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- Data & Tech Driven Clinical Trials

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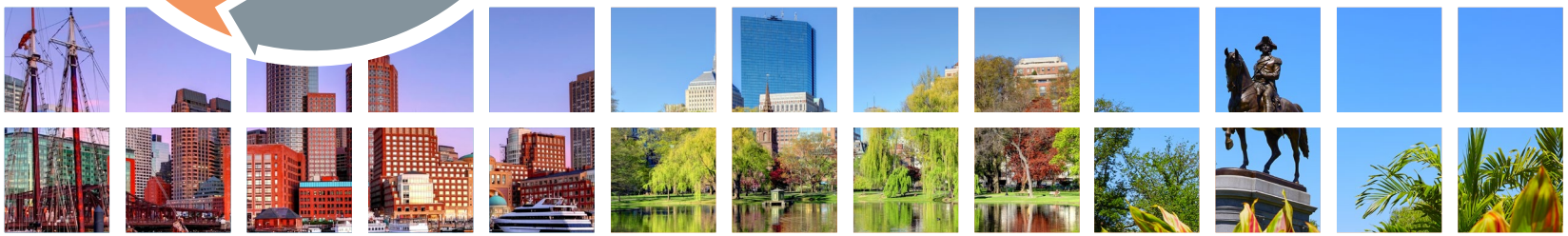
Final Weeks to Register!

Cambridge Healthtech Institute's 6th Annual

Clinical Trial Innovation SUMMIT

April 24-26, 2017
The Westin Copley Place
Boston, MA

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



Conferences

April 24-25

- Clinical Trial Auditing
- Patient Recruitment & Site Selection
- Big Data for Clinical Trials

April 25-26

- Mastering Risk-Based Monitoring
- Outsourcing for Clinical Trials
- Data & Tech Driven Clinical Trials

Plus! 3 Dinner Short Courses

Keynote Speakers

Gregg Larson, Ph.D.
Vice President, Clinical Field Operations, Development, AbbVie

Nina Spiller
Vice President, Clinical Management, Otsuka

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

John Reites
Chief Product Officer & Partner, THREAD

Spyros Papapetropoulos
Vice President & Global Head, Clinical Development, Movement Disorders & Neurodegenerative Diseases, Teva

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Clinical Trial Innovation SUMMIT

About the Event

Cambridge Healthtech Institute's Clinical Trial Innovation Summit brings together leaders from across pharma, biotech and academia to share case studies and best practices on effective clinical trial management and vendor oversight. The 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.

Connect with Us #CLIN17

Hotel & Travel

Conference Venue
The Westin Copley Place
10 Huntington Ave
Boston, MA 02216
Phone: 617-262-9600

Discounted Room Rate
$319 s/d *(includes Complimentary Wi-Fi in Sleeping Room)*

Discounted Cut-off Date
March 27, 2017

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

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Sponsorship, Exhibit, and Lead Generation Opportunities

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

Podium Presentations — *Available within Main Agenda!*
Showcase your solutions to a guaranteed, targeted audience. 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.

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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!

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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.:

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- Focus group
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- Plated dinner with specific conversation focus

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

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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 1,000,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Web Symposia
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For additional sponsorship & exhibit information, please contact:

Ilana Quigley
Sr. Manager, Business Development
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Cambridge HEALTHTECH Institute
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Plenary Keynote

April 25

TUESDAY, APRIL 25 | 10:45 - 11:50 AM

RE-IMAGINING THE CLINICAL TRIAL PROCESS: OVERCOMING CHALLENGES TO INNOVATION

The plenary keynote session will address the current state of clinical development across pharma/biotech and the opportunities and strategies to overcome challenges to innovation.

- Where do opportunities lie in innovating the clinical trial process?
- How do we get pharma to adopt change? Is change moving fast enough?
- How do we get Clinical Ops to innovate? How can we get people to think innovatively at a department level, company level and industry level? What is the best way to innovate?
- How can we involve all the players/stakeholders? How do large, mid-sized and small pharma/biotech approach this?
- What does innovation look like and what does it mean (new technology and devices vs. streamlining existing processes)?
- Are all of these precompetitive collaborations across pharma enough?

Keynote Speakers


Gregg Larson, Ph.D., Vice President, Clinical Field Operations, Development, AbbVie


Nina Spiller, Vice President, Clinical Management, Otsuka


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


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Dinner Short Courses*

April 24 - 25

MONDAY, APRIL 24 | 6:00 - 9:00 PM

SC1: A NEW ERA IN PATIENT RECRUITMENT: UNDERSTANDING SOCIAL AND DIGITAL MEDIA'S POWER TO ACCELERATE YOUR CLINICAL TRIAL

Mastering the process of finding, engaging and activating patients for enrollment into a clinical trial is a key success factor for all biopharmaceutical companies developing new treatments. Patients have transitioned online to seek disease, drug and clinical trial information. Thus, if our industry is looking to intersect with patients for clinical trials, social media cannot be overlooked. In fact, social media for clinical trials must become a basic component of every clinical trial recruitment plan. 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.

Instructor

Sandra Shpilberg, CEO, Seeker Health

**Separate registration required.*

TUESDAY, APRIL 25 | 5:30 - 8:30 PM

SC3: MOBILE HEALTH AND VIRTUAL STUDIES: HOW TO ACCELERATE THEIR USE AND ADOPTION IN YOUR COMPANY

This workshop will explore how mobile health and virtual research studies are being conducted in pharma-focused programs with input from industry leaders on the market, lessons learned, data standards, privacy, platforms in use, adoption strategies and much more on the topic. This session will be interactive with short burst 15 minute presentations that lead to breakout groups for focus on specific topics of interest in small groups. After the discussion, there will be readouts from each group and open discussion and Q&A with all in attendance.

Instructors

John Reites, Chief Product Officer and Partner, THREAD
Joe Dustin, Principal of mHealth, Medidata
Spyros Papapetropoulos, Vice President & Global Head, Clinical Development, Movement Disorders & Neurodegenerative Diseases, Teva

**Separate registration required.*

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Cambridge 25 YEARS HEALTHTECH Institute
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6th Annual Clinical Trial Auditing

April 24 - 25

Building Effective Audit Programs

MONDAY, APRIL 24

THE GOAL OF a clinical trial audit is to ensure that patient safety is observed, that collected data is accurate, and that the conduct of the trial is compliant; to accomplish these tasks, a comprehensive quality management system and risk-based audit plan must be established. Cambridge Healthtech Institute's Seventh Annual "Clinical Trial Auditing" conference will examine best practices and case studies for developing risk-based auditing practices, auditing vendors for qualification and performance, preparing for health authority inspections, and implanting the changes in ICH E6.

7:25 am Conference Registration and Morning Coffee

SETTING THE STAGE FOR A SUCCESSFUL AUDIT

8:25 Chairperson's Opening Remarks
Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, RCQA (Research Compliance and Quality Assurance), University of Miami

> ICH E6 is due to be implemented in mid-2017; hear from Andy Lawton on how these changes affect clinical trial auditing. Understand what the changes are and the steps to take for a successful implantation, including gap analysis, action plans, and project plans.

