Third Annual
Clinical Trial
OVERSIGHT SUMMIT

June 2 - 5, 2014
Hilton Back Bay | Boston, MA

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Cambridge Healthtech Institute,
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Cambridge Healthtech Institute's Third Annual

Clinical Trial OVERSIGHT SUMMIT

June 2 - 5, 2014
Hilton Back Bay | Boston, MA

Mastering Clinical Trial Monitoring

Vendor Management in Clinical Trials

Clinical Auditing Forum

Clinical Project Management Forum

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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
Tuesday PM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials

Afternoon Short Course* Metrics & KRIs: Study Oversight in a Risk Management Environment - How to Make it Work!

Dinner Short Course* Managing the CRO Relationship: From Engagement through Delivery

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

**Separate Registration Required*

Cambridge Healthtech Institute's third 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.

LEAD SPONSORING PUBLICATIONS

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SHORT COURSES*

AFTERNOON SHORT COURSE

(Tuesday, June 3 1:00-3:30 pm)

(SC2) Metrics & KRIs: Study Oversight in a Risk Management Environment – How to Make It Work!

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

Key to the success of QRM is the capacity to leverage existing information in such a way that stakeholders can easily assess whether the processes they are responsible for yield (or will yield) the intended results and quality. This approach helps organizations to proactively identify, manage, and mitigate risks before they manifest into real problems. A risk-based approach requires not only a strategy but tools to define leading and lagging indicators to measure specific risks. As referenced from the recent FDA and EMA guidances, Key Risk Indicators (KRIs) and Critical to Quality (CTQ) metrics should focus on "what really matters" with an emphasis on patient safety and data integrity, and be tied to particular processes within the clinical drug development spectrum. This interactive session is designed to provide its participants with a strong conceptual foundation for defining and developing meaningful Quality Risk Indicators and Critical to Quality metrics along with corresponding thresholds for acceptability of outcomes that can be used across clinical trial processes.

DINNER SHORT COURSE

(Tuesday, June 3 6:00-8:30 pm)

(SC3) Managing the CRO Relationship: From Engagement through Delivery

Michael J. Harte, Founder & President, The Harte Group

In this workshop, we will explore effective and creative approaches to the Sponsor/CRO relationship, from engagement through delivery. Participants will learn to:

Ensure the validity and accuracy of their program: Validate the protocol and assess patient availability and compliance

- Start with the end in mind: Regulatory expectations; data presentation; and study goals
- Consider key points in CRO engagement: CRO pricing; development activity and objectives; the use of electronic systems; vendor workflow and process; taking steps to engage QA support to maintain audit-readiness of your program; encourage input from CRO functional groups for better, creative, and more efficient ways to conduct the program
- Identify ways that the CRO can be held accountable for their deliverables: Deliverable-based vs. time-based contracts; if wrong selection of CRO made, never fear changing
- Ensure total transparency of all parties/functions: Better communication ensures that everyone aware of status and need for their services

**Separate Registration Required*

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Fifth Annual | June 2 - 3

Mastering Clinical Trial Monitoring

Optimizing Site Performance and Improving Efficiency with Risk-Based Monitoring

The fifth annual **Mastering Clinical Trial Monitoring** conference will focus exclusively on the changing landscape and evolving role of clinical trial monitors. This event will bring together thought leaders to share their experiences and insights related to the industry's most topical issues such as the FDA's Final Guidance on Risk-Based Monitoring, the impact of TransCelerate's efforts in the industry, monitoring international clinical trials, and quality systems-based approaches to monitoring. Participants can expect case studies, hands-on activities, and take-away tools that will enhance their monitoring experiences and expand their monitoring expertise.

MONDAY, JUNE 2, 2014

7:00 am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks
Gail Fowler, Vice President, Operations, Rho

RBM IN THE ERA OF THE FDA FINAL GUIDANCE

8:15 The Brave New World of Risk-Based Monitoring
Susan Bosworth-Farrell, BSNMPH, CCRC, CCRP, Clinical Operations, Senior Clinical Research Associate, Abbott Vascular
We have entered a brave new world of monitoring with the FDA final guidance on risk-based monitoring. In an attempt to capture a "snapshot in time" of how both CRAs and CRCs perceiving and are adapting to "remote monitoring" processes, your speaker and a colleague developed a questionnaire for CRAs and CRCs. The results of the survey and a discussion of its implications and recommendations are presented here in an attempt to understand how the draft guidance is being implemented and utilized from both the site and sponsor/CRO perspectives. This survey and the responses it elicited from a range of clinical research professionals provides much insight as to how the process of remote monitoring is being implemented and received at this point in time when new monitoring paradigms are being introduced.

CASE STUDY!

9:00 Challenges and Solutions to Implementing a Risk-Based Monitoring Program within an Academic Research Institute
Gregory Staios, Research Monitor, Research Services, Centre for Addiction and Mental Health
Monitoring is an activity that has historically been neglected within academic research institutes for a multitude of reasons, including a lack of resources. The utilization of risk-based monitoring approaches has allowed for more tailored approaches for monitoring investigator initiated studies that are proportional to study related risk, thus potentially decreasing resources necessary to institute a monitoring program. Recently, our organization, Canada's largest mental health and addiction hospital, has instituted a variety of measures to undertake monitoring of regulated IIS. These include conducting study specific risk assessments, creating monitoring plans, stratifying who will conduct monitoring based on risk, and creating an education and mentorship program for team based monitors. This presentation will provide attendees with a framework for implementation of such programs within their institution.

9:45 Coffee Break and Exhibit Viewing

10:15 Implementing Risk-Based Monitoring: A CRO perspective
Ben Dudley, Executive Director, Alliance Management, Clinical Development Services, Covance, Inc.
This presentation will address the challenges, opportunities, and impacts of risk-based monitoring (RBM) both in theory and as implemented on real-life projects. Drawing on the first-hand experience of the speaker, the audience will hear about how different perspectives on RBM impact expectations. This presentation also explores barriers to RBM implementation, and how working in partnership allows a more clear opportunity to investigate and articulate these issues with stakeholders.

INDUSTRY INITIATIVES: TRANSCELERATE AND ACRES

11:00 ACRES: A Global Systems Approach to Enhancing Clinical Trial Quality, Safety, and Efficiency
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
The Alliance for Clinical Research Excellence and Safety (ACRES) includes global leaders and organizations from the entire clinical research/clinical trials enterprise. Their goal is to provide comprehensive integrated systems-solutions to the many challenges facing clinical research by collaboratively building an open, shared, global infrastructure that benefits all stakeholders while aligning ethical principles with good business and scientific practices. In this presentation, your speaker will discuss ACRES' various initiatives: Site Accreditation Standards, Site-Optics and Quality Informatics, Quality and Safety Initiatives, Product Safety Culture Initiatives, and Global Ethics and Regulatory Innovation.

