Organized by Cambridge Healthtech Institute

#SCOPE2017

Final Agenda

January 24-25

10th Annual

Enrollment Planning and Patient Recruitment:

Successful Recruitment Planning, Forecasting, and Central Campaign Management

- Moving recruitment planning upstream to reduce barriers to participation
- Recruiting & consenting patients digitally to facilitate the new paradigm of patient-centered trials
- Increasing recruitment and retention through a comprehensive patient engagement strategy

January 25-26

4th Annual

Patient Engagement, Enrollment and Retention through Communities and Technology:

Patient Centric Approaches to Optimize Clinical Trial Participation

- What does practical patient engagement mean today?: new approaches, best practices and greatest value
- Improving the clinical trial patient experience: improving consent, communication, engagement, enrollment and retention
- Virtual trials & remote trials: What is the future of truly patient-centric trials?

Register today and join over 1200 of your colleagues

Short Course

- ~~Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster~~

PARTICIPANT ENGAGEMENT AWARD SCOPE 2017

NEW this year...

SCOPE's 2017 Participant Engagement Award

Featured Speakers


Mohanish Anand, Ph.D., Senior Director and Head, Feasibility Center of Excellence, Development Operations, Pfizer


Marisa Rackley, Director, Clinical Research, Global Trial Optimization, Merck


Lori Abrams, Director, Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb


Paulo Moreira, Vice President, Global Clinical Operations - External Innovation, EMD Serono, Inc.


Megan Laker, CoLAB Consultant, CDIO, Eli Lilly and Company


Francis Kalush, Ph.D., Health Programs Coordinator, Professional Affairs and Stakeholder Engagement (PASE), CDER, FDA


Roni Zeiger, M.D., Co-Founder, Smart Patients


Mary Murray, Associate Director, Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb


David Leventhal, Director, Clinical Innovation, Worldwide R&D, Pfizer, Inc.


Ken Getz, MBA, Director, Sponsored Research Programs, Tufts CSDD; Chairman, CISCRP

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January 24-26, 2017
Hyatt Regency Miami
Miami, FL

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Event At-a-Glance

Monday, January 23 PM	Tuesday, January 24 AM & PM	Wednesday, January 25 AM	Wednesday, January 25 PM	Thursday, January 26 AM & PM
Pre-Conference Short Courses (Optional, Separate Registration Required) 2:00 pm – 6:00 pm				
SC1: ~~Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster~~				
SC2 *NEW*: How to Implement RBM on a Budget				
SC3 *NEW*: Clinical Trial Protocol Optimization				
SC4 *NEW*: ~~Managing Clinical Trials in Oncology and Immuno-Oncology~~				
SC5 *NEW*: ~~Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract~~				
SC6 *NEW*: How to Accelerate Digital Health Innovation in Your Company				
Welcome and Networking Happy Hour on the Patio 6:30 pm - 8:30 pm Hyatt Regency Miami's Riverwalk Terrace				
	SITE ACTIVATION: Conference 1A Protocol Development, Global Site Selection, Feasibility, and Site Management		SITE ACTIVATION: Conference 1B Improving Site-Study Activation and Performance	
	RECRUITMENT: Conference 2A Enrollment Planning and Patient Recruitment		RECRUITMENT: Conference 2B Patient Engagement, Enrollment and Retention through Communities and Tech	
	BUDGETING & MGMT: Conference 3A Clinical Trial Forecasting and Budgeting		BUDGETING & MGMT: Conference 3B Managing Outsourced Clinical Trials	
	OUTSOURCING: Conference 4A *NEW* Establishing an Outsourcing Strategy		OUTSOURCING: Conference 3B Managing Outsourced Clinical Trials	
	MONITORING: Conference 5A Implementing Risk-Based Monitoring (Part 1)		MONITORING: Conference 5B Implementing Risk-Based Monitoring (Part 2)	
	DATA: Conference 6A Clinical Data Strategy and Analytics		DATA: Conference 6B Clinical Technology and Innovation	
	REAL WORLD EVIDENCE: Conference 7A Managing Late Stage Research and Observational Studies		REAL WORLD EVIDENCE: Conference 7B Leveraging Real World Data for Clinical and Observational Research	
	PRECISION MEDICINE: Symposium 8A Managing Precision Medicine Trials: Biomarker and Genomics Considerations		PRECISION MEDICINE: Symposium 8B *NEW* Sample, Lab and Diagnostics Services in Clinical Trials	