8:30 Setting the Stage for a Successful Audit: Building Effective Partnerships with Internal/ External Stakeholders
Mark Lepkowski, GCP Audit Lead, R&D Audit and Inspection, Alexion Pharmaceuticals Inc.
This talk will address understanding your stakeholder landscape, educating others about the audit process, and involving stakeholders in the audit planning process. Discuss setting stakeholder expectations before an audit and learn tips to conducting a "no surprise" audit from the opening meeting to the debrief and getting the distribution list for the audit report right.

RISK-BASED APPROACH TO AUDITING

9:00 Assessing Sites' Electronic Health Records for Clinical Research Readiness
Linda Maziarz, Director, Clinical Development QA, America's Region, CDQA, GlaxoSmithKline
The importance of assessing sites' Electronic Health Record (EHR) systems when used as a source in clinical trials is reflected in recent guidance issued by the FDA in the Draft Guidance on the Use of EHR Data and the MHRA Position Statement and Guidance on EHRs. There are many practical challenges for sponsors in how to go about assessing these systems to ensure they adhere to the fundamental elements of data quality (ALCOA). This session will highlight some of the challenges and offer suggestions to support sponsors in the assessment of EHR systems.

9:30 Evolution of an Internal Audit Program
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. The ever-changing rules, regulations, and guidance documents, increased protocol complexity, and evolution of the researchers themselves require continuing review of our audit programs, as well as solicitation of feedback from related compliance programs. This presentation will provide the audience with examples of strategies for review of an existing auditing program, as well as a step-by-step approach to the review of existing structures and of the implementation of new practices. Vision, focus on methodology and an open mind form the basis for successful implementation.

10:00 Networking Coffee Break

10:30 PANEL DISCUSSION: Developing a Risk-Based Auditing Plan for Modern Clinical Trials
Moderator: Anthony Borisow, Senior Quality Manager, Clinical Quality Assurance, Vertex Pharmaceuticals Inc.
Panelists: Ana Sharma, Global Head, Strategy and Operations, Clinical Development Quality, Novartis
Linda Maziarz, Director, Clinical Development Quality Assurance, America's, GSK
Lydia Milne, Associate Director, Clinical QA, Astellas
Mark Lepkowski, GCP Audit Lead, R&D Audit and Inspection, Alexion Pharmaceuticals Inc.
Conventional auditing approaches are no longer efficient: as evolving regulations, complex clinical trial structures and outsourcing strategies, and new tools and technologies for data capture morph the face of clinical trials, a more risk-based approach to auditing is necessary. This panel will discuss best practices and methods for developing a risk-based audit program with insight from various members of a clinical trial team.

11:30 Session Break

AUDITING FOR VENDOR QUALIFICATION AND PERFORMANCE

1:25 Chairperson's Remarks
Anthony Borisow, Senior Quality Manager, Clinical Quality Assurance, Vertex Pharmaceuticals Inc.

1:30 We Hold This Truth to Be Self-Evident: NOT All GCP Vendors Are Created Equal
Robyn Lori, Director, GCP Vendor Management, Vertex Pharmaceuticals
Any given clinical trial may have a number of different vendors participating, with each

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contributing to the trial in different ways. With this in mind, how do we determine the frequency with which we should audit each vendor? This talk will discuss Vertex's risk-based strategy to determine how often audits should be performed to ensure that each trial stays on schedule.

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*

SC1: A New Era in Patient Recruitment: Understanding Social and Digital Media's Power to Accelerate Your Clinical Trial

Please see page 3 for details.

** Separate registration required.*

TUESDAY, APRIL 25

7:25 am Morning Coffee

HEALTH AUTHORITY INSPECTIONS

7:55 Chairperson's Remarks
Andy Lawton, Director and Consultant, Risk Based Approach Ltd.

8:00 Actionable Insight from Health Authority Inspections
Janis Little, Vice President, Global Regulatory Quality, Allergan
As the trend toward health authority inspections grows, companies must be prepared to adjust their operational models to be prepared for these visits. This talk will address the trends in inspections, how common they are, and how to prepare for an audit of clinical trial documentation during mergers and acquisitions. Allergan's "open science" model will also be discussed.

8:30 Lessons Learned from mHealth Canada Health Authority Inspection
Derek Hall, Associate Director, Quality Assurance GCP, Incyte
This talk will discuss Incyte's experience with their recent health authority inspection at mHealth Canada. Lessons learned revolve around policies, documentation, and validation.

ICH E6 R2: EFFECTS ON AUDITING

9:00 ICH E6 (GCP) Addendum – Impact on Use of Audits?
Andy Lawton, Director and Consultant, Risk Based Approach Ltd
ICH GCP (E.6) Addendum was released in December last year and is due to be implemented in mid 2017. ICH GCP forms the basis for companies to undertake clinical trials and so it is essential that preparations are made to build the changes from the addendum into our processes, and yet a large number of companies have not fully addressed the changes. The main changes and the focus of this presentation are in the area of auditing, although not directly addressed the introduction of quality tolerance limits will be a natural limit to the use of audits. This talk will allow attendees to understand the changes in ICH GCP (E6) and the drivers for them, the impact on sponsors, and the essential steps to take for ICH E6, including gap analysis, an action plan, and a project plan.

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION

Re-Imagining the Clinical Trial Process: Overcoming Challenges to Innovation

Please see page 3 for details.

11:50 Keynote Luncheon Presentation: Leveraging Advanced Data Analytics and mHealth for Next-Gen Trials

Sponsored by medidata

Kyle Given, Strategic Consulting Services Principal, Professional Services, Medidata Solutions
Traditional manual methods that use inefficient ways to monitor data quality often delay the identification of clinical trial risks and do nothing to improve the level of overall data quality. In this presentation, Medidata will focus on how changing this approach using advanced data analytics and mHealth solutions can identify areas of risk much faster and more accurately. This shift will have an important benefit on both sites and patients.

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of Clinical Trial Auditing. Stay on to attend Risk-Based Monitoring. See page 10 for details.

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MONDAY, APRIL 24

THE SUCCESS OF a clinical trial hinges upon 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 recruitment and site selection techniques using novel, patient-centric and data-driven approaches.

7:25 am Conference Registration and Morning Coffee

INVOLVING THE PATIENT IN RECRUITMENT AND CLINICAL TRIALS

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

8:30 Reciprocal Patient Relationships before, during and after Trials
Jeremy Gilbert, Vice President, Product & Strategy, PatientsLikeMe
Patients rarely consider research when they are not in a clinical trial, and when they do participate, rarely build any long term connection with other patients or the research they were a part of. The result is disappointed patients and a perpetual challenge in recruiting the next generation of trial participants. In operating a research-oriented, "data for good" network, PatientsLikeMe has developed a number of powerful methods for creating continuous, reciprocal, long-term research relationships with patients. This talk will share what we've learned and discuss its applications to clinical trials.

9:00 Social Media as a Vehicle for Enhancing Patient Involvement in Medicine Development
Phil Golz, Executive Vice President and Chief Revenue Officer, HealthUnlocked, Inc.
Historically, medicine development has been very much focused on the science and evidence required to gain medicine authorization and reimbursement. But today, with more and more medicines targeting the same disease and/or pathway and with ever greater stratification of patient populations within disease areas, involving patients has never been more important. Social Media, with its broad reach and consumer friendly interfaces is becoming an ever more important channel to reach, educate and engage patient populations and can be used to help industry design better trials, which are more suited to the patient populations they seek to serve.

