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#SCOPE2017

Final Agenda

Register by October 28 and SAVE up to $400

8th Annual

SCOPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

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

Event Features

- More than 1200 participants projected for 2017
- 13 Conferences
- 2 Plenary Keynote Sessions
- 6 Pre-Conference Short Courses
- 2 New Symposia
- Clinical Informatics News Best Practices Awards
- New Participant Engagement Awards
- Dedicated Exhibit Hall Hours & Networking Functions

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Event At-a-Glance

Monday, January 23 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

	Tuesday, January 24 AM & PM	Wednesday, January 25 AM	Wednesday, January 25 PM	Thursday, January 26 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 & MGMT	Conference 3A Clinical Trial Forecasting and Budgeting		Conference 3B Managing Outsourced Clinical Trials	
OUTSOURCING	Conference 4A *NEW* Establishing an Outsourcing Strategy		Conference 3B Managing Outsourced Clinical Trials	
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 Clinical Technology and Innovation	
REAL WORLD EVIDENCE	Conference 7A Managing Late Stage Research and Observational Studies		Conference 7B Leveraging Real World Data for Clinical and Observational Research	
PRECISION MEDICINE	Symposium 8A Managing Precision Medicine Trials: Biomarker and Genomics Considerations		Symposium 8B *NEW* Sample, Lab and Diagnostics Services in Clinical Trials	

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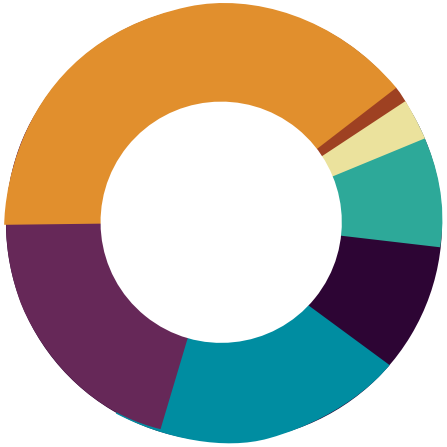
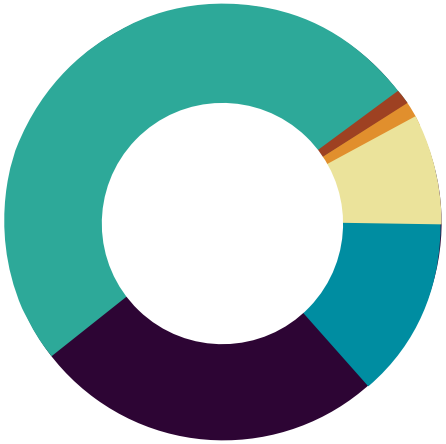
Attendee Demographics



Company Type

CRO	43%
Pharma	20%
Biotech/Commercial	18%
Healthcare/Hospitals	8%
Services/Societies	7%
Academic	3%
Other	1%



Company Title

Executive/Director	50%
Sales & Marketing	25%
Manager	14%
Scientist/Technologist	9%
Professor	1%
Other	1%

> "SCOPE was a wonderful venue to speak with other leaders in the industry and share real world examples. It is the perfect size to make collaboration happen!"

Executive Director, Clinical Operations, Chiltern

Stay Connected

Join the Clinical Trials Ops Executives group

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CHI's INTRONET
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The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people that you want to meet. This online system was designed with your privacy in mind and is only available to registered session attendees of this event.

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Sponsorship, Exhibit and Lead Generation Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

Podium Presentations — *Available within Main Agenda!*

Showcase your solutions to a guaranteed, targeted audience through a 15- or 25-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. 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! Sign on early to secure your talk.

Mobile App Co-Sponsorship

SCOPE provides all 1,200+ conference participants with a mobile app to facilitate communication and navigation of various event features.

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Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

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Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

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- Aisle Signs
- Meter Boards
- Hotel Key Cards

For sponsorship and exhibit information, please contact:

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

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:

- Whitepapers
- Web Symposia
- Custom Market Research Surveys
- Podcasts

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Hotel & Travel Information

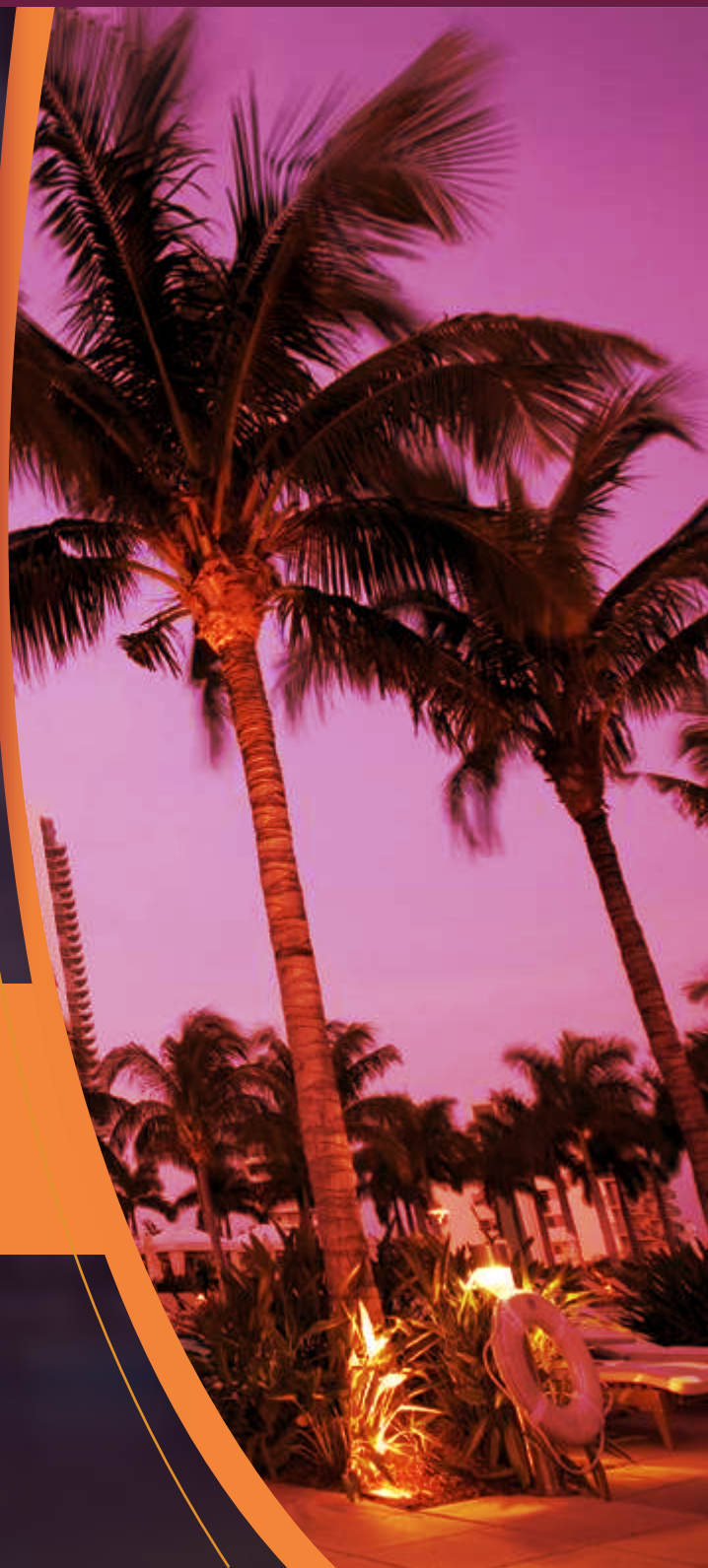
Conference Venue and Hotel:

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**

Why Stay at the Hyatt Regency Miami?

Located on the Miami River in the heart of downtown, the Hyatt Regency Miami provides luxurious amenities and accommodations in a vibrant setting. Explore the Riverwalk and shops at Bayside Marketplace, or walk to world class restaurants, just steps away. The hotel is 8 miles from Miami International Airport, 20 minutes from South Beach, and is adjacent to Miami's free Metromover transportation system. In addition, enjoy complimentary wifi in your guest room!

Visit the travel page of
SCOPEsummit.com
for additional information



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Pre-Conference Short Courses*

Monday, January 23 | 2:00 - 6:00 PM

Join your colleagues for more in-depth, focused learning at an informational and interactive Short Course. Choose one of the Short Courses below for four hours of instruction and discussion in a small group setting. Get your questions answered, network with colleagues, and share ideas.

SC1: Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster
Matt Miller, Vice President, Global Patient Recruitment & Feasibility, StudyKIK
Chris Caldron, Director, Radiant Research
Jerome Chiaro, Project Director, StudyKIK
William Martin, Ph.D., Senior Director, Clinical Development, Alkermes

SC2: How to Implement RBM on a Budget
Brian Nugent, Associate Director, PALM, Clinical Operations, Gilead Sciences
Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences

SC3: Clinical Trial Protocol Optimization
Kenneth Koury, Ph.D., Executive Director, Clinical Biostatistics, Merck Research Laboratories
Sheri Kuss, Associate Director, Clinical Process Development, Teva Pharmaceuticals
Abbe Steel, CEO, Founder, HealthiVibe, LLC
Stella Stergiopoulos, Senior Project Manager, Tufts Center for the Study of Drug Development, Tufts University

SC4: Managing Clinical Trials in Oncology and Immuno-Oncology
Jill Loftiss, Senior Director, Oncology Clinical Ops, AZ/MedImmune

SC5: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract
Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer

SC6: How to Accelerate Digital Health Innovation in Your Company
John Reites, Head, Digital Health Acceleration, Quintiles
Michelle Crouthamel, Lead, Clinical Innovation & Digital Platforms Unit, GlaxoSmithKline
Lucia Soares, Vice President, Healthcare Technology Strategy, Johnson & Johnson
Chris Edwards, CMO, Validic
Jeff Frazier, CEO, THREAD Research

**Separate registration is required.*

After the Short Courses…

Welcome and Networking Happy Hour on the Patio hosted by CHI, DrugDev and Praxis

Monday, January 23, 2017 • 6:30 pm - 8:30 pm
Hyatt Regency Miami's Riverwalk Terrace • Miami, FL

Kick off SCOPE at our Welcome Happy Hour Monday, January 23, 2017, 6:30 - 8:30 pm at the Hyatt Regency Miami, co-hosted by CHI, DrugDev and Praxis. Each year the majority of delegates arrive at SCOPE on Monday with roller bags and exhibit booths in tow so why not stop by for cocktails and hors d'ouerves? Connect with old friends or make some new ones in this casual setting on the Riverwalk Terrace of Hyatt Regency. Come early to attend the pre-conference short courses from 2:00 to 6:00 pm.

Running shoes, jeans, Aloha shirts are all appropriate for Happy Hour.

Cambridge HEALTHTECH Institute

SCOPE SUMMIT FOR CLINICAL OPS EXECUTIVES

DrugDev do more trials

PRAXIS

Plenary Keynotes & Panels

TUESDAY, JANUARY 24

OPENING PLENARY KEYNOTES

RE-THINKING THE DESIGN AND PLANNING OF OUR STUDIES

7:30 am Registration and Morning Coffee

8:20 Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

8:25 Chairperson's Introduction: Reimagining the Patient Experience
Bonnie Brescia, Founding Principal, BBK Worldwide

8:30 Understanding the Value of Communication and Collaboration between Industry-Sites-Patients in the Clinic Clinical Research Enterprise: SCOPE's Role in Making the Connection
Christine Pierre, President, Society for Clinical Research Sites (SCRS)
Increased collaboration has been the drum beat of clinical research for at least a decade. Over the next three days many of the sessions will talk about advances in collaboration and engagement that have been made possible through new initiatives, improved processes, patient-centric design, and new technology. As we look at the needs for collaboration that remain unfulfilled, what is working today can serve as a model for how to go forward.

8:40 Co-Presentation: Bringing Design Thinking into Clinical Trials
Katherine Vandebelt, Senior Director, Clinical Innovation, Eli Lilly and Company

Janelle Sabo, Pharm.D., MBA, Senior Group Director, Product Delivery, Medicines Development Unit, Eli Lilly and Company
This presentation will consider how we can re-evaluate our current approach to the planning and management of our studies. Bringing Design Thinking into clinical trials seems abstract, but embracing new design and planning approaches for clinical trials, de-constructing our current protocol development process, better integrating the customer-patient into our planning, and moving beyond process improvement all fall under this concept. We will share a story from two perspectives that offers a view into our journey.

9:05 INTERACTIVE PANEL: Re-Thinking the Design & Planning Approaches for Clinical Trials
Realizing the potential to transform clinical trials begins with a reimagined clinical trial protocol. Yet clinical trial protocols grow increasingly complex, and protocol amendments continue to impact study timelines and budgets. Join a discussion into how study design and planning can be approached in novel ways, and how organizations are adapting today to leverage this new future.

- Learn how to leverage a range of new data, from real world data to investigator performance data and beyond
- Capture and apply patient insights to drive feasibility, optimization and meaningful endpoints
- Employ 'design thinking' methods to ensure the needs of the participant, investigator and coordinator are considered and realized

Moderator:

Craig Lipset, MBA, Head of Clinical Innovation, R&D, Pfizer, Inc.

Panelists:

Murray Abramson, M.D., Vice President, Global Clinical Operations, Biogen

Bardia Akbari, Pharm.D., Vice President, Product Global Development, Oncology, Genentech, Inc.

Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline

Christine Pierre, President, Society for Clinical Research Sites (SCRS)

Katherine Vandebelt, Senior Director, Clinical Innovation, Eli Lilly and Company

9:45 Grand Opening Coffee Break in the Exhibit Hall

10:45 Join Your Conference Track

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Plenary Keynotes & Panels

Wednesday, January 25 | 1:30 - 4:00 PM

WEDNESDAY, JANUARY 25

AFTERNOON PLENARY KEYNOTES

MOVING TOWARD TRIALS OF THE FUTURE

1:30 pm Organizer's Welcome
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

1:35 Chairperson's Remarks
Clare Grace, Vice President, Site & Patient Access, INC Research

1:40 Plenary Keynote Chairperson's Opening Remarks & Clinical Informatics News Best Practices Awards
Allison Proffitt, Editorial Director, Bio-IT World & Clinical Informatics News

Clinical Informatics News is proud to present its Second Annual Clinical Informatics News Best Practices Awards. This awards program seeks to recognize outstanding examples of applied strategic innovation, partnerships, deployments, and collaborations that manifestly improve the clinical trial process.

1:50 Crawl. Walk. Run… Is This Really the Best Way to Innovate?
Jeremy Sohn, Vice President, Head of Digital Business Development & Licensing, Novartis

The pharma industry is one of the most innovative industries in the world, yet we have struggled to accelerate meaningful change in the ways we run our clinical trials. Why isn't the future now? It is certainly not for a lack of trying or investment, including both successes and failures. We can continue to repeat the past or is it time for us to begin to challenge some of the core principles that have guided us: Should we really crawl…walk…and then run? Should innovation teams exist outside of our mainstream operations or should they be fully integrated? Should we wait for regulatory agencies to get comfortable with technology or should we directly engage agencies to help us solve our collective challenges? Should we innovate independently or should we partner together to accelerate change? Are "innovation" and "transformation" even the right words to use to describe our teams' objectives? In a world where technology changes every 18 months, where product development cycles are getting shorter and shorter, where agile development models allow us to respond in real-time to the needs of our consumers, the time may be right for us to at least question these norms. I know we as an industry can and want to do better.

2:10 Move Digital Health Innovation from PowerPoint to Action
John Reites, Head, Digital Health Acceleration, Quintiles

As leaders of innovation in our companies, we can see the future benefits of digital health as we strive to change the way research is conducted. As we look ahead, however, we still have many barriers to overcome in bringing the promises of digital health into our daily work. This session will explore strategies to move digital health approaches forward including why we must make the change, review of case studies on remote patient research and accelerator execution models.

