Final Agenda

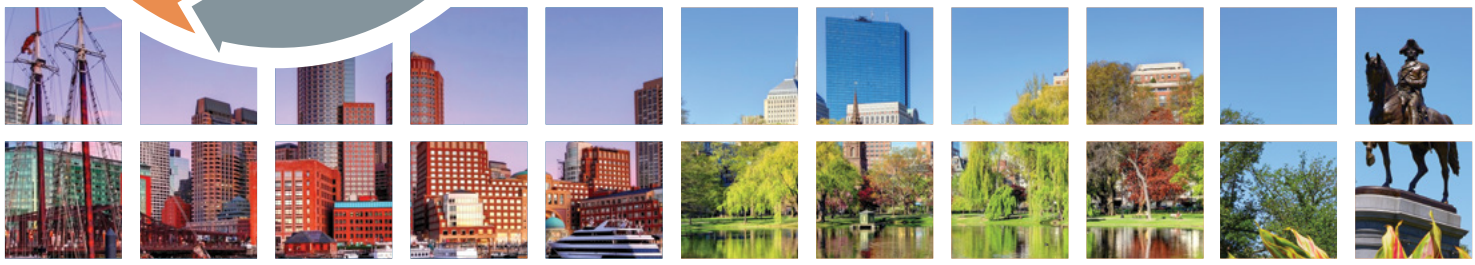
Final Weeks to Register!

May 7-9, 2018 ▪ Boston, MA
Aloft Boston Seaport Hotel

Cambridge Healthtech Institute's 7th Annual

Clinical Trial Innovation SUMMIT

New Technologies, Analytics, Quality Measures and Improved Partnerships for Clinical Trials of the Future



Keynote Presenter

Ashish Atreja, MD, MPH, FACP
Chief Technology Innovation and Engagement Officer, Medicine
Icahn School of Medicine at Mount Sinai

Conference Programs

MAY 7-8

- **Mastering Risk-Based Monitoring:** ENSURING QUALITY IN CLINICAL TRIALS
- **Patient Recruitment & Site Selection**
- **Big Data Analytics, Machine Learning, & Artificial Intelligence**

MAY 8-9

- **Mastering Risk-Based Monitoring:** EFFECTIVE MONITORING & IMPLEMENTATION
- **Outsourcing for Clinical Trials**
- **Data & Tech Driven Clinical Trials**

PLUS **2 Dinner Short Courses!**

ClinicalTrialSUMMIT.COM

Organized by: Cambridge HEALTHTECH Institute

Premier Sponsors: bsi, comprehend

Corporate Sponsors: adaptive clinical systems, saama

Clinical Trial Innovation SUMMIT

About The Event MAY 7-9

Cambridge Healthtech Institute's Clinical Trial Innovation Summit brings together 250 leaders from across pharma, biotech and academia for the perfect blend of high quality presentations and intimate networking. Through case studies, interactive discussions and an active exhibit hall, the summit delivers the real-world experiences and best practices needed to optimize clinical trial management. Presentations span across the most complex areas of trial management, including patient recruitment, site selection, data integration, leveraging existing data sources, mobile technologies, project management, outsourcing, vendor management, budgeting and contracting, quality (QbD) in trial conduct and risk-based monitoring.

Connect with Us

#CLIN18

Dinner Short Courses* MAY 7-8

MONDAY, MAY 7 | 6:00 - 9:00 PM

SC1: Needles in a Haystack: Proven Digital Media Campaigns for Clinical Trials in Rare Diseases & Oncology

Instructor: Heather Hernandez, Director, Business Development, Seeker Health

Finding participants for clinical studies in rare diseases or oncology can be akin to finding needles in a haystack. Given that patients have transitioned online to seek disease, drug and clinical trial information, those needled haystacks are now online. The average person accesses social media many times per day and biopharmaceutical sponsors can leverage that access to promote clinical trials. This course will provide the participants with an advanced understanding of how to use social and digital technologies to master patient engagement and accelerate drug development for medicines for rare diseases and oncology. The methods apply to other categories of diseases as well.

Key Learning Objectives/Why You Should Attend:

- Understand social and digital media opportunities, including Google, Facebook, Instagram, and Twitter
- Understand compliance and controls for social media campaigns
- Understand how to build an effective online pre-screener questionnaire
- Understand how to optimize social media lead generation through A/B testing for text, images, and targeting
- Review rare disease case study of use of social media to accelerate trial enrollment
- Review oncology case study of use of social media to accelerate trial enrollment

**Separate registration required.*

TUESDAY, MAY 8 | 5:30 - 8:30 PM

SC2: Implementing RBM and a Clinical QMS with Limited Resources

Instructors: Brian Nugent, Senior Director, Clinical Compliance, GRAIL, Inc.
Angie Maurer, RN, BSN, MBA, Clinical Quality & Risk Management Consultant, GRAIL, Inc.

Many organizations do not have the budget to be able to implement commercial systems to address RBM, or the ability to hire additional staff to conduct specialized RBM analysis. During this dinner workshop we will share with you steps to take to implement RBM and a clinical QMS for your organization using minimal resources.

Key Learning Objectives:

- Overview of the minimum requirements to meet ICH E6 R2
- Organization's needs assessment tool
- Organization's SOP/workflow assessment and gap analysis tool
- Risk assessment tool
- Clinical QMS assessment tool
- Technology assessment tool and considerations
- RBM and Clinical QMS implementation plan
- Case study of one company's approach to risk management and Clinical QMS
- Change management plan

**Separate registration required.*

SPONSORSHIP, EXHIBIT & 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 the Main Agenda!

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by CHI, and more.

Breakfast & Luncheon Podium Presentations

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives i.e.: (purely social, focus group, reception style, plated dinner with specific conversation focus, etc.)

Exhibit

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

One-on-One Meetings

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.

Additional branding and promotional opportunities are available, including:

- Conference Tote Bags
- Literature Distribution
  (Tote Bag Insert or Chair Drop)
- Padfolios
- Program Guide Advertisement

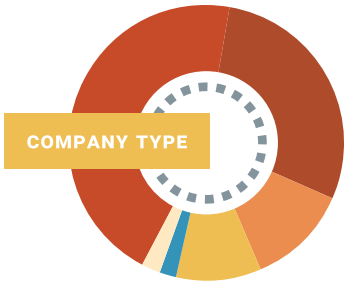
Looking for additional ways to drive leads to your sales team?

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:

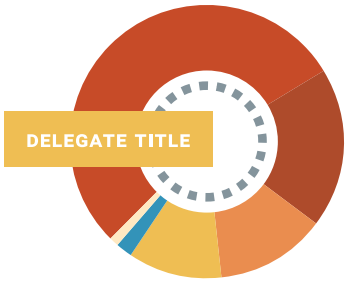
- Whitepapers
- Webinars
- Custom Market Research Survey
- Podcasts

For sponsorship and exhibit information, please contact:
Ilana Quigley | Sr. Business Development Manager
iquigley@healthtech.com | 781-972-5457

2017 ATTENDEE DEMOGRAPHICS



- **45%** Biotech & Pharma
- **29%** CRO
- **12%** Healthcare
- **10%** Services
- **2%** Academic, Government & Financial
- **2%** Societies & Press



- **54%** Executive & Director
- **19%** Manager
- **13%** Sales & Marketing
- **11%** Scientist/Technologist
- **2%** Assistant
- **1%** Professor

Hotel & Travel

Aloft Boston Seaport Hotel
401-403 D Street
Boston, MA 02210
617-530-1600

Discounted Room Rate: $279 s/d
Discounted Room Rate
Cut-off Date: April 13, 2018

Go to the travel page of ClinicalTrialSummit.com for additional info.