9:30 Informed Consent: Moving from Lawyer-Friendly to Patient-Friendly
Julie Walters, Founder, Raremark
For far too long, patients in clinical trials have had to read and sign a 20-page legalistic tome to take part in a clinical trial. Legal and compliance may be delighted by the output but do patients really understand what they are signing? Is there another way of gathering informed consent that is truly understood by the patient AND ticks the boxes for legal and compliance? Raremark has developed a new way of working with patients that is user-led, patient-friendly and ethical. Hear how the new approach works in the real world and how it is possible to put users first, compliance second.

10:00 Networking Coffee Break

SITE SELECTION & FEASIBILITY INSIGHTS

10:30 Novel Approaches to Site Feasibility
Amanda Hayden, Director, Global Clinical Services, Study Start Up, Alkermes, Inc.
This presentation will focus on unique ways to explore site capabilities for participating in clinical trials. Given the limits in standard feasibility questionnaires, it is helpful to apply varied approaches to assess site interest and capacity for performance. Employing different techniques to improve early site feasibility efforts has a dramatic effect on ensuring the inclusion of the right sites for your clinical programs.

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11:00 Setting and Achieving Site Performance Targets: Starting at Site Selection
Brendan O'Neill, Senior Director, Patient Recruitment Programs, Global Clinical Trial Execution, Pfizer
In order to drive down the number of non-performing sites, we are working with our CRO partners to validate a site's access to patients at the time of site selection and establishing a site specific recruitment plan to ensure that sites hit their contracted target. In this session, you will see how planning and technology can come together to ensure that sites and studies are set up for success. You will see the successful impact of this approach at initial study planning and rescue situations.

11:30 Precise and Accurate Site Selection Targeting
Sponsored by goBalto
Robert Wynden, Ph.D., Vice President, Technology & Engineering, Product Development, goBalto
Site selection is best performed when sponsors/CROs use a data-driven approach to create a target site profile based on an algorithm that uses a weighted average of feasibility, study startup metrics, and site experience, informing decisions on the effectiveness of sites to be made.

11:45 Patient Recruitment: Setting Up Studies for Success
Sponsored by BIOCLINICA SEE MORE CLEARLY
Martin Collyer, COO, Patient Recruitment and Retention, Bioclinica

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

12:45 Session Break

NEW TECHNOLOGIES FOR MORE EFFICIENT PATIENT RECRUITMENT & SITE SELECTION

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

1:30 Future Technologies in Site and Patient Recruitment
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis
This presentation will cover current technologies (social media/search engine optimization, targeted digital advertising, etc.) and those on the horizon (artificial intelligence, virtual reality, etc.) for patient recruitment and at sites.

2:00 Social & Digital Media for Accelerating Patient Recruitment
Heather Hernandez, Clinical Operations Manager, Menlo Therapeutics
As more patients seek health information online, social and digital media become powerful tools for patient engagement and enrollment in clinical trials. This presentation will provide a case study of using social media for a clinical trial recruitment plan and the key learnings from our experience.

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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TUESDAY, APRIL 25

7:25 am Morning Coffee

DATA-DRIVEN PATIENT RECRUITMENT AND SITE SELECTION

7:55 Chairperson's Opening Remarks
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis

8:00 Data-Driven Patient Recruitment with Real World Data at Roche pRED
Liping Jin, Data-Driven Recruitment Lead, Pharmaceutical Research & Early Development, Roche Innovation Center New York
With the increasing use of Real World Data (RWD) in the pharma industry, the Data-Driven Recruitment (DDR) team at Roche Pharm Research & Early Development (pRED) would like to share our experience of integrating RWD (e.g. insurance claims, EMR) with trial metrics data to optimize study protocol design and target patient recruitment strategy. While the team has received positive feedback from our business partners (translational medicine, clinical program teams, and study leaders), we would like also to share the challenges to expanding the effort in broader US and international settings.

Discover current and new technologies for study start-up activities, such as patient recruitment and site performance. Hear industry leaders give case studies of their use of social media, search engine optimization, and targeted digital advertising alongside technology on the horizon for clinical trials, such as artificial intelligence and virtual reality.

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8:45 Site Selection and Trial Execution- Pearls and Pitfalls

Sponsored by orphanos a TrialRunners CRO

Darin Curtiss, Pharm.D., Vice President, Clinical Development, Orphanos

9:00 Optimizing Clinical Research through Insight Generation and Data-Driven Approaches

Martine Lewi, Scientific Director, Quantitative Sciences, Real World Evidence, Medical Affairs, Established Products Statistics (RMEDS), Janssen

The presentation starts from a European perspective on health data re-use for optimizing clinical research, comparing the situation – from a data user perspective – with practices in other regions. Lessons learned from the public/privately funded Innovative Medicine Initiative EHR4CR will be shared and the objective of open collaboration with different stakeholders will be emphasized, aiming at the development of a sustainable ecosystem where new partnerships can emerge and clinical research can be optimized through early insight generation.

9:30 Recruiting Beyond Traditional Patient Populations. A Risk-Free Approach

Sponsored by SubjectWell

Ivor Clarke, CEO, SubjectWell

The statistics are familiar - only 4% of Americans have ever participated in a clinical trial and less than half can even recall seeing an ad for patient recruitment. Accelerating enrollment requires growing the total population of people participating. We'll discuss a unique approach that leverages learnings from other industries.

9:45 Who's Keeping Score? A Quantitative Approach to Trial Feasibility

Sponsored by saama

Luke Stewart, MBA, Director, Product Management, Saama Technologies

With most trials failing to meet enrollment timelines, current approaches for feasibility fall short of identifying and minimizing risk. Sponsors must arm themselves with the right tools to own this analysis throughout the trial lifecycle. We will discuss a quantitative approach that operationalizes feasibility score tracking.

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION

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Please see page 3 for details.

11:50 Keynote Luncheon Presentation: Leveraging Advanced Data Analytics and mHealth for Next-Gen Trials

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12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of conference. Stay on to attend Outsourcing for Clinical Trials. See page 12 for details.

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3rd Annual
Big Data for Clinical Trials
April 24 - 25

Harnessing & Unlocking the Potential of Existing Data Sources

MONDAY, APRIL 24

THE VAST VOLUMES of data collected across the clinical trials process offers pharma and biotech the opportunity to harness the information in these big data sets for modelling and predictive analytics used for improved clinical trial design, patient recruitment, site selection, monitoring insights and overall decision making. Harnessing and unlocking the potential in existing data sources, including biomarker, genomic, EHRs, claims data, real world data and clinical trial data, can ultimately lead to improved 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 the clinical trials process.

7:25 am Conference Registration and Morning Coffee

NEW INSIGHTS FOR CLINICAL DEVELOPMENT FROM BIG DATA

8:25 Chairperson's Opening Remarks
Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb

8:30 Implications of Big Data for Drug Development
Ray Liu, Ph.D., Senior Director & Head, Statistical Innovation & Consultation, Takeda
This presentation will describe how to maximize the impact of Big Data on drug development: its methodology, practical challenges and implications.