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See you in Orlando for SCOPE 2018!
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For sponsorship and exhibit information, please contact:

Ilana Quigley
Sr. Business Development Manager
T: 781-972-5457
E: **iquigley@healthtech.com**

Hotel & Travel Information

CONFERENCE VENUE AND HOTEL:

Hyatt Regency Miami
400 South East Second Ave
Miami, FL 33131
T: 305-358-1234
Discounted Room Rate: **$239 s/d**
Discount Cut Off Date: **December 27, 2016**

Visit the travel page of **SCOPEsummit.com** for additional information

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Enrollment Planning and Patient Recruitment:

Successful Recruitment Planning, Forecasting, and Central Campaign Management

January 24-25, 2017

Patient recruitment and up-front enrollment planning are critical to drug development programs. Patient recruitment, if not adequately planned for, can extend your development timeline by a number of years. Retention of patients throughout the life of a clinical trial is essential in order to have complete data sets for your analysis and subsequent filings. In order to optimize both, you have to have a plan and it should take into account all stakeholders from senior management at the sponsor company and the CRO partners, to the sites and investigators and study volunteers. Cambridge Healthtech Institute's Tenth Annual Enrollment Planning and Patient Recruitment conference will cover the topics one should consider when drafting and strategically implementing a patient recruitment plan for a clinical development program.

MONDAY, JANUARY 23

1:00 pm Short Course Registration

Recommended Short Course*

2:00 – 6:00 pm ~~**SC1: Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster ***~~
* Separate registration required; visit our website for full details

2:00 – 6:45 pm Main Conference Registration

6:30 – 8:30 pm Welcome and Networking Happy Hour on the Patio hosted by CHI, Drug Dev, INC Research and

TUESDAY, JANUARY 24

7:30 am Registration and Morning Coffee

8:20 Opening Plenary Keynotes

9:45 Grand Opening Coffee Break in the Exhibit Hall

MOVING RECRUITMENT PLANNING UPSTREAM, DATA-DRIVEN RECRUITMENT & PATIENT-CENTERED TRIALS

10:45 Chairperson's Remarks
Kelly McKee, Advisor, Clinical Innovation, Eli Lilly and Co.

10:50 Pfizer's Approach to Improving Operational Predictability
Mohanish Anand, Ph.D., Senior Director and Head, Feasibility Center of Excellence, Development Operations, Pfizer
Pfizer Feasibility Center of Excellence has been working to leverage data & advanced analytics & data visualization in order to help enable the predictive delivery of the portfolio. This represents an innovative approach to enrollment forecasting challenges that all sponsor companies face. The speaker will share an overview of some of these efforts and early results. Questions from audience members will be encouraged.

11:15 Moving Recruitment Planning Upstream to Reduce Barriers to Participation: Recommendations from the CTTI Recruitment Planning Project
Beth Mahon, Associate Director, Global Clinical Operations - US, Janssen Research and Development
As many as 85% of studies are not completed on time because of recruitment and as many as 30% of sites do not even recruit one patient. This session will include a presentation of key findings and themes from our evidence gathering and consensus building processes that led to recommendations and a systematic framework for moving recruitment planning upstream in the protocol design and development process. These findings include a systematic literature review, multi-stakeholder survey, landscape scan of available recruitment planning tools and processes, and consensus generated at multi-stakeholder expert meeting.

11:40 Recruiting & Consenting Patients Digitally: Facilitating the New Paradigm of Patient-Centered Trials
Nariman Nasser, Vice President, Site Optimization, Continuum Clinical
In the era of the digital patient and a desire to move to remote trials we must explore the benefits and challenges of both recruiting and consenting patients digitally. In this session, we will consider how to seamlessly recruit and consent patients digitally in various scenarios/settings. We will also examine better practices for maintaining relationships with potential participants while engaging them digitally through the recruitment and consent process.

12:05 pm Patient Recruitment: Sponsor Insights
Sponsored by IMPERIAL CLINICAL RESEARCH SERVICES
Melynda Geurts, Vice President, Operations, Imperial
Subject enrollment is a widespread issue in clinical trials, adding significant expense and time delays to the overall scope of studies. We surveyed sponsor operations management personnel to gain insight and assess sponsor attitudes and behaviors in conducting clinical trials. We will identify current decision-making and accountability roles, enrollment metrics, stressors, and tactics with regards to patient recruitment at sponsor companies.