Sponsored by
PERSISTENT

11:45 Realizing the Promise of Cost Reduction in Clinical Trial Monitoring Through Emerging Technologies
Harshal Shah, Director, Life Sciences & Healthcare, Persistent Systems Ltdj
The talk will focus on the impact of SMAC technologies (social, mobility, analytics and mobility) to improve clinical trial monitoring . Illustrative uses cases showcasing the potential to leverage the data available at various stages of the process thereby achieving quality and efficiency, cutting costs along the way.

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Mastering Clinical Trial Monitoring

Optimizing Site Performance and Improving Efficiency with Risk-Based Monitoring

12:00 Luncheon Presentation - Virtual Site Visits: A Powerful Complement to RBM

Sponsored by medpoint digital

Bill Cooney, President and CEO, MedPoint Digital

Virtual Site Visits (VSV) are a powerful yet under-utilized component of site monitoring. New technologies enable monitors and sites to collaborate in real time and perform most or all of the activities of an on-site visit. VSVs can significantly lower cost, improve productivity and enhance quality, while enhancing personal relationships with sites. Attendees will gain understanding of the versatile capabilities of VSVs and how VSVs can effectively complement any RBM program.

1:00 pm Piloting Risk-Based Monitoring: A TransCelerate Member Company Perspective

Ramil Abdrachitov, Clinical Research Director, Clinical Operations, AstraZeneca

This presentation reflects first-hand experience from piloting Risk-Based Monitoring using the methodology developed by TransCelerate. It will guide the audience on important aspects which should be considered implementing RBM. Your speaker will share the experience of AstraZeneca from the ongoing Risk-Based Monitoring pilot study. AstraZeneca's approach to risk assessment, monitoring plan preparation, SDV, and Source Document Review will be described, as well as the feedback from FDA on RBM-related documents. The place and scope of centralized data monitoring, and the division of responsibilities among central, remote, and on-site monitoring will be discussed. Participants will gain from lessons learnt and initial results. This session will help participants implement RBM faster and smarter, and avoid some mistakes. Sharing and discussion of practical experience will facilitate evolution of RBM methodology.

1:45 FDA Investigation Preparation: The Dos and Don'ts

Nancy S. Bakke, Manager, US Clinical Monitoring, Sorin Group CRM and Cardiac Surgery

This presentation provides a step-by-step guide for clinical research sites to understand the inspection process and how to prepare for it. Participants will gain a better understanding of investigator roles, investigation objectives, and investigation preparation for sites and sponsors. The details for developing training plans will be provided. Participants will be given a practical list of inspection do's and don't's. End of inspection details will be discussed, including FDA process, responding to 483s, suggestions for addressing 483 observations, common FDA findings, and FDA responses. This session provides a tactical, practical guide for sites.

CASE STUDY!

2:30 Institutional Risk-Based Monitoring: Three Years Later

Ina Abel, Manager, Clinical Research Monitoring, St. Jude Children's Research Hospital

St. Jude Children's Research Hospital deployed our method of risk-based monitoring in 2010, putting them ahead of the RBM curve. The original institutional monitoring plan was beneficial in many ways, yet caused push back by Principal Investigators, stretched the monitoring resources thin, and occasionally confused priorities. Implementation of a risk-based monitoring plan required patience, planning, a staged roll-out, and strategic communication. Initially criteria were developed for four main risk categories. Open studies were ranked by perceived and calculated risks. For new trials, study risk was determined by monitoring management and study-specific monitoring plans were developed with Principal Investigator input. After three years, virtually all studies are now monitored according to the more focused, risk-based institutional monitoring plan. Participants will learn from St. Jude's challenges and successes.

3:15 Risk-Based Monitoring of Clinical Trials Using JMP® Clinical

Sponsored by JMP Statistical Discovery™ From SAS

Richard C. Zink, Ph.D., Principal Research Statistician Developer, JMP Life Sciences, SAS Institute Inc., JMP Division

Risk-based monitoring (RBM) makes use of central computerized review of clinical trial data to determine if sites should receive more extensive quality review through onsite monitoring. I'll demonstrate an RBM solution in JMP Clinical to assess data quality. Data from patients who experienced an aneurysmal subarachnoid hemorrhage will provide illustration.

3:30 Refreshment Break and Exhibit Viewing

3:50 What's the Difference? Pharma vs. Device Studies

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

Differences between drug and device studies are driven by regulatory definitions, manufacturing processes, and development pathways. Such differences have a direct impact on the lifecycle of the research-to-market process, including how new products are reviewed by regulatory authorities, how protocols are constructed, and how IRBs determine subject informed consent. This talk will highlight the differences between these two types of research. Discussion will include the differences in the Investigational Device Exemption (IDE) regulations versus Investigational New Drug (IND) regulations, marketing timelines, IRB review, and documentation requirements.

MEETING GLOBAL MONITORING CHALLENGES

4:35 Cultural and Socioeconomic Variables in Global Clinical Trials and Its Effect on Risk-Based Monitoring

Vlad Bogin, M.D., CEO, Clinical Research, Cromos Pharma

Risk-based management plans in international trials have to be carefully tailored to local environments. Cultural and socioeconomic domains are extremely important, and failure to factor them in may result in poor data quality and compliance. The newly proposed risk-based monitoring may meet significant logistical challenges if these issues are not considered very early in study design.

5:20 Welcome Reception and Exhibit Viewing
Sponsorship Opportunity Available)

5:45 Short Course Registration

6:00 - 8:30 Short Course 1, Best Practices to Becoming a Preferred Site *(see page 3 for additional information)*

6:20 Close of Day One

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TUESDAY, JUNE 3, 2014

7:30 am Breakfast Presentation: Employing an Innovative Risk-Based Monitoring Approach: A Case Study

Sponsored by PATIENT PROFILES clinical trial software

Meredith Mundy, Director, Clinical Operations, Patient Profiles, LLC.

A risk-based monitoring program looks good on paper, but without the tools to incorporate centralized monitoring, implementation can be a challenge. We review an ongoing randomized clinical trial employing an innovative risk-based approach to data monitoring. This approach is based on advanced statistical methods and a clinical review of graphical patient reports to identify unusual or suspicious data in need of monitoring.

