Barnett International and Cambridge Healthtech Institute's Inaugural

BARNETT EDUCATIONAL SERVICES

Clinical Trial Oversight SUMMIT

June 4–7, 2012
Omni Parker House, Boston, MA

Third Annual

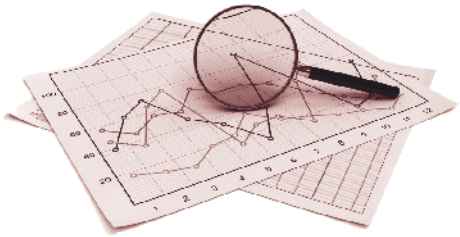
Mastering Clinical Trial Monitoring

June 4–5

Inaugural

Clinical Quality Risk Management

June 4–5



Second Annual

Clinical Auditing Forum

June 6–7

Inaugural

Vendor Management in Clinical Trials

June 6–7

Register by April 27 and Save up to $200

Event Short Courses:

Strategies for Source Documentation Verification (SDV)
Proactive Approaches to Vendor Management
SOP Assessment: Ensuring GCP Compliance in SOPs

Event Highlights:

4 Conferences; ONE Location!
Over 60 Presentations
Panel Discussions
Case Studies
Dedicated Workshops

Organized by:
Cambridge Healthtech Institute

ClinicalTrialSummit.com

Welcome

Dear Colleague,

On behalf of Cambridge Healthtech Institute (CHI) and Barnett International, we invite you to attend the inaugural Clinical Trial Oversight Summit, June 4-7, 2012, at the Omni Park House in Boston, MA. This four-day, one-of-a-kind event 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. The Summit will feature four co-located conferences:

Mastering Clinical Trial Monitoring
June 4-5 – *Third Annual!*

Clinical Auditing Forum
June 6-7 – *Second Annual!*

Clinical Quality Risk Management
June 4-5 – *Inaugural Event!*

Vendor Management in Clinical Trials
June 6-7 – *Inaugural Event!*

Please take a moment to look through the following Summit agenda. We believe that you will find the speakers and topics interesting and informative. As always, we are grateful for the help of the many dedicated faculty and program advisors, and we recognize that without their help and advice, this Summit would not exist.

We look forward to seeing you at the Summit!

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Summit At-A-Glance

Monday AM	**Mastering Clinical Trial Monitoring**	**Clinical Quality Risk Management:**
Monday PM	**Mastering Clinical Trial Monitoring**	**Clinical Quality Risk Management**
Tuesday AM	**Mastering Clinical Trial Monitoring**	**Clinical Quality Risk Management**
Tuesday PM	**Mastering Clinical Trial Monitoring**	**Clinical Quality Risk Management**
	DINNER SHORT COURSE: Strategies for Source Documentation Verification (SDV): Regulatory Requirements and Best Practices	
Wednesday AM	**EVENT SHORT COURSE: Proactive Approaches to Vendor Management**	
Wednesday PM	**Clinical Auditing Forum**	**Vendor Management in Clinical Trials**
	DINNER SHORT COURSE: SOP Assessment: Ensuring GCP Compliance in Standard Operating Procedures (SOPs)	
Thursday AM	**Clinical Auditing Forum**	**Vendor Management in Clinical Trials**
Thursday PM	**Clinical Auditing Forum**	**Vendor Management in Clinical Trials**

Event Short Course and Dinner Courses*

TUESDAY, JUNE 5

Dinner Short Course

5:30 – 8:00 pm Strategies for Source Documentation Verification (SDV): Regulatory Requirements and Best Practices

Instructor: Leslie Humphries, MT, Senior Manager, Clinical Monitoring, DSP Clinical

In this workshop, we will focus on the monitor's responsibilities to understand the need to evaluate source documents during the SDV process, to ensure they adequately meet the regulatory requirements including the ALCOA standard. We will explore the adequacy of medical records, site generated source, sponsor provided worksheets, shadow charts, and electronic medical records (EMRs) as appropriate study source documents, and the risks/benefits of each. In addition, a mock environment will be provided for a hands-on activity that will support the understanding of this evaluation and how to best identify deficiencies and challenges of monitoring each record type. Real FDA audit findings will be discussed which relate to adequate study documentation and monitoring deficiencies. Attendees will take away actionable advice on how to appropriately resolve errors when they are found during the monitoring process, and how to effectively train site staff to ensure better study data documentation and regulatory compliance. Attendees will learn three key elements for improving source document verification:

- Evaluate source for adequacy and regulatory standards
- Identify common errors that lead to audit findings
- Implement appropriate actions to resolve errors/issues

WEDNESDAY, JUNE 6

Event Short Course

8:30 – 11:00 am Proactive Approaches to Vendor Management

Instructors:
Michael J. Harte, Founder and President, The Harte Group
James Kirwin, Vice President and Senior Advisor, Clinical Development Operations, The Harte Group

Vendor management and oversight is now one critical FDA and EMA audit finding. Is your clinical team proactively managing your vendors in order to prepare for these audits? This interactive session will provide valuable and useful tools and techniques to develop corrective and preventive action (CAPA) quality systems, Total Quality Management processes, and integrative management techniques to prepare your organization to better manage your vendors in a compliant manner. In this workshop, we will review approaches to the following activities:

- Designing a vendor qualification program
- Developing a vendor management plan
- Developing integrated vendor/sponsor processes
- Identifying and implementing on-going quality checks to ensure deliverable quality
- Determining quality measures for vendor deliverables
- Developing deliverable standards for vendor work product
- Processes and standards to analyze the vendor's infrastructure and staff assigned to the study
- Developing a program to manage risk, escalate issues, and effectively collaborate with the vendor
- Case Study: Investing in a vendor/sponsor strategic alliance: A proactive method to ensure quality across all functions in clinical operations
- Managing the shifting internal responsibilities of staff in an outsourced environment; the use of tools such as RACI, integrated process flows, and the development and identification of new skills for internal staff

Dinner Short Course

6:00 – 8:30 pm SOP Assessment: Ensuring GCP Compliance in Standard Operating Procedures (SOPs)

Instructor: 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. Too often, however, these documents are not reviewed critically and with enough frequency to make certain the information they convey is accurate and acceptable. 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. In this workshop, we will discuss approaches to evaluating SOPs to ensure they are current and compliant. Course objectives include:

- Examine the true purpose of SOPs and systems for compliant development, implementation, and management
- Discuss the FDA's new expectations for Sponsor/CRO and Clinical Investigator SOPs
- Review recent case studies concerning issues in SOP documentation and implementation practices

**Separate Registration Required*

Become an Active Sponsor!

Brand your company as a thought leader by participating as an active sponsor at Barnett International and Cambridge Healthtech Institute's Inaugural Clinical Trial Oversight Summit. Presenting your solutions or services directly to our top-tier delegates can significantly impact their buying decisions and help you achieve your sales and business development objectives. CHI can customize any sponsorship package to meet your company's needs and budget.

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

User Group Meeting
Take advantage of the prestigious audience in attendance to conduct market research or gather feedback on your new product or service on-site. CHI will provide a meeting room set for 50-75 delegates, equipped with AV including an LCD screen. This presents a rare opportunity to meet with a large, targeted group of end-users, and walk away from the conference with qualified leads and information!