12:40 Luncheon Co-Presentation: Leveraging Digital and Social Media: How Patient Insights and Discoverable Data Can Lead to More Effective and Efficient Patient Recruitment and Retention Campaigns
Sponsored by PRAXIS
Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis
Tricia Barrett, Senior Vice President, Managing Director, Praxis
As the world becomes more and more digital, it is important to tap into the endless amounts of data living and being shared on the Internet. As we have lunch, we'll explore how our industry can utilize this data to determine what is useful and relevant, and then glean insights and understanding before crafting patient-centric enrollment campaigns.

1:20 Coffee and Dessert in the Exhibit Hall

INTEGRATING PATIENT INSIGHTS AND DIVERSITY INTO CLINICAL TRIAL PLANNING

2:00 Chairperson's Remarks
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis

2:05 Understanding FDA Requirements and Implementing the New Reality of Diversity in Clinical Trials
Karen Brooks, Ph.D., Senior Director, Clinical Operations, Adare Pharmaceuticals
Understand 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 research.

2:30 CASE STUDY AND INTERACTIVE PANEL: Improving Patient Diversity in Clinical Trials with Real-Time Enrollment Monitoring
One of the largest problems we are facing when it comes to clinical trial participation is the lack of diversity in our enrollment demographics. The vast majority of trials are dominated by white participants, and it is a trend that has not gone unnoticed by the FDA and other regulatory authorities, who rightly want to see pharma make major strides in improving patient diversity. This session will begin with the Merck case study presentation on their latest Hep-C program and segue into a targeted panel discussion about improving diversity and recruitment.

CASE STUDY: Operationalizing Diversity Initiatives in Clinical Research, a Hep-C Story
Marisa Rackley, Director, Clinical Research, Global Trial Optimization, Merck
The industry understands that diversity in clinical trial participation is important. Translating those values into operational plans for particular trials has been a challenge. Building a framework for teams is critical in order to realize installation of these corporate initiatives. As Hep-C does impact minority populations, it was critical that the trial reflect these demographics and improve upon previous statistics (for example, 1-3% African American participation). In order to achieve their goals, Merck launched a comprehensive strategy leveraging best practices in strategic site selection, patient-facing materials and a real-time enrollment monitoring tool. The results were impressive with a 15% African American participation rate.

2:55 INTERACTIVE PANEL: Improving Patient Diversity in Clinical Trials with Real-Time Enrollment Monitoring
Moderator: Robert Loll, Vice President, Business Development & Strategic Planning, Praxis
Fabian Sandoval, M.D., CEO & Medical Director, Emerson Clinical Research Institute (ECRI)
Marisa Rackley, Director, Clinical Research, Global Trial Optimization, Merck
This panel will discuss the lack of diversity in our enrollment demographics and address these key points in an interactive format:

- Understand the current state of diversity and why it's important to the FDA
- Review Merck's successful Hep-C program and how it worked to achieve these goals
- Learn how to operationalize the activities to support diversity in clinical trials
- Learn from sponsor, site and vendor perspectives how new techniques can make a big difference – through site selection, patient recruitment, site management and technology tools

3:20 Accelerate Clinical Trial Recruitment and Engage HealthCare Providers as Referral Sources with Specialized Clinical Field Resources

Sponsored by QuintilesIMS

Stewart Rosen, M.D. Vice President of Medical Affairs, Quintiles Health Management Solutions, QuintilesIMS

Speed and efficiency have never been more critical in clinical studies. Researchers need to consider new avenues to compress timelines. Even with careful planning, potential barriers can derail study schedules at any stage and impact results. Competition for sites may be intense, slowing the selection process. Activated sites may fail to focus aggressively on patient enrollment or lack the network to find a particular patient population. Specialized Clinical Field Resources such as Clinical Trial Educators can accelerate enrollment, improve site performance and be a primary source to educated referral networks on behalf of sites.