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9th Annual

Mastering Risk-Based Monitoring: PART 1

Proactively Ensuring Quality in Clinical Trials

May 7-8, 2018 ▪ Aloft Boston Seaport Hotel ▪ Boston, MA

ENSURING QUALITY FROM the outset of a clinical trial leads to higher quality, lower risk clinical trials. The ensuing risk assessment and mitigation from the design and planning of clinical trials with the establishment of clinical quality management systems lays the foundation for successful risk-based monitoring (RBM). Cambridge Healthtech Institute's Mastering Risk-Based Monitoring- Part 1: Proactively Ensuring Quality in Clinical Trials conference offers case studies and practical solutions from across pharma and TransCelerate member organizations on proactively building quality standards into clinical trials with emphasis on the latest quality standards and guidelines, including the recent ICH-E6 R2 addendum changes, clinical trial quality in action, and working with various stakeholders on effective rollout of RBM.

MONDAY, MAY 7

7:25 am Conference Registration and Morning Coffee

QUALITY IN CLINICAL TRIALS & RISK ASSESSMENT

8:25 Chairperson's Opening Remarks
Angie Maurer, RN, BSN, MBA, Clinical Quality & Risk Management Consultant, GRAIL, Inc.

8:30 Quality by Design: From Theory to Practice
Sabrina Comic-Savic, MD, 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. Focusing on key objectives is necessary in order to simplify and reduce error.

9:00 Proactive Risk Assessment for the Development of a Robust Integrated Quality Management Plan
Sheri Kuss, Clinical Quality Lead, Clinical Development Quality, Global Product Development, Pfizer, Inc.
Sheri will review the risk management process and tools in place to assist study teams in systematically identifying, assessing and mitigating risks to quality in their clinical trials. The output of a robust Integrated Quality Management Plan (IQMP), which is in alignment with ICH E6 R2, will be addressed. Further, case studies will be shared focusing on the process of IQMP development, timing, elements for the implementation of risk based monitoring as well as implementation challenges and how to overcome them.

> "The conference is very intimate with plenty of naturally occurring networking. Excellent speakers and content!
>
> – Associate Director, Clinical Contracting Services, Boehringer-Ingelheim

9:30 De-Risking the Risk Assessment Process: Ensuring Successful Integration of a Study Risk Assessment Tool into Existing Processes
Sarah Bednarski, Associate Director, Strategic Monitoring, Sunovion
When managing clinical trials we plan for, address, and document risk every day. In many ways, the evolution of risk-based monitoring has arisen out of what the best teams have always done. However, as regulatory authorities have recommended and now required a risk-based approach, a number of positive changes have occurred: novel tools have developed, the industry has set a new precedent for collaboration, and we now have the flexibility to not get hung up on insignificant data. How do we keep the focus on these positive changes, while not losing what we were already doing that was great in the first place, particularly in a culture that may already be fatigued with change?

10:00 Networking Coffee Break

CLINICAL QUALITY MANAGEMENT SYSTEMS

10:30 CO-PRESENTATION: RBM and Clinical QMS from Small Pharma/ Biotech Perspective
Brian Nugent, Senior Director, Clinical Compliance, GRAIL, Inc.
Angie Maurer, RN, BSN, MBA, Clinical Quality & Risk Management Consultant, GRAIL, Inc.
Although not yet a requirement, it is generally accepted that a Clinical Quality Management System (QMS) is important to implement, most especially in our "new" risk-based culture. During this presentation we will be sharing a case study that examines a small pharma/biotech company's perspective and approach to RBM and implementation of a clinical QMS. We will provide a broad perspective and will provide examples of tools and tips to help implement your own systems. It will include the following: 1. Interpretation of the ICH E6 R2 requirements for the small pharma/biotech company, 2. Examination of the company's SOPs, quality documents and templates for compliance and readiness relative to the new requirements which includes the conduct of a gap analysis, 3. Development of a QMS and RBM Implementation Plan, 4. The company's approach to Change Management, 5. Sample QMS case study.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:45 Session Break

1:25 Chairperson's Opening Remarks

1:30 Taking Control of Risk in Clinical Trials
Janis Little, Vice President, Global R&D Quality, Allergan

Group Discounts Available! Special rates are offered to multiple attendees from the same organization.

For more information on group discounts: contact Melissa Dolen at 781-972-5418.

2:00 Ensuring Quality with a Comprehensive and Customizable Clinical QMS Framework for Industry
Janis Little, Vice President, Global R&D Quality, Allergan
Currently, industry guidance for quality in clinical development is fragmented across multiple documents from multiple sources. While quality systems exist in other industries, there is no industry-wide conceptual framework for clinical Quality Management that aims to address quality and monitor and improve performance in complex clinical development-specific environments. Through partnerships with Health Authorities and other industry stakeholders, TransCelerate's Quality Management System (QMS) Initiative has aimed to explore ways to improve quality across the industry. This session will share the initiative's latest assets which support its conceptual framework.

2:30 Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. 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.

4:15 Welcome Reception in the Exhibit Hall

5:30 Close of Day

5:30 Dinner Short Course Registration

6:00-9:00 Recommended Dinner Short Course
Needles in a Haystack: Proven Digital Media Campaigns for Clinical Trials in Rare Diseases & Oncology
Please see page 2 for details. Separate registration required.

TUESDAY, MAY 8

7:25 am Morning Coffee

QUALITY IN THE WAKE OF ICH E6 R2

7:55 Chairperson's Opening Remarks
David Nickerson, Head, Clinical Quality Management, EMD Serono

> Understand the recent ICH E6 R2 changes taking effect and hear case studies and best practices from leaders at EMD Serono, Merck, and Gilead on how to achieve compliance.

8:00 An Overview of Today's Guidelines for Clinical Quality Risk Management
David Nickerson, Head, Clinical Quality Management, EMD Serono
In today's clinical trial landscape, there are several guidelines in place regarding clinical risk management. An overview of the latest regulatory updates such as the EMA guidelines and the ICH E6 addendum will be provided.

8:30 Merck Case Study: Development and Evolution of the Risk Management System to Achieve ICH E6 R2 Compliance for Clinical Trials
Joe Kunakorn, MS, Associate Director, Headquarters Clinical Quality Management, Oncology, Quality & Continuous Improvement, Merck
This presentation will discuss 1. Merck's implementation of the TransCelerate Risk Assessment Categorization Tool (RACT), 2. Development of the quality plan to define metrics for the monitoring of key quality risks, and 3. Evolution of Merck's risk-based monitoring efforts via use of a technological tool and review of the lessons learned.

9:00 Talk Title to be Announced
Jacqueline Gough, Advisor, Clinical Risk Management, Eli Lilly and Company

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION
Transformation through Digital Medicine: The Time is Now!!
Ashish Atreja, MD, MPH, FACP Chief Technology Innovation and Engagement Officer, Medicine, Icahn School of Medicine at Mount Sinai
Value based healthcare and outcome based contracts are reshaping the entire health industry and major players including health systems, payers and pharma. Digital Medicine is an emerging discipline that can enable transformation of health systems to support both patient centered clinical care and research. Dr. Atreja, will provide an overview of current state of the art of digital medicine, review the challenges faced in digital medicine adoption and demonstrate how prescription of digital medicine can support care and research transformation. As Chief Technology Innovation and Engagement Officer, Medicine, Dr. Atreja leads the Sinai AppLab (www.sinaiapplab.org), a one-of-a-kind collaborative hub to build and test disruptive mhealth technologies. Dr. Atreja leads scientific registries for the American Gastroenterology Association and serves on the Innovation Advisory Board for American College of Cardiology. As an intrapreneur, Dr. Atreja has won innovation awards at Cleveland Clinic and Mount Sinai, successfully licensed technologies from academic centers and advises startups, accelerators and Fortune 500 companies in digital medicine. More recently, Dr. Atreja launched the first enterprisewide app curation and prescribing platform (www.rxuniverse.com) and established Network of Digital Medicine (www.nodehealth.org) to connect innovation centers worldwide and share best practices for digital medicine innovation and implementation.