2:20 INTERACTIVE PANEL: Moving towards Trials of the Future

As our industry adjusts to an array of new digital health innovations, consumer trends in connected data and pressure to extensively pilot novel approaches, our teams require a new way of thinking and planning. This session will explore how biopharmaceutical companies are moving these solutions forward to change the way research is conducted and change cultures in their organizations to drive adoption. This panel discussion will include review of the following:

- Innovation initiatives underway today / What initiatives are you engaged with today to move towards trials of the future?
- Balance with innovation development between in-house, external partners, consortiums and startup company resources / How do we strike a balance between moving these initiatives forward in the expanded ecosystem of digital health and clinical research partners?
- Innovation models and accelerators / What innovation execution models are you using and/or seeing are most successful to date?
- Tools to overcome internal challenges / Do you have any tools or processes to share that are helping you move innovation forward in your companies?
- Key Performance Indicators (KPIs) needed to drive change / What KPIs are required and/or needed in the future to move to trials of the future?

Moderator:

John Reites, Head, Digital Health Acceleration, Quintiles

Panelists:

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

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

Lucia Soares, Vice President, Healthcare Technology Strategy, Johnson & Johnson

Jeremy Sohn, Vice President, Head of Digital Business Development & Licensing, Novartis

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

4:00 Join Your Conference Track

Register Online!
SCOPEsummit.com

Interactive Breakout Discussion Groups

Tuesday, January 24 | 3:55 - 5:00 PM

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.
See website for details: http://www.scopesummit.com/breakouts/

5:00 Welcome Reception in the Exhibit Hall

6:15 Close of Day

TABLE 1: Clinical Trials in 2020: Where are We Going?

Moderators: Hassan Kadhim, Business Consultant, IS BP R&DM, Boehringer Ingelheim

Abbe Steel, Founder & CEO, Executive, HealthiVibe, LLC

Matt Hendricks, Partner, Pharmica Consulting

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

What novel approaches to patient engagement will bridge the gap and support greater patient focus throughout life sciences in the next 3 years?

Promising strides have been made with virtual clinical trials and social media sensing. What are the next feasible milestones we will see in trials which will be held up as evidence in 2020 as true technological innovation in our industry?

Considering varied value propositions for genuine clinical trial change on a country by country basis, in which countries do you see the best opportunity for exploration of novel ideas in clinical trials over the next 3 years?

TABLE 2: Embracing Best Practices in Protocol Design to Reduce Protocol Amendments and Improve Trials

Moderators: Stella Stergiopoulos, Senior Project Manager, Center for the Study of Drug Development, Tufts University

Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline

Michael Jay, Vice President, Society for Clinical Research Sites (SCRS)

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 finding success?

TABLE 3: Understanding and Implementing the New Reality of Diversity in Clinical Trials

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

Danielle Darasz, Senior Project Manager or Cameron Snider, Vice President, DrugDev

Karen Brooks, Ph.D., Senior Director, Clinical Operations, Adare Pharmaceuticals

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?

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

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

Silvana Giustino, Global Head, Clinical Development Expert Resources, Roche

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

Michelle Hylan, Clinical Operations Consultant, Rhythm Pharmaceuticals

Identify the challenges inherent when potentially eligible patients are few and far between

Discuss tactical successes and lessons learned

Understand the role of advocacy in recruitment and awareness building

TABLE 5: Strategies for Accelerating Recruitment in Complex Clinical Trials in a Resource Constrained Environment

Moderators: Richard Mayewski, Associate Director, Clinical Trial Intelligence, Global Clinical Trial Leadership, Novartis

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

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

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)

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Interactive Breakout Discussion Groups

Tuesday, January 24 | 3:55 - 5:00 PM

TABLE 6: Optimizing Country and Site Selection: Strategies for Positioning Trials for Success using a Global Footprint

Moderators: Claire Sears, Director, Data Solutions, DrugDev

Shawn Tedman, Lead, Strategic Feasibility, Site & Patient Solutions, UCB BioSciences

Kate Zarish, Director, Strategic Study Start Up, Development Operations, Clinical Field Operations, AbbVie

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

TABLE 7: What Does Patient Engagement Mean Today?: Developing an Overall Engagement Strategy to Better Engage, Gain Insights from and Retain Patients

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

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

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

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

Moving beyond the buzzword of "patient engagement," how can we connect with patients and really understand and integrate their insights into our planning and processes?

How can patient engagement strategies be developed to perpetuate an ongoing and robust conversation with patients as partners?

From a content marketing strategy, how can we in industry facilitate engaging and ultimately authentic human content to connect to people in today's information saturated and very social world?

TABLE 8: Functionality and Technology Related to the TransCelerate Shared Investigator Platform: Current State, Opportunities, & Next Steps

Moderators: Edward Mannello, Feasibility & Recruitment Director, Clinical Operations, AstraZeneca

Navreet Dhindsa, Director, Clinical Operations, Merrimack Pharmaceuticals Inc.

To be Announced, TransCelerate Shared Investigator Platform Representative

What is a seamless user experience for interaction with multiple study sponsors?

How do we achieve harmonized training content delivery (e.g., GCP) and certification?

What are the challenges of secure document exchange to facilitate communication during study planning and study conduct?

What else is needed?

TABLE 9: Quality and RBM

Moderators: Brian Nugent, Associate Director, PALM, Clinical Operations, Gilead Sciences

Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences

What are the most common challenges you encounter when implementing a Quality Management System?

How does a QMS and risk-based monitoring function in combination to enhance clinical trial quality and efficiency?

What are your tips for making a RBM program work well?

How could we improve RBM from its current practice?

TABLE 10: Fiscal Risk Management and Billing Compliance

Moderators: Chris Chan, Senior Director, R&D Finance, Finance, FibroGen, Inc.

Challenges in developing robust budgets while ensuring billing compliance and adherence to CMS regulations

Strategies for fiscal forecasting, such as a risk-based approach

Covering trust costs related to clinical research and distinguishing them from routine care charges

TABLE 11: Wearables in Clinical Trials

Moderators: Jaydev Thakkar, Clinical Trial Design and Management , Global IS Service Owner, Director Information Systems, Amgen

Munther Baara, Senior Director, Development Business Technology, Pfizer

Wearable sensors' impact on trials design and execution

Collecting, integrating, and analyzing wearable devices data

Driving innovation in patient centricity and PROs

TABLE 12: Synergy between Observational and Clinical Studies

Moderators: Mark Price, Senior Director Surveys and Observational Studies, RTI Health Solutions

Lynne Hamm, Senior Director Clinical and Medical Services, RTI Health Solutions

Similarities and differences in operationalizing observational studies vs clinical trials

Building a continuous program that includes post-approval studies

Risk-based monitoring in observational trials

TABLE 13: Contract Language and Limitations

Moderators: JoAnn Pfeiffer, Ph.D., Associate Director, Clinical Research Management, Arizona State University

Débora Araujo, Associate Director, Clinical Contracting Services, Boehringer Ingelheim Pharmaceuticals, Inc.

Typical legal language contained in the CTA that can be problematic and what it means

How to revise language in terms that are understandable from the site and pharma perspective

Examine how contract errors might lead to a breach resulting in major legal and financial implications

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Interactive Breakout Discussion Groups

Tuesday, January 24 | 3:55 - 5:00 PM

TABLE 14: Managing Relationships with High Performing Sites

Moderators: Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP)

Dex Bilkic, MBA, Leader, Business Support Group, Boehringer Ingelheim

Chris Hoyle, Executive Director, Elite Research Network

Jeffrey Zucker, Vice President, Feasibility & Recruitment Optimization, Feasibility & Recruitment, Worldwide Clinical Trials

Identify the key drivers of a productive relationship between sites and sponsors/CROs

Discuss current KPIs and their utility in relationship management

Identify additional "non-traditional" drivers of site / sponsor performance

TABLE 15: Evaluating Bids from Third-Party Vendors and Partners

Moderators: Todd Reul, Associate Director, Global Strategic Sourcing, BioMarin

Challenges in reading and evaluating bids

Strategies for developing a system for evaluation

Tips for translating a bid into a contract

TABLE 16: Visual Analytics in Clinical Research

Moderators: Charlie Romano, Senior Director, Clinical Trial Management, Clearside Biomedical

Steven Sweeney, Vice President, Surgery & Perioperative Care, The Medicines Company

Data Visualizations for Clinical Operations

Focus on Decision Making and Value

Using the Data Properly

TABLE 17: Proposed Changes to the Common Rule

Moderators: Brenda Yanak, Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer

Potential impacts to Informed Consent Documents (ICDs)

Potential impacts to biospecimens

Likelihood of passage and timeframe

TABLE 18: Collaborative Research Platforms: Why Identity Trust is a Must

Moderators: Mollie Shields Uehling, CEO, SAFE-BioPharma Association

Jon Weisberg, Head Director, Communications Public Relations, SAFE BioPharma Association

Collaborating in clinical research safely and securely

Exploring collaborative research programs like Transcelerate SIP and Merck's EngageZone

Understanding Cyber Identity Credentials

Register Online!
SCOPEsummit.com

Data-driven global site selection, improved protocol design, an optimized feasibility assessment process, and effective site management are critical to improving clinical trial timelines and outcomes. Too often companies fail to learn from past mistakes and take the same approach to protocol development, trial planning and program execution. In order to overcome challenges in clinical trial planning, operations and site management leaders should learn from the best practices of their peers, utilize data and technology to support decision making, and improve communication and relationships between Sites, CROs, Sponsors and the Trial Volunteers. Cambridge Healthtech Institute's Seventh Annual Protocol Development, Global Site Selection, Feasibility and Site Management conference will cover the topics one should consider when planning and implementing a trial.

MONDAY, JANUARY 23

Recommended Short Courses*

2:00 – 6:00 pm **SC1: Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster ***

SC3: Clinical Trial Protocol Optimization *
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

IMPROVING TRIAL PLANNING AND PERFORMANCE: PROTOCOL DEVELOPMENT & EVIDENCE-BASED FEASIBILITY

10:45 **Chairperson's Remarks**
April Lewis, Director, Clinical Trial Optimization Solutions, IMS Health

10:50 **Case Study: Re-Designing the Protocol Process, Feasibility and Trial Design in Order to Avoid Downstream Problems**
Silvana Giustino, Global Head, Clinical Development Expert Resources, Pharma Research and Early Development (pRED), Roche
When a sponsor assesses the feasibility of a study, there are two parts of the analysis: firstly, the protocol-level feasibility and analysis of the study design, and secondly, then the site-level feasibility. Often feasibility assessments are not systematic and do not allow for process improvement. We re-thought and re-designed our protocol development and broader feasibility process in order to improve outcomes and timelines. This story is still being told and challenges and progress to date will be shared.

11:15 **Data-Driven Feasibility Approach: Early Indication, Protocol and Site Feasibility**
Silke Strommenger, Ph.D., Head, Feasibility Planning and Analytics, Clinical Development Organisation, Bayer
The data-driven feasibility approach will be managed using an evolving Feasibility Plan that begins during CDP development and will outline the specific steps required for the program and its studies. This plan defines the depth and breadth of feasibility along with planned timelines for feasibility. The aim is to plan early and allow the approach to be tailored to each program/study.

11:40 **Case Study: Site-Level vs. Study-Level Trial Performance Metrics – Is There a Difference?**
Christopher Conklin, Director, Feasibility Center of Excellence, Pfizer
Leveraging data to support evidence-based enrollment planning, country selection, and site identification is a hot topic, and critical to the success of this approach is access to accurate metrics. This talk will present results of an analysis comparing actual site-level performance information (from CTMS data) vs. study-level data from public data sources, overall and for three selected therapeutic categories. The session will conclude with a discussion of the implications of these results on data sources used for evidenced based study planning and the potential need for participation in a cross-company collaboration for sharing of CTMS data.

Sponsored by

12:05 pm **Presentation to be Announced**

12:40 **Luncheon Presentation to be Announced**

Sponsored by SYNEXUS

1:20 **Coffee and Dessert in the Exhibit Hall**

RE-THINKING PROTOCOL DESIGN AND SITE SELECTION

2:00 **Chairperson's Remarks**
Megan Laker, CoLAB Consultant, CDIO, Eli Lilly and Company

2:05 **End to End Data Flow: A Digital Protocol as the Platform for a Clinical Trial**
Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline
The processes and systems downstream of protocol development are highly manual and inefficient often delaying study start up and study reporting by several months on each end. In 2016, the Common Protocol Template (CPT) project is attempting to digitalize key elements of the protocol in order to take advantage

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of ready now technology such as machine learning and artificial intelligence. The audience will learn an up-to-date status of industry adoption of the Template inclusive of how we are engaging the major stakeholders (regulators and investigator sites) to inform future direction.

2:30 CoLAB: Redefining Collaborative Engagement with External Partners for Protocol Development
Megan Laker, CoLAB Consultant, CDIO, Eli Lilly and Company
CoLAB is a capability at Lilly designed to bring together sites and patients to transform the clinical study experience. Prior to the final protocol, Lilly study teams, sites and patients work face-to-face to better understand operational issues within the protocol through a CoLAB Site and Patient Simulation. Site and Patient Simulations are a "dress rehearsal" for a clinical protocol. By engaging your customers upfront, you are paving a path to easier trial implementation.

2:45 Rethinking Site Selection from a Patient Lens
Abbe Steel, MSc, CEO, HealthiVibe, LLC
What we've learned from interviewing clinical trial participants and conducting patient satisfaction surveys is that nothing affects the patient's overall study experience as much as site perception. Quality of communication, convenience, and the respect and encouragement of site staff are among the key themes we uncovered that have a direct impact on the patient's study experience. And yet, typically the current site selection approach makes no use of patient feedback metrics, even though the potential benefits -- to patients and to study success -- are clear.

2:55 INTERACTIVE PANEL: Practical Protocol Design: The Value and Impact of Including the Site
Moderator: Michael Jay, Vice President, Society for Clinical Research Sites (SCRS)
Paulo Moreira, Vice President, Global Clinical Operations - External Innovation, EMD Serono, Inc.
Robert DiCicco, Pharm.D., Vice President, Clinical Innovation and Digital Platforms, GlaxoSmithKline
It's no secret that protocols are rapidly becoming more complex, involving more practitioners and specialty procedures. This complexity extends to the inclusion/exclusion criteria, exacerbating difficulties with enrollment. Obtaining early input from investigators and site personnel can help, but only if they are included effectively and asked the right questions.

- Understanding when and how to engage sites during your protocol development process
- Engaging stakeholders beyond your internal ones (site leads, Site Advocacy Groups (SAGs), patients)
- Learn how to improve your internal protocol design process and integrate the best of outside insights with your science and ops teams

3:20 Presentation to be Announced

Sponsored by BIOCLINICA

3:35 Sponsored Presentation *(Opportunity Available)*

> "Solid material at the conference, good speakers, and a nice variety of topics. I say "ride the wave with SCOPE" as this is a favored conference."
>
> *- Ken W., Director, Outsourcing Lead, Pfizer Inc.*

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. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by DrugDev do more trials

DATA-DRIVEN GLOBAL SITE SELECTION & NAVIGATING THE GLOBAL INVESTIGATOR POOL

8:25 Chairperson's Remarks
Chairperson to be Announced, Bioclinica

8:30 Optimize Country Selection and Start Up Timeline Development
Kate Zarish, Director, Strategic Study Start Up, Development Operations, Clinical Field Operations, AbbVie
In this example, an electronic country intelligence tool is utilized to allow users to review country-specific information enabling data-driven decisions for global site

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selection. It provides quick and user friendly access to country-related study start up data. Expanding capabilities within the tool allows the clinical teams to capture additional country intelligence as the information is identified to best support country selection and study start up plan and time line development.

8:55 Innovation in Data-Driven Site Selection: Benefits and Challenges
Shawn Tedman, Lead, Strategic Feasibility, Site & Patient Solutions, UCB BioSciences
This case study describes some innovative techniques used by the Strategic Feasibility team at UCB. Central to our innovation is the incorporation of new commercial data sources and quantification of qualitative data to help inform the site selection process. True innovation isn't always a smooth process. In addition to the team's successes, this case study will discuss realistic challenges that have been encountered and limitations of our approach. The audience will gain an understanding of a mid-sized pharma company's experience with innovation in the investigative site selection space.

9:20 The Global Investigator Pool: How Close Are We to Knowing the Full Picture?
Edward Mannello, Feasibility & Recruitment Director, Clinical Operations, AstraZeneca
The increased number of studies coupled with high investigator turnover and increasing protocol complexity all point to the need for a change in industry operating practices to help sustain our current investigator base. Investigator registries offer a solution that can benefit both investigators and industry. Attendees will learn about the status of these cross-industry collaborations and gain insight into the ROI for feasibility, site identification, and start-up. The learning objectives for this session are: Characterize the size and scope of the global investigator pool, describe the overlap of principal investigators across pharmaceutical companies, and understand the risk vs. benefit in investigator/metrics access from data sharing of information across companies.