Invitation-Only VIP Dinner/Hospitality Suite
Sponsors will hand-pick 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. Evening will be customized according to sponsor's objectives (i.e. purely social, focus group, reception style or plated dinner, plated dinner with specific conversation focus).

CHI Lead Generation:
CHI can help you with lead generation throughout the year. Our internal database includes over 800,000 prospects in the life sciences. By leveraging the database and mining for your specific requirements, we can produce multiple custom projects which will deliver your prospective buyers: Web Symposiums, Podcasts, White Papers, Custom Market Research Surveys, and more!

Additional exhibiting & promotional opportunities are available!

To explore the various ways your company can participate, please contact:

Ilana Quigley
Manager, Business Development
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Sponsoring Publications: CenterWatch, eCliniqua, PharmaVOICE

Barnett International and Cambridge Healthtech Institute's Third Annual

Mastering Clinical Trial Monitoring

June 4–5

The Premier Event for Experienced Clinical Trial Monitors

MONDAY, JUNE 4, 2012

7:00 am Registration and Morning Coffee

8:00 Welcome & Chairperson's Opening Remarks

Risk-Based Monitoring Case Studies

8:15 Risk-Based Monitoring: Abbott Vascular's Enhanced Monitoring Initiative
Stanley E. Reaves, Jr., RCIS, Senior Clinical Research Associate, Abbott Vascular
John Creech, CCRP, Senior Clinical Research Coordinator, Abbott Vascular
This is a practical session that will provide insight into how Abbott Vascular has implemented a risk-based monitoring approach in the clinical organization. This session will describe how using this risk-based, enhanced monitoring approach has helped to increase efficiencies and produce cost savings while maintaining a high level of quality and compliance in clinical trials. This session also will describe background information and current industry trends, the processes and tools used to implement enhanced monitoring at Abbott Vascular, as well as the challenges and perceived benefits of using this approach.

9:00 A Risk-Based Approach to Monitoring: A Sponsor's Perspective
Linda Tedder, Senior Clinical Project Manager, DePuy Franchise Clinical Operations
A sponsor is responsible for ensuring adequate monitoring per the regulations, and FDA has issued a new guidance document specifically addressing this topic. There are a variety of ways to approach monitoring to ensure that you get the best data, all the while ensuring the quality of the data. Monitoring can be done onsite or offsite, or a combination of both. A sponsor needs to determine what works best for a particular study, and then draft the monitoring plan to ensure that quality is achieved.

9:45 Coffee Break

10:15 Lessons Learned through a Challenging Site FDA Audit: A Case Study
Nancy Bakke, Principal Clinical Study Manager, Clinical Research Monitor, Sorin CRM USA, Inc.
Even though there are no federal regulations against the sponsor completing CRFs, the FDA Inspector's claws came out during this recent FDA Audit. The inspection became about this issue, and nothing else. The practice of sponsor personnel completing case report forms is not the norm; however, there are many other practices that are not against regulations that the Inspector may focus on. In this session, your speaker will provide insight into how to prepare your site for the FDA audit; how to quickly turn the Inspector's focus to where it should be; and how to respond to the 483.

» INTERACTIVE ROUNDTABLE DISCUSSIONS

11:00 Facilitated Breakout Sessions (choose one)
A. Approaches to Site Training: Implementing, Following-Up, Documenting, and Evaluating the Effectiveness of Training Initiatives
B. Monitoring in the Electronic Environment: EMRs, eCRFs, and Tablet-Based EDC
C. Meeting Global Monitoring Challenges: Global vs. US Regulations, Country- and Region-Specific Monitoring, and Achieving Cultural Competency
D. Hiring, Training, and Retaining Monitors
E. Site Budgets and Contract Negotiations: Best Practices, Pitfalls, and Optimizing Efficiencies

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

Quality Systems-Based Approaches to Clinical Trial Monitoring

Join your colleagues at the Clinical Quality Risk Management track for these joint sessions *(for full abstracts see page 6)***.**

1:00 pm FDA Draft Guidance on Risk-Based Monitoring of Clinical Trials
Anne Marie Murphy, Principal, Hyman, Phelps & McNamara

1:45 Clinical Site Issue Escalation: A Vital Process in Clinical Quality Management
Daniel J. Greenwood, Senior Associate Director, Compliance & Quality Management, Boehringer Ingelheim Pharmaceuticals, Inc.

2:30 Transitioning from Auditing to a Quality Improvement System
Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, Regulatory Support and Quality Assurance, University of Miami

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break

Monitoring Techniques, Tips, Tricks, and Apps

3:50 Selecting the Right Sites the First Time: How to Use the Pre-Study Visit to Increase Trial ROI
Manley Finch, Executive Director, HIV Nutrition Network, NPO
80% of clinical trials are not enrolled on time. This delays time to market and increases clinical trials costs. The use of targeted strategies to identify and select the right sites for your trial increases the efficiency and decreases the costs of your trials. The pre-study visit and the CRA are essential in this model. In this session, participants will learn how to:
- Craft and administer an effective site assessment form to preliminarily identify the right centers
- Use the pre-study visit to ensure you have the right sites
- Train your CRAs to be the best at site identification

4:35 Monitoring 2.0: Root Cause Analysis and CAPA Planning at Investigative Sites
Karen L. Gilbert, BS, CCRA, Clinical Trainer & Curriculum Manager, Barnett International
A successfully conducted clinical trial requires comprehensive management of non-compliance by all stakeholders, leading to improved human subject protections and confidence in the integrity of the data. The critical role of the CRA/Monitor in this endeavor is increasingly being recognized, even to the point of its inclusion in the FDA's August 2011 Draft Guidance entitled "Oversight of Clinical Investigations – A Risk Based Approach to Monitoring." This presentation will present strategies to aid clinical research monitors in accomplishing the following:
- Identify and recognize non-compliance
- Understand the root cause
- Facilitate the selection of interventions to correct and prevent recurrence (where applicable)
- Evaluate the effectiveness of the intervention

5:20 Tools, Tricks, Tips, and Apps: Making Monitoring Easier
Sarah Ramey, Clinical Research Associate, Clinical Operations, Duke Clinical Research Institute
In this practical session, we will discuss how to leverage your phone and computer programs in many aspects of monitoring and travel. Have you ever been onsite with internet service down, and you need to know what a mystery conmed does? There's an app for that! You can program an Excel spreadsheet to automatically tell you which subjects are out of window, who needs to sign which consent, and which ones you have monitored. Using these tools and more not only make monitoring easier, they also facilitate critical thinking so you can be a better monitor. Please bring your smartphone or tablet to learn hands-on and to share your own tools, tricks, tips, and apps!

6:05 Welcome Reception *(Sponsorship Opportunity Available)*

7:00 Close of Day One

TUESDAY, JUNE 5, 2012

7:30 am Morning Coffee or Sponsored Breakfast Presentation *(Opportunity Available)*

Site Relationship Management and Performance Improvement

8:00 Site Relationship Management: Achieving Compliance and Commitment
Millie Shultz, Senior Manager, Clinical Operations, Millennium: The Takeda Oncology Company
This talk will address the importance of a strong Site-Sponsor relationship. Working collaboratively can increase both the speed and quality of clinical trial conduct. Approaches to fostering a strong Site-Sponsor relationship will be addressed, including how to incorporate these practices when using a CRO partner. Partnering with sites to leverage key opinion leader (KOL) knowledge to progress a molecule's development plan will also be discussed.

