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Cambridge Healthtech Institute's Fifth Annual

Clinical Trial Innovation SUMMIT

FINAL AGENDA

May 9 - 11, 2016
Westin Boston Waterfront Hotel
Boston, MA

Optimizing Data Quality, Efficiency, Partnerships and Risk Management

2016 CONFERENCE PROGRAMS

MAY 9-10

Mastering Risk-Based Monitoring
Patient Recruitment & Site Selection
Big Data for Clinical Trials

MAY 10-11

Clinical Trial Auditing
Outsourcing for Clinical Trials
Data & Tech Driven Clinical Trials

DINNER SHORT COURSES

Meeting the Customers' Needs. What Are the Expectations of Risk-Based Monitoring?
Therapeutics Risk Management - Bridging Clinical Development with Post-Authorization Practice

FEATURING PRESENTATIONS BY:

Sheryl Jacobs, Vice President, Global Study Operations, Amgen

Janis Little, Vice President, Global R&D Quality, Allergan

Anita Zubak, Executive Director, Global Clinical Trial Operations IT, Merck

Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas

David Nickerson, Senior Director, Portfolio & Vendor Quality, Pfizer

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THE STRATEGY & CONNECTIONS NEEDED TO ADVANCE TRIALS

Cambridge Healthtech Institute's Fifth Annual **Clinical Trial Innovation Summit** will bring together leaders from across pharma, biotech and academia to share case studies and best practices on effective clinical trial management and vendor oversight. The 2016 program focuses on key issues and opportunities in the clinical trial industry, including Patient Recruitment, Site Selection, Data Integration, Existing Data Sources, Mobile Tech, Project Management, Outsourcing, Vendor Management, Budgeting and Contracting, Quality (QbD) in Trial Conduct, Risk-Based Monitoring and Clinical Auditing.

WHAT'S NEW FOR 2016

A Fresh Focus on Vendor Performance and Quality
- What happens after a sponsor selects a vendor? How do you decide how well a vendor and sponsor relationship is developing? Quality assurance, metrics and vendor oversight leaders from across pharma discuss the number and type of metrics needed to best determine if a vendor-sponsor relationship is performing well.

Dedicated Programming for Small and Mid-Sized Pharma/Biotech
- Senior executives from Alkermes, Bluebird Bio, Astellas, and Cerespir provide strategies and tactics for small and mid-sized pharma to form the right partnerships to maximize influence and quality performance with CROs.

Lessons Learned on Risk-Based Monitoring from Companies Further Ahead in Implementing RBM
- TransCelerate member companies and others at BMS, Astellas, and Amgen provide practical solutions and strategies to avoid pitfalls garnered from years of implementation when starting a RBM program.

Discussion of New and Emerging Tech across Pharma for Clinical Trials
- The latest in tech – wearables, apps, electronic consent, etc. – discussed by senior executives and those working at the forefront of tech development from GSK, Merck, Pfizer and Roche

In-Depth Coverage of Secondary Data Use, Data Sharing and Data Privacy
- With advancement of data analytics and the growth of data sources, secondary data use, data sharing and data privacy are paramount to guiding clinical and drug development. Experts from Pfizer and UCB Biosciences examine the issues related to big data in clinical trials.

HOTEL & TRAVEL INFORMATION

Conference Hotel and Venue:
Westin Boston Waterfront
425 Summer Street
Boston, MA 02210
Phone: 617-532-4600

Reservations: Go to the travel page of
clinicaltrialsummit.com

Discounted Room Rate: $289 s/d
Discounted Cut-off Date: April 11, 2016

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

INTERACTIVE PRESENTATIONS
Featuring Team Leaders From:

Alkermes

Allergan

Alliance for Clinical Research Excellence and Safety (ACRES)

Amgen

Astellas

Bluebird Bio

Boehringer Ingelheim

Bristol-Myers Squibb

Cerespir

Department of Veterans Affairs

Forum Pharmaceutical

Genentech

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DINNER SHORT COURSE*

SC1: Meeting the Customers' Needs. What Are the Expectations of Risk-Based Monitoring?

Monday, May 9 | 5:30 – 8:30 pm

The focus of this workshop will be on the main different customers (sites, investigators, monitors, sponsors, etc.) and what we should be doing to satisfy them. The basics of risk-based monitoring have been demonstrated to work, so we will start with the "customer's" expectations, some just assumed and others in guidance, etc.

Instructors:

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

Andy Lawton joined BI 28 years ago. Andy is responsible for managing the statistics, data management and programming groups with BIs UK operation. The group has specialised in the management of large scale trials and the implementation of risk based approaches within them. His experience covers over 33 years in clinical trials, but he also has extensive experience in the areas of computing, statistics, Data Management, RDE and system design. Andy was a founding Committee Member of ACDM and aided in the initiation of CDISC with the provision of the business model. Before joining BI, Andy worked as a statistician in the NHS and in computing in a geophysical exploration company.

Jean Baumann, Change Management Specialist,
JMB Consulting, LLC

{ Gain global and cross-industry perspective during interactive co-presentations.

Join a focused roundtable discussion to gain answers to your most pressing challenges! }

*Separate registration required

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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.

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• Custom Market Research Surveys
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For sponsorship and exhibit information, please contact:
Ilana Quigley
Senior Manager, Business Development
781-972-5457 | iquigley@healthtech.com

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Cambridge Healthtech Institute's Seventh Annual

MAY 9-10
2016

Mastering Risk-Based Monitoring
Ensuring Quality and Effective Monitoring

Proactively building quality standards and risk management into the design and planning of clinical trials leads to higher quality clinical trials. Implementing quality standards early into the clinical trial lifecycle lays the foundation for successful risk-based monitoring (RBM). With wider industry adoption of RBM, Cambridge Healthtech Institute's **Mastering Risk-Based Monitoring** conference offers case studies and practical solutions from across pharma and TransCelerate member organizations on effectively implementing quality risk management plans, assessing technology needs for RBM, and working with various stakeholders on effective roll out of RBM.

MONDAY, MAY 9

7:25 am Conference Registration and Morning Coffee

Case Studies and Lessons Learned on RBM

8:25 Chairperson's Opening Remarks
Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

8:30 CASE STUDY: A Practical Guide to Successful RBM Implementation
Stacy Foley, Project Director, Global Risk-Based Monitoring Implementation, Merck
Effective RBM implementation can be a tricky prospect, which requires careful planning and active engagement from a variety of key stakeholders. This session will step through some fundamental success strategies including building and conducting a thorough implementation plan, communicating with and managing stakeholder expectations, and proactively identifying pitfalls that might complicate your RBM journey.