9:45 Presentation to be Announced
Sponsored by informa
Loni Branon, Director, Sitetrove/Chinatrove, Pharma Intelligence

10:10 Coffee Break in the Exhibit Hall

BEST PRACTICES IN PATIENT-CENTRIC PROTCOL DESIGN AND TRIAL FEASIBILITY

11:10 Chairperson's Remarks
Chairperson to be Announced, BBK Worldwide

11:15 Best Practices in Protocol Design by Reducing Protocol Amendments
Stella Stergiopoulos, Senior Project Manager, Center for the Study of Drug Development, Tufts University
Over the last five to ten years, drug development companies have introduced protocol governance committees to evaluate protocol design and feasibility. However, there is no current study looking to assess the effectiveness of these teams. Tufts CSDD conducted a study in collaboration with 15 large and midsized pharmaceutical and contract research organizations, examined 3,055 protocols across various phases and therapeutic areas to assess the number of protocol amendments. Best practices from companies with a small percentage of avoidable amendments will be discussed.

11:40 INTERACTIVE PANEL: Clinical Trial Feasibility, Evidenced-Based Recommendations, & Protocol Optimization
Moderator: Christopher Conklin, Director, Feasibility Center of Excellence, Pfizer
Marisa Rackley, Director, Clinical Research, Global Trial Optimization, Merck
Stella Stergiopoulos, Senior Project Manager, Center for the Study of Drug Development, Tufts University
Edward Mannello, Feasibility & Recruitment Director, Clinical Operations, AstraZeneca
Feasibility leaders from Astra-Zeneca, Merck and Pfizer will discuss a variety of current topics in feasibility including: leveraging datasets to make evidenced-based recommendations, protocol optimization, predictive analytics & patient centricity in protocol feasibility. The panel members will speak about their respective companies' approach to feasibility, how success is defined within their organizations and how they are overcoming current challenges they are facing. Questions from audience members will be strongly encouraged.

12:10 pm Bridging Luncheon Presentation: The (Evolution) Revolution of Site Feasibility: The Current Model of Site Feasibility is Outdated, but Are We on the Brink of its New Evolution?
Sponsored by imshealth
Alexandra Charge, Senior Manager, Consultative Services, Clinical Trial Optimization Solutions (CTOS), IMS Health
Innovation in technology and expansion of Real World Data (RWD) is substantially changing our industry, offering new approaches to the age-old operational processes in clinical development such as identification of sites and the act of surveying our investigators. With the expansion of RWD, the question now becomes could investigators' input from the chore of site feasibility be minimized to such an extent that the only "feasibility" question remaining is whether they are interested in participating in a given study? This session aims to explore the current use of RWD in site selection and feasibility, and the future advancement in data availability and EMR technologies to further impact these processes.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference
Stay on and attend Part 2: Improving Site-Study Activation and Performance. See page 40 for details.

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10th Annual

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

Recommended Short Course*

2:00 – 6:00 pm **SC1: Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster ***

* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

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 DAC PATIENT RECRUITMENT 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.

Sponsored by PRAXIS

12:40 **Luncheon Presentation to be Announced**

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

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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

> "On point with making the patient experience the best it can be."
>
> *- Deborah R., Clinical Development Liaison, Clinical neuroscience Solutions, Inc.*

Sponsored by QUINTILES

3:20 Accelerate Clinical Trial Recruitment and Engage HealthCare Providers as Referral Sources with Specialized Clinical Field Resources
Stewart Rosen, M.D., Vice President of Medical Affairs, Quintiles Health Management Solutions, Quintiles
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. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by DrugDev do more trials

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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 Platform & Patient Advisory Boards (PABs)
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. TransCelerate's Clinical Research Awareness & Access (CRA&A) initiative seeks to address problems of low clinical research literacy. 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 and share an overall comprehensive patient engagement platform that is hallmarked by the PABs, supported by a patient-centric toolbox and implemented by the trial teams.

9:20 Presentation to be Announced

Sponsored by BIOCLINICA

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
Chairperson to be Announced, 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: Richard Mayewski, Associate Director, Clinical Trial Intelligence, Global Clinical Trial Leadership, Novartis
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

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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 43 for details.

"One of the many valuable messages from SCOPE 2016 was "the future of clinical research is now" - and the presenters provided useful concepts and tools to make implementing that message a reality within our own organizations."

- Kristy M., Deputy Director, KAI Research, Inc.

SCOPE Game Card Raffle!*

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**All prizes are given away on behalf of CHI. Apple®, Bose® and Fitbit Inc are not sponsors or participants of this program.*

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7th Annual

Clinical Trial Forecasting and Budgeting:

Innovative Budgeting and Contracting for Cost-Efficient Trials

January 24-25, 2017

The need for accurate trial forecasting, budgeting, and contracting is continuing to grow as costs continue to rise and pressure to do more with less increases. Developing strategies for better financial planning, budgeting, and contracting can reduce these pressures and lead to streamlined, cost-efficient trials. Cambridge Healthtech Institute's Seventh Annual Clinical Trial Forecasting and Budgeting conference shares best practices and case studies on building more effective budgets and contracts as well as innovative strategies in communicating and negotiating costs with vendors and CROs.

MONDAY, JANUARY 23

Recommended Short Course*

2:00 – 6:00 pm **SC5: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract**
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

STRATEGIES FOR FINANCIAL FORECASTING

10:45 **Chairperson's Remarks**
Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

10:50 **Common Pitfalls Associated with Budgeting and Forecasting for Clinical Trials and How to Overcome Them**
Chris Chan, Senior Director, R&D Finance, Finance, FibroGen, Inc.
There are pitfalls associated with budgeting and forecasting for clinical trials that a majority of companies experience, regardless of their size. This presentation will discuss some of these common pitfalls and ways companies can alleviate and overcome them.

11:15 **Financial Forecasting for an In-House Clinical Trial**
Maryanne Santilli, Associate Director, Clinical Trial Management Finance & Operations, Novo Nordisk
The level of granularity needed for forecasting an in-house clinical trial is great. The sponsor must negotiate with investigators, assess fair market value, and account for lab and ad hoc costs. This talk will examine Novo Nordisk's strategy for financial forecasting as well as discuss tips for working with investigators.

WORKING WITH SITES: PAYMENT

11:40 **Sponsor Strategies for Improved Investigator Site Payments**
Débora Araujo, Associate Director, Clinical Contracting Services, Boehringer Ingelheim Pharmaceuticals, Inc.
As the years pass and many aspects of clinical trials are improved, many of the same concerns can be heard from clinical investigative sites regarding sponsor payments. Regardless of the size of the sponsor or systems available, there are some strategies and practical tips which, if implemented, can help streamline and improve the sponsor-site relationship in the area of investigator site payments.

12:05 pm **Presentation to be Announced**

Sponsored by BIOCLINICA

12:40 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:20 **Coffee and Dessert in the Exhibit Hall**

WORKING WITH SITES: BUDGETING

2:00 **Chairperson's Remarks**
Débora Araujo, Associate Director, Clinical Contracting Services, Boehringer Ingelheim Pharmaceuticals, Inc.

2:05 **PANEL DISCUSSION: Negotiating Site Budgets: When Enough is Enough**
Moderator: Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer
Panelists: JoAnn Pfeiffer, Ph.D., Associate Director, Clinical Research Management, Arizona State University
Janis Witzleb, Head, Study Operations, CSL Behring
This panel discussion will raise questions to the audience about experience negotiating site budgets between the CRO and/or Sponsor, the types of issues that arise, and the game of give and take. We all face difficult negotiations, and often reach stale mate... Who gives in, and why?

2:55 **Budgeting Globally with Sites for Rare Disease Clinical Trials**
Janis Witzleb, Head, Study Operations, CSL Behring
For rare disease clinical trials, finding the right patients is a challenge – they could be anywhere in the world. This talk will discuss working with sites, choosing single versus multiple vendors, and ultimately strategies for budgeting with these sites. We will discuss discovering what the sites need and balancing local law in order to properly budget for your trial.

3:20 **Cost Drivers in Ancillary/Clinical Supply Chain**

Sponsored by ANCILLARE

Michael Brown, Executive Vice President, Business Development, Ancillare, LP
This session will focus on frequently neglected clinical trial forecasting and budgeting for ancillary (non-drug) clinical trial supplies for global studies. These

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supplies include, but not limited to, patient and site consumables, printed materials, nutritional products and equipment (freezer, centrifuges, etc.). Frequently, ancillary supplies represent significant cost, risk, and time drivers in global clinical trials. Topics will include: Techniques for the mitigation of financial risks through proper planning and forecasting, inventory management, plus more.

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

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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. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by DrugDev do more trials

CONTRACTING AND NEGOTIATING WITH OUTSOURCED PARTNERS AND VENDORS

8:25 Chairperson's Remarks
Kym Denny, CEO, hVIVO

8:30 A Practical Approach to Managing the Change Order Process and Limiting the Number of Changes in Scope
Kenneth Wilson, Director, Business Operations; Clinical Outsourcing Lead, Pfizer
This paper will discuss Pfizer's approach to managing ongoing changes in scope including, but not limited to, identification of out-of-scope items, estimating cost, seeking approvals, and when to move to a contractual change in scope. Pfizer's approach is rather complex, but boiling the process down to simple steps, defining the key players, and responsibilities in an ownership matrix, is key to following and successfully executed well-thought-out and valid changes in scope.

> "First time experience and came away with a head buzzing full of ideas for our team!"
>
> *- Karen M., Vitaflo International Ltd.*

8:55 Using Financial Analytics and Modelling to Drive Negotiations with Vendors and Outsourced Partners
Brenda Medina, Associate Director, Clinical Business Operations, Head of Analytics, BioMarin
This talk will focus on strategies for using financial analytics and cost modelling to drive internal decision making around negotiations and contracts with outsourced partners and vendors. See how using clinical financial analytics from past trials can enable better negotiating in future trials and learn from the unique challenges a rare disease company faces. Discuss strategies for sharing and interpreting this data and understanding what role it plays in contracting and negotiating.

9:20 Challenges in Contracting: A Legal and Biotech Operations Perspective
Bruno Gagnon, President, Xenon Clinical Consulting
With the number of people involved as well as the sheer amount of factors to take into consideration – including laws, regulations, and cultures – contracting can become one of the biggest reasons why a clinical trial is delayed. This talk will address the legal perspective of contracting, including understanding laws and regulations plus addressing challenging and intricate clauses. This talk will also examine a non-legal perspective on how to develop clear contracts from the get-go and create processes that allow for a concise review process.

9:45 Sponsored Presentation *(Opportunity Available)*

10:10 Coffee Break in the Exhibit Hall

Register Online!
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CONTRACTING AND NEGOTIATING WITH OUTSOURCED PARTNERS AND VENDORS (CONT.)

11:10 Chairperson's Remarks

11:15 Overseeing International Budgets and Contracts: The Importance of Cultural Awareness in Smooth Negotiations
Kym Denny, CEO, hVIVO
Study set up activities across multiple countries and sites is at best a complex juggling act. What often slows us down is a lack of practical local knowledge about the way people engage in relationships, negotiations, and how various healthcare structures translate into budgeted tasks. To succeed in this setting, it is important to have the right set of expectations and a solid understanding of how culture informs the way we approach collaborating on a project. The aim of this session is to explore how different cultural orientations impact on budget and contract negotiations, and to provide a framework for the global clinical project manager and lead CRA to operate confidently when working on international clinical studies.

11:40 Panel Discussion: Communication for Strategic Partnerships: Establishing Relationships to Enable Better Negotiating and Contracting
Relationships matter. This panel discussion will discuss strategies for establishing relationships between sponsors, CROs, and other suppliers and vendors. Panelists will explore ways establishing a solid relationship will enable better negotiating, contracting, and forecasting.
Moderator: Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University
Panelists: Jay Zinni, Associate Director, Procurement, Incyte Pharmaceuticals
Luke Van Hengel, Corporate Vice President, Business Operations, PAREXEL International
Greg Skalicky, Chief Commercial Officer, inVentiv Health

12:10 pm Bridging Luncheon Presentation to be Announced
Sponsored by DrugDev

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Managing Outsourced Clinical Trials.
See page 46 for details.

> "This year's SCOPE meeting was a great place to hear high quality industry updates and to touch base with old friends and decision makers."
>
> *- Brian N., Associate Director, ClinOps, Gilead Sciences*

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Before any clinical trial can begin, the needs of the trial need to be determined, and with the ever-growing need for efficient and cost-effective trials, establishing an outsourcing strategy for your company and for individual trials is key to keeping things on time and on budget. Cambridge Healthtech Institute's Inaugural Establishing an Outsourcing Strategy conference shares strategies and case studies for determining outsourcing needs, developing RFPs and evaluating bids, as well as contracting with outsourced partners and vendors, including sites, CROs, suppliers, and other vendors.

MONDAY, JANUARY 23

Recommended Short Course*

2:00 – 6:00 pm **SC5: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract**
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

STRATEGIES FOR DETERMINING OUTSOURCING NEEDS

10:45 **Chairperson's Remarks**
Liz Wool, RN, BSN, CCRA CMT, Global Head of Training, Barnett International

10:50 **CO-PRESENTATION: Establishing a Sourcing Strategy in Early Development**
Rich Polgar, Director, Global Procurement, Bristol-Myers Squibb
Scott Rauscher, Associate Director, Global Procurement R&D, Bristol-Myers Squibb
This co-presentation will discuss how Bristol-Myers Squibb is challenging the role of the procurement department in its overall outsourcing strategy. This will be a case example of executing a relationship plan and business partnering to gather business needs, leverage market data, and develop an innovative strategy for implementing speed with the appropriate rigor in the process.

11:40 **Best Practices in Developing and Maintaining an Effective Clinical Outsourcing Strategy**
Todd Reul, Associate Director, Global Strategic Sourcing, BioMarin
This talk will highlight ways to develop and maintain a global outsourcing strategy for your clinical pipeline. We will discuss best practices in regards to aligning with your company's clinical development strategy, incorporating the subtleties of therapeutic areas, techniques to ensure outsourcing processes never limit operational progress, as well as applying lessons learned to continually improve and refine.

12:05 pm **Sponsored Presentation** *(Opportunity Available)*

12:35 **Session Break**

12:40 **Luncheon Presentation** *(Sponsorship Opportunity Available)*
or Lunch on Your Own

1:20 **Coffee and Dessert in the Exhibit Hall**

2:00 **Chairperson's Remarks**
Liz Wool, RN, BSN, CCRA CMT, Global Head of Training, Barnett International

2:05 **Strategies for Outsourcing a Large Development Portfolio**
Ratan Ratnesh, Director, Head, Clinical Outsourcing, Otsuka
This talk will cover how to develop clinical outsourcing strategy to support a large development portfolio. We will discuss developing category strategy to support the outsourcing requirements of your company, the assessment of internal operations and external market to support outsourcing decisions (make vs. buy, portfolio analysis, etc.), how to develop study level outsourcing decisions within the category level sourcing strategies, and supporting new innovation within the outsourcing framework. Finally, we will explore total value management as part of clinical outsourcing rather than focus on just the cost/savings.

RFPS AND BID EVALUATION

2:30 **Driving Value Through RFPs – A Customized Approach to Developing RFPs with Internal Stakeholders**
Benjamin Greenberg, Senior Manager, Lead, Clinical Outsourcing & Operational Analysis, Curis
In the fast-paced and demanding environment of clinical development, speed and quality are paramount, and selecting the right clinical vendor can be the difference between success and failure. By enabling key stakeholders to drive the value in RFP's; the selection, quality, and time to implementation are all improved. The presentation will focus on a process and tools that focus on stakeholders input to drive a better vendor selection process and result.

2:55 **Sourcing Need to Provider Selection Part I: A Strategy for Sourcing Initiatives and Developing Contracts**
Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas Pharma Global Development, Inc.
Your company needs to select a new provider for a particular service. Whether to replace current providers or as a shift in sourcing strategy, we all face the same challenges. What's the best process for identifying an appropriate provider pool? How to conduct a meaningful RFI process to narrow the pool? How to leverage the RFP process to optimize price for quality of service? These and others are questions we should be asking ourselves as part of this process. This talk will

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provide an overview of one strategy to successfully navigate through these tough discussions and negotiations.

