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February 18-21, 2019 • Orlando, FL
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Real World Evidence

10TH ANNUAL SCOPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

Featured Speakers

Martin Marciniak, PhD,
Vice President, US Medical Affairs, Customer Engagement, Value, Evidence & Outcomes, GSK

Tony Hebden, PhD,
Vice President, Health Economics & Outcomes Research, AbbVie

Demissie Alemayehu, PhD,
Vice President, Biostatistics, Pfizer

Cathy Critchlow, PhD,
Vice President, Center for Observational Research, Amgen

Andrew Roddam,
DPhil, Vice President, Head, Epidemiology, RWE & Digital Clinical Platforms, GSK

Gregory Daniel, PhD,
Deputy Center Director, Duke-Margolis Center for Health Policy, Duke University

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Event-at-a-Glance

Monday, February 18 PM

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

(Sponsorship Opportunities Available)

5:00 – 6:15 pm
Monday Evening Kick-Off Plenary Keynote & Participant Engagement Awards

6:15 – 7:15 pm
SCOPE's Kick-Off Networking Happy Hour

Tuesday, February 19 AM & PM	Wednesday, February 20 AM	Wednesday, February 20 PM	Thursday, February 21 AM & PM
SITE ACTIVATION	Conference 1A **Protocol Development, Global Site Selection, Feasibility, and Site Management**	Conference 1B **Improving Site-Study Activation and Performance**	
RECRUITMENT	Conference 2A **Enrollment Planning and Patient Recruitment**	Conference 2B **Patient Engagement, Enrollment and Retention through Communities and Tech**	
BUDGETING & RESOURCES	Conference 3A **Clinical Trial Forecasting, Budgeting and Contracting**	Conference 3B **Resource Management and Capacity Planning for Clinical Trials**	
OUTSOURCING	Conference 4A **Mastering an Outsourcing Strategy**	Conference 4B **Managing Outsourced Clinical Trials**	
QUALITY & MONITORING	Conference 5A **Implementing Risk-Based Monitoring (Part 1)**	Conference 5B **Implementing Risk-Based Monitoring (Part 2)**	
DATA	Conference 6A **Clinical Data Strategy and Analytics**	Conference 6B **Artificial Intelligence in Clinical Research**	
TECHNOLOGY	Conference 7A **Sensors, Wearables and Digital Biomarkers in Clinical Trials**	Conference 7B **Clinical Technology and Innovation**	
REAL WORLD EVIDENCE	Conference 8A **Late Stage Research and Observational Studies**	Conference 8B **Leveraging Real World Data for Clinical and Observational Research**	
BIOMARKERS & BIOSPECIMENS	Conference 9A **Clinical Biomarkers Innovation and Operations**	Conference 9B **Clinical Biospecimen & Central Lab Solutions**	
CLINICAL SUPPLY	Conference 10A **Clinical Supply Management**		

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Plenary Keynote Program

Celebrating its 10th successful year, SCOPE Summit 2019 takes place February 18-21 in Orlando, FL. Over the course of four stimulating days of in-depth discussions in 19 different conferences, 3 plenary keynote sessions, and the ever-popular interactive breakout discussions, the programming focuses on advances and innovative solutions in all aspects of clinical trial planning, management and operations, including: Site Selection and Management, Patient Engagement, Recruitment and Retention, Protocol Optimization, Feasibility, Data Strategy & Analytics, Artificial Intelligence (AI), Sensors and Wearables, Project Management, Outsourcing, Forecasting, Budgeting and Contracting, Quality (QbD) in Trial Conduct, Risk-Based Monitoring, Post-Marketing Studies, Observational Research, Clinical Biomarker Strategy, Clinical Supply Chain, Precision Medicine, and Biospecimens and Central Lab Solutions. SCOPE attracted 1,700 leaders in clinical operations and research in 2018, and each of our conference tracks will feature best practice case studies relevant to clinical operations experts and those new to the field.

MONDAY, FEBRUARY 18

MONDAY USER GROUPS, KICK-OFF KEYNOTE, PARTICIPANT ENGAGEMENT AWARDS

2:00-5:00 pm **User Group Meetings & Hosted Workshops** *(Sponsorship Opportunities Available)*: www.SCOPEsummit.com/pre_conference_user_group_meetings

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 **Pre-Conference Plenary Keynote Opening Remarks**
James Riddle, MCSE, CIP, CPIA, CRQM, Executive Vice President, Kinetiq, a Division of Quorum Review IRB

5:05 **Empowering Humans to Own Their Own Data: A Fireside Chat with Verily**
Scarlet Shore, Product Manager & Platform Lead, Project Baseline, Verily
Project Baseline is developing tools and strategies to empower everyday people to better understand and manage their health through the return of individual research results. Launched in April 2017, Project Baseline will recruit 10,000 participants to better characterize health and the transition to disease. Scarlet will briefly present an overview of Project Baseline and some of the insights from their efforts to-date.

PARTICIPANT ENGAGEMENT AWARD
SCOPE 2019

Underwriter Sponsorship Available

5:30 SCOPE's 2019 Participant Engagement Awards Introduction
Speaker to be Announced

5:35 SCOPE's 2019 Participant Engagement Awards
In Memory of Jerry Matczak #BeLikeJerry #SCOPE2019

Creativity and Engagement in Recruitment and Retention Communications
Designed to inspire innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials, this award embodies the values and personal accomplishments of Jerry Matczak, who sadly passed away soon after receiving the 2017 award. We dedicate this award to Jerry in the hopes that it will serve as a reminder of his ideals and accomplishments.