9:00 Big Data Analytics for Next-Generation Clinical Trials
Kevin Hua, Senior Manager, A.I./Machine Learning Development, Bayer LifeScience iHub
In the pharmaceutical industry, data is largely available, including historical clinical trials, drug databases, electronic medical records, sensors data, human genome, real life experience, scientific publications and social media data. We have been building a big data analytics platform and have defined a set of common analytics models that can be applied to many types of clinical trials. With big data and advanced analytics, we can help clinical scientists make data-driven decisions and reach conclusions faster and more accurately. Big data analytics can not only accelerate clinical trials, but also help reduce the risks and costs associated with clinical trials. Big data analytics plays a crucial role in future clinical trials.

9:30 Clinical Trials Innovations in the Age of Big Data and Advanced Analytics
Kaushik Raha, Ph.D., Associate Director & Head, Emerging Analytics and Advanced Visualizations, Janssen Pharmaceuticals
At Janssen, the data sciences group in partnership with global clinical operations has launched initiatives in site selection, risk-based monitoring, and quality and compliance to bring innovations based on big data and advanced analytics to clinical trials operations. Additionally, we have pioneered the application of technologies such as machine learning, natural language processing, and artificial intelligence to create novel solutions which have resulted in data-driven efficiencies realized from predictive and prescriptive analytics on clinical trials data. This presentation will delve on aspects of this work and present vignettes to highlight the challenges and successes.

10:00 Networking Coffee Break

10:30 Integrated Analytics: A Corporate Experiment
Balazs Flink, M.D., Clinical Trial Analytics Lead, R&D Business Insights and Analytics, Bristol-Myers Squibb
BMS decided to integrate all corporate analytics functions under one organization to drive enterprise level decision-making through data. The desired result is integrated, predictive analytics that help drive R&D strategy and execution, with clear ties to long term financial impacts. This presentation highlights the concept and the early results including the challenges and speaks about the cultural aspects of the change, which are much more complex hurdles than deriving insights from a wealth of data.

LEVERAGING EXISTING DATABASES FOR CLINICAL TRIALS

11:00 The VA Diuretic Comparison Project: A Large Scale Clinical Trial Embedded in a Healthcare System
Ryan Ferguson, Director, Cooperative Studies Program Coordinating Center, U.S. Department of Veterans Affairs
This presentation will discuss a pragmatic "Point-of-Care" clinical trial being conducted within the Department of Veterans Affairs. 13,000 patients will be enrolled at 50 sites using the EHR without any other trial management apparatus. Patients will be followed for outcomes and adverse events through the EHR. The trial is being done at a tiny fraction of the cost of a traditional clinical trial.

11:30 Sponsored Presentation *(Opportunity Available)*

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

12:45 Session Break

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LEVERAGING EXISTING DATABASES FOR CLINICAL TRIALS

1:25 Chairperson's Opening Remarks
Ray Liu, Ph.D., Senior Director & Head, Statistical Innovation & Consultation, Takeda

1:30 Using Existing Databases to Inform Study Design and Data Quality: An Alzheimer's Disease Trial Case Study
Chad Swanson, Ph.D., Director, Neuroscience Clinical Development, Neurology Business Group, Eisai, Inc.
The Alzheimer's Disease Neuroimaging Initiative (ADNI) is a large, natural history study spanning the spectrum of Alzheimer's disease (AD), that provides an accessible data repository intended to further our understanding of the disease through the stimulation of new investigation. The present study used clinical and biomarker data from ADNI to help design a large Phase 2b study in Early AD with a monoclonal antibody targeted against soluble beta amyloid aggregates. Moreover, longitudinal ADNI data were used in a series of analyses to develop a comprehensive clinical data monitoring approach in the ongoing Phase 2 study with methods that can be applied broadly across a variety of datasets and therapeutic areas.

2:00 Clinical Sample Management Enabling Precision Medicine Trials
Ron Bourque, Associate Director, R&D IS, Clinical Business Management & Analytics, MedImmune
We have developed a new and innovative sample management model combining Medimmune Clinical Operations with close alliance/partnership to a central lab. Together the technology we are employing is Labmatrix. This initiative is focused on accepting standardized data from all lab vendors. Discrepant data will be corrected at the source lab and reflected back into the tool. Labmatrix is also receiving consent data from our EDC. The result is a sample management tool that answers 3 fundamental questions: What samples do we have in inventory? What samples should we have and are there discrepancies? What consents do we have associated with each sample?

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*

SC1: A New Era in Patient Recruitment: Understanding Social and Digital Media's Power to Accelerate Your Clinical Trial

Please see page 3 for details.

** Separate registration required.*

TUESDAY, APRIL 25

7:25 am Morning Coffee

DATA-DRIVEN PATIENT RECRUITMENT AND SITE SELECTION

7:55 Chairperson's Opening Remarks
Robert Loll, Vice President, Business Development & Strategic Planning, Praxis

8:00 Co-Presentation: Data-Driven Patient Recruitment with Real World Data at Roche pRED
Liping Jin, Data-Driven Recruitment Lead, Pharmaceutical Research & Early Development, Roche Innovation Center New York
Shuree Harrison, Clinical Program Leader, Development Science and Innovation, Pharma Research & Early Development, Roche Innovation Center New York
With the increasing use of Real World Data (RWD) in the pharma industry, the Data-Driven Recruitment (DDR) team at Roche Pharm Research & Early Development (pRED) would like to share our experience of integrating RWD (e.g. insurance claims, EMR) with trial metrics data to optimize study protocol design and target patient recruitment strategy. While the team has received positive feedback from our business partners (translational medicine, clinical program teams, and study leaders), we would like also to share the challenges to expanding the effort in broader US and international settings.

8:45 Site Selection and Trial Execution- Pearls and Pitfalls

Sponsored by orphanos a TrialRunners CRO

Darin Curtiss, Pharm.D., Vice President, Clinical Development, Orphanos

9:00 Optimizing Clinical Research through Insight Generation and Data-Driven Approaches
Martine Lewi, Scientific Director, Quantitative Sciences, Real World Evidence, Medical Affairs, Established Products Statistics (RMEDS), Janssen
The presentation starts from a European perspective on health data re-use for optimizing clinical research, comparing the situation – from a data user perspective – with practices in other regions. Lessons learned from the public/privately funded Innovative Medicine Initiative EHR4CR will be shared and the objective of open collaboration with different stakeholders will be emphasized, aiming at the development of a sustainable ecosystem where new partnerships can emerge and clinical research can be optimized through early insight generation.

> Make data-driven business and clinical trial decisions faster and more accurately with big data analytics. Takeda, Bayer, Janssen and BMS discuss their big data strategies and its implications for clinical trials and drug development.

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9:30 Sponsored Presentation *(Opportunity Available)*

9:45 Who's Keeping Score? A Quantitative Approach to Trial Feasibility

Sponsored by saama

Luke Stewart, MBA, Director, Product Management, Saama Technologies

With most trials failing to meet enrollment timelines, current approaches for feasibility fall short of identifying and minimizing risk. Sponsors must arm themselves with the right tools to own this analysis throughout the trial lifecycle. We will discuss a quantitative approach that operationalizes feasibility score tracking.

10:00 Coffee Break in the Exhibit Hall

10:45 PLENARY KEYNOTE SESSION

Re-Imagining the Clinical Trial Process: Overcoming Challenges to Innovation

Please see page 3 for details.

