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Second Annual

Clinical Trial OVERSIGHT SUMMIT

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June 3 - 4, 2013

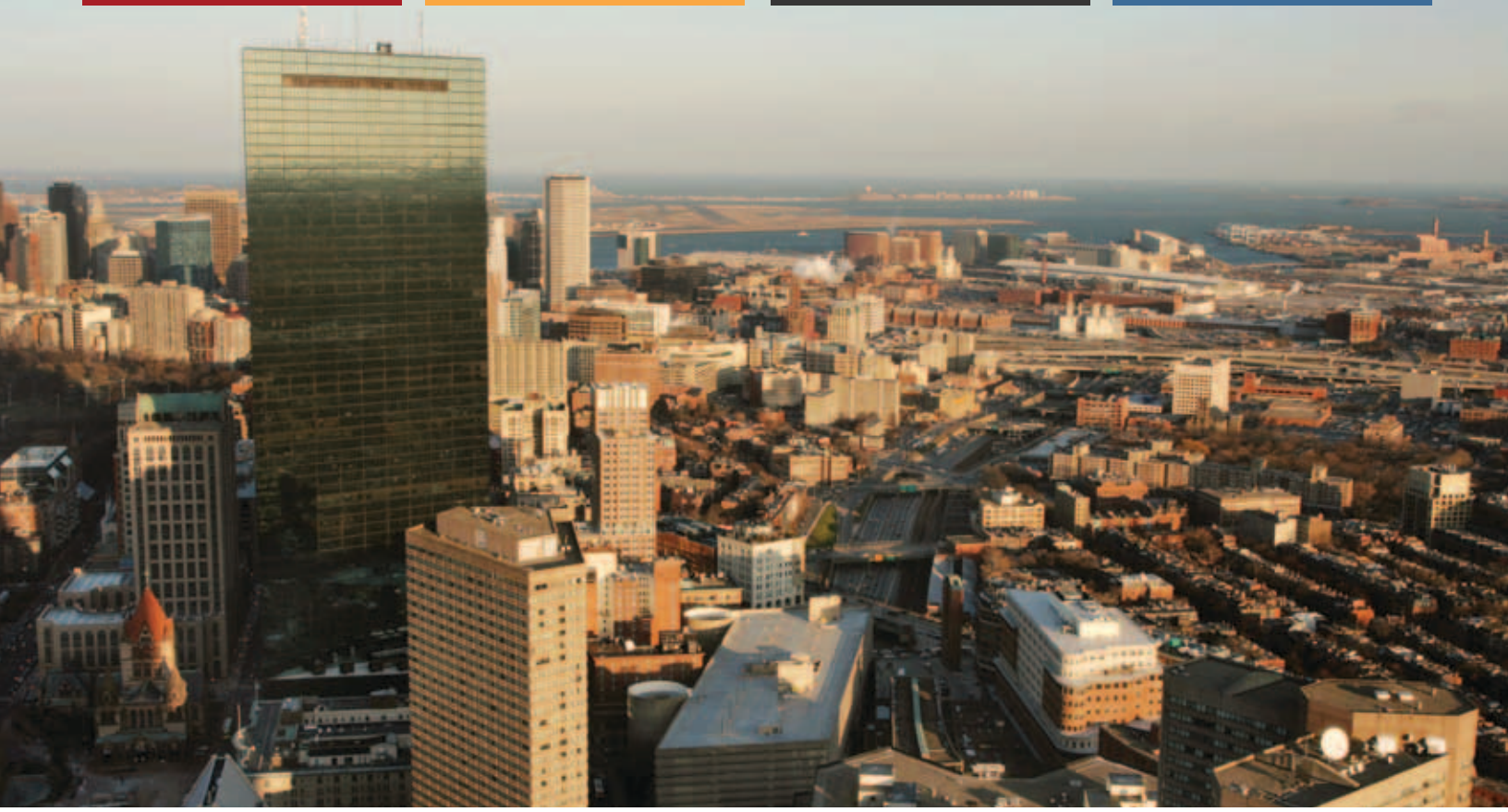
Mastering Clinical Trial Monitoring

Vendor Management in Clinical Trials

June 5 - 6, 2013

Clinical Auditing Forum

Clinical Quality Risk Management



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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
	Dinner Short Course* (SC1) Project Management of CROs	
Tuesday AM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
Tuesday PM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
Wednesday AM	Clinical Auditing Forum	Clinical Quality Risk Management
Wednesday PM	Clinical Auditing Forum	Clinical Quality Risk Management
	Dinner Short Course* (SC2) Quality-Systems Based Approaches to a GCP Auditing Program	
Thursday AM	Clinical Auditing Forum	Clinical Quality Risk Management
Thursday PM	**Post Conference Short Course*** (SC3) Quality by Design: How to Apply It When Setting Up Your Trials	

**Separate Registration Required*

SHORT COURSES*

DINNER SHORT COURSE
(Monday 6:00-8:30pm)

(SC1) Project Management of CROs

Eric Morfin, MBA, PMP, Partner, Clinical Excellence Research Institute; Partner, Critical Skills, Inc.

Ultimately, the challenge facing pharmaceutical companies today is to pursue two seemingly incompatible goals: maintain or increase quality products while dramatically reducing costs and development lead times. In this course, participants will learn all the necessary material for identifying and selecting the right CRO for each segment of the research targeted for outsourcing. Sponsor personnel will learn the techniques required for successfully managing CROs and the shared responsibilities required from the sponsor and the service provider. CRO personnel will gain the full understanding of what is expected of them in the new drug development process. The following issues will be discussed: type and selection of CROs; how the FDA views CROs; sponsor responsibilities; drug development plans; overall outsourcing programs; study-specific designs and accountabilities; proposal evaluation; site visits to CROs; resolving deviations; contract negotiations and partnering with CROs; and FDA- and EMA-based interactions with CROs. Participants can expect to review:

- The pitfalls of the current sponsor/CRO/site relationships and what can be done to overcome them
- The new "Pharma" and the realities of "Virtual Trials"
- Components in architecting the appropriate outsourcing model "Cost vs. Price"
- Determining core capabilities in accordance with what works best globally rather than locally

DINNER SHORT COURSE
(Wednesday 6:00-8:30pm)