9:00 Co-Presentation: Novo Nordisk's Journey into RBM
Kate Owen, Vice President, Clinical Trial Management, Novo Nordisk
Heather Achenbach, Senior Director, Clinical Trial Management, Novo Nordisk
Merging TransCelerate tools & learnings into an existing organization while keeping site relationships top of mind.

10:00 Networking Coffee Break

10:30 Lessons I Wish Someone Had Told Me: Risk-Based Monitoring Implementation Challenges
Sheryl Jacobs, Vice President, Global Study Operations, Amgen
The presentation will share an overview of the Amgen Risk-Based Monitoring model, our status of implementation and lessons learned along the way. Amgen has implemented Risk-Based Monitoring on a number of trials over the past three years, and this discussion will focus on the pitfalls encountered as well as provide advice for anyone seeking to implement risk-based models within their companies based upon some real-world experience.

11:00 Q&A with Case Study Session Speakers

11:30 A Next-Generation Platform for Clinical Data Integration and Risk-Based Monitoring: Why Data and User Centricity Matters
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COVANCE
SOLUTIONS MADE REAL®

Dimitris Agrafiotis, Ph.D., Vice President, Chief Data Office & Head, Technology Products, Covance Inc.
This presentation will outline a new technology platform designed to improve monitoring of clinical trials, resulting in higher quality, faster timelines, and lower costs. Covance's Xcellerate® Monitoring is an industry-leading platform using advanced data integration, analytic, and visualization capabilities to ensure patient safety and data quality throughout the clinical development process. Xcellerate Monitoring provides unprecedented access to all clinical trial data, enables comprehensive assessment and mitigation of risk at the study, site, and patient level.

12:00 pm Strategic Monitoring: Scaling Your RBM Platform for Success
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:::medidata

Kyle Given, Managing Principal, Professional Services, Medidata Solutions
Risk-based monitoring (RBM) continues to take center stage as one of the key areas of disruptive innovation in clinical development. The new ICH E6 addendum due in November 2016 has significant impact on how organizations need to embark on implementing RBM.

In addition, recent research from Transcelerate has provided definitive positive proof points on the value of RBM strategies. Based on our extensive experience, this presentation will discuss our learnings from real-life customer implementations on how you create an optimized, scalable Strategic Monitoring platform. In addition, we will explore current trends and requirements to advance existing strategies and achieve the desired future state of this transformational model within your organization.

12:45 Session Break

NEW TECH, TOOLS AND TECHNIQUES FOR RBM

1:25 Chairperson's Remarks
Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

1:30 Co-Presentation: A Case Study in Searching for a Technology Solution to Support Risk-Based Monitoring (RBM)
Mary Cusack, Associate Director, Bristol-Myers Squibb
Ed Kellar, Director, Global Data Management Operational Support, Astellas, Inc.
(TransCelerate) published "Position Paper: Risk-Based Monitoring Methodology" in May 2013. In the paper, TransCelerate 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, which builds on previous work and sets out the high level elements for consideration when designing and building an integrated technology solution for a RBM platform that includes people, process and technology perspectives.

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This presentation, by the co-leads of the TransCelerate RBM Technology Sub-Team, will describe the steps taken by the TransCelerate Technology Sub-Team to elicit, analyze and publish these system elements 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.

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

5:15 Close of Day

5:15 pm Dinner Short Course Registration *(see page 3 for details)*

TUESDAY, MAY 10

Quality Plans and Change Management for RBM

7:55 Chairperson's Remarks

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

8:00 Establishing a Quality Management System (QMS)

David Nickerson, Senior Director, Portfolio & Vendor Quality, Pfizer

There are currently a few industry initiatives working to provide a common framework for a GCP Quality Management System. Pfizer established a GCP QMS several years ago and is continuously improving the elements of its system and how its performance is measured. The participants in the session will learn how Pfizer used the elements of ICH Q9, Q10 and other guidelines to establish its GCP QMS as well as how Pfizer is looking at assessing clinical trial quality risk and measuring the QMS performance.

8:30 Co-Presentation: A Practical Approach to Integrating Technology in the Design and Implementation of a Risk-Based Quality Management Program

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

Over the past several years, much attention has been directed towards introducing and defining the concepts and day-to-day tools required to carry out Quality by Design (QbD) and Quality Risk Management (QRM) activities. However, many companies have not established a unified Risk-Based Quality Management (RBQM) framework based on a holistic approach within Clinical Operations and are unclear on how to integrate and maximize the use of technology that is available to use today. Gilead began development of this program and framework in 2014 and has now implemented

planned components. This presentation will address the following topics: 1. RBQM framework and its components, 2. How to assess technology to use for your RBQM program, and 3. How to implement a RBQM program for your organization.

9:30 Optimizing Risk and Quality in Managing Observational Research

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Hady Khoury, Vice President, Global Head, Research & Alliance Services, Peri-Approval & Observational Research, Commercialisation & Outcome, ICON plc

Non-interventional or observational study designs are typically common for studies looking to obtain real world data. In this session, learn how using quality by design, risk based monitoring and management, and hub-based centralized site management strategies can comprehensively provide optimal cost effective and balanced risk outcomes for observational research.

10:00 Coffee Break in the Exhibit Hall

Quality Plans and Change Management for RBM

10:40 Chairperson's Remarks

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

10:45 Co-Presentation: ICH E.6 Addendum & Change Management towards a Metrics-Based Future

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.
Jean Baumann, Change Management Specialist, JMB Consulting, LLC

The forthcoming release of the addendum to ICH E.6 (GCP) will encapsulate risk-based methodology into the GCP framework; it will no longer be something to ignore as a fashion, but to use as a launch pad for innovation. The draft addendum will be reviewed and discussed, in particular the short and long term impact to organisations.

Of critical importance to the success of risk based methodologies and the resulting metrics taking hold in an organization, is having a change management strategy that matches the organization's starting point. Specific change management and project management methods will be introduced to optimally implement risk-based methodologies and innovations.

12:15 pm How Signal-Driven SDV™ and Risk Based Monitoring Helps Improve Data Quality and Bring Efficiency to Clinical Trials

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RBM

Badhri Srinivasan, President, Remarque Systems, Inc.

1:00 Dessert Break in the Exhibit Hall

1:30 Close of Conference

Pair this program with **Clinical Trial Auditing** (Page 10) and Dinner Courses on **Expectations of Risk-Based Monitoring** and **Therapeutics Risk Management** (Page 3) to maximize your time at the **Clinical Trial Innovation Summit**

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Cambridge Healthtech Institute's Inaugural

MAY 9-10 2016

Patient Recruitment & Site Selection

Innovating Patient Recruitment and Site Intelligence through Data-Driven Technology

With competition for patients, clinical trial sites and investigators on the rise, the need for successful strategies for patient recruitment and site selection is crucial to the success of a clinical trial. Cambridge Healthtech Institute's **Patient Recruitment & Site Selection** conference features best practices and case studies on successful patient recruitment and site selection techniques using a data-driven approach.