Deadline for submission is November 30th, 2018
SCOPEsummit.com/participant-engagement-award

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

Angela Radcliffe, R&D Practice Lead, Life Science, Capgemini Invent

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

Shwen Gwee, General Manager, Digital Accelerator, Global Drug Development, Novartis

David Fuehrer, CEO, GRYT Health, Two-Time Cancer Survivor

Joseph Kim, MBA, Senior Advisor, Patient Experience and Design Innovation, Eli Lilly

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

6:15 SCOPE's Kick-Off Networking Happy Hour Hosted by CHI *(Sponsorship Opportunities Available)*

7:15 Close of Day

Plenary Keynote Program

TUESDAY, FEBRUARY 19

DIGITAL TRENDS CHANGING HEALTHCARE EXPERIENCE & DOCTOR-PATIENT-CAREGIVER PERSPECTIVES ON TRIALS AND ENGAGEMENT

8:15 am Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

8:20 Chairpersons' Introduction
Matt Miller, President, Co-Founder, StudyKIK
Jerome Chiaro, Chief Patient Advocate, Co-Founder, StudyKIK

8:25 Keynote Kick-Off: Digital Trends That Are Changing the Healthcare Experience
Shwen Gwee, General Manager, Digital Accelerator, Global Drug Development, Novartis
AI and Machine Learning. Blockchain. Chatbots and Voicebots. As technology continues to advance at a rapid pace, the biopharma industry, and in particular the clinical development area, struggles to keep up and adopt/integrate these novel platforms with how they operate. This talk will cover some of the current digital trends that are changing the clinical trial experience, including examples from within and outside the biopharma industry, as well as some of the external forces from other industries that are shifting customer expectations.

8:45 Do Engagement Tools Live Up to Their Hype? Doctor and Patient Perspectives on Study Participation
Moderator: Bonnie Brescia, Founding Principal, BBK Worldwide
Gerald Dryden, Jr., MD, PhD, Division of Gastroenterology, Hepatology and Nutrition, University of Louisville
Linda Glaser, MD, PhD, Medical Director, Coastal Biomedical Research, Inc.
Annie Finstein, Patient
It is generally thought that engagement programs (e.g. apps, travel, and reimbursement tools) enhance the patient and site experience within a clinical research study. But do they really? This interactive session will feature a doctor and a patient who can provide first-hand insight into using these engagement tools and what their effectiveness truly is. This session will be part of BBK Worldwide's Pharma15 Live! web series that tackles some of today's most compelling issues and brings them to the forefront for discussion.

- Perspectives from a doctor and a patient regarding usage of engagement tools – i.e. travel and reimbursement apps
- Shifting the conversation from return-on-investment to return-on-impact.

9:05 INTERACTIVE PANEL: Why Do We Need Caregivers in Clinical Trials; Exploring Real-Life Applications in Engagement and Retention
Moderator: Lynne Becker, Senior Data Analyst, Enterprise Intelligence & Data Solutions (EIDS) Program Management Office (PMO), Deputy Assistant Director Information Operations, Defense Health Agency (DHA)
Thérèse Johnsen, Associate Director, Patient Engagement Management, Novartis
Chris O'Brien, MBA, Vice President, myHealthTeams, Board Member, MHE Research Foundation
Stuart Williams, Impact Ecosystems Architect, Inplace Impact
Elizabeth Allardice, Family Advisory Board, Concussion Legacy Foundation
Alyssa Lanzi, Ambassador & Researcher, Patient-Centered Outcomes Research Institute (PCORI)
Why do we need caregivers in clinical trials? We have oversimplified our lifestyles in many areas but burdened our healthcare. Persons became doctors or nurses to care for others, delivering empathy to their patients. Technology is inhibiting, perhaps limiting these touchpoints, leaving patients to search for compassionate care. Caregivers are quickly becoming essential to a person's healthcare, as well as to complex, confusing and overwhelming clinical trials. How do we integrate this new and essential component in helping us achieve successful clinical trial experiences?

- What a caregiver is not: Are caregivers an extension of a healthline or a patient? Are there legal or ethical implications?
- How involved can a caregiver be? Should they be compensated?
- Who chooses a caregiver? What are the HIPPA or IRB challenges?

9:35-10:35 Grand Opening Coffee Break in the Exhibit Hall

Plenary Keynote Program

WEDNESDAY, FEBRUARY 20

OPPORTUNITIES AND CHALLENGES IN ARTIFICIAL INTELLIGENCE (AI), PATIENT CENTRICITY, PRIVACY

2:10 pm Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

2:15 Chairperson's Introduction
Jackie Kent, Senior Vice President, Head, Product, Medidata

2:20 INTERACTIVE PANEL: Welcome, Pharma, to AI. Here's What You Have Been Missing.
Moderator: David Vulcano, MBA, Vice President, Research Compliance & Development, Hospital Corporation of America (HCA)
Niall O'Connor, Chief Technology Officer, Genospace (Sarah Cannon, the Cancer Institute of HCA Healthcare)
Ron Williams, CEO, Global Business Evolutions
Balazs Flink, MD, Head, Clinical Trial Analytics, Bristol-Myers Squibb
Artificial intelligence (AI) has been utilized in other industries outside of life sciences with varying degrees of sophistication. As pharma learns AI's place in the life sciences industry, it may benefit from learning what other large companies have accomplished with AI and their lessons learned.

- How are healthcare delivery systems using AI to better deliver care and improve efficiencies?
- What similar problems have non-healthcare industries solved with AI?

2:50 INTERACTIVE PANEL: Patient Centricity and Data Permissions
Moderator: Munther Baara, MS, Head, New Clinical Paradigm, Pfizer
Michelle Shogren, Head of Innovation in Portfolio and Operations, Bayer
Lauren Bataille, Senior Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson's Research
Laurie Myers, Global Health Literacy Director, Merck (MSD)
Jane Perlmutter, PhD, President & Founder, Gemini Group
The Patient Centricity and Data Permissions panel will feature technologies and approaches to enable patient centricity of clinical trials and to ensure the patient data rights and good practices.

- Building a patient-centric framework that is both effective and compliant
- Converging patient-facing technology capabilities, the real challenges
- Streamlining direct-to-patient activities and creating a user experience to improve research and outcomes
- Creating the infrastructure to comply with best practices for patient data rights and permissions

3:20-4:05 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

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Interactive Breakout Discussions

TUESDAY, FEBRUARY 19

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 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.

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

Patient Engagement and Recruitment

What Is Holding Back the Adoption of eConsent?