(SC2) Quality-Systems Based Approaches to a GCP Auditing Program

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

This course will provide a review of Quality Systems as applied through development of procedures to control, assure and improve the quality of data and records, as well as the quality and effectiveness of processes and activities related to the conduct and oversight of clinical research. For clinical trials, quality may apply to data (e.g., data are accurate and reliable) or processes (e.g., compliance with the study protocol and GCP; ensuring informed consent; adequate data handling and record-keeping). This session will review how quality is assured through the development and application of standard operating procedures (SOPs) that define responsibilities, specify records to be established and maintained, and specify methods and procedures to be used in carrying out study-related activities. The main focus of the session will be the review of practices for a quality system (e.g., monitoring programs, auditing programs, complaint handling systems) for periodically reviewing the adequacy of clinical trial activities and practices, and for revising such practices as needed so that data and process quality are maintained. Processes in the review will include:

- Study monitoring
- Protocol creation
- Protocol compliance
- Informed consent
- Investigator and staff qualifications
- Records
- Confidentiality/Privacy
- Randomization
- Third party oversight

POST CONFERENCE SHORT COURSE
(Thursday 1:00-3:30pm)

(SC3) Quality by Design: How to Apply It When Setting Up Your Trials

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

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

Quality by Design (QbD) is currently the focus of both regulatory agencies: FDA in sponsorship with the Duke University Clinical Trials Transformation Initiative (CTTI) and the EMA. Both agencies are focusing on QbD in the reflection paper, "Risk-Based Management of Clinical Trials," published in 2011. 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 by Design with a clear focus on the application of these principles. Learning objectives include:

- Apply QbD to ensure the key questions in a trial are addressed
- Build quality at key points in the processes
- Implement a Quality by Design approach to aid decision making
- Understand how applying QbD will build the foundation for your trials' operational aspects, e.g., monitoring and outsourcing

**Separate Registration Required*

SPONSORSHIP, EXHIBIT, AND LEAD GENERATION OPPORTUNITIES

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre and post-show delegate lists. Customizable sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on early will allow you to maximize exposure to hard-to-reach decision makers!

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- Reception style
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Fourth Annual | June 3 - 4, 2013

Mastering Clinical Trial Monitoring

The Premier Event for Experienced Clinical Trial Monitors

The fourth annual Mastering Clinical Trial Monitoring conference will focus exclusively on the changing, significant and growing expectations of clinical trial monitors. Thought leaders will share their experiences related to recent global regulatory agency activities, including the FDA's new risk-based monitoring guidance, tools and techniques of monitoring best practices, monitoring in electronic environments and the challenges associated with monitoring international studies. Themes throughout the conference will be incorporating the latest regulatory requirements and expectations into your monitoring activities, and monitoring in unique environments, including device, IVD and investigator-initiated trials. The conference will feature case studies, hands-on activities, take-away tools, breakout groups and interactivity.

MONDAY, JUNE 3, 2013

7:00am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

RISK-BASED APPROACHES TO MONITORING

8:15 Innovative Cross-Functional Approach to Monitoring: Using the Draft Guidance as a Roadmap to Improved Clinical Data Quality
Lynn King, Assistant Vice President, Operations, Rho
Targeted SDV and risk based monitoring is a topic of increased interest for many companies looking to decrease costs while maintaining quality, but there are few tools and limited information available for monitors on the "how tos" of using these strategies. Our changing approach of data monitoring in the industry requires the tools and team structure to effectively plan and successfully execute risk-based monitoring. Attendees will learn multi-disciplinary approaches to successfully implement alternative monitoring plans and specialized tools for successfully executing risk-based monitoring.

9:00 FDA Risk-Based Monitoring: Understanding the Impact on Daily Monitoring Activities
Ethel Kagan, President, Consulting, Innovations Clinical Research LLC
With risk-based monitoring, the FDA has essentially given industry permission to reduce onsite visits drastically. It is not yet clear how this, as well as the advent of EDC, will affect the traditional CRAs ability to find work. This presentation will provide experienced and novice CRAs with the tools to work effectively in this new environment; provide guidance to companies on how to best utilize monitors to ensure data integrity and patient safety, while still reaping the cost advantages of this novel approach; and demonstrate how study personnel working together as a team create monitoring plans that can stand up to FDA audits. It will provide CRAs with the tools they need to work in this new environment thus protecting their livelihood.

9:45 Networking Coffee Break and Exhibit Viewing

CASE STUDY
10:15 Real World Implementation of Risk-Based Monitoring and the Merging of Traditional Roles to Ensure Quality and Cost-Effectiveness
Candace Friend Shelton, Director, Clinical Monitoring Services, Celerion
This session will provide an example of a real-world successful implementation of risk based monitoring within Early Stage Development Phase I studies. Merging traditional silo operational roles is expected to improve efficiencies to ultimately reduce the time spent and overall monitoring cost. The new CRA-DM-Stats-QA-QC individual ensures the flow of data in real time to a centralized data group, reviews these data continuously, and should be able to immediately evaluate risk with the assistance of technology precluding routine site visits. Well-defined objectives are provided to be agile while allowing continual data evaluation, adjustment, and adjudication thereby producing clean, dependent data while following all local and ICH/GCP standards and ensuring the rights, safety, and well-being of the subjects.

11:00 Interactive Roundtable Discussions

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

SITE MANAGEMENT AND IMPROVEMENT

1:00pm Building Good Research Sites
Vickie Haines, RN, CRA, Senior Clinical Research Monitor, Sorin CRM USA, Inc.
Building quality research sites is a huge task. The painstaking time and money spent interviewing, verifying and qualifying a site is worth its weight in gold to a study's outcome. A good site is comprised of several key elements and resources. Good, clean data will be received from good sites. How do we take a bad site and transform it into a gold standard site? We start with the basics: training, communication, more training, and retraining.

1:45 Creating and Managing a GCP Culture among Study Teams: Tools, Tips and Tricks
Shankar Srinivasan, Ph.D., CCRC (ACRP); Senior Regulatory Specialist, Office of Research Regulatory Support, Mayo Clinic

2:30 Site Relationship Management: Techniques for Site Selection, Proactive Management, Support, and Issue Escalation
Karen L. Gilbert, BS, CCRA, Clinical Trainer & Curriculum Manager, Barnett International
Elizabeth Wilson, CCRA, Manager, Clinical Operations, Covance, Inc.
Managing site relationships is a critically important function of today's clinical research monitor. Sometimes, however, little thought is given to that relationship until something goes wrong. This presentation will introduce techniques that build relationships of mutual trust and respect between site personnel and monitors. A single site relationship case study will be used throughout the presentation to demonstrate the application of the various techniques across time. Participants will learn to:

- Set clear expectations during the site selection phase
- Identify and minimize the impact of site weaknesses
- Support quality improvement efforts at the site
- Promptly manage site issues while preserving the relationship

3:15 Investigator Selection & Site Monitoring - Eliminate Inefficiency and Reduce Costs
Sponsored by @ris global
Simon Sparkes, Senior Vice President, Clinical & Compliance, ArisGlobal
Weaknesses in current investigator selection and monitoring approaches place an intolerable burden on sponsors and CROs. This session will focus on how companies can improve site selection and monitoring techniques, highlighting differences between risk and event-based monitoring while examining best practices in monitoring scheduling and visit conduct.

