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CAMBRIDGE HEALTHTECH INSTITUTE'S FOURTH ANNUAL

CLINICAL TRIAL OVERSIGHT SUMMIT

Optimizing Data Quality, Efficiency, Partnerships, and Risk Management

June 1-3, 2015
Omni Parker House
Boston, MA

Bringing together 250+ highly targeted decision makers

Featuring Presentations by:

Alexion Pharmaceuticals
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and many more!

JUNE 1 - 2

MASTERING CLINICAL TRIAL MONITORING

VENDOR MANAGEMENT IN CLINICAL TRIALS

JUNE 2 - 3

CLINICAL AUDITING FORUM

CLINICAL PROJECT MANAGEMENT FORUM

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ClinicalTrialSummit.com

SUMMIT AT-A-GLANCE

Monday AM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
Monday PM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials

Dinner Short Course 1* Facilitating Investigative Sites' Operational Efficiency: Challenges, Tools, and Methods to Enhance the Clinical Research Enterprise

Tuesday PM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
Tuesday PM	Clinical Auditing Forum	Clinical Project Management Forum

Dinner Short Course 2* Quality by Design in Clinical Research: Is This Only for the Protocol?

Wednesday AM	Clinical Auditing Forum	Clinical Project Management Forum
Wednesday PM	Clinical Auditing Forum	Clinical Project Management Forum

**Separate Registration Required*

ABOUT THE SUMMIT:

Cambridge Healthtech Institute's Fourth Annual Clinical Trial Oversight Summit will feature four co-located conferences covering best practices and recent trends relevant to clinical research monitoring, auditing, clinical quality assurance, site management, and vendor oversight. This four-day summit will include presentations from experts, case studies, interactive breakout discussion groups, workshops, and networking opportunities. Themes throughout will include risk-based approaches to clinical trial management, implementing quality systems-based approaches to GCP compliance, ensuring reliable study data, responding to the evolving regulatory landscape, and preparing sites and clinical research partners for inspection-readiness.

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 the Main Agenda!*
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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!

Invitation-Only VIP Dinner/Hospitality Suite
Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives i.e.:

- Purely social
- Focus group
- Reception style
- Plated dinner with specific conversation focus

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

Additional branding and sponsorship opportunities available!

Looking for additional ways to drive leads to your sales team?
CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program!

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

For sponsorship and exhibit information, please contact:

Ilana Quigley
Sr. Business Development Manager
781-972-5457 | iquigley@healthtech.com

HOTEL & TRAVEL INFORMATION

Conference Hotel:

Omni Parker House
60 School St.
Boston, MA 02108
Phone: 617-227-8600
Website: omnihotels.com/hotels/boston-parker-house

Discounted Room Rate: $269 s/d
Discounted Room Rate Cut-off Date: May 1, 2015

Please visit www.clinicaltrialsummit.com or call the hotel directly to reserve your sleeping accommodation. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted at the discretion of the hotel. Rooms are limited, so book early.

Flight and Rental Discounts are Available:
For details, visit www.clinicaltrialsummit.com and click on the hotel & travel button.

DINNER SHORT COURSE

Tuesday, June 2, 6:00-8:30 pm

(SC2) Quality by Design in Clinical Research: Is This Only for the Protocol?

Liz Wool, RN, BSN, CCRA, CMT, President and CEO, QD-Quality and Training Solutions, Inc.

In the past few years, Quality by Design (QbD) for clinical trials has been communicated and talked about for protocol development and execution. However, translating this QbD approach into "building in quality for the business," that is increasingly expected of the industry by regulatory agencies, is rarely shared for the "how do I do this?" because organizations state "I believe we are doing this already." This workshop will de-code and translate QbD and quality for the research enterprise with examples and interactive activities that will solidify the concepts and framework presented for use within any organization. We will discuss:

- Critical first step: defining quality
- QbD: defined and simplified
- What are QbD and Quality Management Systems (QMS)? How do they relate to each other? How do I know if my organization "has these in place"?
- What are "critical to quality" and "critical control points" in QbD, and why are they important?
- Business practices to QbD principles and methods, and approaches to impart QbD where needed
- Going beyond plans and checklists for quality
- Who is involved and responsible for review?
- Strategies for effective implementation
- Effective training of personnel

Separate registration is required.

Sixth Annual

MASTERING CLINICAL TRIAL MONITORING

Risk-Based Monitoring for Data Quality, Clinical Trial Performance, and Compliance

JUNE 1-2

Changing FDA expectations, risk-based monitoring, and ever-growing demands for cost efficiency are fueling dramatic developments in the world of clinical research. Clinical trial monitors are on the front line of these changes, and must adapt to the world of centralized risk-based monitoring, quality systems-based approaches, and sophisticated technologies designed to improve outcomes. This conference will address these issues. Participants can expect to hear from thought leaders who will share their insights into addressing these challenges and exploiting these opportunities via presentations, case studies, and hands-on activities.

MONDAY, JUNE 1

7:00 am Registration and Morning Coffee

8:00 Welcome & Chairperson's Opening Remarks

8:15 Risk-Based Monitoring Industry Survey Results

Linda B. Sullivan, Co-Founder & President, Metrics Champion Consortium (MCC)

In this session, we will discuss results from the Metrics Champion Consortium (MCC) surveying regarding risk-based monitoring, and answer questions, such as:

- What models are being piloted/adopted?
- Why are they adopting them?
- What metrics are they using as risk signals?
- How has the RBM landscape changed since the 2008 CTTI survey?

INCORPORATING QRM AND QBD INTO RBM

Case Study

8:50 A Holistic Approach to Quality Risk Management

Angie Maurer, BSN, MBA, CCRA – Clinical Operations Consultant, Gilead Sciences, Inc.

Brian Nugent, BSN, DC – Associate Director, Clinical Operations, Gilead Sciences, Inc.

Siloing in organizations causes individuals to not understand the full processes and interdependencies of their operations. This is exactly why a holistic approach to risk management is important. Much attention has been paid to the concepts and day-to-day tools required to carry out Quality by Design (QbD) and QRM activities, however, many companies have not yet designed a holistic approach based upon the establishment of a unified quality and risk management framework within Clinical Operations. In this session, we will discuss:

- Gilead's quality framework and sub-frameworks that address risk management and quality control
- The role of risk management training as a foundational element of risk management
- The role of risk management tools and Risk-Based Monitoring (RBM) within Gilead's QRM framework
- The role of continuous improvement within the risk management system
- Quality and risk management implementation strategies and lessons learned

9:25 Combining Machine & Human Intelligence to Successfully Integrate Clinical Research Data

Sponsored by tamr

Timothy Danford, Ph.D., Field Engineer, Tamr Inc.