11:50 Keynote Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Conference
Stay on to Attend Mastering Risk-Based Monitoring – Part 2: Ensuring Effective Monitoring & Successful RBM Implementation

3rd Annual

Patient Recruitment & Site Selection

Ensuring Study Start-Up Success with Patient-Centric Approaches to Patient Recruitment & Site Selection

May 7-8, 2018 ▪ Aloft Boston Seaport Hotel ▪ Boston, MA

SUCCESSFUL STUDY START-UP hinges on meeting patient recruitment goals and selecting and engaging with clinical trial sites and investigators that can effectively launch study start-up activities. Cambridge Healthtech Institute's Patient Recruitment & Site Selection conference features best practices and case studies on successful patient engagement, recruitment, and site selection techniques using novel, patient-centric and data-driven approaches.

MONDAY, MAY 7

7:25 am Conference Registration and Morning Coffee

PATIENT RECRUITMENT FROM A RESOURCE LIMITED PERSPECTIVE

8:25 Chairperson's Opening Remarks

8:30 Insights from a Large Healthcare System: Solutions to Barriers to Patient Recruitment in Digital Health Research
Ramya Palacholla, PhD, Postdoctoral Scientist, Innovation, Harvard Medical School/ Partners Connected Health
This talk, based on the available literature and extensive digital health research experience of the speaker in one of the largest healthcare systems in the country, will attempt to discuss the importance of recruitment of research participants, the associated barriers and challenges, and various strategies to overcome these barriers.

9:00 PANEL DISCUSSION: Patient Recruitment Strategies for Resource Limited Pharma/Biotech
Jzaneen Lalani, COO, Curemark
Lori Ann Correia, Director, Clinical Operations & Patient Advocacy, Inozyme Pharma
Dawn Harper, Executive Director, Clinical Operations, Strongbridge Biopharma
Kim Kaiser, Principal, Kim Kaiser and Associates, LLC representing LUPUS RESEARCH ALLIANCE
Rose Gerber, Director, Patient Advocacy and Education, Community Oncology Alliance (COA)
Launching a clinical trial hinges on successful patient recruitment. However, this often-difficult task is made even tougher by limited resources and finances. This panel will bring together stakeholders from patient advocacy, sponsors, and sites to discuss innovative approaches and successful case studies which resource limited pharma/biotech can apply to their patient recruitment efforts.

10:00 Networking Coffee Break

RETHINKING PATIENT ENGAGEMENT & THE SITE EXPERIENCE

10:30 Informed Consent Optimization Project Using Patient Voice and Technology
Cassandra Smith, Associate Director, Investigator and Patient Engagement Projects, Global Clinical Development Operations, Janssen R&D
Informed Consent is one of the most important aspects of the clinical research process; it is also one of the areas that most Sponsor companies struggle with, as the document is heavily regulated by the regulations and internal compliance/legal groups. Janssen R&D is undergoing a project to overhaul the ICF document and delivery process to make it more effective and patient-centric.

11:15 E-Source: Why the Slow Adoption by Research Sites?
Chris Hoyle, MBA, Executive Director, Elite Research Network
For both sponsors and sites, e-source provides many advantages including cost savings and cleaner, quality data. So why are sites still reluctant to move from paper to electronic source? During this session a site perspective will be shared as to why the hesitation to transition away from paper and how industry can work together to expedite the adoption of e-source.

11:30 How Do I Create a Patient Centric Protocol and Clinical Trial? *Sponsored by* FIRMA CLINICAL RESEARCH
Michael Keens, MS, COO, Firma Clinical
The clinical trial industry has been undertaking a renewed effort on patient focus within protocols, known as "Patient Centricity." This approach can involve direct patient input on protocols, fewer office visits using home health care and data collection efforts using wearable technology. We'll review case studies and direct patient feedback on the use of home health care visits within trials, considerations when implementing, and examples of benefits and patient perspectives.

12:00 Luncheon Presentation: Filling the Gaps in Site Selection: What You Don't Know Can Help You *Sponsored by* IMS Health & Quintiles are now IQVIA
April Lewis, MS, Director, Offerings and Marketing, IQVIA CTOS
Industry statistics show that we continue to rely on the same investigators over and over, regardless of prior performance. This leads to investigator exhaustion, timeline extension and lost opportunity. This co-presentation from IQVIA CTOS and Informa Pharma Intelligence's Citeline, will highlight a collaboration aimed at delivering a unique combination of data, technology and analytics to optimize the site feasibility process. This joint effort offers 'one-stop site shopping' within placement areas ripe for recruitment success.

12:45 Session Break

RETHINKING PATIENT ENGAGEMENT & THE SITE EXPERIENCE *(Cont.)*

1:25 Chairperson's Opening Remarks

1:30 Understanding the Patient Voice to Achieve the Clinical Trial Registry of the Future and Revolutionize Trial Information Exchange
Christine Crandall, Head, Strategic Clinical Planning, GlaxoSmithKline
With growing calls for transparency of clinical trial information in various countries and increasing recognition of its value, an unfortunate side effect has become a difficult-to-navigate landscape of data and information. TransCelerate has undertaken an initiative to publish a proposal and wireframe mock-up illustrating patient-focused improvements for adoption by government registries. This initiative believes that understanding the situation patients (or caregivers) might find themselves in when visiting a

Discover new ways to fundamentally increase clinical trial awareness and lasting patient engagement from Eli Lilly and the Greater Gift Initiative.

clinical trial registry lends valuable context to their expectations of user experience. Furthermore, patients often lack useful information about a clinical trial before, during, and after their participation; meanwhile, costly and slow recruitment coupled with sub-optimal retention is delaying the delivery of new treatments. This session will discuss a series of post-trial communications templates that the TransCelerate Information Exchange initiative has developed to bridge this gap, and ultimately improve patients' satisfaction with their clinical trials.

2:00 **Redefining the Site Investigator Experience**
Krupa Patel, Director, Business Enablement Organization, Merck
Imagine a world where site investigators could use a centralized point of access for all study related tasks and study information, rather than many portals and platforms, to access studies with every sponsor they work with. Imagine if sponsors could quickly search for and download their latest study documents, and easily access a registry of investigator profiles to assess feasibility for new studies. The Shared Investigator Platform (SIP) was launched with these goals in mind, and continues to evolve with new functionality as it is adopted by additional TransCelerate member companies and their associated investigator sites. The SIP was developed with sites, for sites, to enable greater collaboration with participating sponsors, and make room for higher value activities, like trial execution and spending time with patients.

2:30 **Refreshment Break in the Exhibit Hall**

3:15 **Interactive Breakout Discussion Groups**
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. To get the most out of this interactive session and format, please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.

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5:30 **Close of Day**

5:30 **Dinner Short Course Registration**

6:00-9:00 **Recommended Dinner Short Course**
Needles in a Haystack: Proven Digital Media Campaigns for Clinical Trials in Rare Diseases & Oncology
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TUESDAY, MAY 8

7:25 am **Morning Coffee**

BIG DATA ANALYTICS FOR PATIENT RECRUITMENT & SITE FEASIBILITY

7:55 **Chairperson's Opening Remarks**

8:00 **CO-PRESENTATION: Innovative Clinical Trial Recruitment Strategy Enabled by Smart Data Analytics: Go Where the Patients Are**
Aniket Joshi, Associate Director, R&D Innovation, Otsuka Pharmaceutical
Saloni BehlSaloni Behl, Associate Director, Commercial Planning, Otsuka Pharmaceutical
Almost two-thirds of clinical sites do not meet patient recruitment targets in clinical trials, as per the 2011 Tufts report. There have been a number of approaches explored to boost clinical trial recruitment with some mixed success. While there are tools with promising visuals by leveraging big data analytics, most tools do not provide any actionable insight for study teams to implement in areas "where the patients are". An example of leveraging smart data analytics combining real world data, internal clinical operations data and publicly available resources will be discussed that supported development of a novel and actionable targeted recruitment approach.