8:45 From Monitoring to Site Management: The Evolving Role of the CRA
Tish Bradburn, BS, Associate Manager, Clinical Studies, Terumo Heart, Inc.
The role of a traditional CRA or Monitor is ever-changing. With the recent updates in monitoring guidelines, added industry/sponsor pressure, and complexity of protocols, the CRA role is becoming more of a site management role. How does a site management role benefit a sponsor, a site, or even a traditional CRA/Monitor? What responsibilities can be included in the site manager role? Regulations, business strategies, and overall study management will be considered when discussing the pros and cons of the Site Management Model.

9:30 Coffee Break

9:50 Partnering and Visibility though Effective Communication
Carol Ann Mancuso, RN, BS, Senior Clinical Site Manager, Bristol-Myers Squibb Co.
Trying to manage the myriad of clinical study details often leads to a lack of communication with your sites. We will look at some ways to increase study visibility at the sites you are managing by improving your communication skills through a communication plan. In developing a communication plan, we will look at a few elements for consideration in your plan, e.g., modes of communication, frequency of messages, and other communication methods. We will also look at ways to engage your sites to ensure their commitment to your study, along with the added value soft skills bring to the success of your study.

10:35 Site Management through Analytics, Relationships, and Teamwork: Optimizing Relationships for Performance
Ann Dilworth, MPH, Associate Director, Northeast Region, Regional Clinical Operations, US Site Monitoring Group, Bristol-Myers Squibb
In this presentation, we will discuss how optimizing the monitor-site relationship can maximize clinical trial performance and quality while reducing operational costs. Driven by changes in industry and regulatory authority guidance, the monitor's role is evolving to include risk-based monitoring and the use of electronic data capture. These developments allow for increased connectivity at the site level via more robust and focused discussions, troubleshooting, and collaboration with other site-facing personnel. Your speaker will provide a perspective on the evolution of the site monitor role and the impact that optimizing site relationships can have on performance and quality.

11:20 Applying a Quality Systems Approach to Clinical Research
Lee Truax-Bellows, President & CEO, Norwich Clinical Research Associates Ltd. (NCRA)
Industry continues to fail to meet the minimum regulatory requirements as evidence by the 483s and Warning Letters that are issued by the FDA. These areas of FDA concern remain the same year after year, and include inadequacy in monitoring, securing Investigator compliance, investigational product accountability, training, and IRB oversight. With all the training that companies put their staff through, guidance documents issued by FDA, and continued negative inspections and resulting citations, why does this continue to happen? Perhaps because companies are better at applying a quality systems approach to their manufacturing than they are to their clinical activities. This session will explore the concepts of expanding a quality systems approach to the clinical arena and provide direction on a practical approach to incorporating it into the practice of their daily clinical research activities.

12:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

Monitoring in Unique Environments

1:20 Meeting the Unique Challenges of Medical Device Study Monitoring
Angelia Drake, RN, Surgical Oncology, Baylor Health Care System
Medical device clinical trials pose unique challenges. The monitor needs to be able to help the Investigator achieve the learning curve or determine if the investigator is not right for the study. Additionally, it is important for device study monitors to properly train the study coordinators on recording the desired data variables to ensure appropriate collection of source documents and clean data for the case report forms. Each medical device trial has its own idiosyncrasies, and it takes a skilled monitor to ensure the success of device trials from study launch to study closure.

2:05 Monitoring Investigator-Initiated Trials within a Pediatric Research Institute
Christina McGee, Senior Clinical Research Associate, Office of IND/IDE Support, The Children's Hospital of Philadelphia
The Office of IND & IDE Support at the Children's Hospital of Philadelphia (CHOP) provides regulatory guidance and monitoring for CHOP-sponsored and investigator-initiated IND/IDE research with the goal of assisting sponsor-investigators in meeting their regulatory responsibilities. The monitoring program includes the development of study specific data safety monitoring plans and ongoing monitoring of investigator-initiated research protocols. This presentation will focus on the unique approaches for monitoring this type of research; specifically, on an educational approach to monitoring throughout the conduct of the trial with the goal of minimizing risk, enhancing subject safety, and ensuring compliance with regulations and institutional policies.

2:50 Refreshment Break

3:10 Monitoring the Academic Medical Center: Exploring the Challenges and Opportunities of AMCs
Eric Tomasini, M.B.A., CCRA, Manager, Health Industries Advisory, PricewaterhouseCoopers
This session will familiarize attendees with the unique challenges monitors face when working to assess, initiate, monitor, and close-out large Academic Medical Center Investigative Sites. The session will focus on the etiologic factors of common AMC pain points, challenges in the pre-study feasibility phase of the project, corralling over utilized/undertrained coordinators (i.e., research fellows), as well as tips and tricks on making the most out of time on site. The audience will gain a further appreciation for the distinct challenges AMCs pose for the monitor, in relation to free standing centers and community-based trials. Upon completion of the presentation, the audience will be more informed about how to manage complex AMCs with efficiency and success.

3:55 Monitoring Investigator-Initiated INDs/IDEs in an Academic Setting: Challenges and Lessons Learned
Shankar Srinivasan, Ph.D., CCRC, Senior Regulatory Specialist, Office of Research Regulatory Support (ORRS), Mayo Clinic
Clinical trial monitors in the academic world tend to take on different roles than their industry counterparts. In addition to the typical monitoring activities, they serve as study managers providing support from study inception and IND/IDE submissions to final FDA closeout reports. This increased support comes with its own set of challenges, including limited resources, educating and training study staff, covering multiple specialty areas, and sometimes even covering multiple sites. With an increase in the number of FDA warning letters to IND/IDE sponsors, monitoring FDA regulated studies has become a prime topic in Academic Medical Centers (AMCs) affecting both individual and institutional liability. The presentation will use specific examples to share the lessons learned at a large premier multi-site AMC in the United States.

4:40 Close of Conference

Stay on for the Clinical Auditing Forum and Vendor Management in Clinical Trials (June 6-7)

ATTEND THE DINNER SHORT COURSE*

Tuesday, June 5, 2012 5:30 PM - 8:00 PM

Strategies for Source Documentation Verification (SDV): Regulatory Requirements and Best Practices
Instructor: Leslie Humphries, MT, Senior Manager, Clinical Monitoring, DSP Clinical

** Separate registration required.*

Barnett International and Cambridge Healthtech Institute's Inaugural

Clinical Quality Risk Management June 4-5

Implementing a Comprehensive Quality Management System for Good Clinical Practice

MONDAY, JUNE 4, 2012

7:00 am Registration and Morning Coffee

8:15 Welcome & Chairperson's Opening Remarks

» WORKSHOP AND INTERACTIVE SESSION!

Instructors:
Ken Schiff, B.A., M.B.A., Quality Risk Management Associates, LLC
Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.