Multiple Clinical Research data sources must be integrated and unified to support biomedical analysis and decisions. However the standard, manual approaches to data curation are unable to scale to meet the growing size and complexity of this data. This talk will discuss new methods in data integration, combining the power and speed of machine learning with the accuracy of human expertise.

9:55 Networking Coffee Break and Exhibit Viewing

10:25 Quality by Design: A Lean Six Sigma Approach to Risk-Based Monitoring

Erika Stevens, MA, Senior Manager, Healthcare Advisory Practice, Ernst & Young, LLP

M. Peggy Fay, Ph.D., RN, CCRC, CRA, Director, Global Clinical Monitoring, Medtronic Clinical Operations, Medtronic, Inc.

Currently, no formal process or methodology exists to aid in identification of risk factors impacting monitoring practices. Furthermore, there is great variation in risk identification, analysis, and mitigation strategies throughout the industry. This results in extra manual work and duplication of effort, which in turn increase customer cost variation and create crisis management situations. This session will demonstrate traditional project management methodologies to create and manage a compliant CAPA monitoring system within the QMS. Conventional project management elements will be defined as they relate to the CAPA monitoring system. Concepts such as quality control monitoring procedures, root cause analysis, change controls, resolution of CAPA, and supporting elements such as Scope Creep, Program Evaluation and Review Technique (PERT), Critical Path Analysis, and Gantt Charts will be discussed and mapped back to the project management element of the CAPA system.

11:00 Interactive Roundtable Discussions

11:45 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Lunch on Your Own

SITE QUALITY AND INSPECTION READINESS

1:00 pm Leveraging Inspection Focus Areas to Improve Site Quality

Jessica Masarek, Quality Assurance Consultant, Muse Clinical

In this session, we will explore key inspection focus areas and the practical application of ALCOA so attendees may apply this knowledge to site inspection readiness activities. Monitors will be challenged to consider ways in which they can employ these knowledge areas to improve monitoring and compliance and to better ally with their sites. We will share current examples from the field, explore common findings, and discuss best practices. Important questions will be addressed regarding documentation, preventing audit findings, and inspection readiness. We will also discuss practical approaches to ally with sites in their efforts to identify risk areas and increase compliance.

1:45 Preparing Your Clinical Trial Sites for FDA Inspections

Stuart Halasz, Associate Director, Clinical Quality Management, Merck Research Laboratories

This presentation takes a light-hearted empirical approach to using the BIMO guidance manual and common sense in helping CRAs and Project Managers prepare their clinical research sites for an FDA inspection. It is intended for those new to this activity and includes real-life examples of situations encountered at clinical sites during inspection preparation visits. Participants will take away practical ideas that can be applied immediately.

Case Study

2:30 The Challenges of Conducting Multicenter, Multicultural, and Multilingual Clinical Trials

Diarmuid De Faoite, Communication & Education Manager, AO Documentation and Publishing Foundation, AO Foundation

Working globally creates its own unique set of problems, and your speaker will consider them from multicenter, multicultural, and multilingual perspectives. The impact of culture on a study's success is a real issue, particularly when patient reported outcomes form part of the trial. A trial which is conducted globally requires the use of local language material, but this is an element fraught with the possibility of mistranslation and misunderstanding. Going beyond the available literature on the subject, your presenters will share never-heard-before, first-hand global trial experiences at their academic research organization. Attendees will be sensitized to the many factors which may (negatively) impact on the success of clinical investigations conducted in different countries or cultures. Finally, we will discuss the composition of a research team working in this environment, and examine how to motivate them.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Networking Refreshment Break and Exhibit Viewing

3:45 Engaging with Site Personnel during the Monitoring Visit: Identifying Changes, Retraining Needs, and Opportunities for Improved Research Practices

Megan Jung, Regional CRA Manager, Clinical Studies, BIOTRONIK

Too often monitors conduct the visit without holding meaningful conversations with the clinical research coordinator and principle investigator. However, monitors learn most at the site by having direct conversations about the study conduct. Monitors can identify changes in study staff by reviewing the DOA and IRB documents directly with the CRC. Monitors can evaluate the site's informed consent practices with the CRC. Monitors can review site visits and conduct to confirm that the processes are in accordance with the protocol. Finally, monitors can identify non-compliance through conversations with the site staff. This session will demonstrate the value of engaging site staff to identify areas that need improvement in the site's research practices that administrative document and subject records review do not convey.

Case Study

4:20 A Deep Dive into the Value of GCP Training: A Case Study

Rebecca Carew, Senior Manager – Process Management, Purdue Pharma L.P.

As a sponsor, we have a responsibility to train our investigators. This includes the fundamental training on Good Clinical Practices (GCPs), one component of the overall investigator training curriculum. This case study will discuss the process for assessing investigators for various levels of GCP training needs, assessing the investigator's application of the training, determining when additional oversight and monitoring activities are required, reviewing the trends identified through the training assessments and the process and training improvements resulting from this analysis. The learning didn't stop after the formal training was completed. The training served to be a good use of time and value to the investigator and the sponsor.

4:55 Reception and Exhibit Viewing

(Sponsorship Opportunity Available)

5:45 Short Course Registration

5:55 Close of Day One

TUESDAY, JUNE 2

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

8:15 Chairperson's Opening Remarks

SITE SELECTION AND ENGAGEMENT

Case Study

8:20 Use of Risk Based Metrics in the Selection of Clinical Study Sites: A Sponsor Perspective

Eddy Lyons, CCRP, Senior Clinical Research Associate, Clinical Studies Department, Biotronik, Inc.

Sponsors of clinical studies have several FDA-mandated objectives for the conduct of clinical trials, namely timely enrollment and a high level of compliance. Your speaker will discuss key attributes to consider during the selection of clinical sites from a sponsor's perspective. Such elements as target patient population, competing studies, prior compliance history, experience and prior training of key personnel, workload, research program infrastructure, contracting and reimbursement timelines, and adequate study resources, among others. Your speaker will also present a site grading system using these metrics to target the best sites capable of contributing significantly to enrollment goals and providing high quality data.