8:30 **Bridging the Gap between Data Analytics and Patient Recruitment**
Angelique Hopkins, MPH, Associate Director, Clinical Trial Analytics, Business Insights & Analytics, Bristol-Myers Squibb

9:00 **Attention to Real World Data Opportunities in Clinical Development**
Gurparkash Singh, Manager, Electronic Health Records (EHRs), Janssen R&D
Execution of global clinical trials is a complex, costly, and time-consuming endeavor with operational challenges regarding study design, site selection, screening and enrollment that often result in costly amendments. Real world data (RWD) has the potential to mitigate some of these challenges. We will share our experiences towards finding ways to leverage RWD for clinical trial operation efficiencies. We will also share work of some IT solution providers in this domain.

9:30 **Sponsored Presentation** *(Opportunity Available)*

10:00 **Coffee Break in the Exhibit Hall**

10:45 **PLENARY KEYNOTE SESSION**
Transformation through Digital Medicine: The Time is Now!!
Ashish Atreja, MD, MPH, FACP
Chief Technology Innovation and Engagement Officer, Medicine, Icahn School of Medicine at Mount Sinai
See page 5 for details.

11:50 **Keynote Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:35 pm **Dessert Break in the Exhibit Hall**

1:20 **Close of Conference**
Stay on to Attend Outsourcing for Clinical Trials

Big Data Analytics, Machine Learning, & Artificial Intelligence

Making Meaningful, Data-Driven Decisions in Clinical Trials

May 7-8, 2018 ▪ Aloft Boston Seaport Hotel ▪ Boston, MA

AS NEW TECHNOLOGY and increasing volumes of data become more accessible to the biopharmaceutical industry, how will the industry make meaningful, data-driven decisions aimed at improving the clinical trial process? Cambridge Healthtech Institute's Big Data Analytics, Machine Learning, and Artificial Intelligence for Clinical Trials conference gathers leaders across pharma, biotech and academia to explore the use of artificial intelligence, big data analytics, machine learning, and deep learning for improving the clinical trial process and harnessing existing clinical data for new insights. Discussions and case studies will address challenges and solutions in establishing big data analytic platforms and their use in making meaningful, data-driven decisions.

MONDAY, MAY 7

7:25 am Conference Registration and Morning Coffee

REAL WORLD DATA, BIG DATA ANALYTICS & MACHINE LEARNING FOR EARLY CLINICAL DEVELOPMENT DECISIONS AND TRIAL DESIGN

8:25 Chairperson's Opening Remarks
Margaret McDonald, PhD, Senior Director, Real World Data and Analytics, Patient & Health Impact, Pfizer, Inc.

8:30 Applications of Machine Learning and Text Mining in Electronic Health Record Datasets to Inform Under-Diagnosed Conditions
Alexandra Dumitriu, PhD, Manager, Genome Sciences and Technologies, Pfizer
Real-World Data, such as electronic medical records (EHRs), are valuable resources to inform our knowledge of disease trajectories, outcomes, and costs. But to take advantage of these resources, it is important to identify patients correctly, which is a difficult task to achieve for conditions that are under-diagnosed by physicians. Identification of predictive disease features can help detect patients earlier in the disease process and provide a larger disease population to study important characteristics, such as sub-typing and disease progression. We applied machine learning and text mining methods to identify and extract predictive features from patients' medical histories for poorly labeled conditions of interest. Chart reviews were used to test the reliability of these features and to surface relevant terms used by physicians to tag patients, even in the absence of diagnostic codes.

8:50 Talk Title to be Announced
Hui Cao, M.D., Ph.D., Executive Director, Real-World Evidence, COE for RWE, Global Medical Affairs, Novartis Pharmaceuticals Corporation

> Pfizer, Bayer, and Wake Forest University discuss their use of big data analytics, machine learning, and AI to optimize clinical trial design thereby reducing the time and cost of clinical trial execution.

9:15 How Machine Learning Will Change and Influence the Clinical Trial Development Process
Francis Kendall, Technology Evaluation and Implementation Leader, Product Development, Roche
This talk will discuss how Pharma is starting to explore and adopt Machine Learning techniques in its drug development processes and will also examine the external environment's adoption of Machine Learning and the opportunities offered by the FDA's openness to such techniques.

9:40 Optimizing Clinical Trial Design and Analysis with Artificial Intelligence
Peter Antinozzi, PhD, Assistant Professor, Department of Biochemistry, Department of Internal Medicine (Section of Molecular Medicine), Department of Genomics and Personalized Medicine Research, Center of Diabetes Research, Center on Diabetes, Obesity, and Metabolism, Wake Forest University School of Medicine
The positive impact of artificial intelligence (AI) on clinical trial design and analysis has been enabled by 1) massive data proliferation, 2) increased computational speed, and as the focus of this presentation 3) the rationale integration of diverse data repositories. Post hoc AI analysis of completed clinical trials can often reveal novel and unexpected observations. Understanding the underlying mechanisms of such observations can be greatly aided by iterative AI-analysis of both clinical and basic research data resources. AI-exploration of large clinical datasets, such as electronic health records (EHR), enables patient stratification to improve outcome comparisons and minimize patient risks. Site-specific EHR analysis assists trial feasibility determination. AI-exploration of basic research datasets, such as -omics data, can reveal causative mechanisms, suggest biomarkers, and provide additional insights on patient specific efficacy and risk. Altogether, an integrated AI-data-driven analysis of clinical trial-, EHR- and omics-data provides fresh opportunities to advance clinical trial design and analysis.

10:00 Networking Coffee Break

CLINICAL TRIAL OPTIMIZATION WITH REAL WORLD DATA, BIG DATA ANALYTICS & MACHINE LEARNING

10:30 Leveraging Real World Data and Analytic Tools to Gain Insights Across the Lifecycle
Margaret McDonald, PhD, Senior Director, Real World Data and Analytics, Patient & Health Impact, Pfizer, Inc.
Real world data (RWD) is increasingly used throughout the drug lifecycle, from discovery and development, to launch and beyond. Examples of RWD use include estimating unmet clinical need, optimizing clinical trial design and sample size, informing business development decisions and understanding treatment patterns. Positive developments on RWD use by the FDA along with a greater variety of analytic tools and data sources, some linked, have increased RWD utilization by colleagues throughout the organization. This presentation will provide: 1. Current state of affairs of Real World Data (RWD) sources, 2. External Environment: What's driving the use of RWD , 3. Uses of RWD and tools across Life Cycle.

11:00 Risk-Adjusted Planning for Clinical Trial Optimization
Kevin Hua, Senior Manager, AI/Machine Learning Development, Bayer
Clinical trials are expensive business expenditures. Accurate planning for clinical trials is difficult given the number and variety of sources of uncertainties and the dynamic nature of the trials. Mining data from historical clinical trials to identify the risk factors and their impact on the variances of durations and costs can be used to define risk-adjusted planning for future trials, where durations and costs are aggregated and forecasted at customized confidence levels. Actionable measures can also be identified and simulated on reduction of time and costs for more efficient planning and execution of clinical trials.