11:50 Keynote Luncheon Presentation: Leveraging Advanced Data Analytics and mHealth for Next-Gen Trials

Sponsored by medidata

Kyle Given, Strategic Consulting Services Principal, Professional Services, Medidata Solutions

Traditional manual methods that use inefficient ways to monitor data quality often delay the identification of clinical trial risks and do nothing to improve the level of overall data quality. In this presentation, Medidata will focus on how changing this approach using advanced data analytics and mHealth solutions can identify areas of risk much faster and more accurately. This shift will have an important benefit on both sites and patients.

12:35 pm Dessert Break in the Exhibit Hall

1:20 Close of conference. Stay on to attend Data & Tech Driven Clinical Trials. See page 14 for details.

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8th Annual Mastering Risk-Based Monitoring

April 25 - 26

Proactively Ensuring Quality into Clinical Trials & Effective Monitoring

TUESDAY, APRIL 25

ENSURING QUALITY FROM the outset at the protocol level 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). 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 clinical trial quality, effectively implementing quality risk management plans, and working with various stakeholders on effective roll out of RBM.

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION

Re-Imagining the Clinical Trial Process: Overcoming Challenges to Innovation

Please see page 3 for details.

11:50 Keynote Luncheon Presentation: Leveraging Advanced Data Analytics and mHealth for Next-Gen Trials

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12:35 pm Dessert Break in the Exhibit Hall

NEW PERSPECTIVES ON CLINICAL TRIAL QUALITY

1:45 Chairperson's Remarks

Rajneesh Patil, Senior Director, Risk-Based Monitoring & Analytics, QuintilesIMS

1:50 Using Technology to Drive the Work We Do – Tesla!

Gregg Larson, Ph.D., Vice President, Clinical Field Operations, Development, AbbVie

We have embarked on creating "Tesla", a new system to enhance our ability to manage our portfolio of Clinical Trials. With Tesla we are able to utilize a work flow-based system to drive the activities of Risk Mitigation and Observation Management. This presentation will demonstrate how our new system allows us to proactively manage risks in a transparent way through the life of the study, consistent with the expectations reflected in the ICH E6 updates.

2:20 Risk-Based Clinical Operations Oversight Utilizing Risk-Based Approaches to All Aspects of Trial Oversight

Rosanne Petros, PMP, Associate Director, Clinical Research, Global Clinical Trial Operations– The Americas, Merck

There is much focus on risk-based monitoring and some on risk-based auditing in order to focus site visits but a risk-based approach to all aspects of trial management should be employed from study inception to study close and encompass all study roles. I will be discussing risk based oversight from an operational standpoint.

2:50 pm RBM And The Role Of New Age Analytics In Clinical Trial Quality

Rajneesh_PatilRajneesh Patil, Senior Director, Risk-Based Monitoring & Analytics, QuintilesIMS

RBM models rely significantly on data and analytics to assess risks to site performance, subject safety and data quality. However, the early generations of these models focus on single parameters to identify issues, which, out of context, can often lead to false positives/white noise. The new age analytics models can differentiate the relative risk

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between sites and indicate which sites or subjects are at higher risk. In this session we will explore of few of our implementations as case studies.

3:20 Refreshment Break in the Exhibit Hall

4:05 Co-Presentation: The Critical Role of Issue Management (Systems) in Clinical Research
Andy Lawton, Director and Consultant, Risk Based Approach Ltd.
Anita DiFrancesco, Vice President, Clinical Development, Samumed
Having a robust Issue Management process is an essential part of good practice within clinical trials; not having a system to support this leads to a lack of oversight of what issues are occurring. Issue Management tools often started as independent of the clinical systems, being derived from IT call center tracking tools. More recently, they have become integral parts of CTMS, Site Management Systems and more recently RBM systems. The challenge is how to optimize the use of issue management across the organization. We will firstly give an overview of what an IM system is, the problems if you do not have one and preparation required to optimize. The presentation will be supported with use cases.

5:05 Close of Day

5:05 Dinner Short Course Registration

5:30 - 8:30 Recommended Dinner Short Course*

SC2: How to Implement RBM on a Budget

Please see page 3 for details.

** Separate registration required.*

WEDNESDAY, APRIL 26

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

INITIAL STEPS & INDICATORS TO PAY ATTENTION TO FOR SUCCESSFUL RBM

9:40 Chairperson's Remarks
Rajneesh Patil, Senior Director, Risk-Based Monitoring & Analytics, QuintilesIMS

9:45 Co-Presentation: Trials and Tribulations of Change Management in RBM: What Are They and How to Address Them Head On
Brian Nugent, Director, PALM, Clinical Operations, Gilead Sciences
Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences
With the implementation of ICH E6 (R2) changes upon us, the adoption of risk-based monitoring (RBM) for most organizations is a change management challenge. Finding the right technology and tools to use is one thing, but, how to manage the change that is about to occur within the organization is something that needs just as much attention. In this presentation we will address the following learning objectives: 1. Identify the challenges to Change Management in RBM; 2. How to address each challenge; 3. Identify the key elements of a Change Management plan in RBM; 4. How to implement a Change Management plan that's right for your organization.

10:45 Reducing the Burden of RBM Software Validation in a SaaS Based World
Sponsored by BIOCLINICA SEE MORE CLEARLY
Kristin Mauri, MBA, Global Head – Risk Based Monitoring, Bioclinica
This session provides considerations for implementing and maintaining validation of your SaaS-based RBM technology solution:

- Benefits of choosing SaaS-based products
- Keys to evaluating your RBM SaaS vendor's ability to ease your burden in maintaining a validated state in a SaaS environment

11:00 Coffee Break

11:30 Role of Programmers in Flawless Execution of RBM Trials
Dorothea Ugi, Central Statistical Surveillance Analyst, Risk Management & Central Monitoring, Janssen
Successful roll out of RBM is intricately dependent on real-time access and review of Critical to Quality data and processes. Engaging programmers early in the trial set up and later in the execution can facilitate development of study specific reports. These reports can be used to review CtQ data in real time, allowing for intervention at a particular investigator site, or the trial as a whole, before the signal becomes a regulatory concern. Janssen R&D has been successfully combining a process called "Protocol De-Risking" with identification of study specific reports. The outcome has resulted in more efficient execution with fewer major protocol deviations.

Successful RBM begins with ensuring quality during the design and planning of clinical trials. Case studies from AbbVie, Merck and Samumed showcase new methods of risk mitigation, issue management and oversight plans to ensure quality clinical trials.

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12:00 pm Identifying Failure: Lessons Learned When the Plan Fails - A Case Study for Risk-Based Monitoring
Jessica Masarek, Director, Quality Assurance, Muse Clinical
Implementation of risk-based monitoring comes with a unique set of challenges. As more organizations implement this model, it's critical that we learn from mistakes and adapt accordingly. In this session, we will examine a recent case study and discuss how the failures in appropriate planning and response to signal detection led to critical monitoring findings, resulting in an overall lack of confidence in data integrity at a high enrolling site for a global, pivotal study.