8:10 Chairperson's Opening Remarks

Emily Cantrell, Senior Project Manager, Rho

8:15 Monitoring in the Electronic Environment: Electronic Data Capture (EDC), Electronic Medical Records (EMRs), and Electronic Storage Systems

Lee Truax-Bellows, President, CEO, Clinical, NCRA

Monitors continue to struggle with how to source document verify study data of sites dependent on Electronic Storage Systems EMRs and hybrid EMR/hardcopy medical record systems. The issue will only intensify as more and more organizations move to the utilization of EMRs. In addition, some study data is now being captured directly onto electronic platforms, thereby adding another layer of complexity. A primary task of monitoring is to ensure the data meets the ALCOA principals of accountability, legibility, contemporaneous, original, and accurate study data. This session will focus on the three different types electronic systems, describe the how each is used within a research setting, and provide some practical considerations when monitoring in the electronic age of data capture and management.

9:00 Quality by Design: A Lean Six Sigma Approach to RBM

Erika Stevens, Senior Manager, Advisory Services Health Care, Ernst and Young LLP

This session will demonstrate traditional project management methodologies to create and manage a compliant CAPA monitoring system within the QMS. The conventional project management (PM) elements of Initiation, Plan, Execute, Monitor/Control, and Close will be defined as they relate to the CAPA monitoring system. Specifically, identification of non-conformances vis-à-vis routine quality control monitoring procedures will be defined and mapped within the Initiation PM element of the CAPA monitoring system. Analysis and creation of the non-conformance corrective and/or preventive action via root cause analysis will also be defined and mapped to the Plan PM element of the CAPA monitoring system. Initiation of change controls will be mapped to the Execute PM element and implementation of pre-defined measured CAPA progress will be mapped to the Monitor/Control PM element.

9:45 Coffee Break and Exhibit Viewing

BUILDING RELATIONSHIPS, INCREASING COMPLIANCE

10:05 Site Relationship Management: A CRA's Perspective

Sharon Sothern, BA, CCRP, CRA, Westat

Maintaining a perfect relationship balance between the Clinical Research Associate (CRA) and site can be tricky. The CRA must recognize the importance of professionalism and understand how a site's perception of a CRA can influence site interactions. Having respect for one another and effective communication are the main components of a successful relationship. Once the site relationship is established the CRA must know how to build trust. The CRA and site are a team and both want to produce quality research. This presentation will use real-life scenarios to demonstrate how positive working relationships can be developed at the beginning of a new project and improved, should the relationship start to decline.

10:50 Assessment Tools for Triggered Monitoring Visits

Lesli DeSimone, MSHS, RN, CCRA, CCRP, Clinical Monitoring Manager, Medtronic, Inc.

Based on language in the FDA's Risk-Based Monitoring Guidance, sponsor staff must ask themselves, "What does this really mean and how can I practically apply this to my studies?" Your speaker will discuss and share tools to help determine what is "critical" for your study and what type of monitoring activities are available to provide "effective oversight." These tools will include site evaluation to determine an analysis of the information you have regarding selected sites and the potential influence they have on study time. We will also discuss a datapoint evaluation tool that will help you determine what data is critical to evaluate to reach your goals, and which data is not so critical and how to show an evaluation of these points.

11:35 Principal Investigator GCP Training – Maybe It *Is* Rocket Science!

Shari Zeldin, BS, CCRC, Manager, Clinical Research Compliance Office, University of Wisconsin Carbone Cancer Center

At this time of increased scrutiny of clinical research conduction, training Principal Investigators to understand their important legal and ethical responsibilities is critical... and challenging! Building on the principles of GCP, the presenter will offer real world case examples of PI non-compliance and challenge the audience in how to properly respond. Referencing the FDA CFR and ICH GCP, the audience will work together to identify PI non-compliance in the case studies presented, and determine how it should be reported and to whom. In addition, the presenter will aim to help the audience identify and train PIs to recognize the easily avoidable pitfalls in order to avoid non-compliance, because it shouldn't be rocket science!

12:20 pm Close of Conference

1:00 Short Course Registration

1:00 – 3:30 Short Course 2, Metrics & KRIs: Study Oversight in a Risk Management Environment – How to Make It Work! *(see page 3 for additional information)*

6:00 – 8:30 Short Course 3, Managing the CRO Relationship: From Engagement through Delivery *(see page 3 for additional information)*

Third Annual | June 2 - 3

Vendor Management in Clinical Trials

Ensuring Quality Through Effective Assessment, Qualification, Auditing and Oversight

With growing reliance on third party providers in clinical trials, the need for effective selection and oversight of vendors is more important than ever. At the third annual **Vendor Management in Clinical Trials** conference, we will address the need for quality in the assessment, contracting, implementation, auditing, and ongoing oversight of third party vendors. With growing regulatory expectations for a quality systems-based approach to GCP compliance, sponsors must be certain that their third party vendor partners are "inspection ready." Participants can expect presentations on risk-based approaches to vendor management and all phases of the vendor relationship from assessment to oversight. The event will feature case studies, take-away tools, perspectives on the current regulatory environment, breakout groups, and interactive activities that will enhance participants' expertise.

MONDAY, JUNE 2, 2014

7:00 am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

OUTSOURCING MODELS

8:15 A Study of Outsourcing Models: Options, Approaches, and Impact

Mary Jo Lamberti, Ph.D., Senior Research Fellow, Tufts Center for the Study of Drug Development

Tufts CSDD is conducting a study among top 10 to 12 biopharmaceutical companies to capture specific use of outsourcing models (e.g., FSP, niche, hybrids, integrated alliances). In this study, Tufts CSDD will analyze specific collaboration and risk-sharing models being utilized, their impact on performance, and efficiency to date. The study will also explore ways in which organizations have adapted, and plan to adapt, their collaboration models to achieve greater efficiencies and best practices. The study will benchmark the incidence and impact of various organizational approaches through gathering company data. Company data will be analyzed to provide insight into the structure and type of outsourcing models, transitioning and management of resources and the impact of these collaborations on key performance metrics.