11:30 A Framework to Implement Trial Management Analytics *Sponsored by* saama
Nikhil Gopinath, Senior Product Manager, Saama
Sponsors partner with SIs to reign in data silos. Silos represent challenges for data ingestion, analysis, and presentation. The challenge of preparing and isolating clean data to drive decision-making in trial management is similar across sponsors. Sponsors can adopt a Trial Management Analytics (TMA) framework including initiative planning, source data integration, data organization, analysis of data, and presentation of data to improve the expenditure, quality, success, and safety of clinical studies.

12:00 pm Luncheon Presentation
(Sponsorship Opportunity Available) **or Lunch on Your Own**

12:45 Session Break

1:25 Chairperson's Opening Remarks

1:30 PANEL DISCUSSION: What Are the Opportunities and Challenges with Applying Machine Learning and AI to Clinical Trials?
Moderator: John Cai, MD, PhD, Executive Director, Real World Data Analytics & Innovation, Merck
Panelists:
Kevin Hua, Senior Manager, AI/Machine Learning Development, Bayer
Francis Kendall, Technology Evaluation and Implementation Leader, Product Development, Roche
Laszlo Vasko, Senior Director, Information Technology, Clinical Operations & Innovation, Janssen
Machine learning and AI are transforming how the pharma industry is conducting and working with the resulting data from clinical trials, but many questions and challenges still remain with these new technologies. The panel will discuss:
- Data standard issues and leveraging data for machine learning projects
- Where is machine learning & AI most beneficial for clinical trials (optimizing trial design, patient inclusion/exclusion, etc.)?
- What are the major barriers to ML & AI for pharma?

2:30 Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups
Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. 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.

4:15 Welcome Reception in the Exhibit Hall

5:30 Close of Day

5:30 Dinner Short Course Registration

6:00-9:00 Recommended Dinner Short Course
Needles in a Haystack: Proven Digital Media Campaigns for Clinical Trials in Rare Diseases & Oncology
Please see page 2 for details. Separate registration required.

TUESDAY, MAY 8

7:25 am Morning Coffee

BIG DATA ANALYTICS FOR PATIENT RECRUITMENT & SITE FEASIBILITY

7:55 Chairperson's Opening Remarks

8:00 CO-PRESENTATION: Innovative Clinical Trial Recruitment Strategy Enabled by Smart Data Analytics: Go Where the Patients Are
Aniket Joshi, Associate Director, R&D Innovation, Otsuka Pharmaceutical
Saloni BehlSaloni Behl, Associate Director, Commercial Planning, Otsuka Pharmaceutical
Almost two-thirds of clinical sites do not meet patient recruitment targets in clinical trials, as per the 2011 Tufts report. There have been a number of approaches explored to boost clinical trial recruitment with some mixed success. While there are tools with promising visuals by leveraging big data analytics, most tools do not provide any actionable insight for study teams to implement in areas "where the patients are." An example of leveraging smart data analytics combining real world data, internal clinical operations data and publicly available resources will be discussed that supported development of a novel and actionable targeted recruitment approach.

8:30 Bridging the Gap between Data Analytics and Patient Recruitment
Angelique Hopkins, MPH, Associate Director, Clinical Trial Analytics, Business Insights & Analytics, Bristol-Meyers Squibb

9:00 Attention to Real World Data Opportunities in Clinical Development
Gurparkash Singh, Manager, Electronic Health Records (EHRs), Janssen R&D
Execution of global clinical trials is a complex, costly, and time-consuming endeavor with operational challenges regarding study design, site selection, screening and enrollment that often result in costly amendments. Real world data (RWD) has the potential to mitigate some of these challenges. We will share our experiences towards finding ways to leverage RWD for clinical trial operation efficiencies. We will also share work of some IT solution providers in this domain.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION
Transformation through Digital Medicine: The Time is Now!!
Ashish Atreja, MD, MPH, FACP
Chief Technology Innovation and Engagement Officer, Medicine, Icahn School of Medicine at Mount Sinai
See page 5 for details.

11:50 Keynote Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Conference
Stay on to Attend Data & Tech Driven Clinical Trials

9th Annual

Mastering Risk-Based Monitoring: PART 2

Ensuring Effective Monitoring & Successful RBM Implementation

May 8-9, 2018 ▪ Aloft Boston Seaport Hotel ▪ Boston, MA

AS INDUSTRY ADOPTION of Risk-Based Monitoring increases, it is clear that, although RBM takes many forms – remote, centralized, and risk-based monitoring – successful risk-based monitoring implementation requires developing new roles, analytics and processes among the stakeholders in RBM. Cambridge Healthtech Institute's Mastering Risk-Based Monitoring – Part 2: Ensuring Effective Monitoring & Successful RBM Implementation conference offers case studies, lessons learned, and practical solutions from across pharma and TransCelerate member organizations on effectively implementing RBM, scaling-up roll out of RBM, as well as a prospective look into the future of RBM and its possibilities.

TUESDAY, MAY 8

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION
Transformation through Digital Medicine: The Time is Now!!
Ashish Atreja, MD, MPH, FACP
Chief Technology Innovation and Engagement Officer, Medicine, Icahn School of Medicine at Mount Sinai
See page 5 for details.

11:50 Keynote Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:35 pm Dessert Break in the Exhibit Hall

SMALL & MID-SIZE COMPANY PERSPECTIVES ON RBM

1:45 Chairperson's Remarks
Brian Nugent, Senior Director, Clinical Compliance, GRAIL, Inc.

1:50 Aligning Systems and Outsourcing Model to Implement a Risk-Based Approach
Beth (Elizabeth) Robinson, RN, MSHS, Executive Director, Clinical Compliance and Operations, Horizon Pharma
This presentation will cover: 1. Synthesizing disparate inputs from multiple vendors and systems precludes a predictive and proactive approach; 2. Vendors rarely have the same perception of risk and impact as sponsors do; 3. Despite best efforts, vendors are seldom in a position to deliver a timely and comprehensive prospective risk assessment.

2:20 How to Creatively Implement RBM and Unlock the Potential of the Team
Teresa Ancukiewicz, Senior Manager, Clinical Trials, Boston Scientific
This presentation will be focused on real-life experiences with the Risk-Based Monitoring implementation from a mid-size medical device company. Lessons learned from a successful RBM implementation will be shared. Implications for the outsourcing model and its challenges will be discussed. I will also examine the impact of RBM on the roles and responsibilities, and the opportunities it presents for advancement of clinical trial team members. It will present real lessons learned from the RBM implementation led by the sponsor. The model and experience that will be shared is different than a typical large pharma company, and can be useful for other companies that have limited resources and need a more scalable approach.

2:50 Sponsored Presentation *(Opportunity Available)*

3:20 Refreshment Break in the Exhibit Hall

4:05 CO-PRESENTATION: Making RBM Fit for Purpose: A Small Biotech's View of Implementing ICH E6 R2
Yiwen Sun, Senior Clinical Research Associate, Samumed, LLC
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
This presentation will be in two parts; the first will examine the overall quality imperative within the clinical trial arena, and the second part will focus on Samumed's ICH E6 and RBM journey to current status and future direction. Key points: 1. Understand the quality requirement expected of sponsors, 2. What can be achieved by a small company, current status, and 3. Future direction.

5:05 Close of Day

5:05 Dinner Short Course Registration

5:30-8:30 Recommended Dinner Short Course
Implementing RBM and a Clinical QMS with Limited Resources
Please see page 2 for details. Separate registration required.

WEDNESDAY, MAY 9

8:30 am Interactive Breakout Discussion Groups with Continental Breakfast
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.