12:30 Luncheon Presentation: Comprehensive Risk & Issue Management for Central Monitoring
Sponsored by COVANCE SOLUTIONS MADE REAL
Victor Lobanov, Ph. D., Executive Director, Data Sciences, Covance
Proactive identification of risks, implementation of appropriate monitoring strategies, and early detection and timely resolution of issues are the core of the Risk-Based Monitoring (RBM) approach advocated by the regulatory agencies. This presentation will illustrate how managing risks and issues in a comprehensive and unified manner will allow sponsors to enhance quality and efficiency of clinical development.

1:15 Session Break

LESSONS LEARNED AND CASE STUDIES FOR RBM

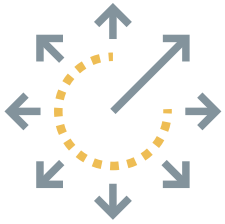
2:00 Chairperson's Remarks
Rajneesh Patil, Senior Director, Risk-Based Monitoring & Analytics, QuintilesIMS

2:05 Co-Presentation: Bridging the Clinical Structure Gap for Holistic RBM: How Fully Integrated Data Empowers Risk Management
David Lacagnina, Technology Evangelist, ThoughtSphere
Andy Lawton, Director and Consultant, Risk Based Approach Ltd.
The introduction of the ICH E6 (R2) addendum means that taking a risk-based approach (RBA) within a sponsor is no longer an option but a requirement. In selecting a system to meet the RBM aspects of a clinical trial, there are four main areas that have to be addressed in the sponsors' system landscape: 1. Risk identification, 2. Risk monitoring, 3. Issue management, and 4. Data integration. This session will focus on data integration. At the earliest stage of the draft guidance from the FDA and EMA on RBM, they identified that the silo'd nature of the sponsor was often a key issue. A silo'd organization structure, is all too often also represented in the data availability. The first requirement is to have access to all the necessary data and the second is to be able to integrate them. So why is data integration so important? Data integration brings to life risks that are not apparent when you examine the data from one source alone, examples shown will include eCRF and audit trail, CTMS, Drug Safety database, etc. As we gain more knowledge about risk then using additional data sources becomes more common.

2:35 Co-Presentation: Evolution of Risk-Based Monitoring Implementation: Implications for Technology, Business Process & Role Development
Mary Arnould, Business Partner, Monitoring Excellence, Regional Clinical Operations, Bristol-Myers Squibb
Esther Huffman, Associate Director, Monitoring Excellence, Bristol-Myers Squibb
This presentation will focus on the lessons learned and best practices resulting from 5 years of RBM implementation. We will look at the relationship between business process and technology, and illustrate how innovation in one area influences the other. The evolution of the CRA role will be discussed including the development of new skill sets to address the evolved expectations, and the creation of new roles to support RBM (Central Monitor, Risk Manager) will also be reviewed. The presentation will also highlight feedback received from sites about RBM, as well as audit results and implications for implementation.

3:05 PANEL DISCUSSION: Addressing the Internal and External Challenges of Implementing RBM
Moderator: Mary Arnould, Business Partner, Monitoring Excellence, Regional Clinical Operations, Bristol-Myers Squibb
Panelists:
Esther Huffman, Associate Director, Monitoring Excellence, Bristol-Myers Squibb
Brian Nugent, Director, PALM, Clinical Operations, Gilead Sciences
Angie Maurer, RN, BSN, MBA, Clinical Operations Consultant, PALM/Clinical Operations, Gilead Sciences
What are the major common barriers and challenges, both internally and externally, to implementing RBM? Panelists discuss some strategies and key concerns that need to be addressed for successful RBM.

3:35 Close of conference. Arrive early to attend Clinical Trial Auditing. See page 4 for details.



2nd Annual

Outsourcing for Clinical Trials

April 25 - 26

Perfecting Quality Partnerships for Clinical Trial Success

TUESDAY, APRIL 25

WITH CROS AND other third-party vendors continuing to take on diverse and numerous clinical trial activities, the need for establishing quality partnerships with pharma and biotech companies continues to grow. Establishing outsourcing needs and relaying that into clear expectations for each partnership from the beginning is key to developing long-term, quality relationships, allowing for efficient and effective clinical trials. Cambridge Healthtech Institute's Second Annual "Outsourcing for Clinical Trials" conference will examine best practices from sponsors, CROs, and vendors on how to optimize such relationships.

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION

Re-Imagining the Clinical Trial Process: Overcoming Challenges to Innovation

Please see page 3 for details.

11:50 Keynote Luncheon Presentation: Leveraging Advanced Data Analytics and mHealth for Next-Gen Trials

Sponsored by medidata

Kyle Given, Strategic Consulting Services Principal, Professional Services, Medidata Solutions

Traditional manual methods that use inefficient ways to monitor data quality often delay the identification of clinical trial risks and do nothing to improve the level of overall data quality. In this presentation, Medidata will focus on how changing this approach using advanced data analytics and mHealth solutions can identify areas of risk much faster and more accurately. This shift will have an important benefit on both sites and patients.

12:35 pm Dessert Break in the Exhibit Hall

OUTSOURCING MODELS AND VENDOR SELECTION STRATEGIES

1:45 Chairperson's Remarks

Thomas P. Lawler III, MBA, PMP, Founder & Managing Partner, BaywynSolutions, LLC

1:50 Transactional Outsourcing: Limited Time, Limited Resources, but the Expectations Remain the Same... Get that Study Outsourced

Craig Coffman, Executive Director, Clinical Business Operations & Outsourcing – Development Operations, Nektar Therapeutics

Strategic partnership models don't work for every company, especially smaller pharma and biotech. This talk will describe how Nektar Therapeutics has utilized the transactional model with a goal of reducing cost and increased speed to startup without sacrificing quality.

2:05 Fit for Purpose Outsourcing – Fulfilling the Varied Needs of Big Pharma

Vatche Kalfayan, Senior Director, Clinical Operations, Pfizer

Large drug development organizations require a broader range of outsourcing solutions that go beyond the Phase 1-3 paradigm. As the need to conduct more efficient trials continues to grow, matching the outsourcing solution to a clinical study requires a two-sided acceptance of needs, challenges, solutions, and a willingness to collaborate. Sponsors and CROs need to remain engaged as both sides pave the path forward to optimal outsourcing of clinical trial services.

2:50 Science Driving Service: A Step-by-Step Collaborative Approach Tailored to Virtual Biotechnology Firms

Lorraine M. Rusch, Ph. D., President, High Point Clinical Trials Center

Elias Sayias, Business Development, High Point Clinical Trials Center

Virtual biotech firms fear finding themselves underserved and unable to find a CRO with the necessary flexibility and responsiveness to meet their needs. Their challenge is not to only to find a service provider, but also the one with the right operational structure and mentality. Dr. Rusch, will present a Case Study and elaborate on HPCTC's "science driving service" principle. Elias will focus on the importance of the "internal champion" in cultivating trust and productive relationships.

3:20 Refreshment Break in the Exhibit Hall

Hear from outsourcing and procurement professionals on key strategies for defining necessary deliverables before selecting your vendors. Ask your questions about determining timelines, key activity needs, and effective communication strategies in order to streamline your outsourcing process.