Case Study

8:55 Dancing with the Stars: Engaging Academic Researchers in Industry-Sponsored Studies

Carol Breland, MPH, Research Recruitment Director, NC TraCS Institute, UNC Chapel Hill

Academic researchers are highly sought after for industry trials as they have extensive experience and expertise in their therapeutic area. However, getting a timely response to even a feasibility questionnaire can often be a frustrating experience for the project team! In this talk, you will learn more about the motivations and barriers that academic principal investigators experience, from personal goals to internal processes and approvals. You will hear best practices for initiating and building trusting relationships and get tips for improving your study start-up timelines. A case study will be presented on how an innovative listening approach has helped build a more productive partnership between an academic medical center and a CRO.

9:15 Sponsored Presentation *(Opportunity Available)*

9:30 Networking Coffee Break and Exhibit Viewing

10:00 Site Relationship Management: Keys to Successful Site Identification, Selection, and Ongoing Oversight

Linda Tedder, Director, US Clinical Project Management, Clinical Operations, DePuy Synthes

One of the key points for sponsors to consider during any clinical study is the successful identification -and selection of "good" clinical sites. Throughout the study, site management is key to ensure enrollment goals are met, continued adherence to the protocol, ongoing regulatory compliance, and overall subject retention. Problems will arise in any clinical study, and how sponsors manage the sites can impact whether a clinical study is successful or not. In this session, your speaker will offer tips, tools, and guidance on identifying and selecting clinical sites, and then managing clinical sites throughout the study. Using site relationship management techniques, your instructor will provide insights into improving the performance and relationships with so-called "difficult" sites, and getting those partnerships back on track.

Case Study

10:35 Study Health Checks: A Compilation of Site-Specific Data Used to Assess Site and Study Trends and Potential Risks

Rosanne Petros, PMP, Associate Director, Clinical Research, Clinical Research Manager US Global Clinical Trial Operations, The Americas, Merck Research Laboratories

11:10 Building Quality by Design (QbD) and Quality Risk Management (QRM) Systems into Clinical Site Operations: An Academic Clinical Research Site Perspective

Marina Malikova, Ph.D., Executive Director, Surgical Translational Research, Operations, Compliance, & Surgery, Boston University

In this competitive global market technology is vastly changing the way the industry conducts clinical trials. The research industry continues to explore how innovative systems and processes can improve quality while reducing cost. The FDA in September of 2013 published guidance on electronic source data in an effort to modernize clinical investigations. However, electronic regulatory binders remain underutilized and represent a cost savings to clinical investigators, CROs, and sponsors. Successfully implementing electronic regulatory binders while maintaining compliance takes expertise from the investigative site, the Clinical Research Associate (CRA), and the Information Technology (IT) team. This presentation will discuss how to design and implement the system with appropriate security measures and the benefits and challenges of using the system.

11:45 Electronic Data Capture: Tablets vs. Desktop. A Sponsor to Site Implementation Perspective

Lynne Becker, MSPH, National Project Manager, Weight Management Center Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina

When you introduce a new medium (tablets) for the electronic data collection, you may open the proverbial Pandora's Box when it comes time to monitor. There are no standardized regulations across commercial or academic regulatory agencies which govern your research site, nor are the IP access points similar from site to site. Other concerns are the quality of optical character recognition (OCR) and optical character mark recognition (OMR); hurdles to minimize site frustration for not only the coordinator, but the PI and the subjects; and the cost of the tablets. If you are considering implementing the full use of tablet technology you must understand and embrace the loss of paper trail during the monitoring process. This presentation will correlate the current best practices of monitoring a paper-based system with a tablet based system.

12:20 pm Close of Conference

Fourth Annual

VENDOR MANAGEMENT IN CLINICAL TRIALS

Ensuring Data Quality Through Effective Selection, Auditing, and Oversight

JUNE 1-2

As the trend toward outsourcing clinical research continues to grow, those charged with vendor qualification, selection, contracting, and ongoing oversight must be ready to meet these expectations. Most importantly, they must consider quality systems-based approaches, risk mitigation and management, and effective tools and techniques for ensuring successful third party vendor partnerships. Thought-leaders will address important themes, including quality systems-based vendor management throughout the lifecycle, risk-based auditing of third party vendors, and addressing quality issues to ensure compliance.

MONDAY, JUNE 1

7:00 am Registration and Morning Coffee

8:00 Welcome & Chairperson's Opening Remarks

8:15 Clinical Trial Vendor Selection: Selecting the Right CRO Strategic Partner

Jennifer Gaskin, CCRP, Operations Director, Clinical Operations, Alliance for Clinical Trials in Oncology (Alliance Foundation Trials, LLC)

Selecting your strategic partner CRO is a daunting task and a large commitment for any organization. The CRO options range from the large, publicly owned companies with a comprehensive menu of services and global resources to privately owned niche providers specializing in specific therapeutic areas. CRO offerings and budgets vary significantly which impedes the ability to do direct comparisons. This session discusses the steps and best practices in the process of selecting the correct CRO partnerships for your organization.

8:50 Re-Engineering the RFP and Bid Defense Meeting Manage Risk and Quality

Liz Wool, RN, BSN, CCRA, CMT, President and CEO, QD-Quality and Training Solutions, Inc.

This session reviews the re-engineering of the RFP and bid-defense meeting to target identification of risks for the potential services to be awarded to your CRO, vendor, or supplier, whether a preferred partnership model, a "company approved list," or based solely on project needs. We will build upon the gaps identified in the selection scoring tool/capabilities assessment tool of preferred provider models to drive the Bid Defense Meeting agenda. The selection activity is the opportune time for assessment of capabilities and risks associated with business methods, processes, services, people, and technology. This new approach also gives the provider the opportunity to communicate their ability and willingness to adjust their approach and methods beyond the RFP, thus beginning a dialogue regarding management and quality oversight methods early on in the partnership, with known risks and gaps identified by stakeholders. This improved process drives business efficiencies and cost savings now, rather than later during trial execution, identifying impact on protocol and data integrity if performance is inadequate.

9:25 Can Best Practices from Outsourcing in Other Industries be Applied to Clinical Development Outsourcing – and if so, How?

Sponsored by vantage partners

Ashley Hatcher, Senior Consultant, Vantage Partners

Alliances and "strategic partnerships (between large pharma companies, small bio-techs, and academic institutions) are increasingly pervasive. But what about "alliances" between bio-pharma companies and CROs? Are true partnerships with CROs (and other suppliers) really possible? What are the risks and benefits of moving beyond a traditional customer-vendor paradigm? In this interactive session, we will explore these and other issues using a number of case studies, and will also discuss how to adapt best practices for strategic outsourcing from other industries to the clinical development context.