MONDAY, MAY 9

7:25 am Conference Registration and Morning Coffee

Innovative Approaches to Patient Recruitment

8:25 Chairperson's Opening Remarks
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis

8:30 Talk Title to be Announced
Aaron Fleishman, Technology and Product Innovation, BBK Worldwide

9:00 PANEL DISCUSSION: Innovative Approaches to Patient Recruitment
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis
Aaron Fleishman, Technology and Product Innovation, BBK Worldwide
Ryan Norris, CTO, Be the Partner
With the increased industry pressure for more efficient and faster clinical trials, patient recruitment remains one area crucial to speedy study start-up. This panel will discuss revamping existing strategies and technologies to aid in patient recruitment in light of the rise and popularity of ever increasing new technologies and social media platforms from mobile apps to wearables and online patient portals.

10:00 Networking Coffee Break

PATIENT PERSPECTIVE ON SITE SELECTION & RECRUITMENT

10:30 Rethinking Site Selection From a Patient Lens
Abbe Steel, CEO, Corporate, 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.

11:00 Using Technology to Drive Site Selection and Site Activation
Emma Morley, Site Identification and Feasibility Manager, DrugDev

11:30 A Breakthrough in Clinical Trials Recruitment
Steven Coca, M.D., Associate Professor of Medicine, Internal Medicine, Icahn School of Medicine at Mount Sinai

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

12:45 Session Break

New Site Selection Techniques

1:25 Chairperson's Remarks
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis

1:30 Site Selection Insights from UCB BioSciences
Shawn Tedman, Associate Director, Site Selection Lead, Site Selection & Engagement, Global Clinical Sciences & Operations, UCB BioSciences, Inc.

2:00 PANEL DISCUSSION: New Site Selection Methods
Abbe Steel, CEO, Corporate, HealthiVibe, LLC
Emma Morley, Site Identification and Feasibility Manager, DrugDev

2:30 Refreshment Break in the Exhibit Hall

3:15 Interactive Breakout Discussion Groups
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4:15 Welcome Reception in the Exhibit Hall

5:15 Close of Day

5:15 pm Dinner Short Course Registration
(see page 3 for details)

TUESDAY, MAY 10

Data Visualization & Analytics Techniques for Clinical Trial Insights

7:55 Chairperson's Remarks
Scott Scarola, Senior Director, Business Analytics, PPD

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MAY 9-10 2016
Patient Recruitment & Site Selection
Innovating Patient Recruitment and Site Intelligence through Data-Driven Technology

8:00 Data Visualization Approach to Clinical Studies Data
Mukta Tripathi, Clinical Science Visual Analytics, Genentech
The presentation will focus on implementation of a data visualization approach for safety signal detection while study is ongoing as well as visualization approach for scenario building for analyses that will be carried out for dose escalation, final analysis to name a few. At Genentech/Roche the process of individual as well as aggregate reviews has been revolutionized by implementing Spotfire for Clinical and Safety Scientists. This talk focuses on advantages of an innovative approach to clinical data visualization using Spotfire.

8:30 Clinical Visualizations Drive Decision Making in Clinical Trials and Translational Research
Philip C. Ross, Director, Data Sciences TR&D, Clinical Pharmacology and Pharmacometrics, Exploratory Clinical and Translational Research, Bristol Myers Squibb
Clinical trials generate large amounts of data that require rapid review to identify emerging signals and trends. These signals and trends are most effectively identified using visualizations. Using the information revealed in the visualizations, clinicians and scientists can make faster, better informed decisions driving translational research and development. The integration of this data and knowledge drives the development of new treatments that will be beneficial for patients.

9:00 Big Data Analytics and Cognitive Computing in Ophthalmology: Innovation in Clinical Research and Development
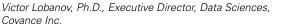*Sponsored by ifa*
P. Lloyd Hildebrand, MD FACS P-CEO, Professor, Department of Ophthalmology, University of Oklahoma
Big Data Analytics and cognitive computing create knowledge that can improve clinical decisions in clinical trials, drug development and direct patient care. Eye care industry providers Topcon (diagnostic imaging), ifa (EHR), and Inoveon (telemedicine) are partnering with the leading Big Data Analytics specialist to create the world's first cognitive computing engine in Ophthalmology

9:30 Raising the Bar for Central Medical Review
Sponsored by COVANCE SOLUTIONS MADE REAL
Victor Lobanov, Ph.D., Executive Director, Data Sciences, Covance Inc.
Periodic review of clinical data is critical for the patient safety and data quality. Covance's Medical Review is aligned with the FDA guidance for a greater role of central monitoring and provides timely, integrated views of all relevant clinical data along with the unique, interactive capabilities to detect outliers and trends, create and analyze cohorts, execute review workflows, annotate clinical data, and communicate observations.

10:00 Coffee Break in the Exhibit Hall

Leveraging EHRs for Protocol Feasibility & Patient Recruitment

10:40 Chairperson's Remarks
Scott Scarola, Senior Director, Business Analytics, PPD

10:45 Using Advanced Software Applications to Leverage EHRs to Support Protocol Feasibility and Patient Identification
Sameer Tandon, Clinical Trial Intelligence Manager, Clinical Sciences & Innovation, Novartis
This presentation will cover the use of a software application to mine EMRs with leading academic institutions with the ability to arrange consultation and identify patients for referral into a clinical trial.

11:15 Integration of Clinical Trials into Clinical Care Using the Electronic Health Record
Mary T. Brophy, M.D., MPH, Director, Maveric Core Laboratory, VA Boston Healthcare System
This session will review efforts by the Department of Veterans Affairs to conduct clinical research as an extension of quality improvement efforts in the clinical care ecosystem. Alternatively termed pragmatic or point-of-care clinical trials, these studies are conducted less expensively and yield results that are more generalizable than traditional study designs. The session will review the Department's efforts in cardiovascular and medical oncology investigations.

11:45 A Technology Platform for Delivering Pragmatic Clinical Trials within a Primary Care Setting in the UK, Using Electronic Healthcare Records
Tim Williams, Ph.D., Head of Research, Clinical Practice Research Datalink (CPRD), Medicines and Healthcare Products Regulatory Agency (MHRA)
The ability to use Electronic Healthcare Records (EHR) as part of a randomized interventional study has been identified as a novel paradigm to manage and deliver clinical data in a real-world setting. Our challenge was to design and build a system to deliver pragmatic trials based on primary care EHR. This resulted in the development of an integrated suite of EHR-centric tools to enable trial design, feasibility and data management to CDISC-ODM standard EDC interfaces, enabling recruitment, minimum data collection, and patient reported outcomes (PROs). The resulting technology platform has benefits in terms of speed, costs and generation of real-world evidence.