3:30 Networking Refreshment Break and Exhibit Viewing

3:50 Herding Cats: Identifying What Site Staff Need from You to Get the Job Done
Sarah Ramey, CRA, Clinical Operations, Duke Clinical Research Organization
Study Coordinators and Principal Investigators often (legitimately) feel they face challenges in complying with widely different/contradictory sponsor expectations. Monitors often (legitimately) feel they face challenges in teaching basic GCP principals. In this session, we will consider:

- The whats and hows to securing compliance
- Common archetypes of staff personalities
- Tailoring negotiation, motivational, and/or corrective techniques to different personalities
- The seasoned monitor's Achilles' Heel: delineating good clinical practice from "perfect clinical practice"

The presenter will draw on her experience of turning around three very different non-compliant sites in different therapeutic areas into compliance. Come ready to discuss your best negotiation, motivational, and corrective techniques.

4:35 The Two Are We: I Need You, and You Need Me. Navigating the Coordinator/Monitor Relationship
Kristen L. Bauer, CCRP, Senior Regional Clinical Research Associate, BIOTRONIK, Inc.
The relationship between a monitor and a coordinator can be fragile and difficult to navigate. Often times there are frustration and discord found on both sides, causing strain in the relationship. Common frustrations shared by monitors include sites being unprepared for visits, little to no oversight by the Investigator, lack of research policies or procedures, and no sense of urgency to bring study into compliance once issues are identified. Common frustrations shared by coordinators include last minute or rescheduled visits, frequent turn over in monitors, a lack of experience/training, and unreasonable action items. Ways to improve a strained coordinator/monitor relationship are to share expectations up front, communicate unique working situations, be flexible, and to share the common goal of wanting the data to be clean, and site to be as close to audit ready as possible.

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

5:45 Short Course Registration

6:00 - 8:30 Dinner Short Course 1, Project Management of CROs
(see page 2 for additional information)

6:20 Close of Day One

TUESDAY, JUNE 4, 2013

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

GCP INSPECTION READINESS

8:00 Avoiding FDA Inspection Land Mines: Preparing for and Surviving FDA Inspections and Potential Outcomes
Lee Truax-Bellows, President, CEO, Clinical, NCRA
FDA Inspections within the US for sites, sponsors, and vendors assisting in the conduct of drug, device, and biological clinical studies are a given. Regretfully, not all participants have an understanding of what such an inspection curtails or how to handle any resulting fallout. This presentation will provide an overview of preparing for an FDA Inspection and how to handle the potential outcomes. It is of extreme importance for these same participants to be prepared in responding to any resulting inspection citations in order to ensure issues do not escalate and place the organization being inspected in a poor light with the FDA. This presentation will assist those groups with obtaining the knowledge they need to avoid those land mines.

8:45 Dictating for Clinical Trials: How Do We (Can We) Re-Train the PI?
Nancy S. Bakke, Manager, Clinical Monitoring, US/Canada, Sorin CRM USA, Inc.
Many FDA warning letters to investigators contain findings of "inadequate case histories (dictated notes) to support data reported on the CRFs. These can also include failure to properly document history of previous disease; failure to document adequately protocol required medication stability; conflicting medical histories by different doctors; and wrong dates or no dates on dictated notes. Topics to be included in this session are:

- How to approach the subject with the PI/study personnel
- Tools for training
- Can we incorporate this into the site initiation visits?
- Examples of 483s related to case histories
- Examples of "monitoring madness" due to poor case histories
- If we can't change their ways, ideas to rectify the problems

9:30 Networking Refreshment Break and Exhibit Viewing

9:50 Best Practices for Managing an Imaging Vendor
Sara Mochel, Clinical Research Assistant 3/Sr CRA, Clinical Operations, Medivation
The relationship with an imaging vendor is key to the overall success of an oncology trial. For many oncology trials, an imaging vendor is used to manage the progression free survival (PFS) endpoint for a trial. In today's clinical research atmosphere, it is necessary to have this function centralized with an imaging vendor. As PFS is usually an endpoint, the management of the imaging vendor becomes crucial to the trial's success. The audience will gain helpful tips for establishing a productive and successful relationship with an imaging vendor.

MONITORING IN 2013

10:35 Is There an App for That? Wireless Technology Utility in Clinical Trial Management
Sandra Lawson, Research Coordinator, Pathology, University of Florida Health System
The prevalence of smartphones and computer tablets has created opportunity and risk for managers of clinical trials. This presentation will objectively examine these technologies and associated applications. This subject is particularly timely for the research community as both hardware and software continue to evolve at a dynamic pace. This presentation allows for the critical analysis and interactive dialogue about the use of such technologies in organized research.

11:20 Techno Savvy Defines the New Clinical Research Professional
Penelope Manasco, M.D., CEO, Executive, MANA Consulting LLC
Risk-based monitoring and electronic systems completely changes the role of the monitor and how studies are set up and delivered. This session describes the processes and software used to deliver the FDA's risk-based monitoring guidance and the use of electronic source. Actual examples of the implementation process and the metrics associated with the implementation will be provided. Participants will come to understand what is necessary to adopt this approach. This presentation provides actual examples of the implementation and describes what the monitor of the 21st century needs to know.

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

1:20 Global CRA Study Establishing Baseline for Workload, Tasks, and Time Utilization
Mary-Lynn Fulton, Vice President, Global Research Operations, PAREXEL
Tufts Center for the Study of Drug Development, in collaboration with 18 biopharmaceutical and CROs, conducted a working group study in 2011 of the global CRA landscape examining key metrics, including workload and time utilization. Both company data and CRA self-reported data were collected. A total of 3,970 CRAs completed the self-report survey. The results indicate that CRA workload is high and assigned tasks vary widely by geographic region. This session will present detailed workload and utilization measures and discuss the implications of the study results. An understanding of the data from this important baseline study will enable industry stakeholders to make the appropriate decisions to drive improvements in CRA effectiveness and efficiency.