9:55 Networking Coffee Break and Exhibit Viewing

THIRD PARTY COMMUNICATION AND COLLABORATION

10:25 Establishing a Strong Communication Channel with Your Third Party Vendor

Nicole Yingst, MBA, CCRP, Patient Recruitment Specialist II, PAREXEL International

Successful vendor relationships have many components, but a key factor is a solid communication pathway. Transparency, upfront goals, and ongoing, organized touch points are vital in establishing and evolving a strong partnership that will lead to a successful project and long-term business. This is seen as a benefit for your company and your clients, as they will reap the benefits of the efficiencies and discounts generally established through longstanding vendor relationships. Attendees will be presented with crucial steps in developing a solid communication pathway with vendors, learn from real-world scenarios, and apply key concepts to their own practices, customizing them to make their own successful pathway in working with their vendors.

11:00 Interactive Roundtable Discussions

11:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:00 pm How Will Risk-Based Monitoring Change Your Relationship with Your CROs?

Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.

In recent months, the Amgen Oversight Team was asked to add a new vendor to our Functional Service Provider (FSP) model. In the following items, your speaker will discuss some of the ways in which her team managed the site transitions and successfully balanced their FSP model across vendors:

- Discussion on managing two vendors in an FSP model; collaboration between vendors
- Proactively managing risk-based on triggers and red flags
- Multi-layer approach to Quality Oversight and Supplier Governance
- Maintaining complete documentation in the TMF
- Ongoing training with the new vendor; i.e., systems, processes, documentation
- Lessons learned from transitioning sites from one vendor to another

1:45 Effective CRO Oversight in a Strategic Outsourcing Model

Joe Pollarine, Director Quality Monitoring & Compliance - Bioresearch Q&C, Janssen R&D – Springhouse US

Outsourcing to a CRO provides opportunities to pharmaceutical companies to delegate a significant part of the trial activities to an external organization. However, the sponsor organization ultimately remains accountable for the integrity of a clinical trial, and therefore, needs to keep oversight and control on the safety of patients and the integrity and credibility of data while managing timelines and budget. The presentation provides an example of how a sponsor can maximize a successful outcome from outsourcing by:

- Establishing a partnership with a preferred CRO provider
- Allowing the CRO to run trials using their own processes and way of working as much as possible
- Creating efficiencies by eliminating redundant activities
- Keeping effective and efficient oversight to position a trial for regulatory filing and marketing approval

Case Study

2:30 Lessons Learned in Developing a Metrics Program to Monitor the TMF at a Vendor

Vinita Leslie, M.A., Director, Trial Master File Process Owner, Knowledge, Records & Information Strategies, Biogen Idec

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Networking Refreshment Break and Exhibit Viewing

3:45 Successful Collaboration and Merging of Multiple Vendors within an FSP

Erika Vento, MBA, Clinical Trials Oversight Manager (CTOM), Amgen, Inc.
Erik Olson, MPH, Clinical Trials Oversight Manager (CTOM), Amgen, Inc.

Monitoring in clinical trials has in the past always been a "routine machine" that sent monitors with a regular frequency to sites to do mostly Source Data Verification (SDV). Data from CSDD Tufts University show that the burden on CRAs grows every year and this is only one reason among many that the classic approach to monitoring does not work anymore. Risk-based management of clinical trials is the methodology that is currently recommended by regulators, however it has some direct consequences on monitoring and clinical trial oversight. With Risk-Based Monitoring (RBM), visits to sites will not include SDV anymore, with some exceptions, and the Monitor has to become rather a coach or mentor to the sites as it was originally intended. This change, however, brings another consequence with it: the CRA job will mostly not be an entry job anymore. CRAs will have to be more senior to be able to talk to the investigators on the same level. When considering all this, what consequences will this have on your relationship with the CROs? This presentation will provide answers.

MANAGING OUTSOURCING QUALITY

Case Study

4:20 Managing Quality in an FSP Monitoring Model

Erik Olson, MPH, Clinical Trials Oversight Manager (CTOM), Amgen Inc.

Amgen has been operating in an FSP (Functional Service Provider) Clinical Monitoring Model for over seven years now, and uses a robust Clinical Monitoring Quality Oversight Plan to ensure that quality is measured consistently across regions globally, and across FSP providers. Having multiple FSP providers globally, with each following Amgen SOPs and using Amgen systems, has contributed to the success of the FSP model implementation. We have refined both the metrics we use to check monitoring quality on an ongoing basis, and now have a defined and transparent, collaborative process to report, monitor and manage both serious monitoring and serious site quality issues from issue identification through resolution.

4:55 Reception and Exhibit Viewing *(Sponsorship Opportunity Available)*

5:45 Short Course Registration

5:55 Close of Day One

TUESDAY, JUNE 2

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

8:15 Chairperson's Opening Remarks

IMPLEMENTING METRICS

8:20 Adopting Standardized Time, Quality, and Efficiency Performance Metrics Across Your Vendors

Linda B. Sullivan, Co-Founder & President, Metrics Champion Consortium (MCC)

In this session, we will present data from the Metrics Champion Consortium (MCC) industry update, and address key areas related to vendor management, such as:

- Utilizing metrics to assess your vendor relationships
- Metric updates to support quality-by-design approaches
- New performance metrics from emerging "e" system vendors (e.g., eCOA, eTMF)

8:55 Using Performance Metrics to Manage Vendors in Clinical Trials

Michael Howley PA-C, Ph.D., Physician Assistant – Certified Faculty Coordinator, MBA Healthcare Concentration, Associate Clinical Professor, Department of Marketing, LeBow College of Business, Drexel University

Sponsors of clinical trials understand their responsibility to oversee and manage their vendors. They are often frustrated, however, by metrics that do not provide adequate oversight of their trials until after the trial is completed. In this session, your speaker will show you how to select scientific performance metrics - or to develop your own measures - that will be valid and reliable. Attendees of this session will be able to provide scientific oversight and management of their clinical trials as they unfold.