VENDOR QUALIFICATION AND CONTRACTING

9:00 Strategies for Vendor Qualification: Strategies, Questionnaires, Pre-Qualification, and Risk Assessment

Treena Jackson, MS, CQA, RAC, CSSGB, Supervisor, Office of Quality Assurance, RTI Health Solutions

Norlonn A. Sturdivant, MT, RAC, Director, Office of Quality Assurance, RTI Health Solutions

Regulatory agencies expect that there are quality expectations set for outsourced work and sponsors are evaluating the vendors on quality with respect to the deliverables. Clinical vendors and CROs play key roles in contributing to market approvals, regulatory deliverable and overall clinical research. It is the sponsor's responsibility to ensure their vendors meet all regulatory specifications for the supplied materials, equipment and/or services. In this session, the audience will gain knowledge regarding the following:

- Strategies for selection, audit, approval, and qualification of vendors based on the service/product being delivered
- Methods and tools used to accomplish a vendor pre-qualification and ongoing qualification
- Risk assessment strategies to determine the timing, method, and nature of audits

9:45 Coffee Break and Exhibit Viewing

10:15 Fundamental Processes for Optimizing Management of Contracts and Financials

Sally Teeters, CCRP, Senior Director, Legal and Business Management, CardioVascular BioTherapeutics, Inc.

This presentation will provide a brief overview of SOX with emphasis of the challenges and impact on sponsors and CROs. We will also discuss the importance of planning and processing of RFPs. Your speaker will facilitate discussion of critical contract terms (e.g., confidentiality, IP, indemnification, insurance) and the "other terms" which tend to be considered non-critical but may have a major impact depending on the circumstances. Examples of other items include introductory provisions, assignment, relationship of parties, venue/choice of law, term and termination, record retention, on-site inspections, and change in personnel. The best practice of minimizing expense and processing of change orders by specifying the format, timing, and approval process will be discussed. Finally, managing financials will be addressed, including EVM, gain quick, and accurate visibility into clinical operations budget performance integrated with your financial and operational plans.

11:00 Interactive Roundtable Discussions

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

1:00 pm Early Outsourcing and Vendor Management

Laura K. Vessey, BS, Director, Early Stage Development Operations and Outsourcing, Merck

Michelle L. Combs, Ph.D., Vice President, Clinical Pharmacology Services, Celerion

What adds up as a conclusion on one side is often misunderstood on the other. The need for defining parameters goes beyond contracts. The understanding of the vendor and the client is easily forsaken if the ends are understood before the means are clear. Often, both sides are talking to their understanding but not realizing they are speaking apples and oranges. This is the voodoo of the argument. Make both understand what you mean, so that with an audit by a client there is not the amazing response of "I didn't ask you to do that...," so to speak.

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Third Annual | June 2 - 3

Vendor Management in Clinical Trials

Ensuring Quality Through Effective Assessment, Qualification, Auditing and Oversight

RISK-BASED VENDOR MANAGEMENT STRATEGIES

1:45 Risk-Based Approaches to Clinical Vendor Management

Ken Shitamoto, MS, PMP, CPRE, Kikai Consulting, LLC

As outsourcing to third parties becomes more pervasive and is used more often for critical functions, the need for effective vendor management increases. Unless we can find efficient ways to perform this effectively, the cost of vendor management will increase significantly without necessarily increasing the quality of delivery. This session provides an overview of risk management models, and provides a road map for developing and applying risk-based vendor management in clinical trials.

2:30 How Risk-Based Approaches Affect Working with Your Service Providers

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

The fact of the matter is that strategic partnerships do not always work. One major reason is the disconnect between protocol development at the sponsor and setting up the clinical trial subsequently at the CRO. Protocol amendments are typical before the trial even starts, followed by amendments related to safety or new regulatory requirements. Risk-based management will have a major impact on working with your service providers, especially regarding protocol development and data management. The latter plays a major role in risk management, since regulators' expectations are that all assessments are based on facts collected during the trial. In addition, RBM needs to be developed jointly with your CRO, requiring a re-thinking of your outsourcing relationship and oversight.

3:15 Risk-Based Monitoring of Clinical Trials Using JMP Clinical

Sponsored by JMP Statistical Discovery™ From SAS.

Richard C. Zink, Ph.D., Principal Research Statistician Developer, JMP Life Sciences, SAS Institute Inc., JMP Division

Risk-based monitoring (RBM) makes use of central computerized review of clinical trial data to determine if sites should receive more extensive quality review through onsite monitoring. I'll demonstrate an RBM solution in JMP Clinical to assess data quality. Data from patients who experienced an aneurysmal subarachnoid hemorrhage will provide illustration.

3:30 Refreshment Break and Exhibit Viewing

IMPROVING VENDOR PERFORMANCE

3:50 The Key Drivers of CRO Performance

Michael Howley, Ph.D., Associate Clinical Professor of Business, LeBow College of Business, Drexel University

How do you know if you are getting your money's worth from your clinical trials? While clinical trials are usually one of the most expensive line items for life sciences companies, this is a very difficult question answer. Managers can waste a lot of time, money, and effort on performance metrics that don't give them the information they need to improve their clinical trials. In this session, the results of the Clinical Trials Outsourcing Project (C-TOP), an academic-industry collaboration that has been working on developing validated instruments to assess CRO performance, will be presented. At the end of this presentation, attendees will be able to recognize performance metrics that are valid and reliable, and identify and focus on the significant and substantial drivers of performance assessment.

CASE STUDY!

4:35 The People Challenges of Implementing a Vendor Oversight Capability

Susan Giddens, Senior Training Manager, Process & Training Management, gRED Clinical Operations, Genentech

Kirsten Morasco, Vice President, Clinical Quality & Compliance, Compliance Implementation Services

Holly Deiaco-Smith, Change Management and Process Improvement Expert, Compliance Implementation Services

Why is it so difficult for study sponsors to perform good vendor oversight? Our presentation will answer this by providing insight into the behavioral and change management challenges that come with implementing a vendor oversight capability. What is a VO Capability? Why is it a "Big Change"? What does that mean for an organization? Your presenters will share the common challenges organizations face when they change their outsourcing model and ultimately implement a VO capability. Susan Giddens of Genentech will share her organization's real-world experience of how they recently underwent a change in their outsourcing model and began implementing a VO capability. She will discuss and provide practical advice on how Genentech addressed these challenges through a comprehensive training and change management approach.

5:20 Welcome Reception and Exhibit Viewing *(Sponsorship Opportunity Available)*

5:45 Short Course Registration

6:00 – 8:30 Short Course 1, Best Practices to Becoming a Preferred Site *(see page 3 for additional information)*

6:20 Close of Day One

Third Annual | June 2 - 3

Vendor Management in Clinical Trials

Ensuring Quality Through Effective Assessment, Qualification, Auditing and Oversight

TUESDAY, JUNE 3, 2014

7:30 am Breakfast Presentation: Employing an Innovative Risk-Based Monitoring Approach: A Case Study

Sponsored by PATIENT PROFILES clinical trial software

Meredith Mundy, Director, Clinical Operations, Patient Profiles, LLC.