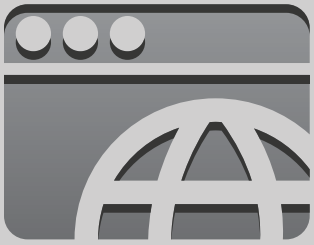
MONITORING GLOBAL CLINICAL TRIALS

2:05 Monitoring International Clinical Trials in Emerging Countries
John R. Wilson, Jr., Ph.D., MPH, Senior Vice President, Beaufort CRO
Prior treatment of this topic has focused on "what is different" about monitoring in emerging countries, and there is a wealth of information outlining such differences. What has historically been missing, however, is "what to do about it." This talk will delve into the differences and challenges with an eye toward constructive, proactive approaches that help ensure that regardless of difficulties, sponsors can come to count on data from emerging countries.

2:50 Networking Refreshment Break and Exhibit Viewing

3:10 Principal Investigator Responsibilities and GCP: The Essential Ingredients for Success
Shari Zeldin, BA, CCRC, Manager, Clinical Research Compliance Office University of Wisconsin Carbone Cancer
This presentation will outline the responsibilities that a Principal Investigator commits to when conducting clinical research. This session will address: Review of 21 CFR 312 Good Clinical Practice - The Standard; the protocol; informed consent; eligibility determination; treatment/adverse events/toxicity; data quality; audits/monitoring; and leading by example

4:10 Close of Conference



Second Annual | June 3 - 4, 2013

Vendor Management in Clinical Trials

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

Strategies and tools for assessing, implementing and improving quality when partnering with clinical service providers will be the focus of the second annual Vendor Management in Clinical Trials conference. 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." Thought leaders will present their compliance-focused vendor management strategies, from selection through contracting and oversight. With domestic and international regulatory inspection trends in mind, speakers will guide attendees in implementing their own vendor qualification and management strategies. Risk-based approaches to vendor management will be addressed, as well as auditing of clinical service providers. Attendees can expect case studies, take-away tools, perspectives on the current regulatory environment, breakout groups and interactive activities.

MONDAY, JUNE 3, 2013

7:00am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

RISK-BASED VENDOR MANAGEMENT STRATEGIES

8:15 Applying Risk-Based Approaches to Vendor Management & Vendor Oversight

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

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

As the sponsor of a clinical trial you are accountable for your service providers. Therefore, appropriate oversight is required. But this is easier said than done. What is deemed "appropriate"? How do I determine the "appropriateness" of oversight? And last but not least, what is the right model for outsourcing? In this session we will answer these questions and provide attendees with methodologies to help in making the right decision.

9:00 Partnering for Clinical Trial Success

Jonathan Andrus, MS, CQA, CCDM, Senior Vice President, Operations, BioClinica, Inc.

It takes too long to start up studies and too long to close them out and get analyzable data. Through sound vendor management practices, including governance and key performance indicators, organizations are able to achieve success far ahead of expectations. Effective vendor management starts with each party viewing each other as a partner. Which skills each brings to the table and how they can effectively harness each other's strengths will be emphasized in this session.

9:45 Networking Coffee Break and Exhibit Viewing

10:15 Impact of Biopharmaceutical Compliance Requirements: Art of Securing Sarbanes-Oxley (SOX) Compliant and Competitive Contractual and Budget Terms

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

The presentation will include 1) a brief overview of Sarbanes-Oxley (SOX) with emphasis of compliance challenges and impact on sponsors and CROs; 2) RFP process and strategy with emphasis on the importance of planning, evaluation, award process; 3) an in-depth discussion of the critical and non-critical contract; 3) key factors to consider when determining budget terms and type of payment terms; 4) the best practice of minimizing expense and processing of change orders; and 5) overview of good contract practices.

11:00 Interactive Roundtable Discussions

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

VENDOR QUALIFICATION AND CONTRACTING

1:00pm A Comprehensive Approach to Qualification of Third Party Providers

Kimberly Washburn, Director, Quality Assurance, Global QA, Quintiles

The quest to develop a holistic approach to the identification, assessment, selection, contracting, and management of vendors is essential as a defensible positioning model to address regulatory and cost/oversight concerns with regards to third party vendor use. The facilitation of a standardized approach to vendor oversight lends itself to a consistent assessment model which is based on defined criteria. A risk-based approach with a defined underlining algorithm permits an organization the ability to apply a standard qualification approach for assessing all vendors, from an initial determination of inclusion/exclusion with the program, to the quality assessment method.

CASE STUDY

1:45 The Contracting Process: Defining the Scope of Work, and Building Quality and Accountability into the Contract

Joe Popowicz, Director, Clinical Operations, Stryker Orthobiologics

Derek Gamber, Regional Sales Manager, MedNet Solutions

Strategic partnerships and functional service provider relationships have helped drive cost and time savings into the clinical development process for large pharmaceutical and medical device companies. This session will review a case study of a medical device company that developed a strategic partnership with an Electronic Data Capture (EDC) supplier. Best practices for vendor selection and contracting will be discussed including:

- Tools to ensure a uniform assessment of capabilities, costs and timelines
- Processes to ensure strategic fit for both parties
- Defining roles and responsibilities as a key component to measure and ensure mutual success

2:30 Diagnostic Trials: A Process for CRO Selection, Qualification and Successful Oversight

Dayna Geralts, Manager, Clinical Affairs, Molecular Diagnostics, Hologic, Inc.

The responsibility of proper diagnostic clinical trial execution is not allowed to be delegated to a CRO per FDA regulations. Therefore, adequate qualification and oversight of CROs executing clinical trials for diagnostic sponsors is critical to a successful study and product approval. This presentation will review a detailed process from identification of CROs to study close out to ensure your study is executed appropriately.

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Networking Refreshment Break and Exhibit Viewing

CRO QUALIFICATION, SELECTION AND OVERSIGHT

3:50 Adapting Outdated CRO Selection Models to Prevail in Extremely Competitive Study Conditions

Pierre Corin, Senior Director, Development Operations, Clinical, Cerexa

The usual model for vendor selection used by the industry is not producing the needed results. CROs constantly rank low on the quality surveys published by the pharmaceutical industry, despite the fact that several of them continue to grow and develop. This presentation will address the need for a more precise and rigorous vendor selection that match the sponsor request more appropriately.