9:15 Sponsored Presentation *(Opportunity Available)*

9:30 Networking Coffee Break and Exhibit Viewing

10:00 Using Warning Letters to Prepare for BIMO Inspections

Valerie Rosemond, Quality Assurance, Johnson & Johnson Vision Care

A Bioresearch Monitoring Inspection from the FDA may delay a product's entry to the market by an average of 14 months and cause the company significant market share to their stakeholders. Companies that receive these types of inspection letters cause additional delays in responding to the regulatory agency. Current trends indicate errors occur despite resources devoted to monitoring, QA audits, and other surveillance or quality activities. Systematic errors can render trial data unreliable and may be unrelated to activities at the clinical investigator sites. The need for proactive risk-based activities is crucial, as is training subject matter experts and researchers for inspection readiness. In this session, we will identify and describe the required areas of specialization and the associated general competencies for investigators in these areas of specialization.

Case Study

10:35 Managing Risks During Project Transition: Person to Person, Team to Team, Sponsor to Vendor, and Vendor to Vendor

Donelle Bussom, RN, MSN, Senior Director, Medical and Safety Services, ICON Clinical Research

Whether you are a pharmaceutical company, CRO, or other service-providing vendor, in the small world of pharmaceutical research, chances are that you have faced some sort of project transition. Project transition comes in many forms: transitioning internally from person to person, team to team, or even vendor to vendor (including transitioning internal projects to external vendors). While there are many reasons for transition, the main reasons typically involve issues around quality, resources, finance, or expertise. Even though we face these situations on a daily basis, transitioning projects is a very risky endeavor for all parties. In this presentation, we will review how to best plan transitions to reduce risks and ensure a smooth handover process through a step-wise approach and case study analysis.

11:10 Sponsor Oversight: The Importance of Auditing in Vendor Management

Beverly Brown, Manager, Global Regulatory Quality, Allergan

11:45 am Close of Conference

6:00 - 8:30 pm SHORT COURSE: (SC2) Quality by Design in Clinical Research: Is This Only for the Protocol?

(see page 2 for additional information)

Fifth Annual

CLINICAL AUDITING FORUM

Quality Management Systems and Risk Mitigation Strategies for Internal Systems and External Partners

JUNE 2-3

Risk-based principles and quality management systems are the new reality of clinical auditing. Building on their foundation of traditional auditing techniques, auditors must now expand and adapt their skills to be effective in this new environment. The forum is designed to help auditors meet these challenges head on, with the goal of strengthening auditing programs and ensuring compliance with risk-based techniques.

TUESDAY, JUNE 2

12:00 pm Conference Registration

1:20 Welcome & Chairperson's Opening Remarks

RISK-BASED AUDITING

1:30 Implementing Risk-Based Auditing

Dirk Gille, Vice President, Head Bioresearch QA, Janssen R&D, Belgium

To ensure patients in high medical need continue to have access to affordable drugs, companies and authorities are looking at means to decrease the cost of clinical trials while still maintaining oversight on patient safety and integrity, and data credibility. A risk-based approach has been encouraged by both EMA and FDA as a means to deploy resources where it matters most based on identified risks. Auditing is an important tool to get detailed insight in the quality and compliance of clinical development and more specifically the execution of clinical trials. This presentation will provide insight on a proposal on how risk-based auditing can be implemented in an organization by deploying a risk management framework, performing a formal risk assessment on the trial, and translating the identified risks and related controls into the audit diagnostic tool, used by the auditor.

2:15 Risk Management: An ICH Perspective

Bob Figarotta, Senior Manager, Clinical, Allergan

ICH Q9 principles outline quality risk management methodologies that can be applied to all types of audit programs. This includes tools to assist in discovering where audit programs should focus their attention and resources, and what to do with risks identified during the planning and execution of the audit program. This presentation will encompass discussion of the following areas of risk management with an ICH Q9 perspective:

- Potential Applications
- Quality Risk Management Process
- Assessments and Controls
- Facilitation
- Methods and Tools

3:00 Networking Refreshment Break and Exhibit Viewing

3:30 Rethinking CAPA Metrics and TMF Metrics: Are You Measuring the Right Things?

Linda B. Sullivan, Co-Founder & President, Metrics Champion Consortium (MCC)

The Metrics Champion Consortium (MCC) has done extensive research into the standardization of metrics that drive clinical trial quality. In this session, your speaker will address:

- How what you measure influences people's behavior
- How adopting performance metrics supports clinical trial planning
- How the right metrics can support your QMS knowledge management program

Case Study

4:05 Building an Effective CAPA Management Process

Venessa Galate, Pfizer, Inc

This presentation will provide an overview on quality issues and the execution of a CAPA, with a focus on building an effective CAPA management process. Topics will include:

- Developing a compliant, effective, and efficient CAPA System
- Conducting a robust, systematic investigation and effectively measuring performance
- Examining quality issues to determine severity, occurrence, and level of impact (systemic vs. non-systemic issues) to prioritize management and remediation
- Addressing systemic issues at multiple sites, executing a CAPA, and overseeing CAPA execution
- Case Study: Reinforce your understanding of CAPA management and execution by applying best practices to manage a systemic quality issue

4:40 Risk-Based Monitoring and Quality Management Systems

Denise M. Shelley, MS, Clinical Project Manager II, Clinical Monitoring Research Program, Frederick National Laboratory for Cancer Research

5:15 Reception and Exhibit Viewing *(Sponsorship Opportunity Available)*

5:45 Short Course Registration

6:00 Close of Day One

6:00 - 8:30 pm SHORT COURSE: (SC2) Quality by Design in Clinical Research: Is This Only for the Protocol?

(see page 2 for additional information)

WEDNESDAY, JUNE 3

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

8:15 Chairperson's Opening Remarks

8:25 Avoiding the Leap from 483 to Warning Letter

Robert Romanchuk, Principal, Schulman Associates, IRB

All too often, sites move on after responding to a 483 only to receive a Warning Letter a few months later. A series of sponsor, IRB, and FDA audits ensue, with business consequences that can be tragic. In worst case scenarios, a good site is taken down simply because they did not respond to a 483 adequately. (Un)fortunately, the records of these events are public and can be consulted by those wishing to avoid this chain of events. This presentation will analyze recent 483s and Warning Letters, examine guidance, and extrapolate best practices to avoid the leap from 483 to WL. Your presenter will share practical experiences from his nine years of investigator site audits on behalf of independent IRBs.