8:30-9:30 Quality Risk Management in Clinical Trials and Pharmacovigilance

The ICH Q9 Quality Risk Management (QRM) guideline facilitates the development and implementation of a systematic risk-based approach to quality management of clinical trials and pharmacovigilance. Similarly, but more recently (August 2011), both the EMA and the FDA published a reflection paper on the application of QRM in clinical trials and an industry guidance document on "Oversight of Clinical Investigations–A Risk-Based Approach to Monitoring," respectively. Industry as well as regulatory bodies have recognized the need and benefits of implementing a risk-based approach to quality management, and are currently gearing up to accommodate this. This course is a timely response to this trend and is designed to provide its participants with a strong conceptual foundation of the principles of quality risk management with a clear focus on the application of these principles. Learning objectives include:

- Define Quality Management System (QMS) Levels for applicable areas in Clinical Trials and Pharmacovigilance
- Build quality at key points in these processes
- Apply QRM principles: Identification and Quantification of Key Risk Indicators (KRIs)
- Implement a Quality by Design approach to overcome shortcomings in quality and compliance
- Leverage existing information to support decision making in resource allocation within clinical trials
- Create a governance model to support mitigation strategies and the overall QMS infrastructure

9:30-11:30 Building Quality at Key Points in the Clinical Trial Process: An Exercise in Developing Key Risk Indicators and Critical to Quality Metrics

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 CTTI initiatives, Key Risk Indicators (KRIs) 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 will provide participants with a strong conceptual foundation for defining what is a meaningful KRI across clinical trial processes, as well as the corresponding thresholds for acceptability of outcomes.

11:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

Quality Systems-Based Approaches to Clinical Trial Monitoring

1:00 pm FDA Draft Guidance on Risk-Based Monitoring of Clinical Trials

Anne Marie Murphy, Principal, Hyman, Phelps & McNamara

The FDA recently issued draft guidance on risk-based clinical trial monitoring. The guidance recommends certain methods of risk-based monitoring for sponsors and CROs. The methods addressed include general monitoring requirements, identifying critical data and processes to be monitored, factors to consider when developing a risk-based plan, and on-site monitoring versus monitoring by certain electronic means of communication. The presentation will address key elements of the draft guidance, the expectations from industry when developing a monitoring/quality risk management plan, and practices for moving towards a risk-based approach. We will also review public feedback from the draft guidance comment period.

1:45 Clinical Site Issue Escalation: A Vital Process in Clinical Quality Management

Daniel J. Greenwood, Senior Associate Director, Compliance & Quality Management, Boehringer Ingelheim Pharmaceuticals, Inc.

One of the key elements of a quality management system is the monitoring of clinical trial sites either on-site or remotely via a centralized monitoring approach. When compliance and quality issues are detected through monitoring, there needs to be a process by which issues can be escalated to the appropriate level of management. This session will focus on:

- Developing a process to escalate site compliance issues
- Establishing a system to identify systemic trends
- Integrating a site issue escalation into a robust CAPA process
- Driving change within the organization through process improvement
- Addressing the challenges: Culture, Systems, Workload & Resources
- Demonstrating value to the trial teams and management

2:30 Transitioning from Auditing to a Quality Improvement System

Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, Regulatory Support and Quality Assurance, University of Miami

The Office of Regulatory Support and Quality Assurance (RSQA) residing within the Office of Research, Miller School of Medicine at the University of Miami is on its way to advance from a well-established auditing program into a quality improvement program to provide support and assistance to the University research community. In the restructuring process, special attention will be paid to create a robust firewall between QA and QC activities. Quality Management approaches, in particular in respect to customer service, will be put into practice throughout the entire process of implementation.

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break

3:50 Good Clinical Practice, Six Sigma, and Lean Methodologies: New Friends on the Playground!

Barbara Osinski, Associate Director, QC GCP Compliance and Training, Clinical Development, Grunenthal USA, Inc.

Lean Sigma are the new "buzz words" being used when discussing Quality Risk Management. But what is it? How can a methodology which originated with manufacturing be applied to the world of clinical? How can an organization introduce a "lean mentality" without compromising quality? Do the regulations allow for this type of paradigm shift? Join us as we discuss a brief history of Lean and Six Sigma, how the methodologies are being applied to Good Clinical Practice and Quality Risk Management, and how it IS possible for everyone to "play nice in the sandbox"!

4:35 Establishing a Quality Risk Management System Capability within Global Clinical Development Operations

Brian J Nugent, RN, BSN, DC, Associate Director, Clinical Trial Excellence and Analytics, Biogen Idec, Inc.

With a growing emphasis on the implementation of risk based approaches to clinical trial quality management, this session will highlight the approach used by one biotechnology company. The presentation will provide insight into Biogen Idec's ongoing development of a Quality Risk Management system. We will touch upon the development drivers, our approach to implementation, Key Risk Indicators, and the challenges and lessons learned to date.

5:20 Implementation of Quality Risk Management Systems to Manage Risks and Foster GCP Compliance in Global Clinical Trials

Nikita Somani, BPharm, M.Sc., Regulatory Manager, TIMI Study Group, Brigham and Women's Hospital

As per the inspections performed by the FDA Office of Scientific Investigations (OSI) in 2010-2011, approximately 4% of the investigators were recommended with rejection of data due to data integrity and GCP non-compliance issues. Such GCP noncompliance issues have been bypassed due to lack of cost-effective and robust quality systems to produce reliable clinical data. Therefore a fundamental shift from traditional approach

to risk- based approach is recommended in how the research is conducted and regulated. The risk-based strategy will target the resources more effectively to those activities that may be imposing greater risks.

6:05 Welcome Reception *(Sponsorship Opportunity Available)*

7:00 Close of Day One

TUESDAY, JUNE 5, 2012

8:00 am Morning Coffee or Sponsored Breakfast Presentation
(Opportunity Available)

GCP Quality Systems

8:30 Applying a Quality Systems Approach to Clinical Research
Lee Truax-Bellows, President, CEO, Management, Norwich Clinical Research Associates Ltd. (NCRA)
Industry continues to fail to meet the minimum regulatory requirements as evidence by the 483s and Warning Letters that are issued by the FDA. With all the training that companies put their staff through, guidance documents issued by FDA, and continued negative inspections and resulting citations, why does this continue to happen? Perhaps because companies are better at applying a quality systems approach to their manufacturing then they are to their clinical activities. This session will explore the concepts of expanding a quality systems approach to the clinical arena and provide direction on a practical approach to incorporating it into the practice of their daily clinical research activities.

9:15 The Elements of an Effective GCP Quality System: Auditing, Monitoring, Training, Controlled Documents, Communication, and Governance
John R. Wilson, Jr., Ph.D., MPH, Senior Vice President, Beaufort LLC
A GCP Quality System is exactly that — a system. It is important to work backward from the goal of ensuring that the data in the clinical trial reports and subsequent regulatory submissions represent what actually happened as subjects were subjected to the intervention. However, clinical research remains a heavily fragmented affair. Study planning, document preparation, training, monitoring, and auditing occur within separate and distinct departments, resulting in numerous inefficient and ineffective handoffs. It is no wonder that FDA investigators frequently find conflicts within an organization's own SOPs. This practical talk will address the synergies and necessary intersections between the various components of a GCP Quality System, e.g., practical pointers in terms of how to systematize the various processes into one cohesive whole.