3:45 End of Session, Beginning of Interactive Breakout Discussion Groups

3:55 Find Your Table and Meet Your Moderator

4:00 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. 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.
View all breakout discussions: http://www.SCOPEsummit.com/breakouts

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation: eConsent: Put "Informed" Back in Informed Patient Consent

Sponsored by DrugDev do more trials

Eric Delente, President, Patient Solutions, DrugDev; Co-founder of SecureConsent (Part of DrugDev)

Electronic informed consent makes the consenting process more efficient and effective for staff, sponsors, monitors, and most importantly patients by presenting the information in formats and language in which patients are comfortable. Join us for breakfast to learn the best practices, latest technological advances, and proven benefits of deploying an eConsent solution - including the impact it has on improving patient satisfaction and retention and help us put "informed" back in patient consent process.

EFFECTIVELY ENGAGING WITH TRIAL PARTICIPANTS AND PABs TO OVERCOME RECRUITMENT CHALLENGES

8:25 Chairperson's Remarks

Mark Summers, CEO & President, ThreeWire, Inc.

8:30 Overcoming Recruitment Challenges in Rare Disease

Elizabeth Carfioli, Associate Director, Patient Recruitment, Clinical Operations, Alnylam Pharmaceuticals

Patient recruitment is challenging, even more so in Rare Disease. This presentation will share recent approaches undertaken at Alnylam Pharmaceuticals, in collaboration with our development partnership and with CROs, to achieve global recruitment goals. We will discuss country and site tailored strategies to address disease awareness to meet not only recruitment goals but longer-term strategies to identify potential patients for future trials through commercialization and share how we collaborate and engage with our sites to bring patients, their families and trials together.

8:55 Increasing Recruitment and Retention through Comprehensive Patient Engagement & Patient Advisory Boards (PABs)

Tanja Keiper, Associate Director, Global Clinical Operations - External Innovation, EMD Serono, Inc.

Co-developed by Paulo Moreira, Vice President, Global Clinical Operations - External Innovation, EMD Serono, Inc.

Struggles with recruitment and retention and efforts focused to address these issues have often overlooked a key objective: bi-directional engagement with patients. This presentation will share solutions for addressing these gaps. Also, the talk will discuss the key role of Patient Advisory Boards (PABs) in clinical development.

9:20 Co-Presentation: Starting Recruitment Before the Site Initiation Visit: 10 Steps

Sponsored by UBC

Heidi Ross, RN, BSN, Project Director, Patient & Physician Services, UBC

LaShell Robinson, MS, Manager, Patient & Physician Services, UBC

This presentation will cover: 1) Reducing time from site activation to first patient enrolled 2) Pre-enrollment activities – building the repository of eligible patients 3) Priming sites for early patient identification and meeting enrollment goals 4) Identifying and mitigating site-specific pitfalls to patient enrollment

9:45 SCOPE's 2017 Participant Engagement Award

brought to you by CHI's SCOPE and Patient Enrollment Advisors

The 2017 Participant Engagement Award is designed to inspire innovation and change in how we communicate to participants in the fields of Recruitment and Retention for clinical trials. Cambridge Healthtech Institute (CHI)'s SCOPE and Patient Enrollment Advisors welcome submissions from every aspect of the industry including Sites, CRO's, Agencies and Sponsors alike to submit their best work in the Patient Recruitment and Retention communications field.

PARTICIPANT ENGAGEMENT AWARD SCOPE 2017

Panel of Judges:

David Sall, President & CEO, Patient Enrollment Advisors

Kelly McKee, Advisor, Clinical Innovation, Eli Lilly and Co.

Jean-Christian Philippi, Founder and Chief Strategy Officer, One Creative

Mark Sloan, M.D., Hematology & Medical Oncology, Boston Medical Center

Submit your entry for SCOPE's 2017 Participant Engagement Award.
Deadline for submission is November 18, 2016.

10:10 Coffee Break in the Exhibit Hall

RECRUITMENT IN RESOURCE-CONSTRAINED ENVIRONMENT:TRADITIONAL TACTICS, ANALYTICS, ENGAGEMENT

11:10 Chairperson's Remarks

Gretchen Goller, MSW, Senior Director, PARS, PRA Health Sciences

11:15 Bringing the Patient Voice and Community into the Drug Development Process

Francis Kalush, Ph.D., Health Programs Coordinator, Professional Affairs and Stakeholder Engagement (PASE), CDER, FDA

FDA's Professional Affairs and Stakeholder Engagement at CDER is has been working with all stakeholders: patients/patient advocates, health professionals and industry to bring the patient voice and perspective into the drug development and approval process. The goal would be to continue the support of novel therapies that directly address the need of patients living with diseases. Learn to effectively engage with FDA. Understand how to bring the voice of the patient into the drug approval process.