12:15 pm Luncheon Presentation
(Sponsorship Opportunity Available) **or Enjoy Lunch on Your Own**

1:00 Dessert Break in the Exhibit Hall

1:30 Close of Conference

Pair this program with **Outsourcing for Clinical Trials** (Page 12) and Dinner Courses on **Expectations of Risk-Based Monitoring** and **Risk Management and Pharmacovigilance** (Page 3) to maximize your time at the **Clinical Trial Innovation Summit**

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Cambridge Healthtech Institute's Second Annual

MAY 9-10 2016

Big Data for Clinical Trials
Harnessing & Unlocking the Potential of Existing Data Sources

With the increased generation of greater volumes of data from ever more varied data sources, pharma and biotech leaders have the opportunity to streamline and advance the clinical trials process if they can properly harness the information in these big data sets. Harnessing and unlocking the potential in existing data sources, including biomarker, genomic, EHRs, claims data, real world data and clinical trial data, can lead to better informed decision making in all aspects of trial design and more importantly better decision making in drug development. Cambridge Healthtech Institute's **Big Data for Clinical Trials** conference gathers leaders across pharma, biotech and academia for discussions and case studies on harnessing existing clinical data to advance clinical trials.

MONDAY, MAY 9

7:25 am Conference Registration and Morning Coffee

Big Data for Clinical Trials

8:25 Chairperson's Opening Remarks
Greg Koski, Ph.D., M.D., President and CEO, Executive Office, Alliance for Clinical Research Excellence and Safety (ACRES)

8:30 PANEL DISCUSSION: Realizing the Dream: What is the Real Power of Big Data and How Can It Be Unleashed?
Greg Koski, Ph.D., M.D., President and CEO, Executive Office, Alliance for Clinical Research Excellence and Safety (ACRES)
Peter Alterman, COO, SAFE BioPharma Association
Jason Paragas, Director, Innovation, Lawrence Livermore National Laboratory
Ashish Cowlagi, Program Director, IBM Watson Health
J. Scott Lowry, MBA, CEO, HealthIDx
Everyone is talking about big data, but the real question is "what can we do with it that we can't do now?" Major challenges are posed by data accessibility and data liquidity--the power of big data can only be unleashed by effective application of analytics and a willingness of all parties to share. This requires an enterprise-wide framework for trust and policies for access and utilization, as well as an established infrastructure.

9:30 Designing, Executing and Managing Clinical Trials in the Age of Big Data, an Architect's Perspective
Manoj Vig, Enterprise Architect Big Data, Information Technology, Shire Pharmaceuticals LLC
Speed of data movement, availability of new data sources and emergence of new technology frameworks have introduced a new world of opportunities in which trials can be designed and executed faster, better and much more economically. This talk will discuss various use cases, available technologies & designs based on big data that can be used in the context of modern clinical trials.

10:00 Networking Coffee Break

Secondary Data Use for Clinical Trials

10:30 Beyond Consent: Overcoming Key Challenges Teams Face When Integrating Clinical and Specimen Derived Molecular Data for Broad Secondary Use
Muzafar Mirza, Director, Information Strategy and Analytics, Clinical Informatics and Innovation, Pfizer, Inc.
Catherine Marshall, Director, Clinical Data Science, Pfizer
Stuart Pearce, Director, Information Strategy and Analytics, Development Operations, Worldwide Research & Development, Pfizer, Inc.
The secondary use of Clinical and Specimen data has opened up a wealth of opportunities for translating data into quantifiable knowledge. There has been an exponential growth in the quantity of clinical data collected to support trials, alongside this a greater focus on collecting biological specimens to enhance value added research. Research teams wishing to delve in to this bank of data have to overcome a multitude of challenges related to broad data reuse. A key project and multi-disciplinary team at Pfizer was formed to investigate aspects of data reuse and tasked with building a comprehensive solution to this challenge. This talk will provide a summary overview of the team's activity and introduce some key solutions that are helping research teams at Pfizer utilize data for secondary use.

11:30 Leveraging Data for Better Site Selection
Scott Scarola, Senior Director, Business Analytics, PPD

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

12:45 Session Break

Secondary Data Use for Clinical Trials

1:25 Chairperson's Remarks
Greg Koski, Ph.D., M.D., President and CEO, Executive Office, Alliance for Clinical Research Excellence and Safety (ACRES)

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Cambridge Healthtech Institute,
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1:30 Facilitating Secondary Use of Clinical Data - One Company's Approach

Liz Roberts, Senior Director, Global Lead, Transparency and Data Sharing, UCB

The ecosystem of care is evolving radically, one such area being greater transparency of clinical trial data and results. This presentation will describe the approach taken by UCB, a global, biopharmaceutical company, including: 1. Involvement and alignment with TransCelerate model approaches to patient-level data (PLD) anonymization and document redaction, and 2. Joining a multi-sponsor request-management system through which researchers can submit proposals for anonymized PLD and redacted study documents.

2:00 PANEL DISCUSSION: Clinical Trial Data Sharing and Data Privacy

Liz Roberts, Senior Director, Global Lead, Transparency and Data Sharing, UCB
Muzafar Mirza, Director, Information Strategy and Analytics, Clinical Informatics and Innovation, Pfizer, Inc.
Robin Jenkins, Head, Clinical Trial Data Sharing & Disclosure, Sanofi

With increased clinical data sharing for secondary use and novel analyses, the questions of informed consent, how much data to share, best practices on managing data requests and patient privacy are paramount. This panel offers insights on data de-identification (where and when it should be used), the types of data to share, managing data requests, and data privacy issues.

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

5:15 Close of Day

5:15 pm Dinner Short Course Registration *(see page 3 for details)*

TUESDAY, MAY 10

Data Visualization & Analytics for Clinical Trial Insights

7:55 Chairperson's Remarks
Scott Scarola, Senior Director, Business Analytics, PPD

8:00 Data Visualization Approach to Clinical Studies Data

Mukta Tripathi, Clinical Science Visual Analytics, Genentech

The presentation will focus on implementation of a data visualization approach for safety signal detection while study is ongoing, as well as visualization approach for scenario building for analyses that will be carried out for dose escalation, and final analysis, to name a few. At Genentech/Roche, the process of individual as well as aggregate reviews has been revolutionized by implementing Spotfire for Clinical and Safety Scientists. This talk focuses on advantages of an innovative approach to clinical data visualization using Spotfire.