9:25 Session Break

CASE STUDIES ON HOW PHARMA IS TACKLING THE CHALLENGES OF RISK-BASED MONITORING

9:40 Chairperson's Remarks
Mary Arnould, Director, Clinical Science Operations and RBM Lead, Astellas

9:45 Best Practices and Observations from Implementing TransCelerate's Risk-Based Monitoring Model Framework
Stuart Shaw, Risk Based Quality Management Implementation Project Lead, Boehringer-Ingelheim
Although regulators were urging companies to move to a risk-based approach, no model framework existed that would have enabled organizations to successfully deploy and scale risk-based monitoring. Five

years ago, a collaboration of multiple global pharmaceutical companies came together to form TransCelerate, aiming to overcome this challenge as one of their founding goals. For the past five years, these member companies have developed model guidelines for targeted, risk-based clinical trial monitoring, ultimately aiming to improve data quality and patient safety, while reducing costs and effort expended on low-value activities. TransCelerate's Risk-Based Monitoring methodology can be adopted by any size organization, and any type or phase of a clinical trial. This session will explore the latest work of this RBM initiative, including new tools to assist implementation, best practices for adoption, and updated member company metrics.

10:15 Talk Title to be Announced
Jacqueline Gough, Advisor, Clinical Risk Management, Eli Lilly and Company

10:45 Sponsored Presentation *(Opportunity Available)*

11:00 Coffee Break

11:30 Using Data Visualization to Make RBM More Effective
Nechama Katan, Central Monitoring Manager, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer
We will explore different visualizations of risk for both clinical and operational data. Different levels of detail (study to individual measurements) will be used to show how the right data visualization increases the value and acceptance of RBM results.

12:00 pm Considerations for Implementing RBM in Special Studies: Adaptive Design, Clinical Pharmacology, Post Marketing, and Pediatric Trials
Mary Arnould, Director, Clinical Science Operations and RBM Lead, Astellas
All types of clinical trials can benefit from a risk based approach. ICH E6 (R2) requires a risk based approach to all clinical studies. This presentation will focus on unique challenges implementing RBM in clinical trials in designs, phases or populations once believed to be "out of scope" for RBM. The flexibility of a RBM program can address the distinctive qualities of these trials and provide greater confidence that data quality and patient safety will be preserved.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)*

1:15 Session Break

CASE STUDIES ON HOW PHARMA IS TACKLING THE CHALLENGES OF RISK-BASED MONITORING *(Cont.)*

2:15 Chairperson's Remarks
Mary Arnould, Director, Clinical Science Operations and RBM Lead, Astellas

2:20 Lessons Learned Implementing RBM in Novo Nordisk A/S
Esther Huffman, Associate Director, Monitoring Excellence, Bristol-Myers Squibb
This presentation will discuss implementation of the TransCelerate Risk Based Monitoring model in Novo Nordisk A/S – a mid-sized pharma company. The presentation will particularly address the challenges the company is facing, moving from a pilot risk based approach covering a few clinical trials to full scale RBM. Focus is on change management and how to support the organization with this shift of paradigm in way of working. Challenges, lessons learned and practical solutions will be shared.

2:50 Central Monitoring on RBM Studies
Carolina Errobidart, Central Monitor, Global Data Strategies & Solutions (GDSS), Bristol Myers-Squibb
This presentation will cover 1. Overview of the BMS approach to RBM and Central Monitoring, 2. Technology Evolution, 3. Managing Risks and Issues, 4. Central Monitoring Successes & Challenges, 5. RBM Metrics, and 6. Sharing Perspectives Across Roles

3:20 RBM's Continuous Journey and Learnings
Nurcan Coskun, PhD, Global Risk Based Monitoring Program and Technology Solutions Manager, Medtronic
RBM has already started with direction from regulatory bodies, and it is still continuing to evolve with the changing landscape of regulations and technology solutions. This talk will provide the evolution of clinical trials with risk based approach in the current setting and how they will continue their journey.

3:50 Close of Conference
Arrive early to attend Mastering Risk-Based Monitoring – Part 1: Proactively Ensuring Quality in Clinical Trials

Hear from large, mid-sized, and small organizations on how to successfully implement a clinical QMS and RBM plan whether your organization has limited resources and finances or larger budgets. Case studies from Samumed, Boston Scientific, and Horizon Pharma provide a small and mid-sized perspective on RBM.

3rd Annual

Outsourcing for Clinical Trials

Building Effective Outsourcing Strategies & Relationships

May 8-9, 2018 ▪ Aloft Boston Seaport Hotel ▪ Boston, MA

AS MORE CLINICAL trial activities are outsourced to contract research organizations (CROs) and other third-party vendors, understanding outsourcing needs and forming effective, quality partnerships are paramount to successful clinical trial execution. Cambridge Healthtech Institute's Outsourcing for Clinical Trials conference provides a new perspective on the entire outsourcing relationship from vendor selection and contracting through to vendor management and project performance and quality. The 2018 program focuses on case studies, lessons learned, and interactive discussion from sponsors, CROs, and other vendors on outsourcing strategy, the RFP and bid defense process, vendor selection, contracting, vendor quality and performance, and working with third party suppliers.

TUESDAY, MAY 8

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION
Transformation through Digital Medicine: The Time is Now!!
Ashish Atreja, MD, MPH, FACP, Chief Technology Innovation and Engagement Officer, Medicine, Icahn School of Medicine at Mount Sinai
See page 5 for details.

11:50 Keynote Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

12:35 pm Dessert Break in the Exhibit Hall

OUTSOURCING STRATEGY & BID DEFENSE

1:45 Chairperson's Remarks
Erin O'Boyle, Senior Director, Clinical Contracts and Outsourcing, FibroGen, Inc.

1:50 Strategies for Smaller Pharma/Biotech to Increase Their Leverage with CROs
Speaker to be Announced

2:20 Presentation to be Announced

> What does oversight in the wake of new ICH E6 R2 changes mean for the Sponsor-CRO relationship? Hear leaders in outsourcing from both the Sponsor and CRO discuss the impact of ICH E6 R2 on oversight.

2:50 New Tufts Study: CRO Oversight Performance Market Survey

Sponsored by comprehend

Beth Harper, MBA, President, Clinical Performance Partners
Rick Morrison, President, Comprehend Systems, Inc.
This session provides an overview of a recent Tufts CSDD market research study focused on the effectiveness and impact of CRO Oversight programs. Join Beth Harper of Clinical Performance Partners as she explores results and implications. Learn about: CRO oversight models, oversight challenges, industry experience, performance metrics, insights into new approaches. Joining Beth is Rick Morrison of Comprehend, who will share industry directions and ways to overcome Oversight challenges including transparency, risk, and compliance.

3:20 Refreshment Break in the Exhibit Hall

4:05 PANEL DISCUSSION: Selecting Suppliers – Full-Service Providers, Functional Service Providers or Somewhere in the Middle?
Moderator: Erin O'Boyle, Senior Director, Clinical Contracts and Outsourcing, FibroGen, Inc.
Rosalie Filling, Vice President, Clinical Operations, Endo Pharmaceuticals
As the pharma industry continuously reevaluates its outsourcing, the panel will bring together representatives from small pharma, large pharma and CROs to discuss outsourcing trends, the pros and cons with consolidating providers (and having 1 sole preferred provider) vs. maintaining multiple suppliers, scenarios when it is most beneficial to choose a full-service provider over functional service providers and vice versa, and the resulting trade-offs with each outsourcing strategy.

5:05 Close of Day

5:05 Dinner Short Course Registration

5:30-8:30 Recommended Dinner Short Course
Implementing RBM and a Clinical QMS with Limited Resources
Please see page 2 for details. Separate registration required.

WEDNESDAY, MAY 9

8:30 am Interactive Breakout Discussion Groups with Continental Breakfast
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.