CASE STUDY

4:35 Leveraging the Sponsor-CRO Relationship for Study Success

Christine E. Buben, MS, MBA, Director, Clinical Operations, Tarsa Therapeutics, Inc.

Rebecca Cope, PMP, Product Manager, BioClinica, Inc.

The partnership between a sponsor and an imaging CRO is a critical one to

ensure study success in clinical trials that rely on imaging for efficacy data. The objectives of this presentation are to:

- Explore unique features that should be considered during imaging vendor selection
- Review operational tactics that promote quality within the CRO team and at clinical sites
- Examine strategies for effective partnership to achieve study milestones
- Present a case study in which Tarsa Therapeutics partnered with BioClinica for a successful pivotal osteoporosis trial

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

5:45 Short Course Registration

6:00 - 8:30 Dinner Short Course 1, Project Management of CROs
(see page 2 for additional information)

6:20 Close of Day One

TUESDAY, JUNE 4, 2013

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

TECHNIQUES FOR SITE MANAGEMENT

8:00 Sites Are Your Least Effective Vendors: Why Your Management of Sites Doesn't Work and How You Can Change That
Adam Chasse, COO, RxTrials
On any given study, about 70% of sites will fail to meet the enrollment target (and almost half of those won't enroll a single subject). You wouldn't accept that from any other vendor segment, and you shouldn't accept it from sites. The solution lies in recognizing that sites have very unique challenges compared to other vendors and understanding what will drive performance. In this session, the audience will gain insights into how sites operate and how to leverage internal skills or outside expertise to achieve better delivery.

CASE STUDY
8:45 The Journey to Regulatory Excellence via an Electronic Research Management System
Mary Jane Welch, DNP, Director, Human Subjects' Protection Program, Research Affairs, Rush University Medical Center
Using the Rush experience as an exemplar, this presentation will identify the process used to determine the vendor, implement the system(s), build acceptance, increase researcher satisfaction, and ultimately achieve accreditation. The presentation will discuss the successes and the lessons learned. Researcher satisfaction metrics will be shared, as well as a tool that was created during the process that has decreased redundancies and increased efficiencies of the processes while increasing the accuracy of the data.

9:30 Networking Refreshment Break and Exhibit Viewing

QUALITY OVERSIGHT OF CLINICAL VENDORS

CASE STUDY
9:50 From Vendor to Partner: Changing the Industry Oversight Auditing Paradigm
Randall Basinger, Senior Director, Systems Compliance Office, Global Quality Assurance, Quintiles
Kevin Saylor, Senior Director, Computer & Lab Systems QA, Millennium Pharmaceuticals, Inc – The Takeda Oncology Co.
This session will introduce the ongoing relationship between a CRO and a Pharmaceutical company and how partnering can hopefully help to change how audit and oversight is accepted by the regulatory authorities. As budgets are tightened and technology provides for other avenues for oversight, is auditing still the best way to ensure quality on your projects. This session will introduce this topic, propose some potential areas where this can change and open up into an interactive forum discussion with the audience to explore other options for changing this approach to quality oversight.

10:35 Clinical Vendor Audit Logistics, Preparation, Conduct and Reporting
Treena Jackson, MS, CQA, RAC, CSSGB, Quality Resource Consulting, Inc.
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:

- The process for selection, audit, approval, and qualification of vendors based on the material/equipment/service being delivered
- The various types of vendors that might be audited
- Methods and tools used to accomplish a vendor qualification
- The maintenance aspects of a vendor management program including handling of non-conformances, and timing and nature of additional audits

11:20 How to Assure High Data Quality and Safeguarding Subject Protection in Worldwide Multi-National Clinical Trials? The Qualified AO Clinical Study Center Project (AOCSC)
Denise Schmid, MSc, Senior Project Manager Monitoring, AO Clinical Investigation and Documentation
Performing clinical investigations on a global scale is challenging. Therefore, we introduced a system to standardize and harmonize processes regarding the conduct of clinical studies at the collaborating investigational clinics. Study centers involved in this program will be qualified as "AO Clinical Study Centers" (AOCSC) network partners by the AO Foundation.

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

1:20 Quality Oversight of Specialty Laboratories
Shannon Hohengasser, Associate Director, Research and Development Compliance, Shire
Special or unique assays may be performed by a limited number of specialty or academic labs in the world. These labs may not have robust quality systems or expertise in GCP, GCLP, GLP, etc. But there are no other options but to use them! This presentation is about how to best manage these vendors to collaboratively bring them into a more compliant state.

2:05 Central IRB Selection: Truths Or Consequences
John M. Isidor, J.D., CEO, Human Subject Protection Consulting, LLC
This session will help attendees:

- Describe the regulatory issues to consider in selecting a Central IRB
- Identify pertinent metrics to ensure appropriate selection
- Understand what tools can be used to predict and evaluate Central IRB performance
- Explain how an FDA audit of a Central IRB could affect a clinical trial
- Identify future regulatory changes that may affect Central IRBs

2:50 Networking Refreshment Break and Exhibit Viewing

3:10 Addressing Quality Issues: Corrective and Preventive Actions (CAPA), Follow-Up and Escalation Plans and Procedures
Ken Shitamoto, MS, PMP, CPRE, CTFL, Corporate Quality Assurance, Affymax, Inc.
Effective CAPA can help overcome vendor management risks by not only eliminating issues, but by providing a means of process improvement and increased vendor collaboration. This session will provide both an overview of CAPA and specifics on how to apply CAPA in vendor management. Learning objectives:

- Understand the elements of an effective CAPA process
- Understand root cause analysis and survey root cause analysis methodologies
- Understand how to determine the effectiveness of a CAPA
- Understand the follow-up and escalation process

3:55 Communication and Responsive Results in Sponsor-Vendor Relationships: The Voodoo in the Details
Deborah Thibodeaux, Lead Consultant, Management, DKT Lab Consulting, LLC
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.

4:40 Close of Conference

Third Annual | June 5-6, 2013

Clinical Auditing Forum

Ensuring Audit Readiness and GCP Compliance Across Clinical Research Functions

The third annual Clinical Auditing Forum, focuses exclusively on regulatory agencies' changing focus and expanding expectations regarding GCP compliance. Thought leaders will relate their experiences ensuring clinical research compliance through strategic approaches to clinical quality assurance and on "GCP Inspection Readiness," with a focus on developing and strengthening auditing programs. Auditing techniques for ensuring compliance, managing non-compliance, root cause analysis and preventive and corrective actions will be a focus throughout. Sessions will address preparing sites for regulatory inspections, including techniques for sites related to billing compliance, self-monitoring and quality management. Real-world examples of risk-based approaches to auditing sites, systems and providers will be featured, and FDA and international regulatory agency expectations and recent inspection trends will be discussed. Attendees can expect case studies, hands-on activities, take-away tools, breakout groups and interactivity.