8:30 Clinical Visualizations Drive Decision Making in Clinical Trials and Translational Research

Philip C. Ross, Director, Data Sciences TR&D, Clinical Pharmacology and Pharmacometrics, Exploratory Clinical and Translational Research, Bristol-Myers Squibb

Clinical trials generate large amounts of data that require rapid review to identify emerging signals and trends. These signals and trends are most effectively identified using visualizations. Using the information revealed in the visualizations, clinicians and scientists can make faster, better informed decisions driving translational research and development. The integration of this data and knowledge drives the development of new treatments that will be beneficial for patients.

9:30 Big Data Analytics and Cognitive Computing in Ophthalmology: Innovation in Clinical Research and Development

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ifa

P. Lloyd Hildebrand, MD FACS P-CEO, Professor, Department of Ophthalmology, University of Oklahoma

Big Data Analytics and cognitive computing create knowledge that can improve clinical decisions in clinical trials, drug development and direct patient care. Eye care industry providers Topcon (diagnostic imaging), ifa (EHR), and Inoveon (telemedicine) are partnering with the leading Big Data Analytics specialist to create the world's first cognitive computing engine in Ophthalmology

9:30 Raising the Bar for Central Medical Review

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COVANCE
SOLUTIONS MADE REAL

Victor Lobanov, Ph.D., Executive Director, Data Sciences, Covance Inc.

Periodic review of clinical data is critical for the patient safety and data quality. Covance's Medical Review is aligned with the FDA guidance for a greater role of central monitoring and provides timely, integrated views of all relevant clinical data along with the unique, interactive capabilities to detect outliers and trends, create and analyze cohorts, execute review workflows, annotate clinical data, and communicate observations.

10:00 Coffee Break in the Exhibit Hall

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MAY 9-10 2016

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Big Data for Clinical Trials
Harnessing & Unlocking the Potential of Existing Data Sources

Leveraging EHRs for Protocol Feasibility & Patient Recruitment

10:40 Chairperson's Remarks
Scott Scarola, Senior Director, Business Analytics, PPD

10:45 Using Advanced Software Applications to Leverage EHRs to Support Protocol Feasibility and Patient Identification
Sameer Tandon, Clinical Trial Intelligence Manager, Clinical Sciences & Innovation, Novartis
This presentation will cover the use of a software application to mine EMRs with leading academic institutions with the ability to arrange consultation and identify patients for referral into a clinical trial.

11:15 Integration of Clinical Trials into Clinical Care Using the Electronic Health Record
Mary T. Brophy, M.D., MPH, Director, Maveric Core Laboratory, VA Boston Healthcare System
This session will review efforts by the Department of Veterans Affairs to conduct clinical research as an extension of quality improvement efforts in the clinical care ecosystem. Alternatively termed pragmatic or point-of-care clinical trials, these studies are conducted less expensively and yield results that are more generalizable than traditional study designs. The session will review the Department's efforts in cardiovascular and medical oncology investigations.

11:45 A Technology Platform for Delivering Pragmatic Clinical Trials within a Primary Care Setting in the UK, Using Electronic Healthcare Records
Tim Williams, Ph.D., Head, Research, Clinical Practice Research Datalink

(CPRD), Medicines and Healthcare Products Regulatory Agency (MHRA)
The ability to use Electronic Healthcare Records (EHR) as part of a randomized interventional study has been identified as a novel paradigm to manage and deliver clinical data in a real-world setting. Our challenge was to design and build a system to deliver pragmatic trials based on primary care EHR. This resulted in the development of an integrated suite of EHR-centric tools to enable trial design, feasibility and data management to CDISC-ODM standard EDC interfaces, enabling recruitment, minimum data collection, and patient reported outcomes (PROs). The resulting technology platform has benefits in terms of speed, costs and generation of real-world evidence.

12:15 pm Luncheon Presentation
(Sponsorship Opportunity Available) **or Enjoy Lunch on Your Own**

1:00 Dessert Break in the Exhibit Hall

1:30 Close of Conference

Pair this program with **Data & Tech Driven Clinical Trials** (Page 14) and Dinner Courses on **Expectations of Risk-Based Monitoring** and **Risk Management and Pharmacovigilance** (Page 3) to maximize your time at the **Clinical Trial Innovation Summit**

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Cambridge Healthtech Institute's Sixth Annual

MAY 10-11 2016

Clinical Trial Auditing
Building Effective Audit Programs

A comprehensive quality management system is crucial to ensuring the two objectives of clinical trial quality – patient safety and data quality. Implementing quality standards coupled with establishing effective audit teams leads to more compliant, higher quality clinical trials. Cambridge Healthtech Institute's **Clinical Trial Auditing** conference offers case studies and best practices on establishing effective audit teams, auditing practices, and CAPA plans.

TUESDAY, MAY 10

10:00 am Conference Registration

Quality Plans and Change Management for RBM

10:40 Chairperson's Remarks

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

10:45 Co-Presentation: ICH E.6 Addendum & Change Management towards a MetricsBased Future

Andy Lawton, Global Head, Data Management, Biometrics & Data Management, Boehringer Ingelheim Ltd.

Jean Baumann, Change Management Specialist, JMB Consulting, LLC

The forthcoming release of the addendum to ICH E.6 (GCP) will encapsulate risk-based methodology into the GCP framework; it will no longer be something to ignore as a fashion, but to use as a launch pad for innovation. The draft addendum will be reviewed and discussed, in particular the short and long term impact to organisations.

Of critical importance to the success of risk-based methodologies and the resulting metrics taking hold in an organization, is having a change management strategy that matches the organization's starting point. Specific change management and project management methods will be introduced to optimally implement risk-based methodologies and innovations.

12:15 pm How Signal-Driven SDV™ and Risk Based Monitoring Helps Improve Data Quality and Bring Efficiency to Clinical Trials

Badhri Srinivasan, President, Remarque Systems, Inc.

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1:00 Dessert Break in the Exhibit Hall

1:30 Session Break

Corrective and Preventitive Actions (CAPAS) for Clinical Trials

1:55 Chairperson's Remarks

Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, RCQA (Research Compliance and Quality Assurance), University of Miami

2:00 CAPA as Part of Quality Systems in Academia

Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, RCQA (Research Compliance and Quality Assurance), University of Miami

The field of clinical research is constantly evolving and CAPA (Corrective Action Preventive Action) is no longer exclusive to manufacturing and laboratory processes. The creation and implementation of corrective and preventive actions as well as fully executed CAPA plans is becoming a cornerstone of high quality clinical research programs. Although CAPA plans are not specifically mentioned in the regulations governing clinical research, FDA and other regulators as well as organizational leadership expect Principal Investigators, sponsors and IRBs to respond to compliance issues via such plans. Risk assessments and root-cause analyses, as well as short and long-term commitments to improve quality, will become a necessary part of a well-functioning research team. This presentation will provide the audience with examples of positive change, heightened awareness and strategies for the creation and implementation of a CAPA system in academia. Essential elements for a robust CAPA system, potential and existing barriers and the placement of CAPA within an organization's quality program will be discussed. The take-home message is that a well-functioning CAPA system is becoming an essential element of any organization's quality assurance program.

