDUAL EVENT PRICING

	Pharma-Biotech-Med Device Company	CRO-Vendor-Tech Consultancy-Services Provider	Academic-Government-Site Hospital

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	$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

Group Discounts are Available!

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

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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.*

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Please use keycode **DVC PDF** when registering!