WEDNESDAY, JUNE 5, 2013

7:00am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

QUALITY SYSTEMS APPROACHES TO AUDITING

CASE STUDY

8:15 Quality Systems: The RSQA Model at the University of Miami

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

Starting in 2011, the Office of Regulatory Support and Quality Assurance (RSQA) residing within the Office of Research, Miller School of Medicine at the University of Miami advanced from a well established auditing program into a quality improvement program to provide support and assistance to the university research community. In 2013, RSQA will implement a university wide CAPA system as well as regulatory support for university researchers to assist with clinicaltrials.gov compliance. Quality management approaches as well as risk management principles are applied throughout the entire process of implementation. This presentation will provide the audience with our experience in transitioning from an auditing to a quality systems approach, and demonstrate how auditing and monitoring can work in a symbiotic relationship to benefit the university's research mission.

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 Networking Coffee Break and Exhibit Viewing

10:15 Creating a Quality Systems-Based Approach to Clinical Trial Auditing that Produces Reliable Data

Bradley Wong, Consultant to Allergan

11:00 Interactive Roundtable Discussions

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

CASE STUDY

1:00pm Investigator Responsibilities: A Real-Life Compliance Issue, and Corrective Action

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

This session will review current device GCP trends for principal investigators and identify common device GCP risks for Investigator/Sponsor Studies. The session will explore investigator issues of device GCP non-compliance among Academic Health Centers (AHCs) and will examine an AHC device case study and corrective action.

SITE INSPECTION READINESS AND STRATEGIES

1:45 Enhancing Auditor Emotional Intelligence

Tabitha K. Westbrook, RQAP-GCP, Manager, Quality Assurance, INC Research, former Head of Quality Assurance, Central IRB

Audits are often viewed as transactional and factual – and rightly so! They are transactional (a process carried out) and must be factual, devoid of as much personal bias and emotion as possible, presenting only facts to the auditee(s). However, the power of advanced soft skills in enhancing the both the transactional and factual aspects of an audit cannot be underestimated. We have all heard stories of auditors who possessed little to no soft skills – and those audits were likely rather painful. The use of appropriate, advanced soft skills also serves to reinforce a culture of quality with the auditee, which is something that most senior management teams today are trying to achieve. The most important soft skill a quality professional can possess is his/her emotional intelligence. In this session, attendees will receive detailed information regarding auditor emotional intelligence, including practical skills that attendees can use to enhance their emotional intelligence and encourage emotional intelligence in others. Real case scenarios will be provided to help illustrate this concept.

2:30 Defining "GCP Inspection Readiness" in Today's Regulatory Environment

Treena Jackson, MS, CQA, RAC, CSSGB, Quality Resource Consulting, Inc.

The session will provide information regarding what "inspection readiness" means as pertinent to the FDA Investigator Site and Sponsor-Monitor Inspections. In the present regulatory environment with heightened regulatory surveillance, it is essential to understand the FDA inspection process and be prepared for a regulatory inspection at all times. The audience will gain knowledge regarding the following:

- Information pertinent to the FDA Investigator Site and Sponsor-Monitor Inspection processes such as selection, conduct, and communication of the inspectional findings
- Preparation activities such as planning meetings to discuss the inspection logistics, roles, and responsibilities
- Ongoing documentation preparedness
- Preparation of standard procedures to address inspection activities such as greeting the FDA investigator(s), inspection room activities, responding to the FDA requests, inspection feedback, and conclusion

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Networking Refreshment Break and Exhibit Viewing

»»INTERACTIVE SESSION!

3:50 Case Study Discussion with a former FDA Medical Officer: What the FDA Looks for at Your Site

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

Warning letters vividly describe errors made, identified by FDA inspectors and classified as deserving attention. Knowing how FDA sees your site and your data helps sponsors, sites, investigators, monitors, and all involved in clinical studies prepare for an FDA inspector. Let this former FDA medical officer share examples of clinical nightmares and errors in Good Clinical Practices (GCPs) that could have been avoided. This discussion with the opportunity of interactive questions and answers will offer practical examples on ways to meet GCPs. Topics addressed include:

- Why Does FDA audit?
- What Does FDA find?
- How can sites and investigators avoid costly errors?

4:35 Warning Letter Discussion with a former FDA Medical Officer: How to Avoid Warning Letters and What Can Be Learned from Them (Session 2 of 2)

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

5:20 Reception and Exhibit Viewing

(Sponsorship Opportunity Available)

5:45 Short Course Registration

6:00 - 8:30 Dinner Short Course 2, Quality-Systems Based Approaches to a GCP Auditing Program *(see page 2 for additional information)*

6:20 Close of Day One

THURSDAY, JUNE 6, 2013

7:30am Morning Coffee or Sponsored Breakfast Presentation

(Opportunity Available)

AUDITING VENDORS AND PROVIDERS

CASE STUDY

8:00 From Vendor to Partner: Changing the Industry Oversight Auditing Paradigm

Randall Basinger, Senior Director, Systems Compliance Office, Global Quality Assurance, Quintiles

Kevin Saylor, Senior Director, Computer & Lab Systems QA, Millennium Pharmaceuticals, Inc – The Takeda Oncology Co.

This session will introduce the ongoing relationship between a CRO and a Pharmaceutical company and how partnering can hopefully help to change how audit and oversight is accepted by the regulatory authorities. Traditionally, the FDA and other regulatory bodies have expected pharma to maintain a Quality Assurance unit overseeing the outsourced or contracted activity via auditing. However, as budgets are tightened and technology provides for other avenues for oversight, is auditing still the best way to ensure quality on your projects? This session will introduce this topic, propose some potential areas where this can change, and open up into an interactive forum discussion with the audience to explore other options for changing this approach to quality oversight.

8:45 IRB/IEC Assessments and Audits

Kara Lemons Harrison, RAC; RQAP-GCP, Director, Quality Assurance, INC Research, former Field Investigator, FDA

Tabitha K. Westbrook, RQAP-GCP, Manager, Quality Assurance, INC Research, former Head of Quality Assurance, Central IRB

Due to the importance of the IRB's/IEC's role with regard to the protection of the rights and welfare of human research subjects, audit professionals should be aware of important nuances that make IRB/IEC audits different than clinical site or other vendor audits. Attendees will leave the session with a better understanding of the current IRB landscape on both the central and local level, AAHRPP® requirements and where to find them, and how to perform and follow up an in-depth IRB audit.