2:30 Building Quality Assurance (QA) and Quality Systems Management (QSM) into Clinical Research Operations

Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

3:00 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break in the Exhibit Hall

Risk-Based Auditing

4:00 Moving Away from a "Conventional" Approach to Auditing in Clinical Trials

Janis Little, Vice President, Global R&D Quality, Allergan

Recent and continuing changes to the regulatory environment – changes in regulation, increased complexity in clinical trials, new approaches to clinical trial conduct such as electronic data capture, electronic medical records and risk-based monitoring, impact the quality of clinical trials and the resulting data. The drive towards a risk-based approach to clinical trial conduct and oversight necessitates a change to clinical audit programs. A "conventional" approach to auditing clinical trials is no longer sufficient. This session will focus on methods and tools that can be considered in developing a clinical trial audit program that is designed for the 21st century, and assuring quality and compliance in today's clinical environment.

4:30 Science-Based Auditing of Clinical Trials

Amer Alghabban, Vice President, GxP QA, Compliance & Training, GxP Quality Assurance, Karyopharm Therapeutics Inc.

Topics covered in this presentation include: 1. Traditional Audit Methodologies, 2. Science-Based Auditing, and 3. Lessons Learned.

5:00 Close of Day

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MAY 10-11 2016

Clinical Trial Auditing
Building Effective Audit Programs

WEDNESDAY, MAY 11

8:30 Interactive Breakout Discussion Groups with Continental Breakfast
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Vendor Performance, Quality and Metrics

9:25 Chairperson's Remarks
Jessica Dolfi, Manager, Solution Consulting, Medidata Solutions

9:30 Speed Networking

10:00 Partnering Quality with Our Quality Partners: Managing Clinical Trial Quality through Oversight and Collaboration with Our CRO Partners
Derek Hall, Associate Director, Quality Assurance GCP, Incyte
This presentation will cover: 1. Managing audits of vendors in a large global market, 2. Establishing quality contacts and regular communication, and 3. Writing and establishing a quality agreement.

10:30 Presentation to be Announced

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10:45 Coffee Break in the Exhibit Hall

11:30 Issue Escalation for Fully Outsourced Studies
Rosemary Dillon, Associate Director, Clinical Outsourcing & Operations, Bristol-Myers Squibb

12:00 pm Vendor/Sponsor Performance Metrics: How Are We Doing?
Randy Krauss, Director, Clinical Process Optimization, Shire
Completing clinical trials in a timely, cost-effective, and safe manner is key to the success of both the vendor and sponsor. The number and types of metrics to be implemented can be dizzying. Understanding what is important to the sponsor will help determine what metrics are best to be implemented. Further, not all metrics are created equal. This talk will focus on developing a metrics hierarchy and how to use them to improve performance.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

1:25 Chairperson's Remarks
Jessica Dolfi, Manager, Solution Consulting, Medidata Solutions

2:00 PANEL DISCUSSION: Project Tracking and Establishing Appropriate Metrics from Both the Sponsor & CRO Perspective
Randy Krauss, Director, Clinical Process Optimization, Shire
Timothy S. LaCroix, MBA, Head, Business Development, PharPoint Research, Inc.
Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas Pharma Global Development, Inc.
From both the sponsor and CRO perspective, we will discuss what are considered the "right" metrics to collect on vendor performance and how well projects are being completed. Are there appropriate "hard" and "soft" metrics that should be considered when working with sponsors, CROs and other clinical vendors (labs, imaging centers, reading centers, etc.)?

3:30 Close of Conference

Pair this program with **Mastering Risk-Based Monitoring** (Page 4) and Dinner Courses on **Expectations of Risk-Based Monitoring** and **Risk Management and Pharmacovigilance** (Page 3) to maximize your time at the **Clinical Trial Innovation Summit**

{ Connect with more than 200 leading pharma, CROs and research teams during dedicated networking times }

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Cambridge Healthtech Institute's Inaugural

MAY 10-11
2016

Outsourcing for Clinical Trials
Perfecting Quality Partnerships for Clinical Trial Success

As more clinical trial activities are outsourced to contract research organizations (CROs) and other third party vendors, successful clinical trial execution increasingly depends heavily upon building quality partnerships. Establishing and maintaining realistic and explicit expectations from each partner in the outsourcing relationship is crucial to running efficient clinical trials. Cambridge Healthtech Institute's **Outsourcing for Clinical Trials** conference features case studies and lessons learned from sponsors and other third party vendors on how to optimize the outsourcing partnership.

TUESDAY, MAY 10

10:00 am Conference Registration

CONSIDERATIONS FOR WORKING, CONTRACTING AND NEGOTIATING WITH VENDORS

10:40 Chairperson's Remarks
Lee Yuan, Conference Director, Cambridge Healthtech Institute

10:45 Considerations for Third Party Vendor Management in a Risk-Focused Environment
Marina Malikova, Ph.D., MA, Executive Director, Surgical Translational Research Operations and Compliance, Boston University
One major reason for unsuccessful partnerships is disconnect between study protocol development at the sponsor level and outsourcing start up and execution of the study to a CRO and/or third party vendors. Risk-based quality management needs to be developed jointly with all parties involved, that will have a major impact on strategic partnerships and allow to meet stringent regulatory expectations in risk-focused environment. Successful vendor relationship have many components, but a key factor is a well-defined communication plan. Transparency, upfront goals, cross check for key milestones and adoption of common quality and risk management strategies are vital in establishing and maintaining strong partnership throughout life cycle of the project.