10:00 Coffee Break

10:20 Risk Mitigation and Management: Hands-On Tools and Techniques
Bradley Wong, Consultant to Allergan
This presentation will provide you with basic tools to analyze and mitigate the possible risk scenarios which you might encounter. Starting with a basic understanding of risk analysis, you will understand the process of identification and prioritization of the risk. Next, as you analyze your risk, you consider your options and choose a solution that will effectively mitigate the risk. Finally, we will discuss documenting your solution and carrying it out. Scenarios will be provided as examples on how this process works.

Implementing a Quality by Design Approach

11:05 Risk-Based Quality Management in Clinical Trials: The EMA Perspective Interpreted
Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.
The current Quality Management Systems implemented and maintained by the sponsors of clinical studies are becoming more costly and time-consuming. In addition, they very often fail to deliver on their promises to keep patients from harm and to ensure that the data produced in the studies are credible. In order to overcome this situation, the EMA has written a reflection paper on how this situation can be remediated with simple measures. However, the change aspect is a key element that should not be underestimated. In this session, participants will learn about the recent thinking at EMA on risk-based quality management of clinical trials, what initiated it, and what EMA puts forward as a solution. As an experienced specialist in risk-based quality management systems, your speaker will comment on the EMA paper and give guidance on how to interpret it.

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

1:05 pm Hypothesis Generation and Evaluation in Clinical Trial Design
Michael Liebman, Ph.D., Managing Director, Executive, IPQ Analytics, LLC
Michael R. Briggs, Ph.D., President, Woodland Pharmaceuticals, LLC
It is well-documented that the pharmaceutical industry is experiencing significant difficulties in maintaining its historical record of drug approvals and financial achievement because of failures in moving compounds from the discovery pipeline to regulatory approval and commercial success. Your speakers are developing and implementing novel applications of knowledge representation, ontology development, and natural language processing to address issues within the pharmaceutical industry. The approach evaluates and refines the hypothesis upon which these trials are based, establishes a comprehensive approach to an early go/no go decision, identifies risk, and improves the probability for success. This session will explore all of the sources of risk that exist, and how they can be identified early in the trial concept and be used to make more effective decisions.

1:50 The EMA Guideline: How to Implement it in Practice?
Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.
In the past, quality was typically the responsibility of the QA department. Quality was mostly synonymous with compliance with regulations and SOPs and the auditing of a portion of the related processes. However, a risk-based approach to quality is not the task of the quality department alone. Each and every person who is responsible for a particular process in clinical trials owns this particular feature, and is therefore also responsible for associated risks. With a Quality by Design (QbD) approach, which is a structured way to setting up processes, one will be in a position to know exactly what to expect and what the risks are that could manifest during the conduct of a trial. The ability to plan ahead will make those who know how the masters of clinical trial management. This presentation will discuss the study design, starting when the protocol has been finalized with a particular emphasis on monitoring, which will become much more differentiated that it was in the past.

2:35 Refreshment Break

Reducing Clinical Trial Liability

2:55 Quality System Deployment in a Clinical Trials Vendor Environment
Jeffrey Brandt, Quality Assurance Manager, Rocky Mountain Poison and Drug Center, Denver Health
With growing regulatory expectations for a quality systems-based approach to GCP compliance, it is imperative that vendor partners are inspection ready. The implementation of a quality system helps assure this requirement. This presentation will describe the components of a quality system and how it can be implemented in a clinical trials vendor partner environment. Your speaker's institution has adopted a QMS to help assure regulatory compliance and quality in its clinical trial group. This presentation will address QMS Management from the vendor's perspective. CAPA (Corrective and Preventive Action) and internal audits performed on a regular basis are just two of the tools used in the RMPDC clinical trial program.

3:35 Managing Clinical Trial Liabilities and Risk
Kevin Quinley, Principal, Quinley Risk Associates
Pete Swayze, Partner, Segal McCambridge Singer & Mahoney
Liability claims and lawsuits arising from clinical trial adverse events are rising. Companies need a cogent and comprehensive risk management plan to "inoculate" themselves from the financial toll exacted by these draining claims. This session will examine cutting edge strategies for both preventing claims and for cushioning companies from the financial hit. Participants will learn to manage clinical trial risks, avoid common mistakes, save money, and minimize Maalox consumption. Session goals include:

- Heightened awareness of common pitfalls that drive clinical trial claims
- Four areas to shore up to prevent clinical trial liabilities
- Common coverage "gaps" and pitfalls in clinical trial insurance coverage – and how to "plug" these gaps

4:20 Close of Conference

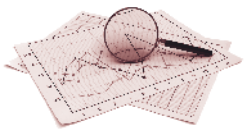
Stay on for the Clinical Auditing Forum and Vendor Management in Clinical Trials (June 6-7)

ATTEND THE DINNER SHORT COURSE*

Tuesday, June 5, 2012 5:30 PM - 8:00 PM

Strategies for Source Documentation Verification (SDV): Regulatory Requirements and Best Practices
Instructor: Leslie Humphries, MT, Senior Manager, Clinical Monitoring, DSP Clinical

** Separate registration required.*



Barnett International and Cambridge Healthtech Institute's Second Annual

Clinical Auditing Forum June 6–7

Ensuring Audit Readiness and GCP Compliance Across Clinical Research Functions

ATTEND THE EVENT SHORT COURSE*

Wednesday, June 6, 2012 8:30 AM - 11:00 AM

Proactive Approaches to Vendor Management

Instructors:
Michael J. Harte, Founder and President, The Harte Group
James Kirwin, Vice President and Senior Advisor, Clinical Development Operations, The Harte Group

** Separate registration required.*

WEDNESDAY, JUNE 6, 2012

8:00 am Event Short Course Registration and Morning Coffee

11:00 Main Conference Registration

12:45 pm Barnett Welcome & Chairperson's Opening Remarks

Audit Readiness, Preparation, and Case Studies

1:00 Review of Recent FDA 483s, Warning Letters, and FDA Activity Related to GCP Non-Compliance
Doreen McGirl, Senior Manager, Global Clinical Compliance, Merck
Much can be learned by reviewing FDA inspection reports and keeping current on upcoming FDA guidances related to GCP non-compliance. Sponsors are encouraged to use these documents as foundations for group meeting agenda topics, to encourage thinking and thus discussion amongst colleagues to improve their own quality systems. This presentation will discuss recent FDA Activities, and provide insight into how sponsors can implement these discussions, and subsequently improve their quality systems by reviewing guidances, recent inspection reports, and non-compliance findings.

1:45 Clinical Trial Self-Monitoring and Auditing Plans
Kelly Willenberg, BSN, M.B.A., CHRC, President, Synergism, LLC
Marianne Parnell, BSN, OCN, M.B.A., Manager, Medical Affairs, Sigma-Tau Pharmaceuticals, Inc.
Clinical Trial Self Monitoring and Auditing plans should be established at every facility performing trials. What are industry standards and how should you set one up? This session will explore this issue from the site and sponsor perspective. Attendees will come away with a commitment to providing a high standard of excellent data and unsurpassed billing compliance quality. Exceed even your own expectations in how you do your clinical trials billing and quality compliance.