9:30 Networking Refreshment Break and Exhibit Viewing

9:50 Ensuring Site Compliance and Managing Non-Compliance, including Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA) for Sites

Doreen McGirl, ASQ-CQA, Associate Director, Compliance, Merck

By partnering audits and monitoring visits, a sponsor can identify site non-compliances and begin the journey of securing compliance. First and foremost, a sponsor needs to identify the root cause of the non-compliance, and then commit to in-place and in-use actions. This presentation will discuss monitoring and auditing techniques, as well as how to identify the root cause of non-compliance. Lastly, discussion will include how to identify, implement, and track corrective and preventive actions.

10:35 Health Canada's Food and Drug Regulations Division 5: Are You Compliant?

Hope Senechal, BSc, CCRA, Internal Clinical Research Auditor, 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. A recent trend in inspection observations is the lack of evidence of Division 5 regulation training received by investigators and clinical research staff. A lack of knowledge of the regulations puts a trial at an increased risk for non-compliance. This session will provide an overview of the regulations emphasizing the responsibilities of the sponsor and the investigator as well as discuss recent trends in inspection observations and the ever-changing research landscape in Canada.

11:20 Risk-Based Auditing: An Approach to Vendor and Site Audits

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

12:05pm Close of Conference

12:30 Short Course Registration

1:00 - 3:30 Short Course 3, Quality by Design: How to Apply It When Setting Up Your Trials *(see page 2 for additional information)*

HOTEL & TRAVEL INFORMATION

Conference Hotel:

Hilton Boston Back Bay
40 Dalton Street | Boston, MA 02115
T: 617-236-1100

Discounted Room Rate: $234 s/d
Discounted Cut-off Date: May 6, 2013

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 discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

Flight Discounts:

Special discount rates have been established with American Airlines for this conference.

- Call American Airlines 1-800-433-1790 and use Conference code 4463BU
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- Contact our dedicated travel agent, Rona Meizler, at 1-617-559-3735 or Rona.Meizler@protravelinc.com

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- Call Hertz directly at 800-654-3131 and use our Hertz Convention Number(CV) 04KL0004
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Second Annual | June 5-6, 2013

Clinical Quality Risk Management

Implementing a Comprehensive Quality Management System for Good Clinical Practice

Focused on meeting the emerging regulatory expectations for a quality systems-based approach to GCP compliance, the Clinical Quality Risk Management track will feature thought leaders' experiences implementing clinical QRM, creating quality systems-based approaches to clinical monitoring and auditing and responding to the evolving landscape within both the FDA and international regulatory bodies. Throughout the conference, quality management systems and the lessons learned during the implementation of those systems will be addressed, as well as the effect of quality risk management on individual clinical roles. Practical applications and takeaway QRM tools will be provided. Attendees can expect to hear case studies regarding the implementation of clinical QRM and Quality by Design, creating a quality systems-based approach to clinical monitoring and auditing that produces reliable data and responding to the evolving regulatory landscape. The conference will feature case studies, take-away tools, perspectives on the current regulatory environment, breakout groups and interactive activities.

WEDNESDAY, JUNE 5, 2013

7:00am Registration and Morning Coffee

8:00 Barnett Welcome & Chairperson's Opening Remarks

8:15 Case for Change: Business Case for QRM
Ken Schiff, BA, MBA, Quality Risk Management Associates, LLC
QRM is a quality management system which helps to improve a company's methods of working in ensuring high quality results and compliance with regulations and internal processes in the conduct of clinical trials, pharmacovigilance, and other functions. Implementing a quality management system has wide-spread applicability within an organization. The fundamental question most organizations ask when pursuing such an approach is "Where do I start?" In order to deliver the message of value for an organization, focus resources on the areas of highest risk – to gain access to required resources and to acquire the needed support for such an initiative in general – is first to build a business case that will serve as a benefit/cost analysis to justify the investment of QRM and the changes it will bring with it.

9:00 An Innovative, Automated Approach to Effective Risk Management in Clinical Development
Roland Rich, Quality & Compliance Excellence, Operations Expert, DevQA, Novartis
This session will explore TAPAS© (Trend and Pattern Alert System), the basis of Novartis' quality risk management (QRM) program. As the risk management approach will receive data almost in real-time, it is possible to monitor and assess risks on an ongoing basis or at appropriate intervals. If a problem is detected, the system can notify the business stakeholder, who can then work to identify any necessary mitigating actions. Over time, the assessment results accumulate and it becomes possible to calculate trend analyses across particular risk indicators and entities. The tool is powered by data that are collected routinely anyway on trial and site performance, and in support of trial analysis.

9:45 Networking Coffee Break and Exhibit Viewing

10:15 Adapting the Risk Quality Management Approach to Clinical Research
Shirley Roach, Regulatory PM, Quality, Allied Technologies and Consulting
You cannot improve what you cannot measure. Developing metrics to measure results and allow for continual quality improvement. Quality risk management tools have not been adapted to clinical research but could have a role in standardized quality practices. We perform global research and we have to ensure results posted in Timbuktu mean the same as those posted from Topeka... we have to have a baseline for quality and build from there.

11:00 Interactive Roundtable Discussions

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

1:00pm Quality by Design: How to Identify Pitfalls and Showstoppers in Advance when Planning Your Trial
Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.
Planning, conducting, and reporting on clinical trials today is becoming increasingly complex. This results in many different problems, such as cost of clinical development and limitation of resources, globalization of trials with complex regulatory, business and scientific environments, risk aversion with little appreciation of risks or what risks actually are, over-interpretation of the regulatory environment, poor design of studies, failure to identify priorities, and lack of proportionality in the implementation of QC activities. In order to overcome these and other issues, a Quality by Design approach must be applied from the very beginning when planning your clinical programs. With QbD, you will know in advance what the key aspects or your particular trial are and how to stay in control to deliver a successful study.

KEY PERFORMANCE AND QUALITY INDICATORS

Quality Risk Management (QRM) at site level requires development of well defined and relevant metrics, Key performance and quality indicators (KP-QI), as well as a solid process for review and follow-up of the identified signals. Both aspects need to be supported by robust information management as well as training and cross-functional communication strategies.