- Is eConsent for every trial? Discuss when eConsent is or isn't appropriate
- Understand IRB and regulatory feedback on the eConsent process
- Discuss how eConsent technology integrates with other systems
- Review a typical implementation timeline and how it impacts all stakeholders

Strategies for Aligning and Accelerating Recruitment in Complex Clinical Trials in a Resource-Constrained Environment

- Dealing with the Acute Patient where timing is critical
- Do traditional/past tactics still work in current environment? What tactics (new and old) work best today?
- Ensuring success for procedure-driven protocols (Non-conventional administration, device and/or diagnostic intense)
- Utilization of supportive field resources to accelerate recruitment (Medical Science Liaisons & Clinical Trial Educators)

Strategies for Patient-Centric Trial Design and Digital Patient Engagement

- What are current digital patient projects gaining traction, engagement pilots, new technologies, the role of patient communities?
- What is a complete digital patient experience? What is required to make this a reality for all trials?
- What are we getting right and what are we getting wrong as we re-align our processes and our research organizations around the patient-centric model?

Understanding and Implementing the New Reality of Diversity in Clinical Trials

- What are the regulatory changes from FDA and updated requirements for ethnicity/race inclusion in trial populations?
- How do you formalize into a clinical development plan at a company level to make it part of corporate culture by educating and training teams so that they can embrace the ethnicity value?
- How do you then implement at project team level and operationalize the activities to support diversity in clinical trials?

Interactive Breakout Discussions

Protocol Optimization and Trial Design

Embracing Best Practices in Protocol Design to Reduce Protocol Amendments and Improve Trials

- What are the updated metrics on the prevalence and causes of protocol amendments and what does this mean for us?
- How can we as an industry improve our process of protocol development?
- What are some community initiatives and individual company approaches to finding success?

How to Start from Scratch to Get Patient Input into Clinical Trial Design

- Speaking to objections from senior leadership
- Discuss how to partner with advocacy organizations in order to obtain patient input
- How to work within timelines to get input from patients

Feasibility and Site Selection

Optimizing Country and Site Selection: Strategies for Positioning Trials for Success Using a Global Footprint

- Optimizing the site feasibility process: Improving global site feasibility assessment to identify sites that will recruit on time and within budget
- Objective country feasibility and selection: Where are the patients?
- Data-driven site selection: Understand the number of sites, their probability of success, and the impact of site non-performance

Study Start Up and Operations

Barriers and Opportunities in Site Adoption of Clinical Trial Technology

- What site facing technology is critical to improving clinical trials?
- What is holding sites back from adopting this technology?
- What can be done to minimize the burden of technology for sites?
- What opportunities exist to streamline and integrate technology in clinical trials?

Identifying and Alleviating Burdens Inherent in Clinical Trials (for Patients, Sites, Caregivers, Investigators and Trial Managers)

- Identifying study requirements that may be burdensome
- Transportation to and from study visits – how can sponsors help
- Helping research sites to alleviate their internal burdens

Partnering with Qualified Investigators and Study Teams for Improved Site Performance, Efficiency, and Execution of Clinical Trials

- Identify inefficiencies in current approaches to investigator training and learn how they impact the conduct and timelines of clinical trials
- Discuss strategies for developing a culture of collaboration between sponsors/CROs and site teams in preparing investigators and their delegates for the quality conduct of clinical trials
- Describe approaches to combining "qualification" and "preparation" activities for site teams

Improving Both Time and Quality in Site Activation and Study Start-Up

- Identifying and consolidating site start up activities that are redundant, inefficient and needlessly complex
- What are key learnings and opportunities for different approaches, including a centralized approach of study activation and site performance?
- How can sponsors, CROs and site streamline site activation and study start-up?

Data and Technology

Wearable Devices in Clinical Trials

- What is the value, beyond scientific interest?
- Where do we want to be in 5 years (and why we are not there already!)?
- Key challenges for industry uptake?
- Opportunities for industry-wide collaborations

Digital Data Transfer and Virtual Trials

- The Digital Health eco-system and its impact on clinical trials
- EHR2EDC: how to implement and advance
- Mastering collaborations between pharma companies and academic medical centers

Artificial Intelligence and Machine Learning: Extreme Case of Data Analytics?

- Will data science and machine learning disrupt the provision of clinical evidence or compliment it?
- With Machine Learning needing big data sets, how can the industry share more data in a precompetitive framework?
- As more Deep Learning techniques are deployed – how can we gain confidence in "Black Box" approaches?
- In what ways, if any, will we have to change how we work with regulators?

Technologies to Enable Patient-Centered Trials

- Innovative digital technologies
- Technologies to capture patient experience
- Framework for converging patient-facing technologies

Clinical Analytics Strategy

- Implementing analytics on top of existing operating model
- Study Start Up Methodology to Adopt a Clinical Analytics Strategy
- Data analytics in outsourced trials

Monitoring and Quality

RBM in a Finance and Resource Limited Environment

- How are you assessing risk and developing an appropriate quality and risk plan?
- In terms of technology, what are nice-to-haves vs. need-to-haves for implementing RBM?
- Who are the stakeholders involved in putting RBM in action at smaller companies?

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Interactive Breakout Discussions

RBM and Critical Reasoning Skills
- How are central monitoring activities different than traditional monitoring?
- How do you train people to do critical problem solving around data?
- How do you uncover root causes of data issues instead of just fixing data afterwards?

Vendor Performance Metrics and KPIs
- How effective are your KPIs for measuring vendor performance and quality?
- What is your strategy for establishing KPIs and metrics? Who are the stakeholders developing performance metrics?
- What are the key areas that should be evaluated for vendor performance and quality?

Building a Clinical Quality Management System (CQMS) from the Ground Up
- What are the minimum requirements for a CQMS?
- What do you need to build a CQMS?
- How to build a CQMS with limited resources and budget
- Learn from each other's current experiences with building a CQMS

Budgeting, Contracting and Resource Management

Coordinating Contracting and Payments to Enhance Efficiencies
- Understand how contracting and investigator payments are connected
- Review standard terms to use on both ends of the contracting process
- Discuss how to improve and implement a plan to streamline operations

Budgeting and Contracting for Remote and Digital Trials
- Understand budgeting needs for remote and digital trials and how they are different from traditional site-driven trials
- Review differences in contracting: Needs, models, and language
- Discuss how to improve and implement a plan to streamline budgets and negotiations

Balancing Budgets and Performance in Resource Management and Capacity Planning
- What are key factors that should be considered when developing a resource plan?
- What situations warrant a bigger focus on cost savings, and which on using other resources?
- How do training and retention programs fit into capacity planning and overall resource management?