Preparing for Regulatory Inspections

2:30 Preparing for a Regulatory Inspection: Investigative Sites
Anna DeMarinis, Principal, The DeMarinis Group, LLC; former FDA Consumer Safety Officer, Health Sciences Administrator, and Policy Analyst
As your clinical trials near completion and you contemplate preparing your FDA marketing approval application, you also should be thinking about which of your clinical Investigators might be inspected by the Agency as part of the application review process. This presentation includes (1) an overview of FDA's clinical Investigator inspection process, including site selection and inspection conduct and follow-up, (2) steps you can take to help your sites prepare, including site audits and FDA inspection preparation visits, and (3) recent FDA inspections statistics and key inspection findings.

3:15 Refreshment Break

3:45 Preparing for a Regulatory Inspection: Sponsors and Monitors
Swati Tendolkar, Program Manager, Global System Quality Assurance, Janssen R&D, a Johnson & Johnson company
The session will provide overview of the FDA Sponsor-Monitor Inspection Process, such as the inspection objectives and the types of sponsor systems reviewed during an inspection. Additionally, your speaker will provide information regarding preparing for a Sponsor-Monitor inspection, inspection logistics, and activities involved during an inspection. We will also review types of FDA Sponsor-Monitor inspection findings, responding to the inspection findings, effective corrective and preventive plan development, and the post-inspection activities.

4:30 Preparing for a Successful eClinical Inspection
Rod Thorell, Director, Quality Management & Compliance, Quality Management & Compliance, PHT Corporation
Global regulatory bodies are making changes that dictate a preference for electronic data capture within clinical trials. This session will demonstrate the critical characteristics that must be properly defined and controlled for a successful submission and inspection. Participants will learn about flaws in key pieces of objective evidence and processes that could jeopardize the acceptance of data. Attendees will learn how to properly execute a successful audit program of vendor oversight, study team activity, and site processes.

5:15 Welcome Reception *(Sponsorship Opportunity Available)*

ATTEND THE DINNER SHORT COURSE*

Wednesday, June 6, 2012 6:00 PM - 8:30 PM

SOP Assessment: Ensuring GCP Compliance in Standard Operating Procedures (SOPs)
Instructor: Elizabeth Ronk Nelson, MPH, President and Senior Consultant, Regulatory Risk Management

** Separate registration required.*

THURSDAY, JUNE 7, 2012

7:30 am Morning Coffee or Sponsored Breakfast Presentation
(Opportunity Available)

Quality Systems Approaches

8:00 Transitioning from an Auditing to a Quality Systems Approach to Monitoring
Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, Regulatory Support and Quality Assurance, University of Miami
The Office of Regulatory Support and Quality Assurance (RSQA) residing within the Office of Research, Miller School of Medicine at the University of Miami is on its way to advance from a well-established auditing program into a quality improvement program to provide support and assistance to the University research community. In the restructuring process, special attention will be paid to create a robust firewall between QA and QC activities. Quality Management approaches, in particular in respect to customer service, will be put into practice throughout the entire process of implementation.

8:45 Defining a Quality Auditing Program around Risk-Based Monitoring
Jan Holladay Pierre, MPH, Manager of Clinical Quality Assurance, DynPort Vaccine Company LLC
Traditional onsite monitoring and the standard practice of conducting 100% source data verification (SDV) is not only labor-intensive and costly, but sets us up for an unrealistic expectation of absolute compliance (zero error rate) and quality. This session will provide risk-based monitoring concepts with specific attention to key changes in FDA's BIMO inspectional program. Attendees will be provided with a Risk Assessment Checklist in order to evaluate their companies' infrastructure from a quality and risk perspective. By the end of the session, attendees will be able to evaluate resources, protocols, plans, procedures, and metrics in a checklist fashion in order to ensure identification of critical data and processes to be monitoring and controlled.

9:30 Coffee Break

9:50 Quality Control Visits to Promote Effective Site Monitoring, Human Subject Protection, and Good Clinical Practice (GCP) Compliance
Laura Paolinelli, Senior Quality Assurance Associate, Quality Assurance, Westat
The FDA is encouraging more effective monitoring of clinical investigations to ensure adequate protection of human subjects and the quality and integrity of clinical trial data. One strategic approach to promote quality monitoring is through the implementation of on-site co-monitoring visits (i.e., monitoring visits performed by both a site monitor and a quality control

(QC) monitor) to ensure that the sponsor and CRO staff are effectively carrying out visit activities in compliance with the study monitoring plan, GCP, and all applicable regulations. For ten years, Westat has been conducting QC monitoring visits to promote high quality monitoring practice among site monitors.

10:35 Auditing Sites for Fraud, Bioethics, or Serious Noncompliance: An Internal Audit Program
Kimberly Dorsch, CCRP, CRCP, Director, Clinical Research, Sentara Medical Group
Sentara Healthcare established the Sentara Research QA Program after fraud was discovered within one of the practices. In this case, the site and the sponsors missed the signs for about eight months. The coordinator pled guilty to falsification of medical records in US Court in September 2011. Your speaker will present this case study and describe Sentara's current audit process used for system-wide compliance audits. In 2009, Sentara formally adopted a Research Quality Assurance Initiative that included an internal audit team. Establishing a Research QA initiative that includes an internal audit team is a huge undertaking. This presentation will discuss the successes and failures Sentara had during the initial roll-out of the program.

11:20 Audits and Assessments
Irina Colligon, Independent Consultant
Most audits need outputs from completed work to judge quality and show what needs correction. Although a valuable tool, an audit does not show how to prevent the wrong. Systematic assessment of the processes and systems employed in generating the outputs help identify key flaws that will lower the quality of the future output. Retrospective data from the audits combined with the prospective assessments provide a more complete picture of effectiveness of a quality system, thus giving the quality unit the insights into how to fulfill their remit of assuring quality.

12:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

Lean Six Sigma and Clinical Research

1:15 Applying Lean Six Sigma Principles in a Clinical Setting
Marie Jackson, Ph.D., M.B.A., Director, Clinical Research Administration & Services, City of Hope
Adopting a process improvement program that incorporates today's best practices is essential to meet clinical research performance goals. Fortunately, the objectives of controlling costs and improving the quality, two goals seemingly at odds with each other, can be achieved simultaneously. Lean Six Sigma is a people-driven system that can improve any work process anywhere in your organization. It uses a data-driven approach to fix root causes of problems and provides tools to ensure corrective actions are sustained. Using real-life case studies, the principles and tools of Lean Six Sigma will be discussed and applied.