9:25 Session Break

BUILDING MORE EFFECTIVE PARTNERSHIPS

9:40 Chairperson's Remarks
Mark Milberg, MBA, MSW, Director, Clinical Procurement and Outsourcing, Ultragenyx

9:45 PANEL DISCUSSION: Rethinking Bid Defense with All Stakeholders – Sponsors, CROs & Third Party Vendors
Moderator: Mark Milberg, MBA, MSW, Director, Clinical Procurement and Outsourcing, Ultragenyx
Owen Charles, RN, MBA / HCM, Outsourcing Manager, Central Clinical Planning & Solutions, Bristol-Myers Squibb
Bid defense is typically a very repetitive and unimaginative process across pharma for both the sponsor and CRO. And as CROs are tasked with outsourcing more services on behalf of sponsor companies, CROs are often conducting their own sourcing of third party vendors. This panel discussion will focus on how to innovatively approach bid defense and involve all stakeholders: CROs, sponsors, and third party vendors. We will explore:
- How Pharma/CRO determine the participants at the bid defense meeting
- What are the main objectives of each party at the bid defense meeting, and how are they achieving them?

10:45 Sponsored Presentation *(Opportunity Available)*

11:00 Coffee Break

11:30 The Evolution of KPIs to KxIs in Strategic Relationships - Getting Value in Your Ability to Report by Leveraging a Holistic Approach to Metrics and Reporting during the Setup of the Relationship
Christopher Rull, Principle Consultant, CR Consulting, LLC; Former Vice President, Head of Business Development & Account Management, UBC
This session will look at some best practices and lessons learned in the creation of your metrics and reporting in new strategic relationships by 1.) empowering the study teams to create the operational and performance metrics they need to work, and 2.) focusing in a balanced suite (Performance, Quality, Finance, and Relationship) of KxIs that can truly provide insight into the value of the partnership and investment.

12:00 pm KPI Development, Deployment, and Revision: A Case Study in Finding the Metrics to Evaluate Our Vendor Relationships
Eric Stary, Manager, Clinical Outsourcing, Pharmacyclics
PCYC is a mid-size biotech with several key vendor relationships across multiple service lines. In the last several years, PCYC and its vendor partners have developed and deployed KPIs for these key partners. In the rollout of these KPIs, it became evident that an element of revision and regrouping is key to refining and further developing those relationships. This talk will be a case study in this iterative process highlighting what went right, what went wrong, and what we have learned together.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)*

1:15 Session Break

VENDOR QUALITY, PERFORMANCE & OVERSIGHT

2:15 Chairperson's Remarks
Mark Milberg, MBA, MSW, Director, Clinical Procurement and Outsourcing, Ultragenyx

2:20 Minimizing Duplication of Resources between BioPharma and Service Providers Teams while Managing Risk
Charlotte French, Independent Consultant; Former Executive Director, Portfolio Relationship & Sourcing Management, Medical and Development, Astellas
This session will provide insight into the importance of the appropriate linkages between the Trial Oversight Plan and an integrated Project Management Plan. How can BioPharma minimize duplication of effort in an outsourced model and effectively meet the oversight requirements of ICH E6? What are some of the challenges in implementing change from management to oversight within the BioPharma?

2:50 PANEL DISCUSSION: Balancing Oversight in the Wake of ICH E6 R2
Moderator: Melissa A. Hurst, MSM, MBA, Clinical Outsourcing Manager, CSL Behring
Michele Stonier, CRO Infrastructure Lead, Vendor & Outsourcing Management, BMS
Dennis Salotti, Vice President, Operations, The Avoca Group
With the industry's need to comply with recent changes in the ICH E6 R2 addendum, how is pharma balancing oversight with their desired number of suppliers? The panel will bring together representatives from small pharma, large pharma and CROs to discuss setting up governance structures, vendor quality, and oversight in light of the new ICH E6 R2 changes.

3:50 Close of Conference
Arrive early to attend Patient Recruitment & Site Selection

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4th Annual

Data & Tech Driven Clinical Trials

Advancing Clinical Trials with New Tools & Analytics

May 8-9, 2018 ▪ Aloft Boston Seaport Hotel ▪ Boston, MA

TECHNOLOGY AND DATA are at the forefront driving clinical trial decision making. With further advancements in new technologies (such as mobile devices and wearables) and the rise of online communities, the pharma and biotech industry are poised to capitalize on these advancements to innovate existing clinical trial processes and systems. Cambridge Healthtech Institute's Data & Tech Driven Clinical Trials gathers leaders across pharma, biotech and academia for discussions and case studies on leveraging new technologies and clinical trial data to advance clinical research. Special focus will be given to the challenges, solutions, and opportunities that lie in the adoption, use, validation, and data collection of digital technologies.

TUESDAY, MAY 8

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION
Transformation through Digital Medicine: The Time is Now!!
Ashish Atreja, MD, MPH, FACP
Chief Technology Innovation and Engagement Officer, Medicine, Icahn School of Medicine at Mount Sinai
See page 5 for details.

11:50 Keynote Luncheon Presentation *(Sponsorship Opportunity Available)*
or Lunch on Your Own

12:35 pm Dessert Break in the Exhibit Hall

PATIENT CENTRIC APPROACHES TO INCORPORATING TECH IN CLINICAL TRIALS

1:45 Chairperson's Remarks

1:50 Innovating the Clinical Trial Ecosystem for Greater Efficiencies and Informed Decision Making
Mohammed Ali, Global Head, Digital Development, Clinical Operations, Boehringer Ingelheim
Innovation is the buzzword that has been used quite frequently across many industries in the last decade. But how do we truly measure it, and how do we truly make sure it is accepted organizationally? One way to approach this is to ensure measurable factors are incorporated well beyond the traditional and immediate use cases of the innovation platform and into all support functions. This will ensure the disruptive technology will have the most benefit across the most varied number of users. Implementation of innovation this way will not only outline and define a path of efficiency for clinical trials within pharma but for as many functions as possible which are supporting the execution of clinical trials in a sponsor's portfolio.

2:20 What to Do (and Not to Do) When Incorporating Technology in Your Upcoming Trial
Georgia Mitsi, Senior Director, Search & Evaluation, Digital Healthcare, Sunovion Pharmaceuticals
Almost everybody gets excited when new, exciting technology is being incorporated into a clinical trial. However, the initial excitement can turn into a logistics nightmare due to lack of digital experience and preparation. In a world that moves so fast when it comes to technological advancements, how can traditional pharma and CRO keep up? This presentation contains a survival kit for new entrants (and not only) in the digital space.

2:50 Better Process = Better Data = Better Outcomes: How a Process Guided CTMS Can Reduce Risk and Improve Quality
Sponsored by bsi
Jens B. Thuesen, CTMS Business Development, BSI Business Systems Integration AG
Your clinical organization runs on process and method. So should your CTMS solution. There are an abundance of solutions that claim to simplify your job, but how many of them depict your actual business processes? In this informative discussion, you will learn how a CTMS with sound foundational process can enhance data rigor, decrease error and training time, and ultimately increase quality—all while lowering cost.

3:20 Refreshment Break in the Exhibit Hall

4:05 Patient Centric and Siteless Clinical Trials
Nina Spiller, Vice President Clinical Management, Otsuka Pharmaceutical Development and Commercialization (OPDC)
With the advent of telehealth technologies, a traditional clinical trial model can be challenged to address some current limitations of site-centric trials. Siteless trials may provide an option for clinical trial participation not currently available to a substantial number of patients, while decreasing burden for those active in traditional site-centric trials. An example from an active pilot will be used to frame scientific and operational considerations when working in the siteless model. Implications for rethinking clinical trial conduct will be explored.

4:35 People behind the Tech - Change Management to Aid Innovation
Michelle Shogren, Head of Innovation in Portfolio and Operations, Pharma Development, Bayer
As technology continues to provide new and wonderful opportunities for clinical trials it is important to plan for the people that will be using and supporting it. While we often think of the patient and try to answer the question "will this population embrace technology?" we sometimes forget about the sites that will need to support it. Lessons learned from a user experience data flow study using a multi-functional app and connected devices will be presented.