11:40 INTERACTIVE PANEL: Recruitment in a Resource Constrained Environment: Do Past Tactics Still Give the Same Outcome in Present Day Scenarios?

Moderator: Jeffrey Kasher, Ph.D., President, Patients Can't Wait

Nariman Nasser, Vice President, Site Optimization, Continuum Clinical

Madeline Geday, Associate Director, Clinical Research, Global Trial Optimization, Merck & Co

Mohanish Anand, Ph.D., Senior Director and Head, Feasibility Center of Excellence, Development Operations, Pfizer

An introspective panel looking at the current landscape we face when trying to enroll patients in a study. Panelists will provide 2 scenarios outlining the tactics used to support the trial, while involving the audience to further the discussion. Topics such as Patient Engagement, increased need for justification in site selections by regulatory authorities, as well as decreased recruitment dollars will be discussed.

- Reinforcement of tactics potentially already known, but potentially not selected due to potential archaic nature
- Introduction to tactics not known or considered
- Industry perspective into how similar all of our trial concerns are
- Help vendors also understand that more must be done with less and bidding may be significantly lower than typical

12:10 Bridging Luncheon Presentation: A Breakthrough in Technology Enabled Clinical Trials Recruitment

Sponsored by clinithink

Steven Coca, M.D., Associate Professor of Medicine, Internal Medicine, Icahn School of Medicine, Mount Sinai

Dr. Coca is presenting on the effectiveness of CLiX ENRICH in accelerating patient recruitment illustrated by two case studies: a retroactive analysis of a trial in which CLiX ENRICH yielded twice the candidates in half the time; and a live trial whereby CLiX identified a large cohort of quality patients.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Patient Engagement, Enrollment and Retention through Communities and Technology. See page 7 for details.

Enrollment planning and patient recruitment are critical to drug development programs and garner a lot of attention by study teams. However, once the hard work of identifying and recruiting a trial subject has been accomplished, they must be retained and remain in compliance. Retention of patients throughout the life of a clinical trial is essential in order to have complete data sets for your analysis and subsequent filings. There are strategies, tools and techniques such as social media platforms and mobile technology, empowered patient communities, and a more informed patient population that need to be understood and engaged. Cambridge Healthtech Institute's Fourth Annual Patient Engagement, Enrollment and Retention through Communities and Technology conference will cover the topics one should consider when planning and strategically implementing a patient engagement and a patient retention plan in the digital age.

Arrive early and attend Part 1: Enrollment Planning and Patient Recruitment.
See page 4 for details.

WEDNESDAY, JANUARY 25

12:10 pm Bridging Luncheon Presentation: A Breakthrough in Technology Enabled Clinical Trials Recruitment

Sponsored by clinithink

Steven Coca, M.D., Associate Professor of Medicine, Internal Medicine, Icahn School of Medicine, Mount Sinai

Dr. Coca is presenting on the effectiveness of CLiX ENRICH in accelerating patient recruitment illustrated by two case studies: a retroactive analysis of a trial in which CLiX ENRICH yielded twice the candidates in half the time; and a live trial whereby CLiX identified a large cohort of quality patients.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes

3:00 Refreshment Break in the Exhibit Hall (Last Chance for Viewing)

WHAT DOES PRACTICAL PATIENT ENGAGEMENT MEAN TODAY?: NEW APPROACHES, BEST PRACTICES AND GREATEST VALUE

4:00 Chairperson's Remarks

Reg Blynn, Vice President, Client Services, Site and Patient Networks, QuintilesIMS

4:05 The Secret Weapon for Patient Engagement and Retention: Other Patients

Roni Zeiger, M.D., Co-Founder, Smart Patients

The traditional models define trial teams and investigators as experts who provide patients their knowledge and care. What if we redefine patients not just as partners, but also as valuable resources for each other before, during, and after trials? Doing so allows us to better support patients while engaging them as clinical trial participants and advocates.