Developing Resource Management Tools for Complex Trials and Diverse Portfolios
- Understand the important factors that need to be tracked to successfully capacity plan and how to integrate them into a tool
- Discuss how to get buy-in from key stakeholders by demonstrating value, cost savings, and efficiency
- Discuss change management and how to roll out a new tool or process

Addressing Current and Future Workforce Challenges
- What competencies are most lacking in the workforce today?
- How are you addressing these challenges?
- What more can and should the industry be doing to create a more skilled and sustainable workforce?

Clinical Supply and Logistics

Clinical Supply in Virtual Trials
- How does clinical supply fit in with the industry trend towards virtual/site-less trials?
- What does clinical ops need to know about direct-to-patient distribution before embarking on a virtual trial?
- What are the logistical, cost and regulatory considerations of direct-to-patient distribution?

Biospecimen and Central Lab Management

Biospecimen, Central Lab and Technology
- Biorepositories: In-house vs. outsourcing
- Advanced informatics for biospecimen management
- Central and reference labs: Building the relationship
- Informed consent and data sharing

Integrating Sample Management into Clinical Trial Cycle
- Regulatory Compliance
- Site Selection Considerations
- RBM Considerations

RWE

RWE to Support Regulatory Decisions and the Medicine Lifecycle
- Leverage the power of RWD to enable evidence-based trial feasibility assessment and patient recruitment
- How can RWD support Clinical Operations and the Medical organization overall?
- What opportunities exist to collaborate between Medical and Commercial on RWD assets and insights?
- Which functions can help bridge and facilitate the ingestion of RWD for actionable insights?
- RWE needs to go beyond analysis and clinical trial is calling new clinical-health service to link healthcare and clinical trial research

RWD To Accelerate Design and Execution of Clinical Trials
- RWD to improve the efficiency of clinical trials
- RWD to accelerate site selection and patient recruitment
- RWD sources and analytics
- RWD to supplement clinical trials

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Pre-Conference User Group Meeting & Hosted Workshops

February 18, 2019
2:00-5:00 pm

Shared Investigator Platform User Forum

Sponsored by Cognizant

The Shared Investigator Platform (SIP) is the success story of TransCelerate BioPharma's collaborative vision brought to reality through a digital platform. SIP is delivering tangible, measurable benefits to sponsors and sites as more and more studies are onboarded and user adoption accelerates exponentially.

Beginning in February 2019, SIP will be available to sponsors outside of TransCelerate membership, as well as directly to CROs. The SIP User Forum is open to anyone whose organization is a current user of the platform or considering its adoption, including technology partners. Investigators and site personnel, who are able to join SIP at any time at no charge, are encouraged to attend.

- Understand the plan for SIP to transition from TransCelerate's incubation to become a Cognizant product in 2020
- Hear from current SIP adopters on the benefits being realized
- See the new features of Version 3.1 and the product roadmap of future releases
- Provide your input on current and future features and functions of SIP

To learn how to register for the Shared Investigator Platform User Forum, please contact Jill Notte at jill.notte@cognizant.com or 862-217-7080.

Trifecta Annual User Group Forum

Sponsored by trifecta

Trifecta is a global leader — and a trusted partner — with decades of experience in clinical trial technology solutions. From accelerating study start up for trials of all sizes to organizing and distributing all critical training and safety data, Trifecta offers a fully integrated, totally comprehensive platform built from the ground up. And through it, we consistently deliver more trial and less error across an entire portfolio of studies. We are proud to be hosting our annual user group meeting at SCOPE.

To learn how to register for the Trifecta Annual User Group Meeting, please contact Karen Olszewski at karen.olszewski@trifectaclinical.com.

Host a User Group on Monday, February 18

Co-locate your User Group meeting with SCOPE Summit. CHI will help market the event & manage logistical operations. We will co-market to prospective attendees and extend your users a discount to attend.

For Partnering & Sponsorship Information, contact:

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Late Stage Research Strategy and Operations

RWE for Regulatory Decisions, Market Access and Pharmacovigilance

Real world evidence solutions have changed the design and execution of peri-approval and post-marketing research. Real time real world data generation, pragmatic trials, next generation databases open new opportunities for post-marketing research as well as regulatory and market access needs. Data generated in peri-approval real world data based studies is essential for multiple stakeholders within and outside pharmaceutical companies, such as regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute's 8th Annual "Late Stage Research Strategy and Operations" conference is designed to facilitate knowledge exchange around all aspects of peri-approval studies and major application of their outcomes/generated data.

MONDAY, FEBRUARY 18

9:00 am – 7:15 pm Registration Open

2:00 – 5:00 pm User Group Meetings (see page 11 for details)

Shared Investigator Platform User Forum *Sponsored by* Cognizant

Trifecta Annual User Group Forum *Sponsored by* trifecta

5:00 – 6:15 pm Pre-Conference Plenary Keynote Panel & Participant Engagement Award (see page 5 for details)

6:15 – 7:15 pm SCOPE's Kick-off Networking Happy Hour Hosted by CHI
(Sponsorship Opportunities Available)

7:15 pm Close of Day

TUESDAY, FEBRUARY 19

7:15 am Registration Open and Morning Coffee

8:15 Opening Plenary Keynotes (see page 5 for details)

9:35 Grand Opening Coffee Break in the Exhibit Hall

RWD TO SUPPORT REGULATORY DECISIONS

10:35 Chairperson's Remarks
Charles Makin, Global Head, Real World Evidence Strategy, Biogen

10:40 RWD: Studies for Formulary Decision Making and Health Technology Assessment – A US Perspective
Martin Marciniak, PhD, Vice President, US Medical Affairs, Customer Engagement, Value, Evidence & Outcomes, GSK
HTA is heavily dependent on real world data (RWD) in part because of its focus on measuring outcomes that extend past that offered by traditional clinical trial data or systematic reviews. RWD, in its many forms (e.g., pragmatic, observational, social media, other) is increasingly viewed as an important part of this process, particularly outside of the United States. What does this mean for the US, and its nascent HTA infrastructure?