11:30 Crafting Effective RFPs for Novel Therapy Studies
Kate Nabewaniec, Director, Clinical Outsourcing, Bluebird Bio
When launching a study investigating unusual or novel therapies, it can be difficult to define the critical success factors of the sponsor/CRO relationship in an RFP, which may result in responses that are too differentiated to evaluate on a common scale. In this presentation we will explore how to tailor the RFI/RFP process to highlight the fit of the CRO's proposed team and tools, and to avoid boilerplate responses and inconsistent pricing (without a bid grid!). Targeted towards smaller biotechs, rare disease, and single study/single product RFPs.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Dessert Break in the Exhibit Hall

1:30 Session Break

Outsourcing Strategies for Small and Midsized Pharma & Biotech

1:55 Chairperson's Remarks

2:00 Small Fish in a Big Pond: Strategies for Small and Mid-Size Pharma to Successfully Partner with CROs
Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas Pharma Global Development, Inc.
The pharmaceutical industry is increasingly evolving towards a model that is built on mutually beneficial partnerships between pharma and the external vendors they work with. In this era of risk sharing, it is increasingly important for pharma and their CROs to have effective strategies for leveraging performance and value. For smaller and mid-size pharma, with limited R&D resources, it is especially important to work in the right partnership model to be able to affect and influence quality and performance within their relationships. This talk will cover different methods to maximize influence and quality performance within these partnerships.

2:30 Outsourcing at Small Biotech Companies: How Could CROs Align Themselves Better with the Needs of Their Clients from the Very First Interactions and Project Planning Discussions
Sophie Egholm Chapelle, COO, Senior Management, Cerespir
Small biotech companies have few resources, and rely on CROs to provide the relevant and expert resources needed for execution of clinical trials. In a recent major and comprehensive bid process for a large and complex, pivotal, adaptive design trial in early Alzheimer's, we found most proposals and project plans to be generic and not sufficiently tailored to the client needs. We suggest very specific areas of improvement in the client/CRO engagement process.

3:00 Managing the Site Payment Process in an Outsourced, Global Environment

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॥॥ medidata

Jessica Dolfi, Manager, Solution Consulting, Medidata Solutions
Sponsors commonly outsource the site payment process to a CRO partner—in fact site payments are managed by CROs on 80 percent of all studies globally. Outsourcing is here to stay. How can sponsors do it better? Answers include: defining KPIs to improve oversight of the payment process, implementing a financial reporting process, and considering site payment technology requirements. This presentation will compare different models for outsourcing site payments, highlighting considerations for choosing the right one.

3:30 Refreshment Break in the Exhibit Hall

4:00 PANEL DISCUSSION: CRO & Sponsor Perspective on Meeting Outsourcing Needs and Challenges of Small and Mid-Sized Biotech and Pharma
Sophie Egholm Chapelle, COO, Senior Management, Cerespir
Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas Pharma Global Development, Inc.
Sponsors and CROs discuss their perspectives and approaches on how to better meet the outsourcing needs of small and mid-sized biotech and pharma.

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5:00 Close of Day

WEDNESDAY, MAY 11

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Vendor Performance, Quality and Metrics

9:25 Chairperson's Remarks

Jessica Dolfi, Manager, Solution Consulting, Medidata Solutions

9:30 Speed Networking

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Derek Hall, Associate Director, Quality Assurance GCP, Incyte

This presentation will cover: 1. Managing audits of vendors in a large global market, 2. Establishing quality contacts and regular communication, and 3. Writing and establishing a quality agreement.

10:30 Resource Planning, Real-Time Project Reporting and Dashboards

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Projects, People & Financials

Donna Gandt, Area Vice President, Unanet

The presenter will demonstrate how customers utilize Unanet to facilitate Resource Scheduling & Skills Management; Time Tracking; Real-Time Reporting on Project Status, Margin, Utilization, etc.; Billing & Revenue Recognition; Integrated Financials.

10:45 Coffee Break in the Exhibit Hall

11:30 Issue Escalation for Fully Outsourced Studies

Rosemary Dillon, Associate Director, Clinical Outsourcing & Operations, Bristol-Myers Squibb

12:00 pm Vendor/Sponsor Performance Metrics: How Are We Doing?

Randy Krauss, Director, Clinical Process Optimization, Shire

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12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

1:25 Chairperson's Remarks

Jessica Dolfi, Manager, Solution Consulting, Medidata Solutions

2:00 PANEL DISCUSSION: Project Tracking and Establishing Appropriate Metrics from Both the Sponsor & CRO Perspective

Randy Krauss, Director, Clinical Process Optimization, Shire
Timothy S. LaCroix, MBA, Head, Business Development, PharPoint Research, Inc.
Marie Rosenfeld, Director, Development Operations, Contracts & Outsourcing Vendor Management Lead, Astellas Pharma Global Development, Inc.

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Data & Tech Driven Clinical Trials

New Tools and Analytics to Advance Clinical Research

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.

TUESDAY, MAY 10

10:00 am Conference Registration

Leveraging EHRs for Protocol Feasibility & Patient Recruitment

10:40 Chairperson's Remarks
Scott Scarola, Senior Director, Business Analytics, PPD

10:45 Using Advanced Software Applications to Leverage EHRs to Support Protocol Feasibility and Patient Identification
Sameer Tandon, Clinical Trial Intelligence Manager, Clinical Sciences & Innovation, Novartis
This presentation will cover the use of a software application to mine EMRs with leading academic institutions with the ability to arrange consultation and identify patients for referral into a clinical trial.

11:15 Integration of Clinical Trials into Clinical Care Using the Electronic Health Record
Mary T. Brophy, M.D., MPH, Director, Maveric Core Laboratory, VA Boston Healthcare System
This session will review efforts by the Department of Veterans Affairs to conduct clinical research as an extension of quality improvement efforts in the clinical care ecosystem. Alternatively termed pragmatic or point-of-care clinical trials, these studies are conducted less expensively and yield results that are more generalizable than traditional study designs. The session will review the Department's efforts in cardiovascular and medical oncology investigations.

11:45 A Technology Platform for Delivering Pragmatic Clinical Trials within a Primary Care Setting in the UK, Using Electronic Healthcare Records
Tim Williams, Ph.D., Head, Research, Clinical Practice Research Datalink (CPRD), Medicines and Healthcare Products Regulatory Agency (MHRA)
The ability to use Electronic Healthcare Records (EHR) as part of a randomized interventional study has been identified as a novel paradigm to manage and deliver clinical data in a real-world setting. Our challenge was to design and build a system to deliver pragmatic trials based on primary care EHR. This resulted in the development of an integrated suite of EHR-centric tools to enable trial design, feasibility and data management to CDISC-ODM standard EDC interfaces, enabling recruitment, minimum data collection, and patient reported outcomes (PROs). The resulting technology platform has benefits in terms of speed, costs and generation of real-world evidence.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:00 Dessert Break in the Exhibit Hall

1:30 Session Break

New Digital Technologies for Clinical Trials: Mobile Health, Apps and Wearables

1:55 Chairperson's Remarks
Anita Zubak, Executive Director, Global Clinical Trial Operations IT, Merck

2:00 Co-Presentation: Use of Digital Mobile App to Keep Clinical Trial Participants Engaged
Kamal Abbassi, BS, MS, Information Manager / Project Manager Early Development Workflows, pRED Informatics, Roche Innovation Center New York
Margaret Chan, Study Leader, Operations, Roche Innovation Center New York
Learn how to improve the clinical trial experience for patients through the use of digital technologies. Digital technologies can improve efficiencies in clinical trials and retention of study subjects. I will share key insights from the making of patient-centric mobile app to keep clinical trial participants engaged, supported and connected.