4:30 CO-PRESENTATION: Patient Engagement, Enrollment & Retention through Communities & Technology

Sponsored by PRA Health Sciences

Gretchen Goller, MSW, Senior Director PARS, PRA Health Sciences

Susan Campbell, Director, Patient Access and Retention Services, PRA Health Sciences

Although protocol and site feasibility services have become standard activities of sponsors and CROs in order to plan and operate clinical trials, patient feasibility has currently not been adopted in the same way. This is partially due to the lack of knowledge of this service offering. Patient feasibility can yield quantitative and qualitative data that offers sponsors insight into patients' motivations and intentions in participating in clinical trials. PRA's strategy is aimed at understanding patient's decision-making process and perceptions about clinical trial participation and protocol-specific studies in order to preemptively identify potential enrollment and retention barriers and key messaging from the patient's perspective. We will be discussing several case studies in this session that demonstrate the importance of this deeper dive into the patient perspective and illustrating that feedback to inform all aspects of a patient recruitment campaign.

4:55 CO-PRESENTATION: Inside Out: A New Approach to Patient Engagement

Mary Murray, Associate Director, Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb

Helen Kellar-Wood, Lead, Diversity & Patient Engagement, Global Clinical Operations, Bristol-Myers Squibb

Patient engagement does not always look and feel the same from internal and external perspectives. How can patient engagement strategies be developed to perpetuate an ongoing and robust conversation with patients as partners? The speakers will address this question, sharing examples and unexpected experiences from the past few years that have led to the development of a new approach.

5:20 CO-PRESENTATION: Patient Group Engagement in Clinical Trials: Best Practices for Best Value

David Leventhal, Director, Clinical Innovation, Worldwide R&D, Pfizer, Inc.

Ken Getz, MBA, Director, Sponsored Research Programs, Tufts CSDD; Chairman, CISCRP

Patient groups are developing diverse skillsets and assets to provide valuable trial services, funding, and ability to enhance collaboration. Research sponsors across the clinical trials enterprise are recognizing the benefits of continuous and meaningful patient group engagement, but all stakeholders need further guidance on operationalizing this new model. CTTI's best practices consolidate actionable recommendations for establishing strong, active patient group engagement during all phases of the research and development lifecycle.

5:45 Reception hosted by Exostar

Sponsored by EXOSTAR

THURSDAY, JANUARY 26

7:30 am Registration

7:45 Breakfast Co-Presentation: The Inspiring Hope Ideathon: Solutioning the Clinical Trial Awareness Gap

Sponsored by INC Research

Christine Phillips, Senior Director, Site & Patient Access, INC Research

Angela Radcliffe, Executive Vice President, Senior Leadership, FCBVIO

To advance society's ability to respond to future healthcare challenges and advance medical innovation we must increase awareness of clinical research and study participation. Clinical research is vital to the development of new drugs and treatments but is dependent on patient participation. The "Inspiring Hope Ideathon" was the first initiative of its kind designed to generate new and unique ideas. The participation and results were groundbreaking and will be shared here!

IMPROVING THE CLINICAL TRIAL EXPERIENCE BY EFFECTIVELY ENGAGING PATIENTS

8:35 Chairperson's Remarks

Aaron Fleishman, Product Innovation and Engagement Strategist, Market Expansion and Product Innovation, BBK Worldwide

8:40 The Hero's Journey: Crowdsourced Art to Celebrate Clinical Trial Participants and Raise Awareness of Clinical Research

Kelly McKee, Advisor, Clinical Innovation, Eli Lilly and Co.

The Hero's Journey is crowdsourced art sponsored by Lilly to celebrate clinical trial participants and raise awareness of clinical research. Once complete, the sculptures will be displayed to the public as part of an art exhibit traveling throughout the United States and will be on permanent public display after the traveling exhibit ends. We will engage communities and raise awareness of clinical trials through the artwork and social media using #herosjourneyart. The project will be complete with results to share in time for SCOPE 2017.

9:05 Improving the Clinical Trial Patient Experience by Effectively Engaging Patients

Michelle Collins, Director, Patient and Investigator Relations, Clinical Field Operations, AbbVie

Enabling timely patient recruitment and maintaining robust patient retention continue to be key challenges in the conduct of clinical trials. Effective patient engagement early in the clinical development process can significantly improve patient recruitment and retention efforts. Additionally, effective patient engagement can also inform clinical trials to improve the experience of patients participating in clinical trials. Enhancing the patient experience is a key objective that should be considered when implementing patient engagement efforts in clinical development.