A risk-based monitoring program looks good on paper, but without the tools to incorporate centralized monitoring, implementation can be a challenge. We review an ongoing randomized clinical trial employing an innovative risk-based approach to data monitoring. This approach is based on advanced statistical methods and a clinical review of graphical patient reports to identify unusual or suspicious data in need of monitoring.

8:15 CRO Strategic Sourcing: A Sponsor's Story

Ian Wyglendowski, Associate Director, Vendor & Outsourcing Management, Global Development Operations, Bristol-Myers Squibb Company

Strategic partnerships were formed between sponsor companies and CROs with the hope to create a new, best-in-class outsourcing model. For sponsors, it offered the possibility of higher confidence in study delivery with reduced oversight and resource utilization. Infrastructure would be established jointly to ensure consistent processes, clear acceptance criteria, and robust partnership-level governance. For CROs, it offered earlier access to a long term view and forecast of the sponsor's book of work enabling better study planning, more effective resource allocation and utilization, and opportunities for developing other enhanced operational capabilities. In this session, BMS will share their experience working in this model since 2010 and some thoughts for how strategic partnerships may evolve in the future.

9:00 Risk Management Strategies for Supplier Quality Programs: A Look at Vendor Strategies from Both Sides of the Audit Table

Erin Driggers, Manager, Supplier Quality, Clinical Services, Almac Clinical Services

Customer audits that include the vendor management program in the scope often times miss the mark. Most often, the vendor management program is assessed for adherence to site SOPs that govern the activity, but do not challenge the scope or depth. The global strategy must rely on robust initial assessments (questionnaires), on-site audits, periodic re-evaluations, and continuous risk management strategies to assure both regulators and customers alike. As a case study, the management of third party vendors utilized for the logistics to support distribution to ASEAN (Association of South-East Asian Nations) sites will be discussed. Your speaker will share his unique perspective as both an auditor of facilities around the world and as a client services contractor whose vendor management program is frequently audited.

9:45 Coffee Break and Exhibit Viewing

10:05 Effective Strategies for Ongoing Oversight of Third Party Vendor or Clinical Research Organization

Stephen Thomas, BSc, Clinical Operations Manager, Hologic

AUDITING YOUR THIRD PARTY VENDOR

10:50 Responding to Audit Observations at Your Third Party Vendor

Kathy Ballensky, MT, CCRA, Third Party Management-Consultant, Lilly Medical Quality, Eli Lilly and Company

When auditing your third party vendor, understanding the audit finding and the severity of the occurrence is an important first step. Audit observations represent deficiencies and are classified according to an assessment of risk to patients, product quality, data integrity and potential for regulatory action. All observations require a response in order to ensure those responsible have given adequate consideration to the observations and are working to correct them. This is an opportunity for sponsors and their partners to unite on the issue and starting working together on a response plan. By partnering at the beginning and involving everyone during the audit response writing process the team will be harmonized on how the issue will be addressed.

11:35 Stop the Audit Treadmill: How Not Auditing Can Improve Your Vendor Management Program

Brandy Schenck, Manager, Quality, Cerulean Pharma, Inc.

Have you ever faced a quality issue with one of your vendors and had the immediate request to just go conduct an audit? Did that solve the problem? There are times when a well-planned vendor audit is just the ticket, but are there situations when it is not the most effective solution. Let's put down the check lists, the SOPs, and that worn out copy of E6 and explore alternative ways to make real-time improvements in vendor performance. Your presenter will demonstrate how to incorporate new tools into the vendor management program that go beyond the standard vendor audit. The session will provide case studies to show situations where the quality audit approach was not the best choice and what alternative strategies were used instead to achieve a successful outcome.

12:20 pm Close of Conference

1:00 Short Course Registration

1:00 – 3:30 Short Course 2, Metrics & KRIs: Study Oversight in a Risk Management Environment – How to Make It Work! *(see page 3 for additional information)*

6:00 – 8:30 Short Course 3, Managing the CRO Relationship: From Engagement through Delivery *(see page 3 for additional information)*

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Fourth Annual | June 4 - 5

Clinical Auditing Forum

Ensuring Audit Readiness and GCP Compliance Across Clinical Research Functions

CHI's fourth annual **Clinical Auditing Forum** will feature best practices for risk-based auditing techniques, quality systems-based approaches to auditing, and ensuring GCP inspection readiness. This event will focus on how to strengthen auditing programs, ensure compliance, manage non-compliance, RCA and CAPA, and international auditing techniques. Participants will benefit from real-world examples of risk-based approaches to auditing sites, systems, and providers, as well as insights, case studies, hands-on activities, and take-away tools for clinical auditors.

WEDNESDAY, JUNE 4, 2014

7:00 am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

8:15 Change at FDA Brings Challenge to Industry

Jerri B. Perkins, M.D., former Medical Officer, FDA

Currently FDA is challenging the oversight of clinical investigations with a risk-based approach. This session will include an overview by a former FDA medical officer of the importance of how high quality monitoring/auditing can help ensure sites are prepared for FDA inspections. Utilizing case studies and questions from participants, we will de-mystify the process of FDA audits using this new Guidance to Industry. Upon completion of this program participants will be able to:

- Ensure investigational study sites are prepared to meet new guidance
- Understand how key aspects of how the guidance may affect your study plans
- Understand FDA's latest approach to risk-based clinical investigations
- Know what steps you can take to become a futurist thinker on FDA

9:00 SOP Assessment: Ensuring GCP Compliance in Standard Operating Procedures (SOPs)

Elizabeth Ronk Nelson, MPH, President and Senior Consultant, Regulatory Risk Management

Standard Operating Procedures (SOPs) are defined as detailed, written instructions that permit processes to be executed uniformly. In an effort to ensure compliance with regulations and guidelines, many sponsors, CROs,and clinical research sites have developed and incorporated SOPs into their operations. Although training of staff and assessment of comprehension and compliance are crucial to implementation, the content and structure of SOPs should be routinely audited to take full advantage of their purpose. The session will introduce regulatory expectations for SOPs and some approaches to evaluating SOPs to ensure they are current and compliant. Session objectives include:

- Discuss the FDA's expectations for Sponsor/CRO, IRB, and Clinical Investigator SOPs
- Examine the systems for compliant development, implementation, and management

9:45 Coffee Break and Exhibit Viewing

AUDITING STRATEGIES AND TOOLS

10:15 Utilization of a Risk-Based Compliance Audit Tool for the Conduct of Audits

Ken Schiff, BA, MBA, Quality Risk Management Associates, LLC

The Compliance Audit Tool will assist auditors in conducting audits and ensuring consistency in capturing and reporting audit findings from compliance audits, such as those performed on clinical trial centers. This risk-based auditing tool contains built in risk assessment methodologies which allows audit findings to be classified by risk impact (high, medium and low).In addition to the classification of audit findings, the use of such a tool will allow trending of audit findings across many types of audits. The compliance audit tool has the ability for automated generation of the audit reports and action plan documents which will allow for a much quicker turnaround time for reporting and CAPA management.