5:05 Close of Day

5:05 Dinner Short Course Registration

5:30-8:30 Recommended Dinner Short Course
Implementing RBM and a Clinical QMS with Limited Resources
Please see page 2 for details. Separate registration required.

As pharma ventures into using more digital solutions (wearables, sensors, and mHealth) within their clinical trials, what are the barriers to their adoption and use? Leaders from Otsuka, Johnson & Johnson, Takeda, and Sunovion discuss their successes and best practices as they implement new digital tech in their organizations.

WEDNESDAY, MAY 9

8:30 am Interactive Breakout Discussion Groups with Continental Breakfast
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.

9:25 Session Break

DIGITAL SOLUTIONS (WEARABLES, APPS, ETC.) IN CLINICAL TRIALS

9:40 Chairperson's Remarks
Michelle Shogren, Head of Innovation in Portfolio and Operations, Pharma Development, Bayer

9:45 Methods to Measure the Impact of Digital Health Innovations as Part of a Clinical Trial
Nnamdi Ezeanochie, MD, DrPH, Manager, Behavior Science, Johnson & Johnson
This presentation introduces digital-compatible research designs and analytic methods to ensure that digital solutions used in clinical trials are efficiently and accurately measured. These research methods include: Continuous Evaluation of Evolving Behavioral Intervention Technology, Multiple Optimization Strategy, and Sequential Multiple Assignment Randomized Trials. The presentation describes each research design/analytic method, and discusses how these methods can be used concurrently to achieve the accurate and reproducible evaluation results.

10:15 Wearables in Clinical Trials
Elena S. Izmailova, PhD, Senior Director, Novel Data Streams and Devices, Takeda Pharmaceuticals International, Inc.
This presentation will cover the following topics: 1. The current state of wearables in the field: the promises and challenges; 2. Meaningful principles for the adoption of wearables in clinical trials: analytical, technical, and clinical; and 3. Examples of wearables in use at Takeda.

10:45 Understanding the Future of Data Interoperability for Clinical Trial Excellence *Sponsored by* adaptive clinical
Sina Adibi, MA, CEO and President, Adaptive Clinical Systems
Join us as we take a few minutes to examine our collective journey of clinical trial data flow then and now and how data interoperability impacts clinical trial success. We will share innovation strategies that your peers are implementing and the technology and processes that are significant for the future.

11:00 Coffee Break

11:30 Regulatory Aspects for Mobile Medical App Development for Commercial and Clinical Trial Use Cases
Michael J. Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline
The presentation will focus on the following points: 1. Mobile Medical Apps are defined as medical devices from its intended use shown through labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives; 2. Mobile Medical App regulation is health risk based to balance patient safety and barriers to technological innovation; 3. Quality management of Mobile Medical Apps; including legal manufacturer (the specification developer) software as a medical device quality management system responsibilities; software requirements/specifications and user acceptance testing; Software version and change control; post-market surveillance includes software incident handling, software recalls/field corrective actions and medical device adverse event reporting procedures.

12:00 pm Elevating Clinical Research - How Innovation in Technology Will Drive the Clinical Trial Process Into a New Era *Sponsored by* SQN CLINICAL
Shiyan Caan, Business Development and Marketing Coordinator, SQN Clinical
Adoption of new technology across a range of sectors has improved processes and efficiencies in significant ways. The clinical space is acknowledging that technology can have an impact on data quality, reduced timelines and savings in costs. With a drive towards patient centricity, the data collection paradigm has to shift to meet regulatory, clinical and commercial needs. Enabling cloud based and mobile technology will remove historical constraints and liberate data collection, reporting and management processes.

12:30 Where's My *&!@$ Credential? Solving the Site User Identity Challenge with Community SSO *Sponsored by* EXOSTAR
Tom Johnson, Senior Director, Life Sciences Business Solutions, Exostar
The e-enablement of clinical studies has created a burden on site users and researchers across the industry. Individuals supporting multiple clinical initiatives must access numerous system accounts and maintain literally dozens of credentials in order to do their jobs. In this presentation, attendees will learn about an innovative Community Single Sign-On solution that truly solves the problem with a single trusted credential. We'll describe how Merck, AstraZeneca, Pfizer, and TransCelerate are participating in the community.

1:15 Session Break

2:15 Chairperson's Remarks
Michelle Shogren, Head of Innovation in Portfolio and Operations, Pharma Development, Bayer

2:20 A Case Study on Wearables & Machine Learning in the PIONEER-HCM Study
Charles Wolfus, Executive Director, Digital Health, Technology and Business Operations, MyoKardia

2:50 PANEL DISCUSSION: Moving beyond Adoption - Challenges and Considerations When Using Digital Solutions (Wearables, Apps, etc.) in Clinical Trials
Moderator: Jennifer Turgiss, Vice President, Behavior Science & Analytics, Johnson & Johnson
Panelists: Elena S. Izmailova, PhD, Senior Director, Novel Data Streams and Devices, Takeda Pharmaceuticals International, Inc.
Georgia Mitsi, Senior Director, Search & Evaluation, Digital Healthcare, Sunovion Pharmaceuticals
Margaretta Nyilas, MD, Senior Vice President Clinical and Business Operations, Otsuka Pharmaceutical Development and Commercialization (OPDC)
Charles Wolfus, Executive Director, Digital Health, Technology and Business Operations, MyoKardia
As pharma ventures into using more digital solutions within their clinical trials, there remains many technical and data challenges that may be overlooked. The panel will discuss how to ensure the adoption of digital solutions and involving stakeholders cross departmentally to address concerns around consent, evolving technology and user experience as the study progresses, and integrating wearable/app data into the trial.

3:50 Close of Conference
Arrive early to attend Big Data Analytics, Machine Learning, and Artificial Intelligence for Clinical Trials.

Pricing and Registration Information

SUMMIT PRICING - BEST VALUE! *(Includes access to all conferences, excludes short courses)*	**Commercial**	**Academic, Government, Hospital-Affiliated**
Standard Registration After March 30, 2018 and On-Site	$2,749	$1,349

BASIC PRICING *(Includes access to one conference, excludes short courses)*		
Standard Registration After March 30, 2018 and On-Site	$1,899	$899

CONFERENCES	
MAY 7 - 8	MAY 8 - 9
Mastering Risk-Based Monitoring: Part 1	Mastering Risk-Based Monitoring: Part 2
Patient Recruitment & Site Selection	Outsourcing for Clinical Trials
Big Data Analytics, Machine Learning, & Artificial Intelligence for Clinical Trials	Data & Tech Driven Clinical Trials

DINNER SHORT COURSES		
One Course	$549	$349
Two Courses	$749	$549

MAY 7 | 6:00 - 9:00 PM	MAY 8 | 5:30 - 8:30 PM
SC1: Needles in a Haystack: Proven Digital Media Campaigns for Clinical Trials in Rare Diseases & Oncology	SC2: Implementing RBM and a Clinical QMS with Limited Resources

CONFERENCE DISCOUNTS

Alumni Discount – SAVE 20%: CHI appreciates your past participation at our clinical trial events. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

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

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

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

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

CHI's 7th Annual
Clinical Trial Innovation SUMMIT

May 7-9, 2018 ▪ Boston, MA
Aloft Boston Seaport Hotel

**Alumni, Twitter, LinkedIn, Facebook or any other promotional discounts cannot be combined.*

How to Register: **ClinicalTrial**SUMMIT.COM
reg@cambridgehealthtech.com | P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please mention keycode **1864 F** when registering.

Please refer to the Registration Code below:

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