9:30 Informed Consent Entering the Digital World: The Transcelerate eConsent Initiative

Holly Beisner, Senior Associate, Site Activation Management, Clinical Operations, Eli Lilly and Company

Co-developed with Hilde Vanaken, Ph.D., Director, R&D Operations Innovation, Janssen Research & Development

While the shift to digital technologies is pervasive, the informed consent process for clinical trials remains paper-based. eConsent can transform the informed consent process by using an array of patient-focused digital components to empower patients and their caregivers to make an informed decision and create process efficiencies for sites, health authorities, IECs/IRBs and sponsors. The eConsent Initiative at TransCelerate provides the first cross-industry perspective on this novel technology, developed over a period of 1.5 years with input from over 14 global pharmaceutical companies.

Sponsored by WORLDWIDE CLINICAL TRIALS

9:55 Patient Recruitment of Alzheimer's Disease: Using Behavioral Research to Create Lasting Engagement and Trial Success

Barbara Zupancic, MS, MBA, Director, Global Patient Recruitment and Retention, Worldwide Clinical Trials

Alzheimer's research is booming and many believe the first person cured from this disease has already been born. Conducting studies in people who exhibit no cognitive deficits (yet) will be the differentiator in finding a cure.

Audiences can expect to learn how to effectively conduct and use findings from Worldwide's extensive Alzheimer's experience. Attendees will learn best practices for developing/implementing a patient-centered strategy focused on using the right channels/messaging for lasting engagement and faster recruitment.

10:20 Coffee Break

RAISING AWARENESS AND PARTICIPATION IN CLINICAL RESEARCH

10:35 Chairperson's Remarks

Matt Hendricks, Partner, Pharmica Consulting

10:40 Content Really Is King! Even in Clinical Research

Jerry Matczak, Consultant, Clinical Innovation, Eli Lilly and Company

Fresh, engaging and ultimately authentic, human content is required to connect to people in today's information saturated and very social world. Clinical research is no exception. Learn from Lilly's experience in bringing a content marketing strategy to clinical research through a multi-channel, internet engaged ecosystem to raise awareness, trust and ultimately participation in clinical research.

Sponsored by BBK WORLDWIDE

11:05 Breaking Down the Barriers of Innovation

Aaron Fleishman, Product Innovation and Engagement Strategist, Market Expansion and Product Innovation, BBK Worldwide

Approaches that include new innovations more often than not see improved engagement, more reliable data and higher retention rates. This session will take a look at how to implement innovation company-wide. We will look at the most disruptive innovations and offer ideas on how to implement them to the benefit of patients and study stakeholders. Also, practical advice on preparing for what's next in the industry, building innovation, and growing with new technology.

11:30 Transition to Shared Sessions

VIRTUAL TRIALS & REMOTE TRIALS: WHAT IS THE FUTURE OF TRULY PATIENT-CENTRIC TRIALS AND HOW DO WE DO THIS NOW?

SPECIAL SHARED SESSION

11:30 Chairperson's Remarks

Matt Hendricks, Partner, Pharmica Consulting

11:35 Remote Trials: Moving beyond the Concept

Hassan Kadhim, Business Consultant, IT RDM, Boehringer-Ingelheim

Remote Trials have been gaining more traction over the past few years as a new and innovative way to run clinical trials. The concept is certainly very interesting, but operationally very challenging to coalesce. In this talk, we will address some of these challenges, review the stakeholders' perceptions around the implementation of Remote Trials, and propose the steps forward to be able to run Remote Trials in the near future.

12:00 pm CoLAB: Redefining Collaborative Engagement with Patients in Clinical Trials

Megan Laker, CoLAB Consultant, CDIO, Eli Lilly and Company

The purpose of CoLAB is to improve Lilly clinical trials by considering the Site, Patient, and Patient-partner perspective. Site and Patient Simulation is one of the ways that CoLAB brings together Lilly study teams, clinical site Study Coordinators, Patients, and Patient-partners to understand real-world feedback on operational issues within our clinical protocols. By engaging your Patients upfront, you can ensure that good science aligns with good patient care. By engaging Patients early in protocol development, you can potentially improve the clinical research patient experience.

12:25 CO-PRESENTATION: Engaging with Sites and Patients to Enable Digital Innovation for Clinical Trials

Elizabeth Beatty, Head, Digital Clinical Trials, Bristol-Myers Squibb

Scott Rauscher, Associate Director, Global Procurement R&D, Bristol-Myers Squibb

In the new healthcare ecosystem and digital age, patients expect care and solutions that are coordinated, convenient, customized, and accessible. Biopharmaceutical companies are doing a lot to address these emerging expectations for patient engagement services and we are all learning a lot on the way. It is important to truly engage with sites, investigators and research volunteers using both traditional and hi-tech means and to learn from those early and ongoing interactions. With Aspire, a unique BMS effort that will be shared in this presentation, we put the focus on the Sites and Patients and the results are guiding other trial planning and management efforts.