Part 1

1:45 Practical Aspects of Developing Relevant Key Performance and Quality Indicators (KP-QIs)
Sina Djali, Director, Quality Monitoring and Compliance/Quality Systems, Janssen
In this presentation we focus on practical aspects of developing relevant KP-QIs. These include both subject level and operational data required to implement a robust internal QRM system. We will also focus on some of the integration and information management aspects of QRM.

Part 2

2:30 Processes in Support of a Risk-Based Approach in Managing Site-Level Compliance
Sean P. Murphy, MS, Associate Director, Global Trial Manager, Janssen R&D
In this presentation we will focus on implementing processes in support of a risk-based approach in managing investigator site level compliance. These will include processes for review of information tailored to the different stages of a trial (initiation vs. execution). We will also discuss the role of a central vs. on site monitoring teams and provide a model on interaction between both in the follow-up of identified signals.

QUALITY BY DESIGN (QbD)

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Networking Refreshment Break and Exhibit Viewing

QRM AND RISK-BASED MONITORING

3:50 Fitting Actual Risk Management Principals into the FDA's New Risk-Based Monitoring Guidance
Lee Truax-Bellows, President, Clinical, NCRA

Risk management has morphed from the good manufacturing arena to clinical study operation activities. It has become the standard not only in the US but also the EU and is receiving more attention on a world-wide basis. Besides being a new expectation by regulatory agencies under good clinical practices, it also is good business practice. To implement, one must first understand and then put such principals into practice. This proposal will provide the participant with some initial knowledge to allow a successful implementation of risk-management under the clinical umbrella.

4:35 Integration of Quality Risk Management and Risk-Based/ Adaptive Monitoring
Stephannie Perrin, Associate Director, Quality Risk Management, Global Quality and Compliance, PPD

As the industry utilization of risk-based monitoring continues to increase along with the development and expansion of the area 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, allows for more focused and efficient resource utilization and allocation. 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 risk-based monitoring plan (Quality by Design). Other QRM tools, such as metrics dashboards, can then be used to capture emerging risks and adapt monitoring plans accordingly. The QRM tools used can help to define "must haves" in a RBM plan and can allow for better resource planning. The integration of these two evolving concepts is key to the success of both models and to streamlining processes within the industry as a whole.

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

5:45 Short Course Registration

6:00 - 8:30 Dinner Short Course 2, Quality-Systems Based Approaches to a GCP Auditing Program *(see page 2 for additional information)*

6:20 Close of Day One

THURSDAY, JUNE 6, 2013

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

8:00 Clinical Quality Risk Management: What Input on (Regulatory) Decision Making?
Markus Hartmann, Ph.D., MDRA, Principal Consultant, European Consulting & Contracting in Oncology

The EU Commission's proposed new Clinical Trial Regulation from July 2012 is a starting point to further implement the concept of risk proportionality in clinical research, as is the EMA draft reflection paper on quality-based risk management issued in August 2011. In line with draft guidance from the FDA, EMA's paper provides a critical assessment of achievements made so far by conventional clinical quality assurance approaches in terms of safeguarding subject protection and data quality. By transferring the quality-by-design concept developed for manufacturing to clinical development, the paradigm shift is obvious: Quality in clinical research shall be considered as "fitness for purpose." Consequently, growing emphasis is put on data reliability and robustness: In the future, problems identified in pivotal clinical trials will tremendously impact agencies' continuous benefit-risk assessment.

QRM TOOLS AND TECHNIQUES

8:45 Implementing Clinical Quality Risk Management: Tools, Techniques and Experiences
Randy Ramin-Wright, MS, Program Manager and QRM Consultant, International Institute for the Safety of Medicines (ii4sm) Ltd.

The presentation will address the following points:

- How to implement the ICH QRM model within a QRM system
- Specific system implementation
- Implementing a quantitative risk model
- Fit for purpose QRM tools
- How to integrate tools into clinical operations
- Practical implementation tips

9:30 Networking Refreshment Break and Exhibit Viewing

CASE STUDY

9:50 Quality Systems: The RSQA Model at the University of Miami
Johanna L. Stamates, RN, MA, CCRC, CHRC, Executive Director, Regulatory Support and Quality Assurance, University of Miami

Starting in 2011, the Office of Regulatory Support and Quality Assurance (RSQA) residing within the Office of Research, Miller School of Medicine at the University of Miami advanced from a well established auditing program into a quality improvement program to provide support and assistance to the University research community. In 2013, RSQA will implement a university wide CAPA system as well as regulatory support for university researchers to assist with clincialtrials.gov compliance. Quality management approaches as well as risk management principles are applied throughout the entire process of implementation. This presentation will provide the audience with our experience in transitioning from an auditing to a quality systems approach, and demonstrate how auditing and monitoring can work in a symbiotic relationship to benefit the University's research mission.

10:35 Building Quality Assurance and Management into Clinical Trials
Christina R. Eberhart, Manager, Health Care Advisory, Ernst & Young LLP

11:20 Use of a Quality Control Check (QCC) as Part of an integrated Quality Oversight Program for Strategic Partnerships
Bonnie J. Trochanowski, CCRP; Global Medical Quality, Eli Lilly and Company; Kathy Ballensky MT (ASCP), CCRA, Global Medical Quality, Eli Lilly and Company

12:05pm Close of Conference

12:30 Short Course Registration

1:00 - 3:30 Short Course 3, Quality by Design: How to Apply It When Setting Up Your Trials *(see page 2 for additional information)*

PRICING AND REGISTRATION INFORMATION

SHORT COURSES

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

Monday, June 3	Wednesday, June 5	Thursday, June 6
(SC1) Project Management of CROs	(SC2) Quality-Systems Based Approaches to a GCP Auditing Program	(SC3) Quality by Design: How to Apply it When Setting Up Your Trials

CONFERENCE PRICING

SINGLE CONFERENCE PRICING *(Includes access to 1 conference. Excludes short courses.)*

Registrations after April 12, 2013, and on-site	$1895	$975

EVENT PRICING BEST VALUE! *(Includes access to 2 conferences. Excludes short courses.)*

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CONFERENCE SELECTIONS:

June 3-4 (Monday-Tuesday)	June 5-6 (Wednesday-Thursday)
Mastering Clinical Trial Monitoring	Clinical Auditing Forum
Vendor Management in Clinical Trials	Clinical Quality Risk Management

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REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

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

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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.

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

Please refer to the Registration Code below:

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