International Perspectives on Audits

2:00 International Audits: Regulatory Requirements, Regional Considerations, and Differences from FDA
Michael G. Duncan, Senior Specialist, Global System Quality Assurance, Johnson & Johnson
This session will provide an overview of differences in requirements and considerations for auditing in different regions around the world. A comparison will be made between the USA, the European Union, and other regions concerning regulatory requirements, and the legal basis for regulations and enforcement. Topics will include: the impact and enforceability of laws versus regulations, directives, and guidances; implementation of ICH guidelines in ICH countries and non-ICH countries; enforceability of contracts with marketing and development partners and external service providers; and exchange of inspection findings between health authorities.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Refreshment Break

3:45 As Clear As Mud: Navigating the World of Health Canada Inspections
Hope Senechal, B.Sc., CCRA, Clinical Research Auditor, Administration, Ottawa Hospital Research Institute
An inspection function for Canadian clinical trials came into effect with the introduction of the new regulations "Drugs for Clinical Trials Involving Human Subjects" (FDR-Div. 5) in 2001. Using Health Canada guidance documents and information gathered from recent inspections, this session will provide an overview of the inspection process as well as identify common areas of noncompliance. By the end of the session participants will be able to:

- Describe Health Canada's inspection process based on published guidance documents and real world experiences
- Identify trends in inspection observations and common areas of noncompliance
- Discuss potential corrective actions, or better yet, tips for avoiding these observations

Auditing Software, Hardware, and SaaS Providers

4:30 Auditing Software-as-a-Service (SaaS) Providers, Data Centers, and Cloud Computing Environments
Chris Wubbolt, Executive Director, Compliance Services, Compliance, QACV Consulting
This presentation will review considerations for auditing Software-as-a-Service (SaaS) providers, data centers, and cloud computing environments, including applicable requirements that these service providers may need to meet to support regulated software applications and electronic recordkeeping. The presentation will also review validation of hosted applications and how validation activities conducted by SaaS providers may impact the validation of sponsor's regulated applications. The differences and similarities between Virtual Machines, Software-as-a-Service, and Cloud Computing will be highlighted.

5:15 Close of Conference

CONNECT WITH US

Barnett International and Cambridge Healthtech Institute's Inaugural

Vendor Management in Clinical Trials June 6-7

Ensuring Quality through Effective Assessment, Qualification, Auditing, and Communication

ATTEND THE EVENT SHORT COURSE*

Wednesday, June 6, 2012 8:30 AM - 11:00 AM

Proactive Approaches to Vendor Management

Instructors:
Michael J. Harte, Founder and President, The Harte Group
James Kirwin, Vice President and Senior Advisor, Clinical Development Operations, The Harte Group

** Separate registration required.*

WEDNESDAY, JUNE 6, 2012

8:00 am Event Short Course Registration and Morning Coffee

11:00 Main Conference Registration

12:45 pm Barnett Welcome & Chairperson's Opening Remarks

Vendor Qualification, Selection, and Contracts

1:00 Implementing a Quality Management Approach to Clinical Vendor Selection
Susan Lubin, Associate Director, Outsourcing; Discovery Medicine & Clinical Pharmacology, Bristol-Myers Squibb Co.
Kristian Hubbard, Manager, Outsourcing; Discovery Medicine Clinical Pharmacology, Bristol-Myers Squibb Co.

1:45 Clinical Trial Success Begins with the Scope of Work: How to Ensure Your Trial is Successful Using the Task Order Agreement
Manley Finch, Executive Director, HIV Nutrition Network, NPO
Clinical trials are often derailed by a fundamental lack of clarity in the scope of work between the sponsor and CRO or other vendors. The devil is in the details. A strong starting point is a detailed Task Order Agreement that clearly outlines the scope of work, the timelines, and responsible parties. Cost overruns, delays, and damaged sponsor/vendor relationships create havoc in clinical development programs, and create a tremendous fiscal and resource burden to the industry. Effective vendor outsourcing depends on clearly defined goals, expectations, and responsibilities.

2:30 Building Quality and Accountability into Vendor Contracts
Sally Teeters, Senior Director, Legal and Business Management, CardioVascular BioTherapeutics, Inc.
The presentation will include: 1) A brief overview of SOX with emphasis of the challenges and impact is has on sponsors and CROs; 2) The importance of planning and processing of RFPs; 3) An in-depth discussion of the critical contract terms, as well as the other contract terms which tend to be considered non-critical but may have a major impact; 4) Key factors to consider when determining budget terms; 5) The best practice of minimizing expense and processing of change orders by specifying the format, timing and approval process; and 6) Identification of good contract practices.

3:15 Use New Technology to Better Manage your Trial Partners and Reduce your Study Costs
Sponsored by encota
Marty Morrow, Principal, Praxis Management International
See how modern technologies like the cloud, search engines and new databases can save your trial time and money. Get tighter control of your data across all study partners by specifying which languages, dictionaries and versions they can use. Eliminate days and weeks from your study timeline and no IT intervention required.

3:45 Haunted by the Contract: How Upfront Mistakes Lead to a Host of Nightmares
Charles Wienbar, Program Manager, Participant Recruitment, Clinical and Translational Science Institute, University of California, San Francisco
This session features a case study of how a poorly written $3 million vendor contract put a $150 million acquisition at risk. The pivotal study was in rescue mode due to a number of compliance issues. The vendor was tasked with auditing ~20 international sites and documenting the corrections. The structure of the agreement was such that the vendor was paid for site monitoring visits, when it was the filing of visit reports that mattered to the company, the FDA, and the acquiring entity. It is a common problem that the payment structure in a contract is not tied to clinically meaningful deliverables. As a result, the incentives of the vendor do not support the strategic objectives of the sponsor. Attendees will gain an appreciation of how a poorly structured contract creates downstream problems at the sites and with data collection, and how a well-written contract can help steer a vendor in the right direction.

4:30 Applying Vendor Management Practices to Clinical Research Sites
Glenda Guest, Vice President, Norwich Clinical Research Associates (NCRA)
You manage the vendors who supply you with materials to manufacture your product, why not apply those vendor management concepts to management of research sites? This presentation is designed to help participants see the parallels between vendor management activities in the manufacturing setting and how they can apply in a clinical research setting. The protocol, investigator agreements, qualification visits, and other activities already performed by the majority of individuals engaged in regulated research are related to manufacturing supplier contracts, vendor qualification audits, and other vendor management activities.

5:15 Welcome Reception *(Sponsorship Opportunity Available)*

ATTEND THE DINNER SHORT COURSE*

Wednesday, June 6, 2012 6:00 PM - 8:30 PM

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

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

** Separate registration required.*

THURSDAY, JUNE 7, 2012

7:30 am Morning Coffee or Sponsored Breakfast Presentation
(Opportunity Available)

Employing Quality Systems with Vendors

8:00 Quality Driven Global Clinical Trial Partnerships: "The Buck Stops Here... Or is it the Rupee?"
Lawrence J. Fiori, Senior Associate Director, Project Compliance Management, Compliance & Quality Management, Boehringer Ingelheim Pharmaceuticals, Inc.
With a wealth of clinical trial operations and more recently clinical trial outsourcing compliance and quality management experience, coupled with the knowledge gained from three recent sponsor inspections, your speaker will share real-life challenges and practical solutions to global clinical trial partnerships. The audience can expect take-away tips, advice, and processes for ensuring quality and compliance oversight, will hear about analogous situations, and gain direction and insight into implementing their own vendor quality oversight processes.

8:45 Quality System Deployment in a Clinical Trials Vendor Environment
Jeffrey Brandt, Quality Assurance Manager, Rocky Mountain Poison and Drug Center, Denver Health
With growing regulatory expectations for a quality systems-based approach to GCP compliance, it is imperative that vendor partners are inspection ready. The implementation of a quality system helps assure this requirement. This presentation will describe the components of a quality system and how it can be implemented in a clinical trials vendor partner environment. Your speaker's institution has adopted a QMS to help assure regulatory compliance and quality in its clinical trial group. This presentation will address QMS Management from the vendor's perspective.