AUDITING THIRD PARTY VENDORS

9:00 Ensuring Compliance Using Mock Inspections
Elizabeth Ronk Nelson, MPH, President and Senior Consultant, Regulatory Risk Management

9:35 Networking Coffee Break and Exhibit Viewing

Case Study

10:20 Achieving Compliance in Human Subject Research: Elements of Compliance Structures and Quality Systems
Helen Miletic, MA, CHRC, RQAP-GCP, Quality Assurance Manager, Research Compliance and Quality Assurance, University of Miami
The field of clinical research is constantly evolving. The ever-changing regulations, rules and guidance documents, increased oversight by regulatory agencies, and the increasing sophistication of the public and of potential research subjects require not only sponsors, but also universities and academic medical centers to stop and reflect on their current practices in the conduct of clinical research. The current climate requires awareness, implementation of a robust compliance structure, use of quality systems, and risk management approaches. In short, a proactive rather than a reactive approach. This presentation will provide the audience with examples of positive changes, heightened awareness, and strategies for the implementation of new and strengthening of existing compliance structures and quality systems. Essential elements for a robust organizational compliance structure and examples of potential/existing barriers in the compliance "culture" will be presented. Attendees will be introduced to existing quality systems at the University as well as those in the planning and implementation stage. The take-home message is that compliance professionals must be viewed as change agents rather than clinical research police.

11:00 Interactive Roundtable Discussions

11:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 pm Decrease Audit Traffic and Increase Audit Value through Broader Audit Scope and Exchange of Information
Dr. Barbara Heumann, Managing Director, GXP-Engaged Auditing Services GmbH
Debra Ploss, Quality Manager, GXP-Engaged Auditing Services GmbH
The sharing of information obtained during audits continues to be a difficult concept in the world of clinical research, although the advantages of this are increasingly apparent. Through exchange of basic information obtained in previous audits, the number of audits conducted at any one facility could be reduced, and the scope of information covered in each audit conducted could be broadened. Instead of covering just the basics of one study, the performance of the site or vendor could be evaluated over several studies, the participation of individual patients in various studies could be followed, and the remediation of issues discovered in previous audits could be followed up. This would give a more transparent and more complete picture of the overall compliance of the facility, aiding in the future selection of appropriate sites/vendors.

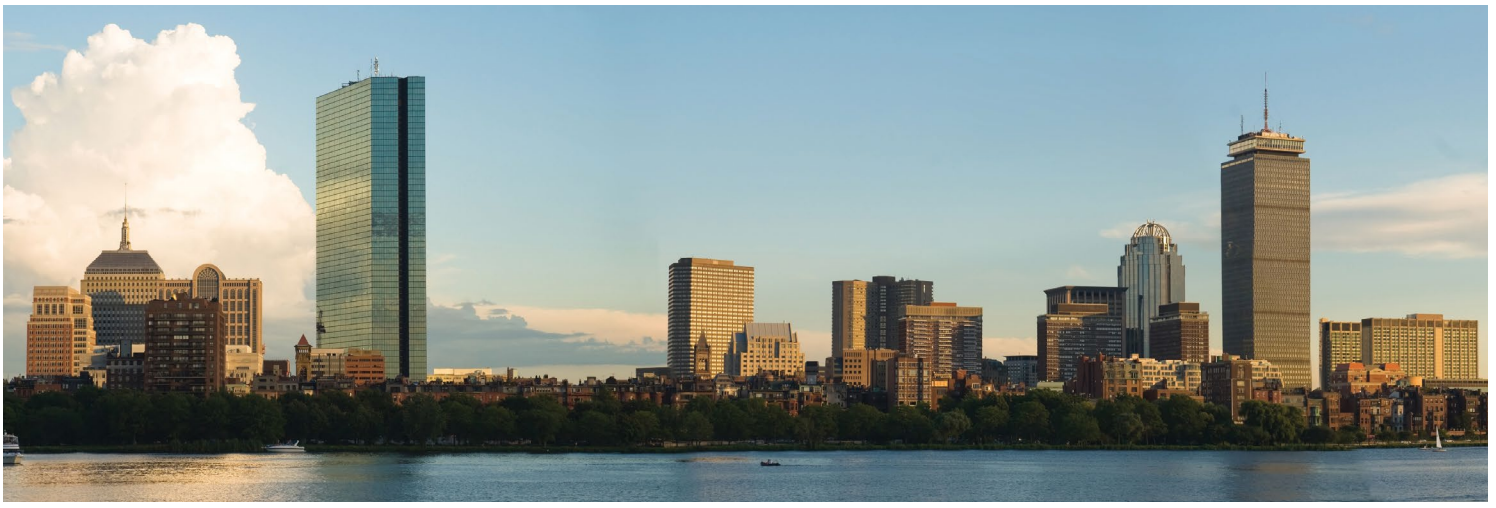
1:50 Risk-Based Audit Planning: Developing a Three Year Strategy
Rita Farrell, Compliance Specialist, Global Quality & Regulatory Compliance – Clinical Trials & Safety (GQRC-CT&S), Bristol Myers Squibb
This session will address the strategy and risk management techniques applied to planning Good Clinical Practice (GCP) audits from both a short and long term perspective. The presentation will include a review of the planning for three audit types: investigator site audits, vendor audits, and internal system audits (including safety related audits). In addition, it will outline the process of obtaining stakeholder input and management endorsement, including the guidelines utilized to obtain data, calculations used to analyze the data, and the resulting documentation.

2:25 Networking Refreshment Break

2:40 Randomized Controlled Trials: Ethics, Consenting, Maintaining the Blind, and Protocol Adherence
Jerri B. Perkins, M.D., former Medical Officer, FDA
Currently (NEJM Dec 18, 2014) FDA is making the case for RCTs (Randomized Controlled Trials) in evaluating Ebola therapies. FDA is challenging industry and the medical community in the necessity of conducting scientifically valid trials and understanding the importance of the placebo effect. This session will include an overview by a former FDA medical officer on the importance of learning how to think like a regulator especially during the consenting process, maintaining the blind and protocol adherence. This presentation will use case studies to demonstrate the power of RCTs to achieve success. Bring your questions and join the discussion as we learn to see through the eyes of a regulator. Upon completion of this program participants will be able to better prepare investigators and site for current study design challenges to fulfill both ethical and regulatory requirements.

3:15 Managing Global Inspections
Bob Figarotta, Senior Manager, Clinical, Allergan

3:50 pm Close of Summit



Sixth Annual

CLINICAL PROJECT MANAGEMENT FORUM

Managing Risk and Improving Performance in Outsourced Clinical Trials

JUNE 2-3

Clinical trial outsourcing has become a focal point for the Clinical Project Manager. For those managing these trials, it is imperative to know how to improve study outcomes, maximize efficiency, and apply risk-based best practices, techniques, and tools to the outsourced relationship. The forum will address the specific challenges, needs, and opportunities in outsourced clinical trials, where thought leaders will share their experiences, best practices, and case studies.