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4:05 PANEL DISCUSSION: Avoiding the Blame Game: Defining Deliverables before Selecting Your Vendors
Moderator: Craig Coffman, Executive Director, Clinical Business Operations & Outsourcing – Development Operations, Nektar Therapeutics
Panelists:
Vatche Kalfayan, Senior Director, Clinical Operations, Pfizer
Darin Curtiss, PharmD, Vice President, Clinical Development, Trial Runners
The key to selecting an appropriate vendor begins with understanding exactly what is needed from them. This panel will discuss strategies for determining timeline and key activity needs and communicating them to all those involved in sourcing, evaluating, and procuring CRO partners and other vendors.

5:05 Close of Day

5:05 Dinner Short Course Registration

5:30-8:30 Recommended Dinner Short Course*

SC2: How to Implement RBM on a Budget

Please see page 3 for details.

** Separate registration required.*

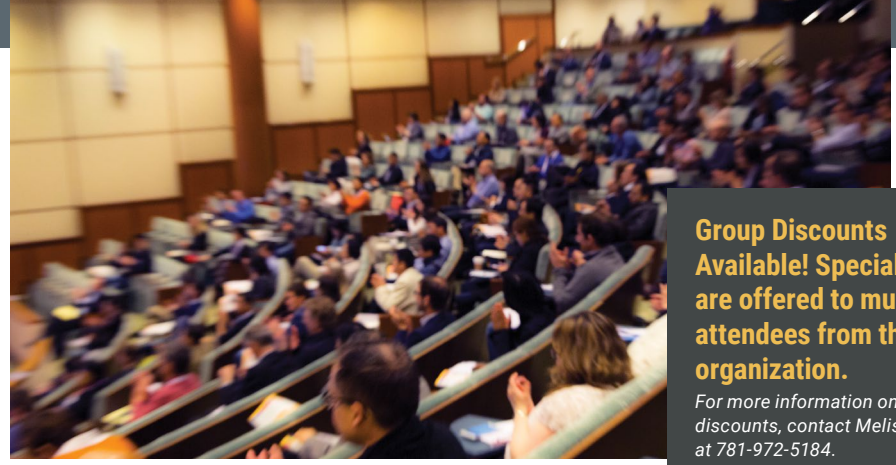
WEDNESDAY, APRIL 26

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

BUDGETING FOR AND CONTRACTING WITH VENDORS AND OUTSOURCED PARTNERS

9:40 Chairperson's Remarks



Group Discounts Available! Special rates are offered to multiple attendees from the same organization.
For more information on group discounts, contact Melissa Dolen at 781-972-5184.

9:45 The Major Compliance Mistake You Are Making and How to Fix It Now
Sponsored by LMK Clinical Research Consulting
Sholeh Ehdaivand, President and CEO, LMK Clinical Research Consulting

10:00 PANEL DISCUSSION: Contracting Strategies for Today's Clinical Trials
Moderator: Thomas P. Lawler III, MBA, PMP, Founder & Managing Partner, BaywynSolutions, LLC
Panelists:
Danielle Hyland, Senior Project Manager, Independent Consultant
David Kim, Vice President, Business Development and Executive Consultant, Celeritas Solutions
Natalia Romashkina-Timanova, Head, Project Management Office, Flex Databases
Traditional contracting strategies have been very "one-size-fits-all," but the changing landscape of outsourcing models has given rise to alternative strategies, such as flexible contracts. This panel will discuss the evolution of business models that allow third-party vendors, CROs, and sponsors to develop custom contracts for modern clinical trials.

11:00 Coffee Break

11:30 Budget Forecasting and Tracking: Teamwork and Transparency
Kenneth Olovich, Chief Financial and Procurement Officer, Chorus
This talk will discuss how the application of budgetary and invoicing models can lead to increased trust. What do sponsors really need to help them manage CRO and trial related expenses? Some budgetary models require more effort to set up than others; when is it worth the investment? The timing of spend and the accurate projection of the same is just as important as the total spend–this talk will discuss finding the balance.

12:00 pm Effective Management of Outsourced Site Contract Negotiation
Danielle M. Boram, Esq, MPA, Clinical Contracts Attorney, Associate Director of Contract Management, Clinical Development, ImmunoGen, Inc.
Efficient site contract negotiation is critical to support important clinical operation milestones around site activation. While the outsourcing model can provide increased flexibility and access to industry expertise, it is necessary to implement strategies to maximize the value of the collaboration. In this talk I will highlight important strategies for increasing the efficiency and effectiveness of outsourcing site contract negotiation.

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

1:15 Session Break

DEVELOPING EFFECTIVE PARTNERSHIPS AND VENDOR RELATIONSHIPS

2:00 Chairperson's Remarks
Danielle Hyland, Senior Project Manager, Independent Consultant

2:05 All About the Base: Developing a Solid Foundation with Our CRO Partners
Barbara Skinn, Ph.D., Operations Portfolio Lead, Global Clinical Operations, Bristol-Myers Squibb
Organizations talk about partnerships and the importance to success. Few teams take the time to consider the qualities and behaviors that develop and grow a strong and reliable partnership. This

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presentation will share team survey results about a study's partnering, concerns, and strengths. Actions to enhance the partnership will also be presented.

2:35 Establishing a Team Atmosphere for Creative Problem Solving
Thomas P. Lawler III, MBA, PMP, Founder & Managing Partner, BaywynSolutions, LLC
Although we always plan for success, drug development projects are always a series of problems and solutions. When the going gets tough, teams often find themselves distracted from moving ahead, and instead, they start circling their wagons and looking for a person/partner to blame. This talk will look at how to create an atmosphere of trust within our teams to keep the focus on the end game as opposed to playing the blame game.

3:05 The Importance of Creating Effective Partnership Frameworks When Outsourcing Investigator Site Payments
Débora Araujo, Associate Director, Clinical Contracting Services, Boehringer Ingelheim Pharmaceuticals, Inc.
Whether fully outsourcing a trial or only the investigator site payment piece, many sponsors fail to see the importance of constructing an effective framework early on for a successful partnership with CROs and site payment vendors. Investigator site payments should not be viewed as simply a line item and cost within CRO and vendor contracts which sponsors do not need to think about but rather they should be seen as a direct extension of the sponsor's brand, ultimately affecting the relationship and trust with investigator sites.

3:35 Close of Conference. Arrive early to attend Patient Recruitment & Site Selection.

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TUESDAY, APRIL 25

TECHNOLOGY AND DATA are at the forefront in 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.

10:00 am Conference Registration

10:45 PLENARY KEYNOTE SESSION

Re-Imagining the Clinical Trial Process: Overcoming Challenges to Innovation

Please see page 3 for details.

11:50 Keynote Luncheon Presentation: Leveraging Advanced Data Analytics and mHealth for Next-Gen Trials

Sponsored by medidata

Kyle Given, Strategic Consulting Services Principal, Professional Services, Medidata Solutions

Traditional manual methods that use inefficient ways to monitor data quality often delay the identification of clinical trial risks and do nothing to improve the level of overall data quality. In this presentation, Medidata will focus on how changing this approach using advanced data analytics and mHealth solutions can identify areas of risk much faster and more accurately. This shift will have an important benefit on both sites and patients.