12:50 INTERACTIVE PANEL: Digital Clinical Trial Lessons Learned: Panel Discussion from Pharma Innovators Who Have Run Virtual Trials

Moderator: Matt Hendricks, Partner, Pharmica Consulting

Hassan Kadhim, Business Consultant, IT RDM, Boehringer-Ingelheim

Michelle Crouthamel, Lead, Clinical Innovation & Digital Platforms Unit, GlaxoSmithKline

Alex Simmonds, Associate Director, Health IT, Bristol-Myers Squibb

Margaretta Nyilas, MD, Sr. Vice President, Clinical and Business Operations

Jane Rhodes, Senior Director, New Initiatives, Innovation Hub, Biogen

In the past year, several large Pharma companies have begun experimenting with a new breed of reimagined clinical trials which leverage wearables and fewer sites. Now the results from the first round of these experiments are in, and the pioneers who ran the studies are ready to share their findings. Join us as we discuss what aspects of these studies are ready for prime time, where there is still work to be done, and most importantly, how patients have reacted to this shift. The conversation will focus on platforms & technology from industry veterans, startups, and established newcomers such as Apple and their ResearchKit platform.

1:15 Closing Remarks

1:20 SCOPE 2017 Conference Adjourns (see you in Orlando for 2018!)

SCOPE's Interactive Breakout Discussion Groups

are a must-attend part of the conference and take place on Tuesday afternoon.

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. 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.

TABLE 1:	**Clinical Trials in 2030: Where are We Going?**
TABLE 3:	**Understanding and Implementing the New Reality of Diversity in Clinical Trials**
TABLE 4:	**Rare Disease and Other Hard-to-find Populations: A Discussion about Adapting Traditional Patient Recruitment and Engagement Strategies for Today's Most Challenging Studies**
TABLE 5:	**Strategies for Accelerating Recruitment in Complex Clinical Trials in a Resource Constrained Environment**
TABLE 7:	**What Does Patient Engagement Mean Today?: Developing an Overall Engagement Strategy to Better Engage, Gain Insights from and Retain Patients**
TABLE 11:	**Wearables in Clinical Trials**
TABLE 14:	**Managing Relationships with High Performing Sites**

For full details on the breakout discussion groups, visit **SCOPEsummit.com/breakouts**

Pricing and Registration Information

CONFERENCE PRICING

	Commercial	Academic, Government, Hospital-affiliated
BEST VALUE! - Includes access to the entire 3-day SCOPE program (Does not include access to pre-conference short courses)		
Registration after December 23, 2016, and on-site	$2,849	$1,349
BASIC CONFERENCE PRICING - Includes access to ONE conference or ONE symposium (Does not include access to pre-conference short courses)		
Registration after December 23, 2016, and on-site	$1,899	$1,025

Tues-Wed (Jan. 24-25)	Wed-Thurs (Jan. 25-26)
1A: Protocol Development, Global Site Selection, Feasibility and Site Management	1B: Improving Site-Study Activation and Performance
2A: Enrollment Planning and Patient Recruitment	2B: Patient Engagement, Enrollment and Retention through Communities and Tech
3A: Clinical Trial Forecasting and Budgeting	3B: Managing Outsourced Clinical Trials
4A: Establishing an Outsourcing Strategy	3B: 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: Clinical Technology and Innovation
7A: Managing Late Stage Research and Observational Studies	7B: Leveraging Real World Data for Clinical and Observational Research
8A: Symposium: Managing Precision Medicine Trials	8B: New Symposium: Sample, Lab and Diagnostic Services in Clinical Trials

CONFERENCE DISCOUNTS

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 Discount*	20% Off	20% Off
SAFE BioPharma Association membership discount*	10% Off	10% Off

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Melissa Dolen at 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

Video and or audio recording of any kind is prohibited onsite at all CHI events.

**Alumni, SAFE BioPharma Association, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.*

How to Register: **SCOPEsummit.com**

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Please use keycode **RCTF** when registering!

Please refer to the Registration Code below:

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