9:30 Coffee Break

9:50 Partnering for Clinical Trial Success: Johnson and Johnson Vision

Care (Vistakon) and BioClinica
Jonathan Andrus, Vice President, Data and Study Operations, BioClinica, Inc.
Miguel Amador, Project Lead, Johnson and Johnson Vision Care (Vistakon)
Effective vendor management starts with each party viewing each other as a partner. JJVC and BioClinica partnered together to change the way that they were doing clinical trials. It was taking too long to start up studies, close them out, and get analyzable data. Through sound vendor management practices, including governance and key performance indicators, both organizations were able to achieve success far ahead of expectations. Participants will learn tips, tricks, and techniques for managing the relationship, and ideas around how to work effectively together using metrics and other project related data.

Ongoing Vendor Quality Management

10:35 Developing a Cost-Effective, Risk-Based Approach to Vendor Management
Lori Fontaine, Principal Consultant, Clinical, Boston Biomedical Associates
Kerri DiPietro, Director, Global Clinical Sciences Quality, Boston Scientific Corporation
In a tough economy, with increased pressure to deliver compliant clinical trials on time and within budget, developing a risk-based strategy to ensure vendor compliance is important. It starts with an understanding of risk management methodology and the application of those methods in designing processes and procedures to allow for efficiency and compliance within your Vendor Management Program. Participants will learn the requirements from regulatory agencies and other standards, and how to develop and maintain such a program.

11:20 Vendor Management: Balancing Outsourcing with Oversight
Terri Hinkley, RN, BScN, M.B.A., CCRC, Director, Clinical Operations, Helix BioPharma Corp.
Agencies are increasing their scrutiny of vendor oversight activities of outsourcing relationships. Sponsors need to ensure they're maintaining an appropriate level of involvement to ensure compliance with regulatory requirements. Your speaker will address the regulatory position on vendor oversight, and will discuss FDA warning letters issued on this topic. Participants will receive concrete action plans they can implement to be compliant in this area.

12:05 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

CRO, SMO, and IRB Oversight and Audits

1:15 Best Practices in Outsourcing to CROs: How to Create Productive Relationships with CROs
Elizabeth Shewell, Senior Director, Outsourcing, Incyte Corporation
This session will give a broad overview to individuals looking to learn more about the Insource vs. Outsource model, how to determine the right strategy for your company, how to get your vendor relationship started, and how these relationships can differ based on the sponsor/vendor size. Your speaker will review key principles to a successful sponsor/vendor relationship. This will be an interactive forum for discussion of what has worked and what hasn't for a small biotech, and why their choices may or may not work for your company.

2:00 Quality Management Case Study of SMOs
Fiona Jeitner, Manager, Clinical Quality Assurance, Eisai, Inc.
Understanding the function of site management offices (SMOs) is critical to ensure a regulatory compliant clinical trial. There is much confusion in the industry leading to auditors not giving themselves enough time, or visiting the correct location, to review essential and other non-trial master file related documents. This session provides a case study of the auditing process to ensure a study managed through an SMO is compliant with federal regulations, ICH GCP guidelines, and industry best practices. The audience will gain insight into how an SMO functions, how it is set up, and which clinical trial related function are performed where.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Refreshment Break

3:45 Oversight of Clinical Monitoring Vendors: Auditing Case Studies
Elizabeth Ronk Nelson, MPH, President and Senior Consultant, Regulatory Risk Management
This session will review recent issues in outsourcing from an auditor's perspective. Monitoring roles and responsibilities will be highlighted with topical regulatory communication. The impact of risk-based monitoring on outsourcing and suggestions for control will be presented. Session topics will include: development of appropriate monitoring reports; getting the right people involved; prequalification and monitoring assessments; review of SOPs; risk-based training; oversight; co-monitoring procedures; and critical review of reports.

4:30 Central IRB Selection: The Times They Are A-Changin'!
John Isidor, J.D., Senior Director & Founder, Schulman Associates IRB, Inc.
A critical part of any successful multi-center clinical trial is identifying, vetting, and partnering with a Central IRB. In this session, your session leaders will help participants answer the following questions:
- What is the FDA's current view regarding the use of Central IRBs?
- Are there regulatory changes being considered which will mandate the use of Central IRBs?
- What factors should a sponsor or CRO consider in selecting a Central IRB?
- How should the performance of a Central IRB be evaluated?

5:15 What Comes First…The Contract or the Audit?
Marya Ferrigan, QA Auditor, Quality Assurance, Rho
You've decided to outsource a clinical aspect of the trial… now what? If you contract first, you may be stuck and lose leverage with the vendor. If you audit first, it may delay the use of vendor services. Which is the better choice? Participants will learn how to assess the significance and implications of contracting prior to understanding the ins and outs of the vendor, determine an appropriate audit strategy, create a successful vendor audit outcome, prepare a pre-audit questionnaire, develop an audit plan, and create an audit checklist.

6:00 Close of Conference

Hotel & Travel Information

Conference Hotel:
Omni Parker House Boston
60 School Street
Boston, MA 02108
Phone: 617-227-8600
Discounted Room Rate: $239 s/d
Discounted Cut-Off Date: May 4, 2012

Please visit our conference website to make your reservations online or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the reduced room rate. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space-and-rate-availability basis. Rooms are limited, so please book early.

Flight Discounts:
Special discounts have been established with American Airlines for this conference.
- Call 1-800-433-1790, and use Conference code 7162AX
- Go to www.aa.com/group, and enter Conference code 7162AX in promotion discount box
- Contact our designated travel agents at 1-877-559-5549 or wendy.levine@protravelinc.com.

Car Rental Discounts:
Special rental discounts have been established with Hertz for this conference. Please use one of the following methods:
- Call HERTZ, 800-654-3131, and use our Hertz Convention Number (CV): 04KL0003
- Go online www.hertz.com, and use our Hertz Convention Number (CV): 04KL0003

Barnett International and Cambridge Healthtech Institute's Inaugural

Clinical Trial Oversight SUMMIT

June 4–7, 2012
Omni Parker House, Boston, MA

Pricing and Registration Information

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
Single short course	$495	$270
Two short courses	$795	$520
Three short courses	$1095	$770

June 5	June 6
Strategies for Source Documentation Verification (SDV): Regulatory Requirements and Best Practices	Proactive Approaches to Vendor Management
	SOP Assessment: Ensuring GCP Compliance in Standard Operating Procedures (SOPs)

CONFERENCE PRICING

Single Conference Pricing (Includes access to 1 conference; excludes short courses)		
Advance Registration Discount until April 27, 2012	$1645	$845
Registrations after April 27, 2012, and on-site	$1845	$945
Multi Conference Pricing (Includes access to 2 conferences; excludes short courses)		
Advance Registration Discount until April 27, 2012	$2450	$1025
Registrations after April 27, 2012, and on-site	$2595	$1095

June 4-5	June 6-7
Mastering Clinical Trial Monitoring	Clinical Auditing Forum
Clinical Quality Risk Management	Vendor Management in Clinical Trials

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.

Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact Liz Andrews at +1-781-972-5418

If you are unable to attend but would like to purchase the Clinical Trial Oversight Summit CD for $600 (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**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **CTL F** when registering!

Please refer to the Registration Code below:

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