3:20 Sponsored Presentation *(Opportunity Available)*

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

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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. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by DrugDev do more trials

CONTRACTING AND NEGOTIATING WITH OUTSOURCED PARTNERS AND VENDORS

8:25 Chairperson's Remarks
Kym Denny, CEO, hVIVO

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12:10 pm Bridging Luncheon Presentation to be Announced

Sponsored by DrugDev do more trials

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Managing Outsourced Clinical Trials. See page 46 for details.

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Implementing Risk-Based Monitoring – Part 1:

Integrating Quality into Clinical Trials

January 24-25, 2017

Quality and risk management of clinical trials begins with the design and planning of clinical trials at the protocol stage. Cambridge Healthtech Institute's Third Annual Implementing Risk-Based Monitoring – Part 1: Integrating Quality into Clinical Trials conference provides guidance on how to holistically and proactively build quality standards into clinical trials starting at the protocol stage with emphasis on the latest quality standards and guidelines, including ICH-E6, thereby ensuring higher quality clinical trials and laying the foundation for successful risk-based monitoring.

MONDAY, JANUARY 23

Recommended Short Course*

2:00 – 6:00 pm **SC3: Views and Conversations on Risk-Based Monitoring**
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

QUALITY STARTING AT THE PROTOCOL LEVEL

10:45 **Chairperson's Remarks**
Janis Little, Vice President, Global R&D Quality, Allergan

10:50 **Overcoming Challenges During Quality Protocol Development**
Sheri Kuss, Associate Director, Clinical Process Development, Teva Pharmaceuticals
Implementing Risk-Based Monitoring takes effort upstream to incorporate Quality by Design and Risk Management principles during the protocol development process. Bringing the right stakeholders together during protocol design to identify risks, thresholds and mitigation plans is paramount. This course will review overcoming protocol development challenges in an effort to promote quality, simplification, compliance with regulations, alignment with endpoints and realistic patient participation.

11:15 **Quality by Design: From Theory to Practice**
Sabrina Comic-Savic, M.D., MPH, Vice President, GCP Compliance, The Medicines Company; CTTI Quality by Design Team Member
This presentation gives an overview of CTTI's work on facilitating implementation of Quality by Design principles to improve effectiveness and efficiency of clinical trials. Unnecessary complexities burden clinical trial economics and quality outcomes. Quality in clinical trials is defined as absence of errors that matter. Focus on key objectives is necessary in order to simplify and reduce error.

11:40 **Moving Beyond Risk Assessment: A Comprehensive Risk Management and Protocol Development Process that Builds Quality into Clinical Trials**
Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC
This session describes a framework for a structured, proactive risk management process and the success factors for implementing and managing it. It also touches upon evaluating protocol design quality. The structured process includes three stages of Risk Management: Risk Assessment, Risk Mitigation and Control, and Issue Management. Based on the TransCelerate RACT questionnaire, the framework was collaboratively developed with input from 15 clinical research industry-related organizations (drug development and CROs).

12:05 pm **Sponsored Presentation** *(Opportunity Available)*

12:40 **Luncheon Presentation** *(Sponsorship Opportunity Available)*

1:20 **Coffee and Dessert in the Exhibit Hall**

HOW TO APPROACH THE ICH E6 ADDENDUM

2:00 **Chairperson's Remarks**
Sheri Kuss, Associate Director, Clinical Process Development, Teva Pharmaceuticals

2:05 **Adherence to ICH E6 GCP Guidelines: An Exercise in Mapping Standards, Controls and Metrics**
Jonathan Rowe, Ph.D., Executive Director & Head, Quality Performance and Risk Management, Pfizer
The ICH E6 addendum is a move to modernize the GCP guidelines. Organizations involved in clinical research need to evaluate their own quality standards, processes and procedures in order to ensure that existing and new GCP requirements can be delivered. An overview and example of approaches used to identify strengths and gaps in GCP coverage will be provided that incorporates SOPs, controls and metrics. The approach is easily transferred to any size organization.

2:30 **CO-PRESENTATION: Sponsor and Vendor Partnering to Implement a ICH E6 Compliant Risk Management Model**
Brian Nugent, Associate Director, Clinical Operations & Process, Gilead Sciences
Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences
Partnering with CROs and Vendors on risk management in clinical trials brings with it the blending of diverse approaches to applying the principles now found in ICH E6. There are a number of pain points that may need to be addressed including: Data transfers, transparency, sharing of EDC data, customization of reports, and oversight. This case study presentation will blend the viewpoints of both sponsor and vendor and highlight the experiences of both in addressing this now common business challenge.

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3:20 Sponsored Presentation *(Opportunity Available)*

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. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by DrugDev do more trials

ASSESSING CLINICAL QUALITY MANAGEMENT SYSTEMS

8:25 Chairperson's Remarks
Chairperson to be Announced, Quintiles

8:30 Assessing the Clinical Quality Management System: Part 1
Janis Little, Vice President, Global R&D Quality, Allergan
This session will focus on a conceptual approach to assessing a Clinical Quality Management System (CQMS) that will assist an organization in determining the "health" of their CQMS. The conceptual approach that will be described in this session is designed to assess the general elements that comprise a CQMS (in line with the TransCelerate CQMS Conceptual Framework) as well as the overall system in regard to how those elements impact and complement each other.

8:55 Assessing the Clinical Quality Management System: Part 2
Michael Husovich, Director, Global R&D Quality, Amgen
This session will provide methodology and tools to equip an organization to effectively complete an assessment of its current Clinical Quality Management System vs. the TransCelerate CQMS Conceptual Framework. Particular attention will be given to the identification of elements that impact each other as well as identification of elements that enable an organization to move toward a more proactive or preventive approach to Quality Management. An example or case study assessment will be given.

> "I best express my experience with one word, 'SCOPE' - A satisfied communication of peoples' experiences."
>
> *- Melissa P., President, Advances In Health*

9:20 Supporting Global Clinical Operations and Integrating Quality and Auditing into Management Systems
Joanne Spallone, Global Development Quality Audit Head, Franchise Operations and Strategy, Novartis
The logic and benefits of Quality by Design and proactive analysis and mitigation of risks to GCP quality are broadly recognized. So, what are your actual steps in accomplishing this in a large company with multiple projects and global teams? How do you gather the key stakeholders and organize a Quality strategy to support global clinical operations teams and how do you measure success? This presentation will share lessons learned as we implemented quality and auditing into our management systems.

9:45 Sponsored Presentation *(Opportunity Available)*

10:10 Coffee Break in the Exhibit Hall

EMBEDDING QBD, RISK ASSESSMENT AND RISK MANAGEMENT FOR RBM

11:10 Chairperson's Remarks

11:15 A Risk-Based Monitoring (RBM) Implementation: A Roadmap and Lessons Learned
Justin Stark, Director/Head, Risk Based Monitoring, UCB Biosciences, Inc.
Practices associated with RBM are becoming established within clinical development and are anticipated to become expected by regulators with the anticipated revision to the ICH E6 GCP guidelines. This presentation will discuss the implementation of a risk-based approach to ensure protection of patient safety and the reliability of clinical trial results within a mid-size pharma company. The discussion will focus on embedding QbD and pro-active identification and management of risk coupled with fit-for-purpose data surveillance and oversight in collaboration with CRO partners and share an implementation roadmap and lessons learned.

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11:40 'Stop Light Syndrome': Why We are the Biggest Risk of All
Gareth Adams, Founder, Syniad Consulting
Despite advances in regulatory guidance, technologies and collaborative industry bodies such as Transcelerate and CTTI, little-to-nothing has been done to address the biggest risk of all - us. This presentation will look at the effects of psychological, social, cognitive and emotional factors on the behaviors of organizations and individuals as they look to implement risk-based quality management practices.

12:10 pm Bridging Luncheon Presentation to be Announced *Sponsored by* OmniComm eClinical Solutions for Life™

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Implementing Risk-Based Monitoring-Part 2.
See page 48 for details.

"SCOPE was the perfect conference to attend! The conference size was just right that allowed for great learning from a variety of organizations. The topics were relevant to the current issues being discussed today. And, majority of the attendees were in management level positions which allowed for even better interactions and discussions during the sessions due to the level of experience shared from everyone. It's a conference you don't want to miss!"

- Angie M., Clinical Operations Consultant, Gilead Sciences, Inc.

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9th Annual

Clinical Data Strategy and Analytics:

Enabling Data Driven Clinical Trials

January 24-25, 2017

E-clinical technology is changing the landscape of the clinical research industry and healthcare IT in general. Digitalization of healthcare data, mobile data capture technologies, and cloud storage of data are a few of the main technological advances that influence clinical research informatics. The technological advances have been coupled with novel data visualization solutions, and this powerful duo is helping to develop a new paradigm of data-driven clinical trials. Cambridge Healthtech Institute's Ninth Annual Clinical Data Strategy and Analytics conference is designed to bring together clinical research informatics experts to discuss the challenges and find solutions necessary to navigate and thrive in this rapidly changing environment.

MONDAY, JANUARY 23

Recommended Short Course*

2:00 – 6:00 pm **How to Implement RBM on a Budget**
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

ENABLING DATA DRIVEN CLINICAL TRIALS

10:45 **Chairperson's Remarks**
Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Meyers Squibb

10:50 **Quality, Risk, Analytics, and Speed: Industry Trends and the Impact on the Direction of Clinical Data Management**
Gary Thompson, Senior Director, Data Sciences and Solutions and Biometrics Sourcing, Eli Lilly
The clinical development industry is experiencing a confluence of several streams of change - including rapid adoption of risk-based quality management approaches, increasing receptivity to electronic data collection, and application of advanced analytics and data visualization to clinical trial execution and analysis. Each of these changes would be significant by itself, but together they present unprecedented challenges and opportunity. This presentation explores the implications of these trends and how clinical data strategy will increasingly become the key to successful clinical development.

11:15 **Analytics Linked to Strategy & Execution**
Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Meyers Squibb
BMS decided to integrate all corporate analytics functions under one organization to drive enterprise level decision-making through data and organically improve the way these matrixed teams work. The result is integrated, predictive analytics that help drive R&D strategy and execution, with clear ties to long-term financial impacts. This presentation highlights the concept and the early results including the challenges and cultural aspects of the change.

11:40 **Analytics to Drive Better Decisions in Clinical Development**
Matt Austin, Director of Data & Analytics, Amgen
Discussion of analytics that help teams make better decisions in the clinical development process.
Examples will include:
- Predictive models for enrollment
- Optimization of the geographic distribution of sites
- Power vs. assurance

Sponsored by ERT Innovating Better Health

12:05 pm **Presentation to be Announced**

12:40 **Luncheon Presentation to be Announced**

Sponsored by OmniComm eClinical Solutions for Life

1:20 **Coffee and Dessert in the Exhibit Hall**

CENTRALIZED MONITORING

2:00 **Chairperson's Remarks**
Matt Austin, Director of Data & Analytics, Amgen

2:05 **Centralized Monitoring in Action: A Case Example**
John Rodermund, Global Head, Clinical Research Data Management and Centralized Monitoring, AstraZeneca
Centralized Monitoring in the world of Risk-Based Monitoring can be taken as two different approaches (Quality-Based or Efficiency-Based). The talk will show an example of a Quality-Based approach to Centralized Monitoring.

2:30 **SMART - Site Management at Your Fingertips**
Dan Serretti, Director, MRL IT, Merck
To address technology deficits and regulatory risk, Merck has created a Site Monitoring Authoring & Review mobile app to bring our Clinical Research Associates' experience into the 21st century and make Merck a partner of choice and industry leader in site monitoring technology. SMART will enable our site monitoring organizations through a simple and easy to use digital solution that allows real-time management and monitoring of our clinical trials.

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2:55 Risk-Based Monitoring in a Multi-Study International Phase III Program
Mary Flack, M.D., Senior Clinical Program Leader, Immunology, Boehringer-Ingelheim
Stuart Shaw, Biostatistics & Data Monitoring, Boehringer-Ingelheim
Monika Moersch, Biostatistics & Data Monitoring, Boehringer-Ingelheim
Based on recommendations from Transcelerate, Boehringer-Ingelheim (BI) has developed a tool to identify study risks and evaluate the risk level of each trial. This tool has been used for risk assessment in several previous studies, but this was the first time it was used at a program level. Based on the risks identified, we produced weekly reports (SCORE) rating site performance in 6 different areas (Safety, Investigational Product, Recruitment and Discontinuation, Data Quality, Staffing facilities & supplies, and Program Specific parameters).

3:20 Sponsored Presentation *(Opportunity Available)*

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

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5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by DrugDev

CLOUD AND DIGITAL SOLUTIONS, DATA VIZUALIZATION

8:25 Chairperson's Remarks
Pam Duffy, IT Lead, Core Clinical Solutions & Services, Pfizer

> "Amazing conference providing practical, up-to-date industry knowledge for your toolbox!"
>
> *- Debora A., Senior Manager, Clinical Finance, PTC Therapeutics*

8:30 Integrating In-House and Cloud-Based Infrastructure
Pam Duffy, IT Lead, Core Clinical Solutions & Services, Pfizer
Cloud computing brings numerous advances such as speed, agility, flexibility, elasticity and innovation. What does that mean to clinical development and how can we take advantage of it? This presentation will share Pfizer's experience with implementing cloud computing in clinical trials and elaborate on the problems and solutions for integrating in-house and cloud-based infrastructure.

8:55 Leverage Strategic CRO Partnership in Clinical Innovations
Heather Zigmund, Pharm.D., Senior Director and Head of Clinical Services, MedImmune
Formal partnership governance and oversight plays an important role to play in improving partnership effectiveness and efficiency. However, getting the most out of a partnership is not just about standardising and streamlining existing processes. It's about continually embracing the entrepreneurial spirit to work smarter. This presentation will review how to leverage strategic CRO partnerships to advance clinical innovations within your organization.

9:20 Data Visualization Techniques for Safety Signal Detection and Efficacy Evaluation in Clinical Studies
Mukta Tripathi, Medical Data Review Specialist, PDC Business Ops, Product Development, Genentech
At Genentech/Roche data visualization approach to clinical study data has revolutionized the process of individual data review as well as aggregate review to identify outliers or detection of safety signal. This talk focuses on advantages of implementing data visualization tool for efficiency and scenario building to study trends within clinical data.

9:45 Sponsored Presentation *(Opportunity Available)*

10:10 Coffee Break in the Exhibit Hall

DATA INTEGRITY AND TRANSPARENCY

11:10 Chairperson's Remarks
Thomas Haag, Learning and Process Lead, Digital Development, Novartis Pharmaceuticals

Register Online!
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11:15 eSource & Data Integrity

Thomas Haag, Learning and Process Lead, Digital Development, Novartis Pharmaceuticals

When faced with the concept of adopting eSource in your organizations clinical trial program, what are the key domain changes faced related to the data collection process? This presentation will examine the Domains of Changes related to the Adoption of eSource faced by Sponsors, Suppliers, and Health Authorities. Key changes in the areas of Data, Application, and Technology along with the less obvious changes to Process, Organization and Location will be addressed.

11:40 TransCelerate Clinical Data Transparency: Returning Plain Language Summaries Implementation Guide and Toolkit

Jessica Scott, Director, North America Medical Policy and Advocacy, Global Medical, GlaxoSmithKline

Jaime Houde, Manager, Clinical Trial Transparency, EMD Serono, Inc.

New regulatory requirements and increasing patient and consumer expectations have brought the development and distribution of aggregate results summaries in plain language to the forefront as a new arena for clinical trial transparency. Sponsors will need to establish new policies and procedures for effective and efficient delivery with awareness of the challenges and potential risks and ways to mitigate those risks. The TransCelerate Data Transparency workstream has developed an Implementation Guide and Toolkit to help sponsors think through all aspects of the process and has provided examples of best practices in the toolkit.

12:10 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference

Stay on and attend Part 2: Clinical Technology and Innovation. See page 50 for details.

> "An ideal setting for networking and knowledge sharing of best practices. Sponsors, CROs, sites and vendors all united to tackle the best approaches in conducting clinical trials so novel medicines can reach patients faster."
>
> *- Susie C., Associate Director, Novartis*

Group and Company Discounts!

Group Discounts are Available! Special rates are available for multiple attendees from the same organization. For more information on group discounts, contact Melissa Dolen at 781-972-5418.