11:00 Interactive Roundtable Discussions

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

1:00 pm Risk-Based Approach to Internal Audit Schedule

Ellen Liedel-Sargent, Director Clinical Quality Assurance, ICON , Plc.

Implementing an internal audit schedule can help appropriately assess the risks and utilize resources in the most cost effective manner. Annual audit schedules should address site audits, process audits, project- or program-specific audits, and vendor audits. The audit plan should be based on timely identification of risks or issues that allow mitigation in order to preserve the quality of the data and safeguard the study participants. A systematic process can be accomplished using the EMA approach of risk-based quality management in clinical trials. Specifically:

- Identification of risks or areas of risk, and understanding their impact
- Decision making on identification of areas of high risk that may require mitigation or confirmation that potential risks are properly addressed
- Ongoing effectiveness checks to ensure mitigation is providing desired outcome

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FDA FINDINGS, TRENDS, AND READINESS

CASE STUDY!

1:45 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., CCRA, MA, Clinical Investigation, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

At Boston University, we have established Quality by Design (QbD) parameters and Quality Risk Management (QRM). QbD and QRM are a new expectation by regulatory agencies under GCP. In light of RBM and the expansion of QRM, the need for the integration of these two concepts becomes apparent. The premise behind RBM is that monitoring quality can improve by leveraging existing data intelligence. This, in turn, calls for more robust quality assurance (QA) systems focused and efficient resource utilization and allocation at the clinical site level. QRM is the proactive identification and mitigation of risks. By combining these two concepts, the inherent risks identified up front can feed into the design of the RBM plan QbD. This session will demonstrate practical aspects of developing key performance and quality indicators at all stages, and follow-up of the identified signals.

2:30 Regulatory Trends: Review of Recent FDA 483/Warning Letters Findings for Sponsors, IRBs, and Sites

Paul Papagni, Executive Director, Research, Holy Cross Hospital CHE

FDA findings serve as an excellent training and audit preparedness tool to ensure that you are focusing on relevant risks. Research teams, sponsors, and IRBs can learn from the past mistakes of others and utilize findings as a checklist for future self-audits and training. "We are in this together" the FDA is helping to align and delineate priorities to ensure safe, high quality clinical trials. Is your "risk-based" plan adequate to address unanticipated problems? After this session, participants will be able to:

- Develop a checklist for compliance based on FDA findings
- Identify current "hot topics" and trends in research compliance
- Develop training programs to anticipate FDA Visits and ensure "audit readiness"

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break and Exhibit Viewing

3:50 International Audits: Regulatory Requirements, Regional Considerations and Similarities and Differences from FDA

Speaker to be Announced

4:35 Comparing Drug to Device GCPs: ISO 14155 to ICH E6

Lee Truax-Bellows, President, CEO, Clinical, NCRA

Back in 1996 the US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) adopted the ICH E6 guideline in regards Good Clinical Practice (GCP) for drug studies and more recently (2012) FDA's Center for Devices and Radiological Health (CDRH) recognized the ISO 14155 Standard for GCP conduct within medical device studies. Though there are many similarities between the two, each also has unique characteristics, right down to why FDA can adopt one but only recognize the second. This presentation will outline the purpose of the ICH E6 guideline and the ISO 1455 Standard. Differences and similarities between the two approaches will be discussed.

5:20 Welcome Reception and Exhibit Viewing *(Sponsorship Opportunity Available)*

6:20 Close of Day One

THURSDAY, JUNE 5, 2014

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

IMPROVING OUTCOMES THROUGH COMPLIANCE

8:00 We're from Compliance and We're Here to Help – Really We Are!

Anne Adams, MS, J.D., Chief Compliance Officer, Emory Healthcare and Associate Vice President, Clinical Trials Compliance, Emory University

Emory University has developed a value-based proactive Clinical Trial Compliance Program. Understand how Emory supports the mission of quality initiatives and reviews, PI education, accountability, and the development of tools that increase compliance with protocols, regulations, and GCP. Learn how the program supports PIs to help meet their responsibilities, ensure integrity of the data, and build trust with sponsors and the community. Explore lessons learned in rolling out a compliance program, database development for trending reports of review findings, building consensus, and coordinating efforts with the IRB and Research Compliance. We will discuss mandatory clinical trial education development and feedback from the PIs. Learn how a program supports greater efficiency and improved outcomes through a better trained workforce, defining roles and responsibilities, and identifying and addressing problems early in a clinical trial.

8:45 Achieving Compliance in Research: The Implementation of Quality Improvement Systems

Johanna Stamates, RN, MA, CCRC, CHRC, Executive Director, Research Compliance and Quality Assurance, University of Miami

The field of clinical research is constantly evolving – the new and ever-changing regulations, rules and guidance documents, increased clinical research oversight by regulatory agencies, and the increasing sophistication of the public and of potential research subjects require not only sponsors, but also universities and

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Clinical Auditing Forum

Ensuring Audit Readiness and GCP Compliance Across Clinical Research Functions

academic medical centers, to stop and reflect on their current practices in the conduct of clinical research. The current climate requires awareness, use of quality systems, risk management—in short, a proactive rather than a reactive approach. This presentation will provide the audience with examples of positive changes, heightened awareness, and the implementation of quality systems to change the university's research compliance role from that of a policeman to that of a supporting and collegial partner.

9:30 Coffee Break and Exhibit Viewing

9:50 Final Guidance on Electronic Source Data in Clinical Investigation

Amy Moore, RQAP-GCP, Senior Auditor, Systems Compliance Office, Shared Business Services, Quintiles

What regulations govern the use and address the myriad concerns of EHRs in clinical research? And how can the data collected in them be leveraged for use as source data? This session will focus on the Final Guidance on Electronic Source Data in Clinical Investigations (Sept. 2013), HIPAA, Meaningful Use, Part 11, and some best business practices that fulfill the requirements of source data as listed in 21 CFR 312.62 and ICH. We will discuss real-world examples of where we are now in terms of availability and use as source in clinical studies with EHRs both in the US and globally. Special attention will be given to current challenges and successes with EHRs for source data in clinical research and what is just around the corner–integrated EHR/EDC systems.