12:35 pm Dessert Break in the Exhibit Hall

TECH TOOLS AND THE FUTURE OF CLINICAL TRIALS

1:45 Chairperson's Remarks

Karim Damji, Senior Vice President, Products, Solutions & Marketing, Saama Technologies

1:50 Intelligent Automation & Robotics in Clinical Development: An AbbVie Case Study

Aman Thukral, Assistant Director, Strategy & Innovation, Clinical Data Sciences, AbbVie

AbbVie piloted robotics in one of the clinical development functions. Currently, the data sciences group creates accounts for investigators and site staff in the Interactive Response Technology (IRT) system by entering information manually using the admin module. The process is labour-intensive, time-consuming, and error-prone. To mitigate these challenges, a robotics software was deployed that used human credentials and worked on the front end admin module to create accounts. The robot also ensured the training and other requirements before access was provided.

2:20 Remote Trials: Moving beyond the Concept

Hassan Kadhim, Business Consultant, IT RDM, Boehringer Ingelheim

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

2:50 pm RBM And The Role Of New Age Analytics In Clinical Trial Quality

Rajneesh_PatilRajneesh Patil, Senior Director, Risk-Based Monitoring & Analytics, QuintilesIMS

RBM models rely significantly on data and analytics to assess risks to site performance, subject safety and data quality. However, the early generations of these models focus on single parameters to identify issues, which, out of context, can often

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lead to false positives/white noise. The new age analytics models can differentiate the relative risk between sites and indicate which sites or subjects are at higher risk. In this session we will explore of few of our implementations as case studies.

3:20 Refreshment Break in the Exhibit Hall

4:05 PANEL DISCUSSION: What Do Clinical Trials Look Like in 2020?
Hassan Kadhim, Business Consultant, IT RDM, Boehringer Ingelheim
John Reites, Chief Product Officer & Partner, THREAD
The panel will discuss existing technologies (apps, data viz tools, wearables, sensors, etc.) and analytics and where they may take us for clinical trials in the future. These technologies will help address the challenge of patient recruitment, clinical trial onboarding, remote clinical trial visits and more.

5:05 Close of Day

5:05 Dinner Short Course Registration

5:30 - 8:30 Recommended Dinner Short Course*

SC3: Mobile Health and Virtual Studies: How to Accelerate Their Use and Adoption in Your Company

Please see page 3 for details.

** Separate registration required.*

WEDNESDAY, APRIL 26

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

WEARABLES, SENSORS, DIGITAL BIOMARKERS, AND MHEALTH FOR CLINICAL TRIALS

9:40 Chairperson's Remarks
Manoj Vig, Enterprise Architect Big Data, Information Technology, Shire Pharmaceuticals

9:45 Validating Digital Tech for Clinical Trials
Georgia Mitsi, Senior Director, Search Evaluation, Digital Healthcare, Sunovion

10:15 Are We Ready to Use Wearable Sensors in Clinical Studies?
Bhaskar Dutta, Principal Biomedical Informatics Scientist, AstraZeneca
Wearable sensor technology, often coupled with cell-phone applications, brings the promise of improving management of chronic diseases, identification of adverse effects in clinical trials, use of new efficacy endpoints, gaining understandings of diseases and patient behaviors. Fulfillment of these promises and future adoption of wearable sensors in clinical studies will depend on several factors, such as quality of the sensor data, patient engagement, cost, and regulatory requirements. Currently, several wearable sensors are commercially available, hence, requiring a comprehensive review of the sensors based on the above-mentioned parameters. We carried out a study to compare wearable sensors in healthy volunteers and implemented a comprehensive data analysis strategy. Findings of this study have paved the way for improved design of future studies involving wearable sensors.

10:45 Refocusing on Risk Mitigation in Starting Clinical Trials
Sponsored by goBalto
Robert Wynden, Ph.D., Vice President, Technology & Engineering, Product Development, goBalto
Risk-based challenges are escalating as clinical trials become more global and complex. A focus on study startup, including best practices for the identification and mitigation of potential risks before they occur is essential to stem the tide of study delays and cost overruns, often leading to rescue studies.

11:00 Coffee Break

11:30 PANEL DISCUSSION: Considerations for Using Wearables/mHealth to Accelerate Clinical Trials
Georgia Mitsi, Senior Director, Search Evaluation, Digital Healthcare, Sunovion
Bhaskar Dutta, Principal Biomedical Informatics Scientist, AstraZeneca
Joe Dustin, Principal of mHealth, Medidata
As pharma and biotech companies increasingly look towards new digital tools to help monitor patients during clinical trials, there are many considerations that need to be taken into account before their selection and use. The panel will cover such topics as commercial vs. medical grade wearables and sensors, regulatory concerns and data quality.

12:30 pm Luncheon Presentation *(Sponsored Opportunity Available)*

1:15 Session Break

DIGITAL TECHNOLOGY AND DATA MOVING CLINICAL TRIALS TO A PATIENT-CENTERED MODEL

2:00 Chairperson's Remarks
Manoj Vig, Enterprise Architect Big Data, Information Technology, Shire Pharmaceuticals

Wearables, sensors and mHealth hold many promises for clinical trials, but what are some key considerations for pharma before using these new technologies for clinical trials? Hear from those already in the trenches using these new digital tech weigh options of commercial vs. medical grade wearables/sensors, discuss regulatory concerns and deal with data quantity and quality.

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2:05 Co-Presentation: Connecting Clinical Trials, Patients and Physicians with the Help of Digital Technologies and Big Data
Manoj Vig, Enterprise Architect Big Data, Information Technology, Shire Pharmaceuticals
Venki Balakrishnan, Analytics Solution Architect, Shire Pharmaceuticals
This talk will focus on emerging trends in Mobility, Big Data, distributed search, connected devices and machine learning that can be applied to take relevant trials to patients and their physicians instead of continuing with the traditional model that is focused on finding patients based on historical metrics. We will discuss how mobile health applications are not only improving the patient-physician relationship and overall outcome of a treatment but how they are also shifting the entire health eco-system from a "research focused" model to a "patient focused" model. Mobile apps of various nature will be playing an enormous role in taking healthcare models to the next level in years to come.

3:05 Complexity in Clinical Trial Design and Conversion to Commercial Success
Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC
Clinical trials focus on the need to achieve clinical success and FDA approval, but this is not a guarantee of commercial success, only the first step. While real world clinical practice and real world patients may not be included in trial design, a lack of understanding the complexities that they present can lead to success at the trial level but failure of the product. Our modeling enables better decision making as to what to include and exclude in trial design and patient recruitment.

3:35 Close of Conference. Arrive early to attend Big Data for Clinical Trials. See page 8 for details.

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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 17, 2017 and On-Site	$2,749	$1,349

BASIC PRICING *(Includes access to one conference, excludes short courses)*

Standard Registration after March 17, 2017 and On-Site	$1,899	$899

CONFERENCES

APRIL 24 – 25	APRIL 25 – 26
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DINNER SHORT COURSES

One Course	$599	$349
Two Courses	$899	$599

APRIL 24 | 6:00 - 9:00 PM	APRIL 25 | 5:30 - 8:30 PM	APRIL 25 | 5:30 - 8:30 PM
SC1: A New Era in Patient Recruitment: Understanding Social and Digital Media's Power to Accelerate Your Clinical Trial	~~SC2: How to Implement RBM on a Budget~~	SC3: Mobile Health and Virtual Studies: How to Accelerate Their Use and Adoption in Your Company

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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.

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