Melissa Dolen
Account Manager
Cambridge Healthtech Institute
T: 781-972-5418 | E: mdolen@healthtech.com

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6th Annual

Managing Late Stage Research and Observational Studies:

Strategies and Technologies to Enable Non-Interventional Studies

January 24-25, 2017

Non-interventional studies are an integral part of product development plans. Product safety profiles, comparative effectiveness data as well as health economic evidence obtained from non-interventional studies, are essential for multiple stakeholders. These stakeholders include but are not limited to regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute's Sixth Annual Managing Late Stage Research and Observational Studies conference is designed to facilitate knowledge exchange around all aspects of observational research from the designing and managing of post-approval studies, to applying the obtained data to pivotal business and medical decisions. Similarities and differences between clinical and observational studies will be addressed by the top industry experts.

MONDAY, JANUARY 23

Recommended Short Course*

2:00 – 6:00 pm Implementing Social Media, Digital Marketing and Other New Strategies for Patient Recruitment
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm Welcome and Networking Happy Hour on the Patio

TUESDAY, JANUARY 24

7:30 am Registration and Morning Coffee

8:20 Opening Plenary Keynotes (see page 8 for details)

9:45 Grand Opening Coffee Break in the Exhibit Hall

WHY AND HOW OF OBSERVATIONAL RESEARCH

10:45 Chairperson's Remarks
Rachel Edwards, Ph.D., Executive Director, Global Clinical Program Management, Amgen US

10:50 Synergy between Observational and Clinical Studies
Cathy Critchlow, Ph.D., Executive Director, Amgen Center for Observational Research
To fully capitalize on the value and efficiencies created by an optimal portfolio of observational and clinical studies, organizational challenges due to processes associated with study design, execution and reporting that were originally created to support randomized clinical trials must be recognized and resolved. Organizational opportunities resulting from the synergies between observational and clinical studies will be discussed.

11:30 Monitoring Post-Marketing Studies: Specific Features and Requirements
Rachel Edwards, Ph.D., Executive Director, Global Clinical Program Management, Amgen US
Variability in data quality and standard of evidence required drive decisions regarding the type of study monitoring needed to assure study validity, for example, fully monitored versus another model such as risk-based monitoring or real life data review. The challenges associated with trying to assure 'fit-for-purpose' study design and execution, including monitoring to best support study and organizational objectives, will be discussed.

12:05 pm Presentation to be Announced

Sponsored by QUINTILES

12:40 Luncheon Presentation: Managed Access Programs: Design and Operational Considerations to Maximize Value

Sponsored by PAREXEL
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Peggy Schrammel, Vice President, APAC and Scientific Affairs, PAREXEL ACCESS, PAREXEL
Managed Access Programs (MAPs), also known as Compassionate Use, Named Patient Programs or Expanded Access, are growing in popularity, not only as a means of providing life-saving investigational therapies to needy patient populations, but also as a vital piece of the commercialization strategy. As these programs are not mandated, knowing how to design and effectively execute these programs to bring maximum value to a variety of stakeholders is key. This session will explore elements of successful design, key operational strategies that minimize cost while providing a positive investigator and patient experience, and how small additions to a core MAP strategy can be useful in supporting upcoming product commercialization goals.

1:20 Coffee and Dessert in the Exhibit Hall

STRATEGIZING PERI-APPROVAL RESEARCH

2:00 Chairperson's Remarks
Melva Covington, Ph.D., Senior Director, Strategy Lead, Sanofi Field Medical

2:05 Synergies in the Operationalization of Clinical and Observational Studies
Mark A. Price, MA, MEd, Senior Director, Surveys and Observational Studies, RTI Health Solutions
Lynne Hamm, Senior Director, Clinical & Medical Services, RTI Health Solutions
While randomized controlled trials are the gold standard for evaluating drug safety and efficacy, observational studies have become increasingly important in recent years to generate real world data on burden of illness, treatment patterns, health care resource utilization, safety outcomes, treatment effectiveness, adherence, and health-related quality of life among other things. This presentation will explore these differences as well as synergies and lessons learned that could benefit scientists engaged in both clinical and observational research.

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2:30 Strategic Approaches to Building Customer Engagement Models: Creating Synergizes in Real World Outcomes and Clinical Trial Evidence for Value

Melva Covington, Ph.D., Senior Director, Strategy Lead, Sanofi Field Medical

This presentation will cover several key topics such as approaches to strategic planning and environment assessment to build customer engagement models that address scientific needs of payors, health care providers and patients, understanding how to navigate the risks and uncertainties to maximize engagement outcomes, leverage scientific information for alignment in a matrix environment and with external stakeholders, and build effective performance standards to evaluate impact and measure success of models.

2:55 PANEL DISCUSSION: Meeting the Evidentiary Needs of Multiple Stakeholders by Better Non-Interventional Studies

Moderator: Cathy Critchlow, Ph.D., Executive Director, Amgen Center for Observational Research

Topics to be discussed include but are not limited to the following:

- What are key considerations and approaches to balance scientific and commercial values of non-interventional studies?
- What are common utilization of non-interventional studies in supporting clinical development programs?
- How can evidences generated from non-interventional studies be used in discussions with regulatory agencies during product development and post-marketing in support of establishing product benefit risk profile, continual safety monitoring, and risk management and mitigation activities, as well as fulfilling regulatory post-marketing safety requirement (PMRs and FUMs)?

3:20 Presentation to be Announced

Sponsored by

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

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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. Click here for details.

> "From the Clin Ops executives to the individual contributors, THIS is the place to spend your time and budget to learn and meet innovators! As a first time attendee, the value of this conference with topic offerings and participants is GOLDEN!"
>
> *- Betsy F., Consultant, BAFallen Consulting LL*

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation to be Announced

Sponsored by

RWD IN OBSERVATIONAL STUDIES

8:25 Chairperson's Remarks

William Spalding, Ph.D., Director, Epidemiology Lead in Global Health Economics and Outcomes Research and Epidemiology, Shire

8:30 Building Differentiated Value Propositions in an Evolving Environment

Riad Dirani, Ph.D., Vice President, Global Health Economics and Outcomes Research (GHEOR), Teva Pharmaceuticals

With the continued shift towards a value-focused healthcare system, it has become even more critical for pharma companies to build solid value propositions for their products and offerings. An important component of this approach is developing a sound, scientifically robust research program utilizing real-world evidence (RWE) as well as P4 planning in the peri-launch phase. This presentation will provide an overview of this approach and examples of its application.

8:55 Opportunities and Challenges in the Use of RWE to Support Product Value Propositions

William Spalding, Ph.D., Director, Epidemiology Lead in Global Health Economics and Outcomes Research and Epidemiology, Shire

Data sources for RWE studies have evolved from use of administrative claims databases to assess disease burden and treatment outcomes, to use of anonymized electronic health records that include contextualized physician notes. While EHR provides a robust data source that goes beyond that available via administrative claims, they have their own unique methodological challenges. This talk will focus on some of these challenges, and explore potential next-step evolution in RWE originating out of EHR studies.

9:20 Patient Access and Outreach: The Role of Disease Foundations to Secure and Manage Real World Data
Ginger Spitzer, Executive Director, Foundation of Sarcoidosis Research
This presentation will focus on the valuable role of non-profit disease research foundations in securing and managing real world data through patient registries, clinical trial network, and recruitment. Given the "neutral third party" status of theses non-profit organizations, issues in compliance and logistics can be navigated more easily. In addition, unlike CROs, foundations are more likely to provide viable and applicable patient information and outreach. This presentation will discuss registries, patient member databases, networks, social media outreach, and other techniques for securing and managing data.

9:45 How to Conduct Successful Post-Approval Research Using a Unique Combination of Technology, Infrastructure and Skill
Sponsored by BIOCLINICA
Nayan Nanavati, COO, Bioclinica
Managing late stage research and observational studies is a costly and complex endeavor, if you rely on protocols and regulations from pre-market clinical trials that do not match the needs and requirements of post-approval research. Fortunately, you can reduce costs by 15-20%, increase patient compliance and data collection by 25-30% by leveraging post-approval-specific technologies, strategies, and resources. Attend this presentation by Bioclinica to discover a better way of managing late stage research and observational studies.

10:10 Coffee Break in the Exhibit Hall

CONTINUITY OF PHARMACOVIGILANCE EFFORTS IN CLINICAL AND OBSERVATIONAL STUDIES

11:10 Chairperson's Remarks
Sean Zhao, M.D., Head, US Patient Safety Surveillance, AstraZeneca

11:15 Strategic and Practical Considerations in Combining Clinical Trials and Observational Studies for Product Safety Profile Assessment
Sean Zhao, M.D., Head, US Patient Safety Surveillance, AstraZeneca
By combining clinical trials and observational studies, pharmaceutical companies may be able to overcome above limitations and challenges, to effectively and efficiently assess product safety profile and to fulfil regulatory' s post-marketing safety requirements in the early phase of product marketing. This presentation will discuss strategic thinking and practical considerations in how to combine clinical trials and observational studies to assess product risk profile during early phase of product marketing.

11:40 Leveraging Real-World Observational Data for Safety Contextualization throughout a Product's Life Cycle: A Case Study
Jamie Geier, Ph.D., Epidemiology, Pfizer
While many randomized clinical trials include at least one control group, the size of the control groups and duration of treatment may not permit precise comparative assessments for adverse events with low frequency or long latency. The use of indirect comparative methods can provide such context, but must take into account potential differences in the populations compared whose characteristics may vary. Data from observational sources can be used to provide these comparisons. This discussion will highlight approaches to address the strengths and weaknesses of observational data sources via a case study.

Sponsored by inVentiv Health
12:10 pm Bridging Luncheon Presentation to be Announced

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference
Stay on and attend Part 2: Leveraging Real World Data for Clinical and Observational Research. See page 52 for details.

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2nd Annual

Managing Precision Medicine Trials:

Biomarker and Genomics Considerations

SYMPOSIUM

January 24-25, 2017

The concept of personalized or precision medicine, with medical decisions, practices, and/or products being tailored to the individual patient, has brought to life several types of clinical trials that involve biomarkers. Effective management of these trials can be complicated and require specific operational approaches. CHI's Second Annual Managing Precision Medicine Trials symposium is designed as an educational event to discuss solutions to overcome operational and scientific challenges with various types of studies including trials with biomarker-based stratified trials, trials for biomarker discovery and trials with biomarkers as end points. Study design specifics and operational challenges in biomarker-involved clinical trials will be discussed by experts from top pharmaceutical companies.

MONDAY, JANUARY 23

Recommended Short Course*

2:00 – 6:00 pm **Managing Trials in Oncology and Immuno-Oncology**
* Separate registration required; please see page 7 for details

6:30 – 8:30 pm **Welcome and Networking Happy Hour on the Patio**

TUESDAY, JANUARY 24

7:30 am **Registration and Morning Coffee**

8:20 **Opening Plenary Keynotes (see page 8 for details)**

9:45 **Grand Opening Coffee Break in the Exhibit Hall**

STRATEGIZING DESIGN AND OPERATIONS IN BIOMARKER-DRIVEN TRIALS

10:45 **Chairperson's Remarks**
Brenda Yanak, Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer

10:50 **Operational Challenges and Opportunities in Design and Implementation of Biomarker Selective Clinical Trials**
Bardia Akbari, Pharm.D., Vice President, Product Global Development, Oncology Genentech, Inc.
Advancements in diagnostic technologies and greater understanding of the underlying molecular pathophysiology of diseases has led to propagation of discovery and development of targeted therapies. Despite the potential to clear higher efficacy bar, early and late stage development of target therapies in biomarker-selective patient populations introduces unique scientific, operational, regulatory, and commercial challenges. In this talk we will examine some of these challenges.

11:30 **Conducting Genomic Research in Global Clinical Trials**
Karina Bienfait, Ph.D., Head, Global Genomics Policy, Process and Compliance, Principal Scientist, Clinical Pharmacogenomics and Operations, Genetics and Pharmacogenomics (GpGx), Translational Medicine, Merck Research
This presentation will provide an overview of Merck's clinical pharmacogenomics strategy. Challenges encountered in conducting genomic research in the context of global clinical trials will be discussed as well as strategies and solutions to manage requirements from global health authorities and IRB/IECs

12:10 pm **Interactive Discussion: Clinical Operations to Adjust to the Concept of Personalized Medicine**
Topics to be discussed include but are not limited to the following:
- Applying the concept of personalized/precision medicine to clinical development
- Unique operational challenges of early and late stage development of therapies in biomarker-selective patient population
- Leveraging pharmacogenomics in clinical research
- Operationalizing biomarker-based randomization
- Multi-drug multi-sponsor trials: New paradigm leads to new challenges
- Collaboration and exchange of information regarding molecular profiling and treatment selection
- Regulatory challenges and impact on FDA submission strategies
- Commercial challenges and solutions

12:40 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:20 **Coffee and Dessert in the Exhibit Hall**

INNOVATIVE TECHNOLOGY SOLUTIONS

2:00 **Chairperson's Remarks**
Karina Bienfait, Ph.D., Head, Global Genomics Policy, Process and Compliance, Principal Scientist, Clinical Pharmacogenomics and Operations, Genetics and Pharmacogenomics (GpGx), Translational Medicine, Merck Research

2:05 **Operationalizing Precision Medicine**
Brenda Yanak, Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer
Success stories in Precision Medicine generally focus on an individual scientific scenario, for example, in the Oncology space. Other success stories focus on a specific technology implemented. This talk will focus on building policy and process infrastructure to operationalize Precision medicine at the enterprise level, as well as discuss the changing external environment and how that impacts infrastructure considerations.

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2:50 Operationalizing Clinical Trials at a Cancer Center
Leigh Burgess, Chief Research Operations Officer, Duke Cancer Institute
The Duke Cancer Institute Information Systems (DCI-IS) is a shared resource providing information systems to DCI members in support of clinical, translational, and basic biomedical research. The resource provides infrastructure, personnel, technical support, assistance and consultation for database development, application development, servers, and web applications. The goal of the resource is to provide comprehensive computational support to enable researchers to use technology in the most efficient manner possible to accomplish their research goals. In addition to network server support, DCI-IS provides support for large scale servers and software for the DCI's Biostatistics and Bioinformatics Shared Resources.

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. Click here for details.

5:00 Welcome Reception in the Exhibit Hall

6:30 Close of Day

WEDNESDAY, JANUARY 25

7:30 am Registration

7:45 Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

IMPLEMENTING BIOMARKER-DRIVEN TRIALS

8:25 Chairperson's Remarks
Amir Handzel, Ph.D., Statistical Science Director, Astrazeneca

8:30 Critical Decisions in Designing and Implementing Precision Medicine Trials
Jim Stolzenbach, President, Jim Stolzenbach Consulting, LLC (former Vice President for Abbvie Renal and Immunology Therapeutic Development)

> "Cutting edge topics and industry leading speakers. Very informative!"
>
> *- Rita P., Clinical project manager, Boston Biomedical Associates*

This presentation will describe the experience and considerations in designing and implementing personalized/precision medicine trials. Protocol development, company-wide collaboration strategies and trial oversight will be discussed

- What is the state of the science that will support the design elements of the trial?
- Is the trial designed to "Learn" or "Confirm"?
- Is there organizational alignment on each function's role in conducting the trial?

9:00 Use of Biomarkers to Guide Clinical Development in Inflammatory Disease
Mary Flack, Senior Clinical Program Leader, Boehringer-Ingelheim
Sudha Visvanathan, Translational Medicine, Boehringer-Ingelheim
Patients with inflammatory diseases have disordered immune responses. In the case of psoriasis, this leads to the skin plaques that are the hallmark of the disease. It is increasingly recognized that there is also systemic immune dysregulation associated with an increased risk of metabolic syndrome and the potential for accelerated atherosclerosis. Utilizing comprehensive biomarker analysis integrated within the Phase I and II clinical studies, Boehringer Ingelheim has identified molecular biomarkers in the skin associated with positive clinical responses. In addition, we are using methods to identify pro-inflammatory adipokines in the blood that may influence the increased risk of cardiovascular disease and may be modulated by treatment. Through integration of clinical, immunohistochemical and RNA sequencing data, we have begun to identify patterns that can differentiate blockade of one therapy against another.