11:10 Considerations for Use of Real World Evidence to Inform Regulatory Decisions
Cathy Critchlow, PhD, Vice President, Center for Observational Research, Amgen
Real world evidence (RWE) will be increasingly used in regulatory submissions seeking approval for a new indication, label expansion, or new product marketing authorization. The 21st Century Cures Act places additional focus on the use of RWE in regulatory decision making. While growing availability of data and sophistication of analytic tools have transformed RWE generation, challenges impeding full realization of benefit from RWE involve issues such as data quality and what constitutes "substantial evidence" when using RWE as supporting or pivotal evidence. Considerations to help ensure the advancement of suitable RWE use cases to enable appropriate impact of RWE in regulatory decision making will be discussed.

11:40 Use of Real World Data (RWD) to Assess Cardiovascular Safety of Prucalopride to Support a New Drug Application in the US
William Spalding, MS, Director, Outcomes Research-Epidemiology, Shire
Prucalopride belongs to the 5HT4 agonist drug class, and 2 previously approved 5HT4 agonist drugs have been removed from the market for increased risk of adverse cardiovascular (CV) events. Shire, in agreement with the FDA, sponsored a CV safety study based on RWD from clinical use of prucalopride in European markets where prucalopride has been marketed since 2009. This talk discusses rationale for use of RWD to assess drug safety.

12:10 pm Using Technology to Maximize Patient Choice While Minimizing Burden in Post-Approval Research *Sponsored by* ERT
Chris Watson, PhD, Director, Product Strategy, Digital Patient Product Management, ERT
With the rise in importance of prospective patient data capture as part of real-world evidence analysis how can we make it simpler and easier for patients to participate - and remain engaged - in post-approval research? What role does technology play and how can advances in consumer technology simplify the process for patients, investigators and sponsors?

12:40 Transition to Lunch

Organized by Cambridge Healthtech Institute
A Division of Cambridge Innovation Institute

12:45 LUNCHEON CO-PRESENTATION: Optimizing Real World Research Design: Methodologic and Regulatory Perspectives
Sponsored by Syneos Health
Stuart McCully, PhD, Vice President, Regulatory Advisory Services, Syneos Health
David Thompson, PhD, Senior Vice President, Real World Evidence Advisory, Syneos Health

1:25 Coffee and Dessert Break in the Exhibit Hall

RWD TO SUPPORT REGULATORY DECISIONS (CONT.)

2:05 Chairperson's Remarks
Hui Cao, PhD, Executive Director, Real World Evidence, Global Medical Affairs, Novartis Pharmaceuticals

2:10 A Practical Paradigm of Using RWE for Seeking Regulatory Decisions in Label Expansion or New Indication
Hui Cao, PhD, Executive Director, Real World Evidence, Global Medical Affairs, Novartis Pharmaceuticals
21st Century Cure Act required the FDA to provide a framework and guidance for evaluating RWE in the context of drug regulation to support approvals of new indications for previously approved drugs and to support or fulfill post-approval study requirements. We established a practical paradigm to guide drug projects teams in developing high-quality RWE proposals to the FDA for these two areas.

2:40 Enhancing the Credibility of Real-World Evidence to Expand it Usage by Decision Makers
Marc Berger, MD, Chair, Real World Evidence Advisory Committee, SHYFT Analytics

3:10 Accelerating Clinical Research by Mining and Leveraging Electronic Health Records Data
Sponsored by OPTUM
Todd Johnson, MD, MBA, Senior Vice President, Clinical Research, Optum
We've all heard the statistics. Half of all clinical trials miss their timelines. Eleven percent of trial sites don't enroll a single patient. It can cost $2-3 billion dollars to bring a new drug to market. This is an incredibly challenging area that is ripe for new ideas and approaches. Optum is now ready to launch a solution that will significantly change the way clinical research is done. It's called the Digital Research Network and its goal is to combine EHR data (80+ million lives), leading-edge cloud-based technology, study design expertise and our existing relationships with research-ready provider groups in a way that only Optum can. The result will be an entirely new way to conduct clinical research that will shorten time to market and reduce the overall cost of clinical research.

3:40 A Dialogue on FDA Draft Framework for Real-World Evidence Programs
Jacqueline Corrigan-Curay, JD, MD, Director, Office of Medical Policy, CDER, FDA
The session is dedicated to a discussion on the FDA Draft Framework for Real-world Evidence Programs that was issued in December, 2018.
Q&A Moderator: Hui Cao, PhD, Executive Director, Real World Evidence, Global Medical Affairs, Novartis Pharmaceuticals

BREAKOUT DISCUSSION GROUPS

4:10 Find Your Table and Meet Your Moderator

4:15 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions. 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. See website for details: www.SCOPEsummit.com/breakouts.

5:00 Welcome Reception in the Exhibit Hall
Sponsored by ADVARRA

6:30 Close of Day

WEDNESDAY, FEBRUARY 20

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: ICF Authoring - The Next Evolution of Informed Consent
Sponsored by IQVIA
Eric Delente Head, Patient Consent, IQVIA Technologies
This session will explore how the recent introduction of informed consent form (ICF) authoring systems, including IQVIA ICF Author, have evolved the informed consent process by allowing sponsors and CROs to create, distribute, and track ICFs from a centralized portal, whether using paper forms or eConsent. It will also explore the features and benefits of these portals, showing why sponsors and CROs should consider adoption.

8:15 Session Break

RWD SOURCES AND ANALYTICAL APPROACHES

8:20 Chairperson's Remarks
Ken Light, Executive Vice President, Corporate Strategy, OmniComm Systems

Organized by Cambridge Healthtech Institute
A Division of Cambridge Innovation Institute

8:25 Real World Considerations for Using Real World Common Data Models and Rapid Analytics
Guo Li, Director, Real World Evidence (RWE) Analytics, Novartis
Use of real world data (RWD) has evolved over the last several decades to a point where the body of evidence for any research question can easily be addressed across multiple databases with the use common data models (CDMs). These CDMs can enable rapid insight generation by improving interoperability across different data types and different geographies, but also come with some important practical limitations.