PERFORMING MOCK AUDITS

10:35 Performing Mock Inspections to Identify Strengths and Address Weaknesses

Michael G. Duncan, Program Manager, Global Systems, Quality Assurance, Johnson & Johnson

Swati A. Tendolkar, BPharm, MT(ASCP), MS, Program Manager, Global System Quality Assurance, Johnson & Johnson

RISK-BASED AUDITING TECHNIQUES

CASE STUDY!

11:20 Implementing a Risk-Based Auditing Approach in Clinical Trials

Federico Feldstein, J.D., Senior Director, Quality Assurance, Pfizer

Karine Julien, MBA, MSc, Disease Area Lead, Cardiovascular/Metabolic Disease, Pfizer Medical Quality Assurance

Risk-based auditing is intended to help identify key priority programs for audit purposes. The process begins with the active involvement of key stakeholders across an organization to perform risk assessments, leading to the implementation of a risk-based auditing approach to mitigate risk at an enterprise level. It also allows for a greater focus of resources on priority programs, while still maintaining in-depth assessment of patient safety and rights, data quality and study integrity, and compliance with protocols. This presentation will discuss some approaches to the implementation of risk-based auditing activities, critical to success factors and the benefits of the implementation of this process, as well as a case study of the implementation of risk-based auditing at Pfizer for clinical trials.

12:05 pm Close of Conference

1:00 Short Course Registration

1:00 – 3:30 Short Course 5, Quality by Design for Success: QbD in the Design and Planning of Your Clinical Trial *(see page 3 for additional information)*

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Fifth Annual | June 4 - 5

Clinical Project Management Forum

Risk-Based Approaches to Maximizing Trial Performance

The effects of globalization, social media, and risk-based approaches to clinical trials have had a profound effect on project managers. CHI's fifth annual **Clinical Project Management Forum** will address the many responsibilities of clinical project managers, and evolving issues such as ensuring the delivery of high quality and highly valuable data, improving performance, optimizing patient recruitment, mitigating risk, and navigating the various challenges and opportunities of global clinical trials. Participants will benefit from case studies, take-away tools, perspectives on the current regulatory environment, breakout groups, and interactive activities.

WEDNESDAY, JUNE 4, 2014

7:00 am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

RISK-BASED APPROACHES TO PROJECT MANAGEMENT

CASE STUDIES!

8:15 Risk Management and Implementation of Strategic Project Management Tools in Clinical Trials

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

At Boston University, we have analyzed clinical trials testing fibroblast cell based agents. These studies have similar objectives, study design, inclusion/exclusion criteria, and outcomes of biological trials. We have attempted to develop and implement strategic management tools in order to improve performance and compliance. We have developed and implemented project management tools such as Schedule Performance Index (SPI) and Cost Performance Index (CPI) that yielded higher enrollment and better compliance rates. Also, we performed risk assessment and Cause-Effect Analysis which allowed us to accelerate start-up activities, and increase compliance and efficiency during the execution phase. After this session, participants will be able to explain concepts of strategic management tools, design a risk management plan, perform Cause-Effect Analysis, calculate schedule performance and cost performance index, assess efficiency of clinical trials, and improve performance and compliance.

9:00 Mitigating Clinical Study Risks Utilizing a Robust Catalog of Targeted Reports

Rosanne Petros, Clinical Project Manager US, Global Clinical Trial Operations–The Americas, Merck Research Laboratories

In an effort to include those study sites with the greatest chance of success, Merck has developed metrics reports showing cycle times for many factors related to site readiness: IRB submission and approval, contracting, and first subject enrolled. In addition, the metrics include variances between anticipated and actual subjects screened and enrolled, as well as a comparison of site versus overall screen failure and discontinuation rates. Once sites are selected, we continue to monitor site ready data with another group of targeted reports. These reports track planned, latest estimate, and actual dates for study start up activities, focusing on outliers which could trigger potential timeline slippage. After site ready milestones are met, we focus on site recruitment and retention, including indicators surrounding potential patient risk. Using a risk-based model, monitors visit sites based upon factors such as number of subjects enrolled, subjects ongoing, subjects screened, number and type of protocol deviations, and site issues such as site staff turnover.

9:45 Coffee Break and Exhibit Viewing

10:15 Coverage Analysis, Budgeting, and Pre-Award Practices Limiting Fiscal Risk in Clinical Research

Erika Stevens, Senior Manager, Advisory Services Health Care, Ernst and Young LLP

This session identifies pre-award processes and institutional approaches to increasing fiscal return and mitigating fiscal compliance risk for clinical trials. The ability to develop robust budgets and ensure billing compliance for clinical trials is a challenge for many sites. Furthermore, guaranteeing adherence to CMS regulations can be a struggle. Poor fiscal forecasting and undefined billing compliance practices associated with clinical trials increases the risk of deficits and OIG investigations. This session describes the strategies for covering true costs related to clinical trials research, illustrates techniques for avoiding false claims, and evaluates case studies. Participants will be able to:

- Describe the processes for fiscal oversight of clinical trials research
- Recognize key tools for managing fiscal/regulatory activities
- Apply leading practice to coverage analysis oversight

11:00 Interactive Roundtable Discussions

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

KEY PERFORMANCE AND QUALITY INDICATORS

1:00 pm A Holistic Approach to Managing Clinical Trials

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

In 2011, FDA and EMA each published papers on risk-based approaches to managing clinical studies. FDA focused directly on monitoring as such; EMA's publication reviews clinical development and how a risk-based approach can help overcome current issues. Many sponsors have embarked on this new course, but many are struggling to complete the change. There are some essential questions that need to be answered:

- Why do sponsors face difficulties when implementing a risk-based approach?
- 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 RBM promises? What needs to be done to make it happen?
- Focusing where it really matters, how can we detect real quality improvements?