10:10 Coffee Break in the Exhibit Hall

BASKET AND N-OF-1 TRIALS

11:10 Chairperson's Remarks
Mary Flack, Senior Clinical Program Leader, Boehringer-Ingelheim

11:15 The VA Research Precision Oncology Program
Louis Fiore, M.D., Executive Director, Department of Veterans Affaris, MAVERIC
The Department of Veterans has created a national consortium of medical centers that participate in precision oncology clinical trials. The intention of the program is to allow all patients equal access to clinical trials, despite geographical variation relative to cancer centers. Different models of patient participation are in place and under development to enable recruitment of patients from medical centers with a wide range of expertise. The Program is participating in studies sponsored by the National Cancer Institute, American Society of Clinical Oncology and a variety of pharmaceutical companies.

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11:40 Innovative Trial Designs for Precision Medicine: Intertwining Science and Clinical Operations
Amir Handzel, Ph.D., Statistical Science Director, Astrazeneca
A decade ago the iSPY and BATTLE trials ushered in a new type of clinical trials specifically tailored for Precision Medicine. These novel designs addressed difficulties in using standard randomized trials for testing increasingly complex scientific hypotheses and operational obstacles. The new Umbrella and Basket trial designs have solved some previous challenges but raised new ones requiring tight cooperation between scientific, clinical development and clinical operations teams.

12:10 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Close of Conference
Stay on and attend Part 2: Sample, Lab and Diagnostic Services in Clinical Trials. See page 38 for details.

> "The SCOPE conference is a great meeting to take in fresh ideas, new perspectives, meet new friends and breathe in cool, ocean air to refresh your work of bringing new therapies to patients!"
>
> *- Marie J., Director, Parkland Health and Hospital System*

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Inaugural

Sample, Lab and Diagnostics Services in Clinical Trials:

Infrastructure to Support Biomarker-Driven Trials

SYMPOSIUM

January 25-26, 2017

The availability of high-quality biological specimens, laboratory access and diagnostics services are of utmost importance for biomarker-driven clinical trials and future research. Regulations exist to provide direction in many aspects of clinical research conduct, however more formal regulations that direct the collection and management of biospecimens are needed. The Inaugural Sample, Lab and Diagnostics Services in Clinical Trials symposium brings together leading experts, representing clinical sponsors, to discuss challenges and identify actions to improve infrastructure for biomarker-driven clinical trials.

Arrive early and attend Part 1: Managing Precision Medicine Trials. See page 35 for details.

WEDNESDAY, JANUARY 25

12:10 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 9 for details)

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

TECHNOLOGY SOLUTIONS AND OUTSOURCING PRECISION MEDICINE TRIALS

4:00 Chairperson's Remarks

Brenda Yanak, Ph.D., Director, Precision Medicine Leader, Clinical Innovation, Pfizer

4:05 Leverage Strategic CRO Partnership and Technology Innovation to Modernize Clinical Sample Management and Compliance in Managing Precision Medicine Trials

Rebecca Simamora, Senior Director, Clinical Operations Head, MedImmune

Daniel Joelsson, Director, Global Business Planning & Operations, MedImmune

With the shift towards biomarker-driven trials and precision medicine, the complexity and number of samples collected during studies has increased steadily. At the same time, the operational models and IT systems to deal with this complexity haven't always kept pace. More and more internal resources are being spent on sample logistics, resources that could be better spent managing studies. This talk will show that by creating strategic partnerships with central labs and implementing an innovative technology solution, those resources can be freed up to focus on driving pipeline projects forward.

5:05 Interactive Discussion: Biospecimen Handling Technology and IT Framework in Biomarker-Driven Trials

Topics to be discussed include, but are not limited to, the following:

- Clinical informatics solutions for additional logistics challenges of biomarker-driven clinical trials
- Managing sample collection to support clinical trials
- Assuring the quality and the sample-test-result flow
- Addressing the issues related to global trials
- Widely available and in-house IT application for sample management

5:45 Close of Day

THURSDAY, JANUARY 26

7:30 am Registration

7:45 Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

SAMPLE AND BIOSPECIMEN MANAGEMENT

8:35 Chairperson's Remarks

Audrey Plough, Executive Director, Operations, Clinical Research Operations, Immune Tolerance Network, University of California, San Francisco

8:40 GSK Biological Sample Management Strategy

Kimberly Bojczuk, Investigator, Discovery Supply - Global Biological Assets, RD Platform Technology & Science, GSK

GSK is executing a strategy to maximize investment in biomaterials including clinical trial subject samples. As such, we are rationalizing our storage strategy for short, medium and long term storage by creating life cycle management and centralizing on-site materials where shared and secondary use creates scientific value.

- Standardizing storage formats and technology
- Automated storage systems to reduce effort for delivering just-in-time samples
- Legacy IT landscape challenges
- Considerations for shared and secondary use

9:10 Management of Biospecimens Collected in Complex Biomarker-Driven Clinical Trials: Convergence of IT Solutions with Classical Clinical Practice

Michael Tanen, Director, Clinical BMx Specimen Management, Merck Research Laboratories

Recent progress in translational medicine has created the need for new and innovative ways to manage clinical biospecimens. The demand to develop systems and processes to manage the requirements of integration, consent, data sharing, and association with clinical data has pushed the traditional approaches of past generation biorepository systems into the 21st century. The next-generation biorepository will need to be integrated, agile, and provide an intuitive user experience that can drive greater access to, better decisions from, and foster comprehensive information that will lead to improvements in patient care. The ability to access and generate the right data at the right time will become standard as we move into a period of precision medicine and individualized care.

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9:40 Sample Management: 10 Essential Elements of a Sample Management Plan
Audrey Plough, Executive Director, Operations, Clinical Research Operations, Immune Tolerance Network, University of California, San Francisco
This presentation will focus on sharing the Immune Tolerance Network's (ITN) sample management experience and lessons learned over the past 17 years by providing an overview of the ITN's sample collection, tracking, and QA/QC processes and systems which have been applied to ensure specimen quality, data standardization by minimizing inter-operator/inter-site variability, and sample data discrepancies.

10:10 Coffee Break

SOURCING LAB AND DIAGNOSTICS SERVICES

10:35 Chairperson's Remarks
Jonathan Reuter, Associate Director Global Procurement R&D, Clinical Labs, Bristol Meyers-Squibb

10:40 Central Lab Sourcing: Challenges and Solutions
Jonathan Reuter, Associate Director Global Procurement R&D, Clinical Labs, Bristol Meyers-Squibb
Methodology for selection of Central Lab partners in a changing marketplace. Navigating the diverse needs of Central Lab stakeholders and translating needs into business requirements and selection criteria. Flexibility in sourcing strategy to account for growth in technology and capabilities

11:15 Best Practices: Companion Diagnostic and Biomarker Lab Management
Shruthi Sampath, Biomarker Operations Program Leader, Genentech
- General roles and responsibilities
- Working with a diagnostic partner and shared lab oversight
- Global Study set-up and ethics/compliance considerations
- Operational considerations
- Regulatory landscape
- Case study

11:50 Outsourcing Tissue Histopathology Investigations in Support of Clinical Trials for Novel Therapeutics: Considerations and Perspectives
Keith Wharton, Ph.D., Molecular Pathologist, Preclinical Safety, Novartis
Tissue histopathology investigations are central to discovery and preclinical development of novel therapeutics and routine medical care, but their variable use in human clinical trials represents a missed opportunity to improve our understanding of disease and the effects of various therapies on disease. Here we discuss, within a question-based framework, major considerations when implementing tissue histopathology biomarker investigations in clinical trials for novel therapeutics.

> "This was a great gathering of key players in the clinical research enterprise. I learned a lot from the many conversations I had with speakers and attendees, and found everyone very eager to share and exchange ideas."
>
> *- Karen C., Executive Director, Informa/Citeline*

> "SCOPE sets the bar for what a conference should be. A great opportunity for Sponsors, Sites and suppliers to connect and discuss truly innovative ways to improve the clinical trial process."
>
> *- Scott R., Associate Director, BMS*

12:25 pm Interactive Discussion: Biobanks to Serve Clinical Trials
Moderator: Jonathan Reuter, Associate Director Global Procurement R&D, Clinical Labs, Bristol Meyers-Squibb
Panelists: Speakers of the Session
Topics to be discussed include, but are not limited to, the following:
- Operational considerations: Sample procurement, identification and de-identification
- Regulatory considerations
- Running in-house biobanks
- Partnering with commercial biobanks

12:50 Closing Remarks

12:55 SCOPE 2017 Conference Adjourns (see you in Orlando for 2018!)

Register Online!
SCOPEsummit.com

Improving Site-Study Activation and Performance:

Strategically Implementing a Process for Rapid Study Start-Up

January 25-26, 2017

Clinical trial site activation and efficient study start up are critical to drug development programs, in terms of time, cost and quality of data. In order to improve start-up times and outcomes, one needs an experienced clinical research investigator, motivated and capable team members, committed partners, and efficient communication by all. Everyone (Sponsor, CRO, Site) must communicate and execute effectively in order to accelerate clinical trial timelines and optimize study site activation. As an industry, we agree that we must improve the study feasibility process, better engage our patients, standardize metrics by which we measure success, better utilize data and analytics, and develop effective patient recruitment and retention programs. In addition, embracing cross-industry initiatives to standardize and improve processes in trial start up and management and moving beyond process improvement to enable digital innovation for clinical trials (remote trials, virtual trials, mobile health) are two key trends to consider when evaluating your own approaches in your studies. Cambridge Healthtech Institute's Fourth Annual Improving Site-Study Activation and Performance conference will cover these issues and topics one should consider when strategically implementing a process for rapid study start-up.

Arrive early and attend Part 1: Protocol Development, Global Site Selection, Feasibility and Site Management. See page 13 for details.

WEDNESDAY, JANUARY 25

12:10 pm Bridging Luncheon Presentation: The (Evolution) Revolution of Site Feasibility: The Current Model of Site Feasibility is Uutdated, but Are We on the Brink of its New Evolution?

Sponsored by imshealth

Alexandra Charge, Senior Manager, Consultative Services, Clinical Trial Optimization Solutions (CTOS), IMS Health

Innovation in technology and expansion of Real World Data (RWD) is substantially changing our industry, offering new approaches to the age-old operational processes in clinical development such as identification of sites and the act of surveying our investigators. With the expansion of RWD, the question now becomes could investigators' input from the chore of site feasibility be minimized to such an extent that the only "feasibility" question remaining is whether they are interested in participating in a given study? This session aims to explore the current use of RWD in site selection and feasibility, and the future advancement in data availability and EMR technologies to further impact these processes.

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 9 for details)

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

INTERNAL AND EXTERNAL COLLABORATIONS TO DRIVE SITE ACTIVATION AND PERFORMANCE

4:00 Chairperson's Remarks

Joan Chambers, COO, CenterWatch

4:05 Rethinking Relationships in Biotech with CRO Partners, Sites and Patients to Improve Outcomes

Murray Abramson, M.D., Vice President, Global Clinical Operations, Biogen

Establishing relationships between sponsor companies and CROs can be challenging. The goals, business models, and definitions of success are different for each relationship. This presentation will focus on identifying alignment considerations that will contribute towards a more successful relationship that will meet the needs for both CRO and biotech companies.

4:30 Integrating and Leveraging Startup Documentation and Data to Speed Site Activation

Sponsored by Veeva

Jason Methia, Vice President, Vault Study Startup, Veeva

Because study startup documentation and associated data (including milestone information) are often managed in multiple systems, sponsors and CROs have little visibility into the complete startup picture. This session will explore leveraging a single system for documentation and data to actively manage and navigate through the most complex startup activities.

4:55 Participating in Industry Collaborations: Translating the External Experience into Business Practice

Virginia Nido, Global Head, Industry Collaborations, Genentech, a member of the Roche Group

As an industry, we are facing many challenges in drug development. There are old challenges (recruitment, site qualification, complex protocols, informed consent forms) and there are new challenges (real world data and electronic health records, mobile trials, eConsents and eLabels). How can we address these challenges and still get innovative therapies to patients efficiently? Many of us participate in industry consortia. How can we get the most out of participating in consortia by bringing the resulting solutions into our day-to-day practice? Learn how Roche and other leading pharma companies are realizing the value of industry collaborations.

5:20 INTERACTIVE PANEL: Turbocharged Site Activation for Exceptional Performance

Moderator: Christine Pierre, President, Society for Clinical Research Sites (SCRS)

Craig Lipset, MBA, Head of Clinical Innovation, R&D, Pfizer, Inc.

Dex Bilkic, MBA, Leader, Business Support Group, Boehringer Ingelheim

Site activation can be the end of an exhausting process that started well before anyone met the site and goes through to contract and regulatory packet completion. Launching the site into active performance on the study requires a new input of fuel. We'll discuss what really works when it comes to energizing sites.

5:45 Close of Day

Register Online!
SCOPEsummit.com

THURSDAY, JANUARY 26

7:30 am Registration

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

Sponsored by INC Research

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

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!

STRATEGIES TO ENGAGE QUALITY INVESTIGATORS & REDUCE SITE ACTIVATION TIMELINES

8:35 Chairperson's Remarks

8:40 Site-Sponsor Relationships and Key Drivers of Site Performance

Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP)

This session will present proprietary data from a survey of sites that identifies critical aspects of successful relationships between sites and their CRO and sponsor research partners, including communication, protocols, and monitoring. This new research for the first time confirms those aspects of clinical trials that sites believe are most critical to successful site relationships and clinical trial quality, and how their CRO and sponsor partners are performing on those items.

9:05 Models to Support Different Types of PIs and Understanding the Value of Each: ACRP Certified PIs & Research Naive PIs

David Vulcano, AVP & Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

This talk will present two studies, by a sponsor and by a large site organization, on determining the quality and compliance differences between certified and non-certified PIs and PIs. The first study uses protocol adherence as an endpoint and the other uses FDA audit results as an endpoint. The talk will then present an analysis useable to justify to regulators (i.e., OIG) a particular percentage increase in payments to certified PIs over those non-certified PIs. Overall, if you're a Sponsor, CRO, SMO or site administrator interested in site quality, this is a story…with data… that you should hear.

9:30 CO-PRESENTATION: Case Study: Using Trial Participant Experience Surveys to Improve Clinical Trials

Bert Hartog, Ph.D., Director, R&D Operations Innovation, Janssen

Abbe Steel, MSc, CEO, HealthiVibe, LLC

This talk will share how patient satisfaction feedback was collected via online survey upon completion of a Week 60 follow up visit of a ten-country psoriasis study. We will share first the methodology and results of a survey development study and explain how Janssen conducted a global pilot implementation study. This talk will focus on how benchmarking patient experience globally by evaluating the feasibility and value in gathering anonymous feedback from patients through a satisfaction survey has helped Janssen better understand the needs of patients and will help improve their studies in the future.

> "Collaborate and learn, not just buzzwords, attendees really get knowledge and ideas from SCOPE."
>
> *- Michael V., Contract and Budget Analyst, NewLink Genetics*

9:55 Presentation to be Announced

Sponsored by goBalto

10:10 Relationship Building in the Digital Age

Sponsored by Frenova Renal Research

Brigid Flanagan, Senior Director, Clinical Development, Frenova Renal Research

In-person investigator meetings are increasingly rare as technology depersonalizes clinical trial conduct, weakening bonds among team members. We'll discuss why relationships are critical, ways you can set yourself apart by building personal relationships and how to integrate digital technologies and traditional communications to enhance clinical conduct and investigator performance.

10:20 Coffee Break

IMPROVING SITE ACTIVATION (& RE-ACTIVATION) AND ENROLLMENT THROUGH A DISCIPLINED ENGAGEMENT, CONSENT AND START-UP PROCESS

10:35 Chairperson's Remarks

10:40 Are Your Sites Really Ready? Key Lessons for Optimizing Site Performance: Re-Engagement & Rethinking Process and Consent

Liam Eves, Executive Vice President, Humatics, hVIVO

Skyrocketing development costs and increasingly complex disease indications and regulatory pathways means every minute at the investigator site counts. To meet today's challenges, sites need to be ready to enroll the day they receive IRB approval. In order to meet this pressing business objective, sites need two critical things: an effective recruitment and workload plan, and tightly controlled oversight of that plan as it is executed. Reacting rapidly to variances against your plan can avoid months of delay further downstream in the project. This session aims to highlight effective enrolment management strategies that can help sites run more effectively, focusing in on the all-important augmentation of tactics to ensure solutions are deployed to prevent delay and keep your trial running smoothly.