8:55 Using Data and Analytics to Synthesize Real-World Evidence
Victoria Gamerman, Associate Director, Biostatistics, Head, Health Informatics & Analytics, Boehringer-Ingelheim Pharmaceuticals, Inc.
In this presentation, learn about an integrated approach to understanding real-world evidence needs throughout the medical organization. Two case studies will be highlighted: (1) an observational US-based registry in a rare disease to capture the real-world patient journey; and (2) a global survey of patients and physicians in a chronic condition. A future outlook on RWD standards and the role of Big Data in RWE generation will be shared.

9:25 Identifying Breast Cancer Stage and Biomarker Status in Administrative Claims Data Using Predictive Modeling
Cynthia de Luise, PhD, Senior Director, Epidemiology, Worldwide Safety and Regulatory, Pfizer, Inc.
Claims databases lack stage and receptor status to identify cancer populations. From Anthem's Cancer Care Quality program validation sample, we used regression and machine learning techniques to construct a predictive model to identify advanced stage ER+/HER2- breast cancer (ASBC) patients. The model (c-statistic=0.93; PPV=91%; Sensitivity=54%) was applied to the HealthCore Integrated Research Database (HIRD) to identify an ASBC cohort. Predictive modeling can identify cancer stage and receptor status in claims.

9:55 The Role of RWD After Safety Signals are Identified: Analytic Approaches to Refining a Safety Signal
Sponsored by UBC
Irene Cosmatos, Senior Research Specialist, Database Analytics Automation, UBC

10:25 Coffee Break in the Exhibit Hall

INTERNAL CONSIDERATIONS AND OPERATIONAL CHALLENGES

11:20 Chairperson's Remarks
Sean Zhao, PhD, Head, US Patient Safety Surveillance, US Medical Affairs, AstraZeneca Pharmaceuticals, Inc.

11:25 Considerations and Challenges Associated with the Implementation of an Integrated Value-Based Pharmaceutical Data and Evidence Strategy
Tony Hebden, PhD, Vice President, Health Economics & Outcomes Research, AbbVie
Pharmaceutical companies have identified the need to define value to key access stakeholders as critical to ensuring appropriate patient access to new medications. This approach requires that companies not only define value in terms of the classical RCT evidence required to obtain regulatory approval, but also develop new processes, infrastructure and governance to ensure less traditional types of evidence are generated and leveraged appropriately.

11:55 Cross-Company Coordination of Post Marketing Research Efforts
Sean Zhao, PhD, Head, US Patient Safety Surveillance, US Medical Affairs, AstraZeneca Pharmaceuticals, Inc.
There are many types of post marketing research activities, including clinical trials, patient registries, epidemiology studies, health economic and outcome researches, etc., having been used for multiple purposes, i.e., fulfilling regulatory post marketing requirements (PMRs), supporting in risk management activities, closing clinical evidence gaps, generating real life clinical evidences in supporting formulary decisions, etc. It is important to strategically plan and implement these studies and activities through a cross-company coordination. The presentation will discuss how to involve cross-company functions in post marketing research activities and when a post marketing research activity's scientific purposes can be combined with commercial goals and when they should be separated.

12:25 pm Transition to Lunch

12:30 pm BRIDGING LUNCHEON PRESENTATION: Sharper Images: How Rollover Studies Can Mitigate Post-Market Study Commitments
Sponsored by PRA Health Sciences
Meg Richards, PhD, MPH, Executive Director, Scientific Affairs, Real World Solutions, PRA Health Sciences
Over the past decade, the FDA has increasingly approved new products based on fewer and shorter trials. This reflects a lifecycle evaluation approach, which stresses continued monitoring of safety and effectiveness after the product has been marketed. Sponsors can be assigned numerous post-market commitments whose delay may result in real-world safety and effectiveness challenges. Properly designed rollover studies can provide a wealth of information about the product well in advance of marketing.

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Close of Conference

Stay on and attend Part 2: Leveraging RWD for Clinical and Observational Research . See page 60 for details.

Leveraging RWD for Clinical and Observational Research

Data Integration and Real-Time RWE Generation

The abundance of data generated during routine health care is growing in significance and should be used for clinical and observational research. Patient electronic records, registries, data from pharmacy and social media, and wearable sensors have been increasingly used as eSources. This process requires strategizing, utilizing novel data technologies, as well as close collaboration between pharmaceutical companies and organizations that possess the data. CHI's 4th Annual Leveraging RWD for Clinical and Observational Research conference will discuss challenges and solutions with secondary use of existing healthcare data to support the medicine lifecycle.

Arrive early and attend Part 1: Late Stage Research Strategy and Operations. See page 34 for details.

WEDNESDAY, FEBRUARY 20

11:30 am Registration Open

12:30 pm BRIDGING LUNCHEON PRESENTATION: Late Stage Research Strategy and Operations

Sponsored by

Meg Richards, PhD, MPH, Executive Director, Scientific Affairs, Real World Solutions, PRA Health Sciences

1:10 Coffee and Dessert Break in the Exhibit Hall

2:10 Plenary Keynotes (see page 7 for details)

3:20 Booth Crawl & Refreshment Break in the Exhibit Hall, Last Chance for Exhibit Viewing

RWD TO ACCELERATE THE DESIGN AND EXECUTION OF CLINICAL TRIALS

4:05 Chairperson's Remarks

Marc Berger, MD, Chair, Real World Evidence Advisory Committee, SHYFT Analytics

4:10 Using Learning Health Systems to Capture Real World Data in Routine Care

Charles Makin, Global Head, Real World Evidence Strategy, Biogen

As the availability and use of RWD continues to increase rapidly, demand is outpacing supply. While a variety of data sources abound, individual data gaps and lack of interconnectedness create unique challenges for users vying for precise insights. In this evolving scenario, learning health systems are emerging as a comprehensive source of patient-level data, combining patient information that traditionally resides in discrete verticals. This session discusses the best practices, challenges and limitations of this approach.