3:00 Endpoints To Insights: Integrating External Data Feeds Into The Broader eClinical Ecosystem
Nick Neri, Platform Manager, ERT

Sponsored by
ERT *Innovating Better Health™*

Effective data surveillance is critical for ensuring safe and cost-effective clinical trials. With safety and efficacy endpoints often being captured outside of the primary study database, the increased use of patient reported outcomes, and the emergence of wearable's in research, we are experiencing the tip of the spear in a new research paradigm. The ability to harmonize these data into actionable information and unlock the power behind your data is critical for success. In this presentation, Mr. Neri will share real-world use cases on the integration and analysis of these data using cloud technologies, and explore the approaches being taken by different research organizations as they prepare for this "new normal."

3:30 Refreshment Break in the Exhibit Hall

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MAY 10-11
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Data & Tech Driven Clinical Trials
New Tools and Analytics to Advance Clinical Research

4:00 The Use of Mobile Health Technology in Improving Clinical Trials
Michelle Crouthamel, Project Manager, ID, NS, Digital PPU, Projects Clinical Platforms & Science, GlaxoSmithKline
The ability to efficiently develop new medicines for patients with unmet needs is limited by the current model for clinical development. Fundamentally, the conduct of clinical trial has not changed significantly over the last few decades. Emerging digital and mobile health technologies have the potential to improve the conduct of clinical trials, allowing for more efficient development of new medicines for patients. Seeking patients' input into the design and conduct of clinical trials is now possible via mobile devices, sensors and remote technologies that can enhance recruitment, retention, adherence and clinical endpoint measurement. Data and experiences from a number of clinical trials will be summarized, highlighting the opportunities and challenges in this new area of clinical development.

4:30 Wearables in Health: In Theory and in Practice
Samuel Volchenboum, M.D., Ph.D., Associate Professor, Pediatrics and Fellow of the Computation Institute; Director, Center for Research Informatics; Associate Chief Research Informatics Officer, Biological Sciences Division; Associate Director, Institute for Translational Medicine, University of Chicago Medical Center
The way in which clinical trials are deployed is rapidly evolving. With FDA-approved use of wearables, physicians and researchers are realizing an opportunity to meaningfully improve patient experience and outcomes by generating and analyzing rich and objective data at the point of experience. Using real-world use cases, Dr. Samuel Volchenboum will explore the process of passively collecting patient data and evaluate the impact of wearables on the effectiveness and accuracy of clinical trials.

5:00 Close of Day

WEDNESDAY, MAY 11

8:30 Interactive Breakout Discussion Groups with Continental Breakfast
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Emerging Technologies for Clinical Trials

9:25 Chairperson's Remarks
Nick Neri, Platform Manager, ERT

9:30 Co-Presentation: Experimenting with Emerging Technologies in Clinical Research – Case Study Examples
Omar Ceren, Senior Specialist, Global Development Architecture & Innovation IT, Merck
Anita Zubak, Executive Director, Global Clinical Trial Operations IT, Merck
Jeffrey R. Sachs, Senior Principal Scientist, Merck

This presentation will review Merck's approach to innovation experiments, with review of specific case studies including wearable technology, "smart sampling" using dried blood samples, electronic informed consent. The presentation will cover selection, structure, results analysis, and lessons learned of the experimentation with emerging technologies.

10:30 Sponsored Presentation *(Opportunity Available)*

10:45 Coffee Break in the Exhibit Hall

11:30 PANEL DISCUSSION: Using Wearables to Accelerate Clinical Trials
Hamid Najafi, CTO and Co-Founder, Sensoplex, Inc.
Haiming Wu, Principal Engineer, Technical Development, Biogen
Patrick Hankey, Principal Platform Adoption, Patient Cloud & mHealth, Medidata
Marc Sebes, Vice President, Product Management, Validic
Jeremy Sohn, Vice President and Head, Digital Business Development & Licensing; Ad-Interim Global Head, Digital Development, Novartis

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

1:55 Chairperson's Remarks
Nick Neri, Platform Manager, ERT

2:00 Remote Trials to Drive Patient Centricity
Hassan Kadhim, Business Consultant, IS BP R&DM, Boehringer Ingelheim
With the emergence and increasing ubiquity of digital technology in several industries, and with the increasing need of patient-centric trial design, several initiatives have been recently launched within the pharmaceutical industry to promote change in clinical research towards a more patient-centric approach. This talk will describe one potential initiative to conduct clinical trials in a remote fashion, and will propose a remote clinical trial model for the pharmaceutical industry to perform clinical research. We will also discuss several considerations in order to apply this model, and address challenges and benefits of the model.

2:30 A Guide & Lessons Learned: From Innovation Island to Innovation Mainland
Jeremy Sohn, Vice President and Head, Digital Business Development & Licensing;Ad-Interim Global Head, Digital Development, Novartis

3:30 Close of Conference

Pair this program with **Big Data for Clinical Trials** (Page 8) and Dinner Courses on **Expectations of Risk-Based Monitoring** and **Risk Management and Pharmacovigilance** (Page 3) to maximize your time at the **Clinical Trial Innovation Summit**

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Pricing and Registration Information

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Registration after April 15, 2016 and on-site	$2699	$1299

BASIC PACKAGE (Includes access to 1 conference, excludes short courses)

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Advance Registration Discount until April 15, 2016	$1649	$849
Registration after April 15, 2016 and on-site	$1849	$899

May 9 - 10, 2016	May 10 - 11, 2016
T1 Mastering Risk-Based Monitoring	T4 Clinical Trial Auditing
T2 Patient Recruitment & Site Selection	T5 Outsourcing for Clinical Trials
T3 Big Data for Clinical Trials	T6 Tech Innovation in Clinical Trials

DINNER COURSES

	Commercial	Academic, Government, Hospital-affiliated
One short course	$599	$349
Two short courses	$899	$599

Monday, May 9 5:30-8:30 pm	Tuesday, May 10 5:30-8:30 pm
SC1 Meeting the Customers' Needs. What Are the Expectations of Risk-Based Monitoring?	~~SC2 Therapeutics Risk Management - Bridging Clinical Development with Post-Authorization Practice~~

CONFERENCE DISCOUNTS

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

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

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