TUESDAY, JUNE 2

12:00 pm Conference Registration

1:20 Welcome & Chairperson's Opening Remarks

1:30 Clinical Trial Vendor Oversight: The CRO Strategic Partner

Jennifer Gaskin, CCRP, Operations Director, Clinical Operations, Alliance for Clinical Trials in Oncology (Alliance Foundation Trials, LLC)

Outsourcing clinical trials is a rapidly growing trend, affecting all professionals at all levels of clinical research. This session begins with insights into how sponsor companies should approach the selection of CRO strategic partners, and continues into how to manage the ongoing relationship while providing adequate oversight. Your presenter will share real-world techniques for implementing best practices and avoiding pitfalls in the outsourced clinical trial model.

2:15 Using Risk-Based Management to Improve the Quality of Your Clinical Trials

Michael Howley PA-C, Ph.D., Physician Assistant – Certified Faculty Coordinator, MBA Healthcare Concentration, Associate Clinical Professor, Department of Marketing, LeBow College of Business, Drexel University

Typical risk-based management techniques usually involve enhanced auditing approaches to identify quality problems after they occur. In this session, your presenter will show you how you can use risk-based quality metrics to identify and correct quality issues before they become problems.

2:30 Sponsored Presentation *(Opportunity Available)*

3:00 Networking Refreshment Break and Exhibit Viewing

Case Study

3:30 Using Analytics and Visualization Tools to Identify and Evaluate Risk and Support Decision-Making

Rosanne Petros, PMP, Associate Director, Clinical Research, Clinical Research Manager US Global Clinical Trial Operations, The Americas, Merck Research Laboratories

Merck has developed and utilizes metrics reports which allow coarse or finer granularity of focus to identify risk within clinical trials and support decision making regarding study course. Based on robust and accurate underlying data, reports can be run and distributed to the upper and middle study management tiers down to the site management level. The majority of data used to support these reports is obtained from Merck's CTMS (Clinical Trial Management System) and supplemented from data from EDC, IVRS, and study-specific data repositories. Reports and graphs show study milestone, enrollment metrics, protocol deviations, action items, subject tracking and SDV, data metrics, and monitoring visit data. Data "cuts" and associated visualization can be at the therapeutic area, region, country, study, or site levels to provide objective risk evaluation within the confines of a therapy area, program, region, country, study, or individual site or institution.

4:05 Implementing Risk-Based Monitoring – It Is Not Rocket Science!

Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.

Many sponsors have embarked on the new course of risk-based study management and risk-based monitoring, but many are struggling to complete the change. There are some essential questions that need to be answered:

- What is the reason for the difficulties that sponsors face when implementing a risk-based approach to monitoring?
- How can we overcome these difficulties? What are the key elements that need to be considered?
- How come most of the sponsors cannot realize the cost saving potential that risk-based monitoring promises? What needs to be done to make it happen?
- With monitoring focused where it really matters, how can we detect real quality improvements?

This presentation will address the most appropriate approach to a risk-based monitoring concept and its components, and will give answers to the most intriguing questions on how to establish a risk-based monitoring approach in your company.

Case Study

4:40 Can Big Data Help in Detecting and – Even More Importantly – Preventing Fraud in Clinical Trials?

Roland Rich, Quality & Compliance Excellence, Operations Expert, DevQA, Novartis

Both patients and investigators can commit fraud for different reasons. For investigators, fraud is often viewed as fabricating, manipulating, or deleting data; whereas for patients, fraud is most likely enrolling at two or more clinical trials sites for a variety of reasons. Despite the many available statistical tools, fraud is very difficult to detect. One method is to use the lab data and to compare patients amongst each other to look for similarity. This way, quite early, we can diagnose some signals that could indicate a potential cause of fraud. Using TAPAS, our risk assessment tool, we run this data weekly across all studies and at all sites, giving us a possibility to see such cases.

5:15 Reception and Exhibit Viewing

(Sponsorship Opportunity Available)

5:45 Short Course Registration

6:00 Close of Day One

6:00 - 8:30 pm SHORT COURSE: (SC2) Quality by Design in Clinical Research: Is This Only for the Protocol?

(see page 2 for additional information)

WEDNESDAY, JUNE 3

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

8:15 Chairperson's Opening Remarks

EFFECTIVE PARTNERSHIP MODELS

8:25 Cyber-Connectedness with Your CRO: Compliance and Peace of Mind

Mollie Shields-Uehling, President and CEO, SAFE-BioPharma Association

Betsy Fallen, Global Head of Program and Business Development, SAFE-BioPharma Association

Cyber-connectedness in outsourced trials is more important now than ever before. Companies need to know, with certainty, that they can trust the

identities of individuals on the other side of electronic transactions who are allowed access to valuable trial-related information assets and who are eSigning electronic documents. Created by the biopharmaceutical industry, FDA, and EMA, SAFE-BioPharma is the industry standard for identity management and for applying digital signatures to electronic documents. Beyond business peace of mind, this is an issue of regulatory compliance, including the upcoming EMA eSubmissions digital signature requirements. The company developing the TransCelerate Shared Investigator Platform portal is adopting the SAFE-BioPharma standard, as has the company to which it has outsourced development of its identity management component. Your speakers will provide multiple perspectives, including SAFE-BioPharma leadership, an experienced expert responsible for guiding use of technology in drug development, and a representative to discuss the use of the standard in clinical development.

9:00 Applying Strategies to Successfully Operationalize Atypical Studies of Rare Diseases Through a Successful Global Partnership

Patricia Nowowieski, Head, Global Clinical Operations, Cambridge, Global Clinical Operations, Alexion Pharmaceuticals

Donna Holloway, Director, Clinical Project Management, Quintiles

In order to bring medicines to patients with devastating ultra-rare diseases, traditional study designs for large, randomized trials need to be reconsidered. Using the four phases of study execution: planning, initiation, conduct and close-out, we will discuss the benefits of a nimble and flexible partnership to address the complexities of ultra-rare diseases and the necessity to tailor high-impact solutions to trial operations. Attendees will improve their understanding of how to:

- Operationalize atypical studies of rare diseases, in which every data point matters
- Identify factors leading to a successful global collaboration, allowing rapid mobilization in countries/regions at the time a subject is identified

9:20 Sponsored Presentation *(Opportunity Available)*

9:35 Networking Coffee Break and Exhibit Viewing

10:20 Adaptive Monitoring: How to Manage Sites Without Visiting Them

Roland Rich, Quality & Compliance Excellence, Operations Expert, DevQA, Novartis

Adaptive Monitoring uses real-time performance metrics to oversee sites on a daily basis, and permits us to focus attention on the areas that need it the most. Using our TAPAS tool, the central analytic function team and the central monitoring team have access to reports that enable them to focus their work based on continuously tracked site performance metrics. This means that problem sites receive earlier and more frequent visits, while sites showing no major difficulties receive fewer visits at much greater intervals, as long as they continue to maintain a timely flow of high-quality data and show satisfactory performance on study activities. Combined with remote monitoring, adaptive monitoring allows better allocation of resources and definitively helps sponsors to dramatically boost efficiency, increase quality, and reduce risk, without collecting less data. Ultimately, Adaptive Monitoring reduces site visits and cut some costs, without sacrificing data quality or safety.