4:40 Challenges and Opportunities with Use of Real World Evidence in Drug Development

Demissie Alemayehu, PhD, Head, Vice President, Biostatistics, Pfizer

With the growing demand for new medicines to meet critical healthcare needs with speed and efficiency, it has become essential to explore novel approaches and data sources. Thanks to the prevailing digital revolution, and advances in predictive analytics and computing platforms, a new frontier has emerged to enhance the drug development process. We elucidate pertinent aspects of the use of real world evidence in regulatory settings, with emphasis on study design, analytical strategies, data quality and regulatory requirements.

5:10 Automation Beyond CRF Population. Why a Disruptive Platform to Support Multiple Data Sources Will Future Proof Your Clinical Trials

Sponsored by ORACLE Health Sciences

Greg Jones, Enterprise Strategy Architect, Life Sciences, Oracle Health Sciences

Please join this provocative session to discover how preparing your clinical research platform for EHR as a data source to automate population of CRFs can serve as a catalyst for full disruption of your clinical research approach. Implementing strategies to manage expanding data sources is the path to the future of conducting clinical trials. Join this session to understand how you can prepare for this new world. Why planning beyond CRF automation, and looking at full scale data management of legacy and emerging data sources, as well data sources we haven't imagined yet, will help future-proof your clinical development.

5:40 RWD Strategies for Improving Development and Access to Innovative Therapeutics

Gregory Daniel, PhD, Deputy Center Director, Duke-Margolis Center for Health Policy, Duke University

This presentation will include an overview of the requirements on FDA, established by the sixth reauthorization of PDUFA and the 21st Century Cures Act, to consider the use of RWE. This session will also include emerging recommendations by stakeholders regarding a framework and approaches for evaluating data quality, improving observational studies, and how broader RWE might be considered along with other factors to reach regulatory evidentiary requirements.

6:10 – 7:10 Networking Reception

Sponsored by DrFirst

THURSDAY, FEBRUARY 21

7:15 am Registration Open

7:45 BREAKFAST PRESENTATION: A User's Perspective into a Unified Imaging and EDC Approach
Sponsored by medidata

Troy Schneider, Director, Imaging Strategy, Medidata
Sarah Halek, Head, Innovation Design, ICON Medical Imaging

Come hear from a client on how using an imaging management technology on a unified platform considers the entire clinical trial process, providing configurable, intelligent workflows that complements the users and aligns to protocols, automating de-identification, edit checks, and workflow management, thereby reducing clinical trial timeline, cost, and risk. The platform ensures that correct data is presented to the right users at the right time, eliminating data reconciliation tasks and bringing visibility and access.

8:15 Session Break

LEARNING FROM EU: SALFORD STUDY AND BEYOND

8:20 Chairperson's Remarks
Kyle Ricketts, Marketing Manager, Bio-Optronics

8:25 Creating the Extensible Data Platform of the Future to Better Leverage Real World Data (RWD)

John Yonchuk, Manager, Digital Clinical Trials, GlaxoSmithKline

With the ever expanding number and types of real world data (RWD) sources, it is more critical than ever for Pharma to be able to analyze, interpret, and act upon RWD in a fast, efficient, interoperable, and extensible manner. Creating a data model and a data platform across a clinical operations organization presents opportunity but also challenges that Pharma must get right in order to succeed.

ADVANCES IN RWD ANALYTICS

9:00 CO-PRESENTATION: Real-World Data & Analytics Empowered Clinical Trials Design

Xia Wang, PhD, Director, Health Informatics & Global Medicines Development, AstraZeneca
Jane Fang, MD, Head, Clinical Business Management & Analytics, MEDI Biologics Unit, AstraZeneca

Patient-centric drug product development starts with a characterization of the targeted patient population. Real world evidence data (RWD) provides a new way to gain such insights. Incorporating RWD-use into current study planning process will advance and innovate trial design, conduct and patient recruitment. The talk will feature a RWD-empowered trial feasibility and patient recruitment process that has joined the expertise from different fields such as feasibility function, informatics and data scientists, study teams, technologists and sites.

9:35 Data-Driven Patient Recruitment with Real World Data

Liping Jin, Data-Driven Patient Recruitment Lead, Pharma Research and Early Development, pREDi Early Development Workflows, Roche

With the increasing use of Real World Data (RWD) in the pharma industry, Data-Driven Recruitment (DDR) team at Roche Pharm Research & Early Development (pRED) would like to share our experience of integrating RWD (e.g. insurance claims, EMR) with trial metrics data to optimize study protocol design and target patient recruitment strategy. While the team has received positive feedback from our business partners (translational medicine, clinical program teams, and study leaders), we would also like to share the challenges to expanding the effort in broader US, Europe and international settings.

9:55 Leveraging RWD for Clinical and Observational Research
Sponsored by

Jane Quigley, Senior Vice President, Real World Evidence, PRA Health Sciences

When will be ready for the real world? Let's find out together!

10:25 Networking Coffee Break *(Sponsorship Opportunity Available)*

SUPPLEMENTING CLINICAL TRIALS IN ONCOLOGY WITH REAL WORLD EVIDENCE

11:10 Chairperson's Remarks

Marion Brayer, Head, Clinical Operations, SOPHiA GENETICS

11:15 Supplementing Clinical Trials in Oncology with Real World Evidence

Kavita Sail, PhD, Associate Director, Health Economics and Outcomes Research, AbbVie

Real world evidence is growing in importance and can be used effectively in oncology to test sub-populations, identify risk groups and even inform the right population prior to conducting a clinical trial. Studies using big data require expertise in handling and pose unique challenges related to potential bias and complex data management strategies. It's important that these studies are conducted with expert data scientists alongside medical and clinical reviewers for correct data interpretation.

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Transition to Shared Sessions

BLOCKCHAIN: GAMECHANGER IN CLINICAL RESEARCH?

Chairperson's Remarks

Ramzi Najm, Senior Associate, Waife & Associates

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12:20 Blockchain Opportunities for Patient Data Donation & Clinical Research

Munther Baara, MS, Head, New Clinical Paradigm, Pfizer

Imagine a solution that makes it easy to aggregate health data in a secure, trusted, automated, and error-free way. A solution which enforces rules, privacy, and regulations in a mutually agreed upon manner, resulting in a smart-contract between patient and healthcare stakeholders. This enables patients to aggregate their data from diverse health sources and share what they choose to with their physicians and researchers.