Register Online!
SCOPEsummit.com

10:50 Accelerating Clinical Trial Timelines by Optimizing Study Site Activation
Navreet Dhindsa, Director, Clinical Operations, Merrimack Pharmaceuticals, Inc.

The amount of time spent in the start-up phase of a clinical trial can have a significant impact on overall trial timelines. Developing a strategy early-on during the planning phase of the trial can help to reduce the time spent in this phase and eventually time to data. Furthermore, site activation has a direct impact on patient enrollment and the overall study timelines, and, per some studies, it is even the direct driver of patient enrollment. This presentation will provide strategies to identify challenges early and to reduce site activation timelines.

11:05 Sponsored Presentation *(Opportunity Available)*

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

11:35 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
Debbie Profit, Ph.D., Leader, IT, Otsuka
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!)

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SCOPEsummit.com

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 16 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 (see page 9 for details)

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

Michelle Hylan, Clinical Operations Consultant, Rhythm Pharmaceuticals

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 Presentation to be Announced

Sponsored by PRAHEALTHSCIENCES

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

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

Mary Murray, Associate Director, 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.

Bennett Levitan, M.D., Senior Director, Benefit-Risk Assessment, Janssen Research & Development

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 Close of Day

THURSDAY, JANUARY 26

7:30 am Registration

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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
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 Presentation to be Announced

10:20 Coffee Break

> "Outstanding, informative and forward looking!"
>
> *- Onelia F., Chief Executive Officer, Miami Dade Medical Research Institute*

RAISING AWARENESS AND PARTICIPATION IN CLINICAL RESEARCH

10:35 Chairperson's Remarks

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 Talk Title to be Announced
Aaron Fleishman, Product Innovation and Engagement Strategist, Market Expansion and Product Innovation, BBK Worldwide

11:30 Transition to Shared Sessions

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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

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

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

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1:15 **Closing Remarks**

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

> "Out of all of the professional conferences I attend, I rate SCOPE as number one in providing attendees with sessions that offer a wide array of topics related to the day-to-day operations of clinical trials from many different perspectives (site, pharma, CRO, academic, and vendors). Information shared in the presentations can be directly applied to improve our operations. Scope provides opportunities to interact with colleagues who are experts in their fields, expanding my network. I came away from the conference recharged and excited, with new resources I can actually use and share, and many ideas to implement innovative changes that have been successful in other organizations."
>
> *- JoAnn P., Associate Director/Faculty, Arizona State University*

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As more clinical trial activities are outsourced to contract research organizations (CROs) and other third party vendors, sponsors and their partners must learn to form effective and quality partnerships. Effective management of outsourced clinical trials requires realistic and explicit expectations from each partner in the outsourcing relationship as well as the ability to measure partnership and project performance and quality. Cambridge Healthtech Institute's Third Annual Managing Outsourced Clinical Trials conference features case studies and lessons learned from sponsors and CROs on how to measure vendor quality and performance as well as optimize the outsourcing partnership to achieve more efficient clinical trials.

Arrive early and attend Part 1: Clinical Trial Forecasting & Budgeting OR Establishing an Outsourcing Strategy. See page 20 for details.

WEDNESDAY, JANUARY 25

12:10 pm Bridging Luncheon Presentation to be Announced

Sponsored by DrugDev do more trials

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 9 for details)

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

ACHIEVING SUCCESSFUL OUTSOURCING PARTNERSHIPS

4:00 Chairperson's Remarks
Christopher Rull, Vice President, Global Head, Service Provider Management, EMD Serono

4:05 Sourcing Need to Provider Selection: Part II: A Strategy for Translating Contracts into an Effective Partnership
Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas Pharma Global Development, Inc.
You've navigated the stormy sea of provider evaluation and selection and the contract is signed. What next? How do you carry the momentum forward into the post contract phase to evolve the relationship from sponsor-provider to sponsor-partner? Which providers should be considered for true partnership? What makes a partnership successful? This talk will provide proposals for how to make the evolution from provider to partner. Suggestions for what a good partnership can look like and which provider categories are most likely to benefit from a true partnership.

4:30 How a Clinical Team Avoided $420k in CRO Change Orders

Sponsored by comprehend

Rick Morrison, CEO, Comprehend
Learn how a leading clinical development team revolutionized their relationships with their CROs. Understand the best practices they put in place to continuously manage study quality and achieve milestones on-time and on-budget across their portfolio of trials. This session will outline the 5 best practice steps they took to avoid delays and costly overruns in areas such as: enrollment, site productivity, medical monitoring, and data management.

4:55 Co-Presentation: Exploring the Linkages of End-to-End Business Process with Operational Performance for Successful Partnerships in Clinical Development
Charlotte French, Senior Director, Global Head, Contracting & Outsourcing, EMD Serono
Christopher Rull, Vice President, Global Head, Service Provider Management, EMD Serono
This session will provide the participants with an overview of the End-to-End Business Processes required to support the successful Operational Delivery of clinical trials. In today's economic and competitive climate there is an increased need for service providers to support their Partners with the necessary financial transparency throughout a project lifecycle, from initial budgeting to provision of forecasting data to support the Financial Operating Plan process. We will share best practices on how this data can be utilized by Project Leadership at both the sponsor and service provider to manage resource assignment for operational delivery of the associated studies, monitor performance and provide reliable forecast data utilizing activity based methodologies.

5:45 Close of Day

THURSDAY, JANUARY 26

7:30 am Registration

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

Sponsored by INC Research

Christine Phillips, Senior Director, Site & Patient Access, INC Research
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ENSURING QUALITY SPONSOR-SERVICE PROVIDER RELATIONSHIPS AND PERFORMANCE

8:35 Chairperson's Remarks
Rick Morrison, CEO, Comprehend

8:40 Like Mars & Venus...Only Worse: Exploration of Common Peeves in the Sponsor/Service Provider Relationships and Potential Ways to Mitigate
Chris Chan, Senior Director, R&D Finance, FibroGen, Inc.
The sponsor/vendor relationship has been an ongoing issue and challenge

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throughout the ongoing history of outsourced drug development activities. This presentation will identify some of these issues and discuss ways to alleviate.

9:05 So I Contracted with My Vendor…Now What?!
Tenley Koepnick, Director, Drug Development Operations, Allergan
The development of an ongoing, iterative, and collaborative vendor oversight dialog is a natural and needed progression following the outsourcing and contract execution process. This session will explore the often under-valued, yet GCP-required need for a Sponsor to maintain proper vendor oversight. Even more so, we will explore practical techniques that a Sponsor or Vendor could implement to drive the quality of vendor deliverables throughout the contract duration. Focus will be on building positive Sponsor-Vendor relationships with examples of what has worked (…and what has not worked).

9:30 Topic to be Announced
Elspeth Carnan, Global Head, R&D Operational Excellence, Sunovion Pharmaceuticals

9:55 A Data-Driven Approach to More Effective Studies Strategies
Sponsored by PAREXEL YOUR JOURNEY. OUR MISSION.®
G. Paul Evans, Ph.D., Corporate Vice President, Global Site Solutions, PAREXEL International
A discussion on a data-driven method for applying actionable intelligence and predictive analytics to produce more effective study strategies. Transforming data into knowledge can be applied in various arenas ranging from protocol design, country and site selection, site access, patient enrollment, quality, and satisfaction. The data can ultimately improve feasibility, drive better enrollment solutions, and mitigate risk.

10:20 Coffee Break

MEASURING AND EVALUATING VENDOR & SPONSOR PERFORMANCE TO BUILD A WIN-WIN PARTNERSHIP

10:35 Chairperson's Remarks

10:40 CO-PRESENTATION: A Model Methodology for Building a Win-Win Partnership between a Sponsor and CRO
Sponsored by Advanced Clinical
Mark Mann, Head, Clinical Outsourcing and Contracts, Upsher-Smith Laboratories
Julie Ross, President, Advanced Clinical
The model methodology for building a win-win partnership between a Sponsor and CRO starts with trust and vulnerability. You need to break down barriers and build behaviors and actions which will determine desired outcomes. Each organization not only needs to track performance and deliverables, they need to track the "right stuff", because true success is measured beyond contract deliverables.

11:20 Sponsored Presentation *(Opportunity Available)*

> "From the nitty-gritty operational level details to the high-level philosophical approaches – SCOPE is the conference to be at!"
>
> *- Dex B., Leader, Business Support Group, Boehringer Ingelheim*

11:35 A Method for Establishing a Set of Sponsor & Vendor Oversight Metrics
Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC
The model followed by today's sponsors is to outsource most, if not all, functional area study tasks to vendors. Sponsor resources no longer do; they manage. This session provides the steps for establishing effective metrics for managing oversight; metrics that matter and that report results at the appropriate oversight level. We will outline the use of a Clinical Trial Process Map, Critical Success Factors, Key Performance Questions and the proper application of metric visualizations to communicate result trends when developing and reporting oversight metrics.

12:00 pm PANEL DISCUSSION: Determining a Good Sponsor/Vendor Partnership
Réne Stephens, Executive Director, Global Head, Global Contracts & Outsourcing Management (GCOM), Astellas
Tenley Koepnick, Director, Drug Development Operations, Allergan
Linda Sullivan, Co-Founder & President, Metrics Champion Consortium LLC
Chris Chan, Senior Director, R&D Finance, FibroGen, Inc.
The panel will discuss each function's role and perspective on how they measure and evaluate a good sponsor-vendor relationship and how the group factors each function's perspective to make decisions that affect the sponsor-vendor relationship.

12:50 Closing Remarks

12:55 SCOPE 2017 Conference Adjourns (see you in Orlando for 2018!)

Register Online!
SCOPEsummit.com

3rd Annual

Implementing Risk-Based Monitoring – Part 2:

Ensuring Effective and Efficient Monitoring and Data Quality

January 25-26, 2017

Risk-based monitoring (RBM) approaches promise to improve clinical trial efficiency while ensuring data quality. As industry adoption of RBM increases, it is clear that successful risk-based monitoring implementation requires developing new roles, analytics and processes among the stakeholders in RBM. Cambridge Healthtech Institute's Third Annual Implementing Risk-Based Monitoring – Part 2: Ensuring Effective and Efficient Monitoring and Data Quality conference offers case studies and practical solutions from across pharma and TransCelerate member organizations on effectively working with various stakeholders in RBM as well as leveraging technology to benefit RBM.

Arrive early and attend Part 1: Implementing Risk-Based Monitoring – Part 1. See page 26 for details.

> "SCOPE brings together the leaders in clinical trial operations like no other conference. It is the place to be for connecting with colleagues and leaders in innovation and implementation."
>
> *- Thomas K., Chief Development Officer, TrialReach*

WEDNESDAY, JANUARY 25

12:10 pm Bridging Luncheon Presentation to be Announced

Sponsored by OmniComm eClinical Solutions for Life™

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 9 for details)

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

BRINGING TOGETHER KEY STAKEHOLDERS FOR RBM

4:00 Chairpersons' Remarks

Brian Nugent, Associate Director, Clinical Operations & Process, Gilead Sciences & Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences

4:05 RBM Change Management Successes: Stories and Lessons Learned

Jean Baumann, Change Management Specialist, JMB Consulting, LLC

Every organization has not only its own systems and processes surrounding the introduction of RBM, but also its management strategy and tactics directing the transformation. In this summary of research conducted with organizations implementing RBM, we identify both common themes and unique change management challenges that organizations encounter, the techniques and tools employed, and the lessons learned along the way. We will share success (and failure) stories that have been shared with us so that others may capitalize upon (or avoid) these during their own journeys implementing RBM.

4:30 Presentation to be Announced

Sponsored by QUINTILES

4:55 PANEL DISCUSSION: Bringing Together Key Stakeholders in RBM

Brian Nugent, Associate Director, Clinical Operations & Process, Gilead Sciences
Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences
Ken Wu, Clinical Operations Consultant, Kenneth Wu and Associates, LLC

The panel will discuss creating and organizing a successful clinical ops team around implementing risk-based monitoring and the delicate balance in deciding what is essential vs. nice to have for an organization of your size, whether small, mid-size or large.

5:45 Close of Day

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RBM IMPLEMENTATION CASE STUDIES: LESSONS LEARNED TO DATE

8:35 Chairperson's Remarks

8:40 Risk-Based Monitoring (RBM) Case Study

Lynne Cesario, Risk Based Monitoring Program Lead, Clinical Sciences and Operations, Global Product Development, Pfizer

Recent draft updates to the ICH E6 GCP Guidance will require sponsor companies to incorporate sound quality risk management (QRM) approaches into every clinical study. How do companies convene key stakeholders, optimize resources and ultimately implement this? This presentation will share examples and key learnings from our ongoing work in Risk-Based Monitoring (RBM).

Register Online!
SCOPEsummit.com

9:05 Designing and Implementing an Analytical Risk-Based Model at Janssen R&D
Stephanie Clark, Associate Director, Risk Management-Central Monitoring, Janssen Research & Development, LLC
RBM implementation is probably one of the most complex endeavors the industry is trying to tackle since the advent of EDC in the 90's. There are several cross-roads that companies encounter as they embark on the RBM journey, and for each organization there are unique challenges. However, in many cases the key components of a successful RBM program are universal. Join as Stephanie shares her insights on the Janssen experience in designing and implementing an Analytical Risk-Based model of study management and monitoring across the company portfolio..

9:30 Lessons Learned from RBM Deployments
Jacqueline Gough, Advisor, Clinical Risk Management, Eli Lilly and Company
Risk-Based Monitoring (RBM) is changing the way companies are conducting clinical trials. Implementing RBM requires companies to re-evaluate processes and tools for monitoring as well as how they perform their early trial planning. The key decision points in the building and deployment of an RBM capability will be discussed as well as the most common pitfalls.

9:55 Making RBM Work for Your Organization
Sponsored by PARAGON SOLUTIONS *Value Envisioned. Value Delivered.*
Karen McCarthy Schau, Principal Consultant, Clinical Optimization Practice, Paragon Solutions
It can be overwhelming to think about everything that needs to occur prior to deploying an RBM solution. We will provide a framework that will guide your deployment planning. Additionally, we will discuss trends/best practices for each component of the solution (technology, data, organizational design (Sponsor and CROs), processes, and governance). At the end of this session, you should feel more comfortable as you begin your deployment journey.

10:20 Coffee Break

TECH SOLUTIONS TO RBM

10:35 Chairperson's Remarks

10:40 Implementing Risk-Based Monitoring Solutions from a System and Architecture Perspective
Michael Bem, IT Manager, Medicines Development, Eli Lilly and Company
Through the use of quality and risk approaches into the scientific design and operational conduct of clinical trials, risk can be mitigated and issues can be detected early or prevented entirely. Lilly initially implemented a risk-based monitoring solution through integrated data flows with internally built visualizations. In addition, we have partnered with a third party to implement our long term solutions via a third party provider as a software as a service. This talk will discuss the technical approaches and architectural challenges we have used to build the solutions with our internal solution and with our third party.

11:05 Sponsored Presentation *(Opportunity Available)*

11:35 Novel Approaches to RBM that are Less Time Consuming and Resource Intensive: Two Examples from Novartis – Central Statistical Monitoring and Virtual Site Visit
Grant Simmons, Director, ClinOps Insights & Innovation (CII), Global Operations Services, IDFR, Novartis Pharma
Central statistical monitoring relies on common stat tools for identification of outliers, trends and patterns, which are highlighted to the central monitors for interpretation with the field. Virtual site visits employ video chat technology to link up the field monitor, central monitor and study coordinator to quickly address issues together. Central monitoring can review more data using visualizations and stat-based tools than via manual review of reports or eCRFs. Earlier identification of possible trends centrally allows FMs to better plan onsite vs. remote visits. And if sites are amenable, the REMs can be by VC if there are elements the site can show the FM and central monitor to resolve observations sooner than an upcoming onsite MV.