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1:45 Remote Control: Managing Teams You Rarely See
Stephanie J. Zafonte MSN, RN, CCRP, Nurse Consultant/Clinical Project Manager, EHDB/DMID, NIAID, NIH, DHHS

GLOBAL CLINICAL TRIAL CHALLENGES AND OPPORTUNITIES

2:30 Multi-National Clinical Studies: The Good, The Bad, and The Ugly
Kenneth K. Kleinhenz, Vice President, Global Regulatory Affairs, Cytori Therapeutics, Inc.
Multi-national clinical studies are frequently utilized as a means to expedite study enrollment and involve influential multi-center institutions, leading to high-quality publications and investigator podium presentations that facilitate early commercial credibility. Depending on the nature of the medical product to be studied, careful consideration must be given to which countries are chosen for multi-national studies. When complex and innovative medical products are involved, we must consider all aspects of the multi-national strategy, including regulatory history, structure, leadership, burden, and credibility, as well as potential patient population and the primary language of the prospective clinical trial country. This presentation will address the pros and cons of common clinical trial countries, and share practical experiences with a novel medical device that processes adult stem cells in the same surgical procedure.

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break and Exhibit Viewing

3:50 Strategies for Success in Emerging Markets
Mauro Martinelli, Associate Director, Emerging Markets Specialist, Clinical Development, Quintiles
Emerging Markets are increasing their relevance in global clinical trials, especially as some of them are becoming strategic from a commercial point of view, supported mainly, by significant development of a middle class demanding more and better medications, paired to an increased prevalence of typical diseases of the Western World. Such is the case of Brazil, and to a certain extent, of Mexico and Argentina. Governments are increasing their expenditure in healthcare, while industry is trying to reduce cost. Focusing attention on where to allocate enrollment is a key factor. Companies that have seldom worked outside the US and EU will need to assess other markets, and Latin America has a key role in this regard.

CASE STUDY!

4:35 Overcoming the Challenges in Global Clinical Trials: A Clinical Trial in Asia
Larn Hwang, Ph.D., Vice President Regulatory & Clinical Operations, Sorrento Therapeutics Inc.
Trials in Asia are becoming increasingly popular with the growing number of competing trials in US/EU. Asia trials are expected to be faster to set up, more rapid regulatory submission, quicker patient enrollment rate, and lower study costs. We would like to share our experience in conducting oncology trials in Singapore and Malaysia. The hurdles and advantages of these trials will be presented. The regulatory framework of each country will also be addressed. We will compare and contrast oncology trials between the US, EU, and Asia.

5:20 Welcome Reception and Exhibit Viewing *(Sponsorship Opportunity Available)*

5:45 Short Course Registration

6:00 – 8:30 Short Course 4, Take Control of Your RCA and CAPA Activities to Achieve Clinical Excellence *(see page 3 for additional information)*

6:20 Close of Day One

THURSDAY, JUNE 5, 2014

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

MANAGING SITES TO SUCCESS

8:00 Selecting and Qualifying Clinical Sites and CROs
Dayna Geralts, Senior Manager, Clinical Operations, Hologic, Inc.

8:45 Maximizing Site Performance from Start-Up to Close-Out
Musa Mutyaba, CCRA, Infinity Pharmaceuticals, Inc.
Much wanted and needed outcomes of subject recruitment and data quality are heavily dependent on high performing sites. A high performing site almost always has good working relations with the sponsor/CRO. To become a site's sponsor/CRO of choice, it's important to partner with them if implementing Quality by Design is to be at all feasible. Clinical Project Managers are integral in building this relationship and are tasked with defining metrics to measure the "health" of the study. During this talk, we will examine strategies that can be employed to engage sites, enhance the relationship, and in turn improve performance. Collaborative risk management, real-time performance and risk assessment analytics, and targeted training plans will be discussed, and a case study of an effective site partnership model will be presented.

9:30 Coffee and Exhibit Viewing

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CASE STUDY!

9:50 How to Be Agile Oriented in Managing the Clinical Site

Ahmed R. Saleh, Ph.D., MS, CCRP, Director, Clinical Trials, Laboratory of Viral Diagnostics, University of Maryland, Baltimore, School of Medicine

Site success using new successful management plans can help sites compete and still save money. This session will demonstrate what the Agile model of project management means and how it can be adopted in site management. Some of the tools that will be discussed are the thorough planning for the study well before the start, planning the evaluation intervals and the expected goals at each interval, and examining the output before moving from one interval to the other. Case studies from Academic Research Organizations (ARO) will clearly show the differences of the endpoint results. Learners will be able to:

- Define the Agile model and its core elements.
- Apply the Agile model in the clinical site, from the time a new study is assigned to the site.
- Approach the implementation of the study with new criteria to re-evaluate and adapt to the interim model designed

CASE STUDY!

10:35 Putting a Price on Priceless: Establishing a Correlative Sciences Program at Your Research Centre

Vanessa Speers, MSc, BEd, CCRP, Manager, Correlative Studies Program & Clinical Trials Support Unit, Princess Margaret Cancer Centre

Correlative studies are becoming increasingly common in all phases of clinical research. Consequently, the management of bio-specimens has become a significant issue when planning out the logistics of a successful study. This presentation will provide an overview of components of a correlative sciences program, the requirements for establishing a successful program, and the benefits that it provides to both clinical research personnel and patients. Learning from the experience of PMCC, one of the top five cancer research centres in the world, attendees will discover what a correlative sciences program does on a daily basis, what the requirements are to set-up and manage a program, the requirements to manage all of the logistics, and the benefits that it can provide to both patients and clinical research personnel.

11:20 Fun, Easy, and Popular: How to Apply Social Marketing Principles to Subject Recruitment Planning

Carol Breland, Research Recruitment Director, The North Carolina Clinical and Translational Research Institute, The University of North Carolina at Chapel Hill

Subject recruitment can be frustrating, time-consuming, and expensive. Planning for subject recruitment is critical to the success of trials, but project teams often have a little more than a vague idea about how they will recruit beyond querying their database. It doesn't have to be this way! Using social marketing principles developed over the past 40 years in public health and commercial marketing campaigns, potential volunteers can more easily be identified, targeted, and recruited. Using social marketing principles fosters an individualized approach to recruitment planning that takes into account the needs and desires of a particular target audience, and acknowledges the benefits and barriers to volunteer participation for a particular trial. This presentation will outline some general concepts taken from social marketing principles and how to apply them to recruitment planning, and how to create a recruitment plan.

12:05 pm Close of Conference

1:00 Short Course Registration

1:00 – 3:30 Short Course 5, Quality by Design for Success: QbD in the Design and Planning of Your Clinical Trial

(see page 3 for additional information)

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.

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(SC3) Managing the CRO Relationship: From Engagement through Delivery

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June 2 - 3, 2014	June 4 - 5, 2014
Mastering Clinical Trial Monitoring	Clinical Auditing Forum
Vendor Management in Clinical Trials	Clinical Project Management Forum

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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.

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