12:40 Blockchain's Opportunity Today and Potential for the Future

Mal Postings, Vice President, Head, Innovation/Emerging Technologies & Chief Architect, Research & Development Solutions, IQVIA

Today, blockchain is about a data workflow using general ledger type sharing of information. Here, it is important to understand the role of a governing body to engage the stakeholders and own the smart contract rules of working. The future is moving more broadly into trusted distributed data sharing. This will start with enablement of distributed queries and then move into the ability to construct virtual data stacks.

1:00 INTERACTIVE PANEL: Blockchain in Clinical Research

Moderator: Ramzi Najm, Senior Associate, Waife & Associates

The most significant costs to clinical trials are in time and resources to insure the com-pleteness, accuracy and integrity of patient data. Blockchain technology has the potential to transform and simplify the exchange of data among business partners in clinical re-search. Can blockchain solutions be applied to reduce the time to bring new biopharmaceu-tical products to market while reducing the cost of achieving that objective? The presenta-tions and discussion will address this opportunity and the path to its implementation.

- What is the realistic path for the adoption of innovations such as block chain for sponsors, sites and CROs?
- Do service providers (CROs) play a leading or trailing role in the facilitating for the industry and why?
- Unlike EDC, block chain technology requires sites to take an active role rather than waiting for sponsors/CROs to deliver the capabilities, how does that impact adoption?
- Thoughts on global adoption
- Thoughts on business process implications and feasibility for transition

1:20 Transition to Lunch

Sponsored by accenture

1:25 LUNCHEON PRESENTATION: Intelligent Operations: Envisioning a Better Way to Deliver R&D Outcomes

Jennifer Duff, Managing Director, Life Sciences, Accenture

The research and development landscape is changing and new technology is presenting complex challenges to traditional ways of working. In order to successfully navigate this change, the industry needs to transform their core ways of working. Accenture will share perspective on how these forces are shaping the future of R&D Operations, elaborate on how Accenture is partnering with the industry to enable the pivot, and how this transformation is key to long-term success and improved outcomes.

1:55 Closing Remarks

2:00 SCOPE Summit 2019 Adjourns

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Comprehensive sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

Podium Presentations — Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a user group. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

Host a User Group on Monday, February 18

Co-locate your User Group meeting with SCOPE Summit. CHI will help market the event & manage logistical operations.

Additional sponsorship & branding opportunities include:

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- Refreshment Breaks – 3rd day added includes table top exhibit space
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Looking for additional ways to drive leads to your sales team?

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

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For additional information, please contact:

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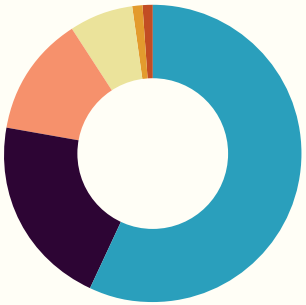
2018 ATTENDEE DEMOGRAPHICS



Company Title

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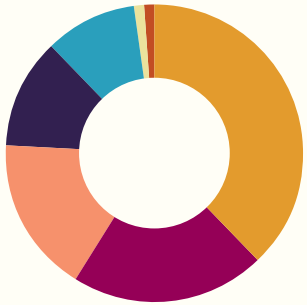

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Other	1%

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Hotel & Travel Information

Conference Venue and Hotel:

Hyatt Regency Orlando
9801 International Drive
Orlando, FL 32819
T: 407.284.1234

Reservations: Go to SCOPEsummit.com/hotel-and-travel
Discounted Room Rate: $284 s/d (Price Includes Resort Amenities)*
Discounted Room Rate Cut-off Date: January 22, 2019

Why Stay at the Hyatt Regency Orlando?

- Complimentary Wi-Fi in guestrooms
- Located on International Drive, stop #21 on the I-Ride Trolley: Situated across the street from the Orange County Convention Center, and moments away from dining, shopping, and entertainment
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- Eclectic dining: Seven on-site restaurants, serving coastal Floridian fare, poolside snacks and cocktails, rustic Italian food and steaks, and much more
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Transportation:

- The Hyatt Regency Hotel is only 15 minutes from the Orlando International Airport, with multiple transportation options to get to the hotel and around Orlando. Go to SCOPEsummit.com/hotel-and-travel to see all transportation options.

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Go to the travel page of
www.SCOPEsummit.com
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Pricing & Registration Information

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BEST VALUE! *Includes access to the entire 3-day SCOPE event, plus Monday Evening's Pre-Conference Plenary Keynote Panel and Kick-Off Networking Happy Hour*		
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Registrations After January 18, 2019 and On-Site	$1,999	$1,029

TUESDAY, FEBRUARY 19 - WEDNESDAY, FEBRUARY 20	WEDNESDAY, FEBRUARY 20 - THURSDAY, FEBRUARY 21
1A: Protocol Development, Global Site Selection, Feasibility, & Site Management	1B: Improving Site-Study Activation and Performance
2A: Enrollment Planning and Patient Recruitment	2B: Patient Engagement, Enrollment & Retention through Communities & Tech
3A: Clinical Trial Forecasting, Budgeting and Contracting	3B: Resource Management and Capacity Planning for Clinical Trials
4A: Mastering an Outsourcing Strategy	4B: Managing Outsourced Clinical Trials
5A: Implementing Risk-Based Monitoring (Part 1)	5B: Implementing Risk-Based Monitoring (Part 2)
6A: Clinical Data Strategy and Analytics	6B: Artificial Intelligence in Clinical Research
7A: Sensors, Wearables and Digital Biomarkers in Clinical Trials	7B: Clinical Technology and Innovation
8A: Late Stage Research and Observational Studies	8B: Leveraging Real World Data for Clinical and Observational Research
9A: Clinical Biomarkers Innovation and Operations	9B: Clinical Biospecimen & Central Lab Solutions
10A: Clinical Supply Management	

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Alumni Discount: Cambridge Healthtech Institute (CHI) appreciates your past participation at 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.

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Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Melissa Dolen at (+1) 781-972-5418

If you are unable to attend but would like to purchase the Summit for Clinical Ops Executives (SCOPE) CD for $750 (plus shipping), please visit SCOPEsummit.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/ Cancellations Policy, go to healthtech.com/regdetails

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