12:00 pm CO-PRESENTATION: Searching for a Technology Solution to Support Risk-Based Monitoring (RBM)
Ed Kellar, Director, Global Data Management Operational Support, Astellas, Inc.
Mary Cusack, Associate Director, Global Clinical Operations, Bristol-Myers Squibb
TransCelerate published "Position Paper: Risk-Based Monitoring Methodology" in May 2013. They proposed transformational process improvements in industry monitoring practices utilizing a methodology based on quality risk management, designed to both increase efficiency and enhance data integrity while maintaining adherence to good clinical practice. In 2014, the TransCelerate RBM Technology Sub-Team followed this paper with a White Paper, "Technology Considerations to Enable the Risk-Based Monitoring Methodology", which provided a description of the technical capabilities needed to support RBM. Now, the RBM Technology Sub-Team has published a second White Paper, "TransCelerate Risk-Based Monitoring Technology Considerations Part 2" which builds on previous work and provides a thorough set of specific system considerations for a RBM platform that includes people, process and technology perspectives. This presentation will describe the steps taken by the TransCelerate Technology Sub-Team to elicit, analyze and publish this comprehensive set of user and system considerations and the business use cases that drive them, with input from the vendor community and member companies. In addition, we will review vendor provided recommendations and case studies from TransCelerate member companies and discuss the current state of RBM technology solutions.

12:50 Closing Remarks

12:55 SCOPE 2017 Conference Adjourns (see you in Orlando for 2018!)

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E-clinical technology is changing the landscape of the clinical research industry and healthcare IT in general. Digitalization of healthcare data, mobile data capture technologies, and cloud storage of data are a few of the main technological advances that influence clinical research informatics. The technological advances have been coupled with novel data visualization solutions, and this powerful duo is helping to develop a new paradigm of data-driven clinical trials. Cambridge Healthtech Institute's Ninth Annual Clinical Data Strategy and Analytics conference is designed to bring together clinical research informatics experts to discuss the challenges and find solutions necessary to navigate and thrive in this rapidly changing environment.

Arrive early and attend Part 1: Clinical Data Strategy and Analytics. See page 29 for details.

WEDNESDAY, JANUARY 25

12:10 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 9 for details)

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

NOVEL RESEARCH ECOSYSTEM

4:00 Chairperson's Remarks
Jaydev Thakkar, Clinical Trial Design and Management, Global IS Service Owner, Director Information Systems, Amgen

4:05 Transforming Clinical Trials and Patient Engagement with Digital Health Innovations – Wearables, Sensors and Mobile Apps
Jaydev Thakkar, Clinical Trial Design and Management, Global IS Service Owner, Director Information Systems, Amgen
Sindhya Govind, IS Lead, Clinical Trial Patient Engagement Technologies, Amgen
Is all the buzz around Digital Health a hype or is there a real opportunity to transform clinical trials and leverage technology for increased patient engagement and retention? This presentation will take you on a journey to explore use of Digital Health innovations in clinical trials and share lessons learned from initial pilots.

4:30 Presentation to be Announced
Sponsored by BIOCLINICA

4:55 Empowered Patients + Electronic Health Records + Data Access = Transformational Opportunity for Research
Craig Lipset, Head of Clinical Innovation, Pfizer
The White House Precision Medicine Initiative provided funding for Sync for Science, with commitments from the largest EHR vendors to support such patient-centered data movement for research. Even the most recent iOS update from Apple is creating enabling opportunities, as HealthKit can now enable consumers to load and share their EHR data. Enabling this future state is bringing benefits for all stakeholders in the research ecosystem, from research sponsors to the patients looking to participate in finding new cures.

5:20 How Will the Digital Healthcare Impact Pharmaceutical Development
Francis Kendall, Global Head, Statistical Programming and Analysis, GLIDE Future Investigation Team Lead, Genentech
The healthcare world is being positively disrupted by digital technologies and information. What is the knock on impact on pharmaceutical development, how are we being disrupted, what are the opportunities?

5:45 Close of Day

THURSDAY, JANUARY 26

7:30 am Registration

7:45 Breakfast Presentation: The Inspiring Hope Ideathon: Solutioning the Clinical Trial Awareness Gap
Sponsored by INC Research
Christine Phillips, Senior Director, Site & Patient Access, INC Research
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!

WEARABLES AND DIGITAL TECHNOLOGY

8:35 Chairperson's Remarks
Chairperson to be Announced, OmniComm

8:40 mClinical Is Changing the Way We Execute Clinical Trials
Munther Baara, Senior Director, Development Business Technology, Pfizer
There is no day that passes by where we don't hear about new technology and initiatives helping business bridge the gap and evolve the organization though digital transformation, I will share with you:

- An enterprise vision for mobile tools supporting the development portfolio
- Delivering the user experience that study participants deserve
- Making the case with internal stakeholders
- Functionality for today and tomorrow

9:05 Trends and Utility of Virtual Technology in Clinical Trials
Yechiel Engelhard, M.D., MBA, Senior Director Patient Technologies, Teva
Traditional site-centric trials are designed around the benefits and limitations of the site itself, and aggregate data in a sporadic and retrospective nature. Virtual trials

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are designed with and for the patient, with wearable and digital devices helping to provide remote, continuous monitoring throughout the trial. This leads to more objective and efficient data collection. This talk aims to explore the user perception and system benefits of wearable and digital devices in a clinical trial setting.

9:30 Complementing Clinical Trials with Digital Biomarkers from Real World Smartphone Data: Science or Still Fiction

Christian Gossens, Ph.D., Global Head Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development

Kamal Abbassi, Information Manager, Project Manager, Roche Innovation Center

Objective and high frequency measures of disease progression strengthen the clarity of clinical endpoints. Two years ago, we started into digital biomarker research for Parkinson's Disease by providing patients in an interventional clinical trial with mobile sensors they carry day in and day out. This presentation will discuss how this data from outside the clinic is complementing the standard clinical data captured during normal site visits.

9:55 Presentation to be Announced

Sponsored by Clinical ink

10:20 Coffee Break

VIRTUAL AND REMOTE TRIALS

10:35 Chairperson's Remarks

Munther Baara, Senior Director, Development Business Technology, Pfizer

10:40 Closing Our Clinical Trial Databases within 72 Hours of LPLV

Debbie Profit, Ph.D., Leader, IT, Otsuka

Otsuka has used eSource technology in nine trials over the last several years. We have seen a number of significant differences in the conduct of these trials which has led to a corporate-wide objective of accelerating our timelines by closing our study databases within 3 days of the last patient visit.

11:05 Sponsored Presentation *(Opportunity Available)*

SPECIAL SHARED SESSION

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

Debbie Profit, Ph.D., Leader, IT, Otsuka

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!)

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Non-interventional studies are an integral part of product development plans. Product safety profiles, comparative effectiveness data as well as health economic evidence obtained from non-interventional studies, are essential for multiple stakeholders. These stakeholders include but are not limited to regulatory agencies, payers, health care management organizations, formulary inclusion decision makers, healthcare professionals, and patients. Cambridge Healthtech Institute's Sixth Annual Managing Late Stage Research and Observational Studies conference is designed to facilitate knowledge exchange around all aspects of observational research from the designing and managing of post-approval studies, to applying the obtained data to pivotal business and medical decisions. Similarities and differences between clinical and observational studies will be addressed by the top industry experts.

Arrive early and attend Part 1: Managing Late Stage Research and Observational Studies. See page 32 for details.

WEDNESDAY, JANUARY 25

Sponsored by inVentiv Health

12:10 pm Bridging Luncheon Presentation to be Announced

12:50 Coffee and Dessert in the Exhibit Hall

1:30 Plenary Keynotes (see page 9 for details)

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

RWD TO INFORM TRIAL DESIGN

4:00 Chairperson's Remarks

Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence for Respiratory, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

4:05 Systematic Approach to Use RWD to Inform Trial Design: Going beyond Simple Feasibility

Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence for Respiratory, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

The use of Real World Data (RWD) to optimize trial design has been widely recognized. However, the majority of work in this area has been providing simply trial feasibility, i.e. patient counts based on the inclusion and exclusion criteria. We will present our ground-breaking pilot work that goes beyond the feasibility and applies a structured, systematic approach to assess the impact of each item in the trial criteria on recruitability, efficacy endpoints and risk. The combined insights will allow the trial team to design a clinical trial that could include most real-world patients without compromising the efficacy and increasing the potential risks.

> "SCOPE is my favorite conference. It's great for networking and has interesting and relevant topics which are kept fresh and interesting. Keep it up!!"
>
> *- Janet J., VP Strategic Patient Engagement, Synexus*

4:30 Impact of ICD-10 Transition on Conducting Retrospective Observational Database Studies and Pragmatic Clinical Trials

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Rebecca Levin, MPH, Senior Research Scientist, UBC

U.S. healthcare providers are now required to use the ICD-10-CM version of the WHO's disease classification which offers a substantial increase in the number and specificity of disease and procedure codes over ICD-9-CM. Our presentation will explain significant enhancements with ICD-10 and describe the strengths and limitations of available mapping tools to translate between ICD-9 and ICD-10 codes.

4:55 Empowered Patients + Electronic Health Records + Data Access = Transformational Opportunity for Research

Craig Lipset, Head of Clinical Innovation, Pfizer

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5:20 How Will the Digital Healthcare Impact Pharmaceutical Development

Francis Kendall, Global Head, Statistical Programming and Analysis, GLIDE Future Investigation Team Lead, Genentech

The healthcare world is being positively disrupted by digital technologies and information. What is the knock on impact on Pharmaceutical Development, how are we being disrupted, and what are the opportunities?

5:45 Close of Day

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THURSDAY, JANUARY 26

7:30 am Registration

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

Sponsored by INC Research

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

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!

INTEGRATING EVIDENCE GENERATION WITH RWD

8:35 Chairperson's Remarks

Usman Iqbal, M.D., Senior Medical Affairs Leader, Neuroscience, Global Medical Affairs, AstraZeneca

8:40 From Efficacy to Effectiveness: Studying the Effects of Medicines in Usual Care Settings

Andrew Roddam, Ph.D., Vice President & Head, Real World Evidence and Epidemiology, R&D Projects, Clinical Platforms & Sciences, GSK

This talk will discuss the opportunities available to study the effects of medicines in more usual care settings than is typical in controlled clinical trials. We will discuss the challenges encountered in trying to design and operationalise such studies as well as discussing the opportunities presented by the ability to utilise technologies such as EHRs and digital data capture to make the experience more real-life for patients and physicians.

9:05 Expanding Insight into Real World Oncology Practice through Linked Datasets

Elizabeth MacLean, Pharm.D., Director, Global Health and Value/Outcomes & Evidence, Pfizer

Prescription records alone provide limited information on patient characteristics and other treatment experience. However, linking datasets can broaden insight into patient, provider and reimbursement characteristics. This presentation will discuss the experience of linking a de-identified specialty pharmacy database with de-identified medical and pharmacy databases to examine real world use of axitinib in patients with renal cell carcinoma.

> "This was a great gathering of key players in the clinical research enterprise. I learned a lot from the many conversations I had with speakers and attendees, and found everyone very eager to share and exchange ideas."
>
> *- Karen C., Executive Director, Informa/Citeline*

9:30 Leverage RWE Data in Clinical Trial Protocol Design and Site/PI Selection

Jane Fang, M.D., Head, R&D Information and Analytics for Clinical Biologics, AstraZeneca/MedImmune

This presentation will provide use case examples on how to use real world evidence data and trial competition analytics to optimize clinical trial protocol development, patient population identification, patient recruitment and site/PI selection. The talk will also cover the strategy and business adoption to use RWE and trial competition information in today's drug clinical pipeline development.

9:55 Presentation to be Announced

Sponsored by inVentiv Health

10:20 Coffee Break

INTEGRATING EVIDENCE GENERATION WITH RWD (CONT.)

10:35 Chairperson's Remarks

Kelly Zou, Ph.D., PStat®, Senior Director and Analytic Science Lead, Real World Data & Analytics (RWDnA), Global Health & Value (GH&V), Pfizer, Inc.

10:40 Approaches and Methodologies to Develop High Quality Databases and Real World Evidence (RWE) Ecosystem for Observational Research

Usman Iqbal, M.D., Senior Medical Affairs Leader, Neuroscience, Global Medical Affairs, AstraZeneca

Building a powerful platform of real-world data (RWD) is essential to providing leading-edge clinical, medical and commercial insights to the entire organization. However, developing meaningful and high quality databases warrants application of intricate data science that entails the ability to link detailed patient characteristics and information flows across different data sets to create a singular de-identified architecture, and provide a complete 360 degree view of the health care ecosystem.

11:05 Sponsored Presentation *(Opportunity Available)*

11:35 The Opportunity and Challenge of Real World Data in Drug Development: Can We Have Them All?

Xia Wang, Ph.D., Principal Health Informatics Scientist, Informatics Lead RIA, AstraZeneca

This talk relates the practices of how real world data (RWD) is being utilized at AstraZeneca spanning from clinical studies, observations research and commercial insights. The contents cover broader concepts of real world data including patient

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level electronic medical record (EMR), administrative claim database, survey and social media, etc. The clear business impacts will be demonstrated through the use cases of RWD analytics, along with the discussions of observed RWD gaps and our exploration to address these challenges.

12:00 pm Accessing and Generating Real-World Evidence via DataMart and Distributed Research Network

Kelly Zou, Ph.D., PStat®, Senior Director and Analytic Science Lead, Real World Data & Analytics (RWDnA), Global Health & Value (GH&V), Pfizer, Inc.

A Real-World DataMart contains claims and transactions for healthcare resource utilization, electronic health records, surveys, linked datasets and other digital data collected outside a traditional clinical trial. To enhance the effectiveness and efficiency of health care delivery, it is important to understand risk factors for disease progression, treatment patterns, and utilization. Fruitful collaborative research opportunities exist across different healthcare stakeholders including academia, industry and government. A distributed research network is useful for generating real-world evidence. Examples on collaborative observational studies are illustrated.

12:25 Extracting Additional Value from Clinical Data

Edward Bowen, Senior Director, Translational & Bioinformatics, Pfizer

TransCelerate is leading a collaboration across 12 companies to share placebo and standard-of-care (PSOC) clinical data for secondary research. Realized use cases include developing a standing safety cohort for providing context around SAEs observed in ongoing trials, and using data from prior trials to reduce the number of patients in new proof-of-concept trials. This discussion will discuss use cases for PSOC data, challenges around data sharing, successes to date, and important patient benefits.

12:50 Closing Remarks

12:55 SCOPE 2017 Conference Adjourns (see you in Orlando for 2018!)

"SCOPE: Some Conferences Offer Premium Engagement!"

- Annie W., Clinical Operations Manager, Bolton Medical, Inc.

"Overall a great event. Full of insight and food for thought!"

- Frederic M., Lead UX, Medidata Solutions

"First time experience and came away with a head buzzing full of ideas for our team!"

- Karen M., Vitaflo International Ltd.

"It was really beneficial to attend this conference and hearing different perspectives, advances and future plans."

- Nurcan C., Clinical Operations, Medtronic

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* *http://www.contractpharma.com/heaps/view/2607/1/*

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	Commercial	Academic, Government, Hospital-affiliated
Single Short Course	$699	$399

Monday (January 23)	
SC1: Social Media, Digital Marketing and Technology Growth Hacks to Enroll Patients Faster	SC4: Managing Clinical Trials in Oncology and Immuno-Oncology
SC2: How to Implement RBM on a Budget	SC5: Developing Your Custom Strategy for Requests for Proposals (RFPs) through to Final Contract
SC3: Clinical Trial Protocol Optimization	SC6: How to Accelerate Digital Health Innovation in Your Company

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BEST VALUE! - Includes access to the entire 3-day SCOPE program
(Does not include access to pre-conference short courses)

Early Registration Discount until October 28, 2016	$2,449	$1,149
Advance Registration Discount until December 9, 2016	$2,649	$1,249
Registration after December 9, 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)

Early Registration Discount until October 28, 2016	$1,549	$825
Advance Registration Discount until December 9, 2016	$1,699	$925
Registration after December 9, 2016, and on-site	$1,899	$1,025

Tuesday-Wednesday (January 24-25)	Wednesday-Thursday (January 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	5B: Implementing Risk-Based Monitoring-Part 2
5A: Implementing Risk-Based Monitoring-Part 1	6B: Clinical Technology and Innovation
6A: Clinical Data Strategy and Analytics	7B: Leveraging Real World Data for Clinical and Observational Research
7A: Managing Late Stage Research and Observational Studies	8B: New Symposium: Sample, Lab and Diagnostic Services in Clinical Trials
8A Symposium: Managing Precision Medicine Trials	

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.

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Pricing and Registration Information

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
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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 781-972-5418.

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

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.

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