11:00 Interactive Roundtable Discussions

11:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 pm Building a Global System: Promoting Accountable Research

Greg Koski, Ph.D., M.D., Co-Founder & President, ACRES; former Director, Office for Human Research Protections, U.S. Department of Health and Human Services

ACRES, a non-profit multi-sector stakeholder collaborative working in the public interest, is a one-of-a-kind, innovative initiative building an open, integrated global system for clinical research. Adapting lessons from other industries that have successfully implemented principles of systems and safety engineering, such as transportation, communications, and information technology, ACRES is applying these principles to the clinical research process to build a true system that will increase safety, efficiency, and professionalism of the endeavor globally, benefiting all stakeholders, especially patients. ACRES believes that disruption alone is insufficient – our goals must be constructive – building the future together, for the benefit of all. This session will highlight and discuss the Alliance's current initiatives, progress, and expectations.

MANAGING OUTSOURCING RISKS

1:50 Risk-Based Approached to Outsourced Relationships: Best Practices, Tools, and Techniques

Lynnette Wright, Global Contracts & Outsourcing Lead (GCOL), Astellas Pharma Global Development, Inc.

As the pharma industry is shifting its traditional outsourcing model where the sponsor develops a long-term relationship with suppliers, the sponsor needs to evaluate the benefits and risks of the best approach for outsourcing. Appropriate controls need to be in place to reduce business risks and to comply with the requirements of FDA for the vendor oversight by the sponsor. During this session, your speaker will share some of the best practices to manage the risks of outsourcing and to ensure regulatory compliance. What if you knew the outsourcing risks and how to avoid the pitfalls of sourcing? What are the best practices to manage sponsor/supplier relationship? The objective of this session is to:

- Better understand the risks sponsors face with outsourced relationships
- Explore best practices to mitigate risk and implement controls to handle identified risks

2:10 Sponsored Presentation *(Opportunity Available)*

2:25 Networking Refreshment Break

2:40 Predictive Modeling to Optimize Enrollment Outcomes in Outsourced Phase III Studies: A Case Study

Moe Alsumidaie, MBA, MSF, Chief Data Scientist, Annex Clinical

Predicting and changing future outcomes has always been a concept of the past, until today. Enrollment performance continues to be a key challenge and resource intensive component of conducting Phase III research in outsourced studies. During this session, hear how a clinical operations team was able to precisely forecast trial completion dates as early as 30% in trial enrollment, predict and react to future operational outcomes, and implement breakthrough business research tools to uncover enrollment performance issues. Understand the analytical strategies that were executed to:

- Precisely forecast, predict and benchmark trial completion date ranges
- Foresee slowdowns and upturns in enrollment momentum
- Uncover performance issues
- Improve future enrollment outcomes

3:15 Integrated Quality Oversight in Clinical Trials

Dirk Gille, Vice President, Head Bioresearch QA, Janssen R&D, Belgium

To ensure patients in high medical need continue to have access to affordable drugs, companies and authorities are looking at means to decrease the cost of clinical trials while still maintaining oversight on patient safety and integrity, and data credibility. A risk-based approach has been encouraged by both EMA and FDA as a mean to deploy resources where it matters most based on identified risks. Pharmaceutical companies need to control risks related to patient safety, protocol non-compliance, budget (over) spending, trial timelines, etc. This presentation addresses an integrated risk-management approach towards oversight in clinical trials, following some of the key CTTI principles: starting off with the clinical team from an integrated risk assessment of the trial, de-risk the protocol and implement controls to mitigate the identified risks, and manage the residual risks through an integrated quality plan.

3:50 pm Close of Summit

CAMBRIDGE HEALTHTECH INSTITUTE'S FOURTH ANNUAL

CLINICAL TRIAL OVERSIGHT SUMMIT

Optimizing Data Quality, Efficiency, Partnerships, and Risk Management

June 1-3, 2015
Omni Parker House
Boston, MA

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One short course	$699	$399
Two short courses	$999	$699

Monday, June 1 | 6:00-8:30 pm	Tuesday, June 2 | 6:00-8:30 pm
~~(SC1) Facilitating Investigative Sites' Operational Efficiency~~	(SC2) Quality by Design in Clinical Research

STANDARD PRICING

BEST VALUE! (Includes access to 2 conferences, excludes short courses)

	Commercial	Academic, Government, Hospital-affiliated
Registration after May 8, 2015 and on-site	$2399	$1149

Please select TWO conferences you will most likely attend. Select one from June 1-2 and one from June 2-3.

June 1-2, 2015	June 2-3, 2015
Mastering Clinical Trial Monitoring	CIlinical Auditing Forum
Vendor Management in Clinical Trials	Clinical Project Management Forum

BASIC PRICING

(Includes access to one conference, excludes short courses)

	Commercial	Academic, Government, Hospital-affiliated
Registrations after May 8, 2015 and on-site	$1799	$799

Please select ONE conference you will most likely attend.

June 1-2, 2015	June 2-3, 2015
Mastering Clinical Trial Monitoring	CIlinical Auditing Forum
Vendor Management in Clinical Trials	Clinical Project Management Forum

CONFERENCE DISCOUNTS

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.

Alumni Discount: Cambridge Healthtech Institute (CHI) appreciates your past participation at The Clinical Trial Summit. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

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

If you are unable to attend but would like to purchase the Clinical Trial 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.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/ Cancellations Policy, go to http://www.healthtech.com/regdetails

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

How to Register: ClinicalTrialSummit.com

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Please use keycode CTL F when registering!

Please refer to the Registration Code below:

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