Third Annual
Clinical Trial OVERSIGHT SUMMIT

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

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Cambridge Healthtech Institute,
250 First Avenue, Suite 300,
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BARNETT EDUCATIONAL SERVICES

Third Annual
Clinical Trial OVERSIGHT SUMMIT

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Mastering Clinical Trial Monitoring

Vendor Management in Clinical Trials

Clinical Auditing Forum

Clinical Project Management Forum

ClinicalTrialSummit.com

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

Proposals are still being accepted! If you are interested in being a speaker at the Clinical Trial Oversight Summit, please contact:

Rachel Meyers, Director, Barnett International
a division of Cambridge Healthtech Institute (CHI)
T: (+1) 781-247-6269 | E: rmeyers@barnettinternational.com

SUMMIT AT-A-GLANCE

Monday AM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
Monday PM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
	Dinner Short Course* Best Practices to Becoming a Preferred Site	
Tuesday PM	Mastering Clinical Trial Monitoring	Vendor Management in Clinical Trials
	Afternoon Short Course* Metrics & KRIs: Study Oversight in a Risk Management Environment - How to Make it Work	
	Dinner Short Course* Managing the CRO Relationship: From Engagement through Delivery	
Wednesday AM	Clinical Auditing Forum	Clinical Project Management Forum
Wednesday PM	Clinical Auditing Forum	Clinical Project Management Forum
	Dinner Short Course* Take Control of Your RCA and CAPA Activities to Achieve Clinical Excellence	
Thursday AM	Clinical Auditing Forum	Clinical Project Management Forum
Thursday PM	**Post Conference Short Course*** Quality by Design for Success: QbD in the Design and Planning of Your Clinical Trial	

**Separate Registration Required*

LEAD SPONSORING PUBLICATIONS

Bio·IT World · nature · The Scientist — Exploring Life, Inspiring Innovation

SPONSORING PUBLICATIONS

PharmaVOICE · Clinical Informatics News — Clinical Trials to the Clinic

MEDIA PARTNERS

CenterWatch · www.PharmCast.com – Pharmaceutical Internet – · SelectScience® The Fastest Way to Expert Opinion

SHORT COURSES*

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

(SC1) Best Practices to Becoming a Preferred Site

Janet Ellen Holwell, CCRC, CCRA, Clinical Research Consultant

Mirror, Mirror, on the wall, who's the fairest site of them all? It could be you! This workshop will explore best practices for FDA-compliant source and regulatory documentation and the tools that can help to get you there. Join us to learn how to best prepare for a monitoring visit or site audit/inspection. Most non-compliance noted through monitor visits, regulatory inspections, and audits stem from inadequate and inconsistent documentation at sites. Learn techniques to better manage your regulatory files and prepare to answer sponsors, auditors, and inspectors regarding screening/enrollment numbers, subject withdrawal, informed consent, recruitment efforts, delegation of authority, protocol violations and adverse events. Identify what is adequate source. What do I really need to file in my site master file? What are "extras" that will make my site preferred by sponsors? Tips and tricks for managing the regulatory file will be provided through tools/worksheets/templates and interactive activities. Best practices for documentation and management of investigational product will be shared. Objectives include:

- Identify the extra steps needed to take for unblinded components of trials
- Recognize the importance of quality in clinical trials by identifying key areas for improved documentation and communication
- Identify key areas for improved documentation and communication leading to better quality
- Manage documentation of recruitment efforts effectively

AFTERNOON SHORT COURSE
(Tuesday 1:00-3:30 pm)

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

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

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

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

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

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

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

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

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

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SHORT COURSES*

DINNER SHORT COURSE

(Wednesday 6:00-8:30 pm)

(SC4) Take Control of Your RCA and CAPA Activities to Achieve Clinical Excellence

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

In 2011 and 2012, 47% and 43% respectively of the FDA audit findings were related to Corrective Action/Preventive Action. The findings identified a lack of systematic root cause analysis. Attend this hands-on workshop to:

- Streamline your clinical operations timelines by quickly identifying the root cause of any deviation and getting the project back on schedule
- Minimize your audit risks by establishing a reliable CAPA process demonstrating a systematic, step-by-step Root Cause Analysis and Corrective Action Process
- Integrate your CAPA processes with other Continuous Improvements Tools such as Six Sigma
- Analyze real-life RCA/CAPA case studies in small groups and individually

POST CONFRENCE SHORT COURSE

(Thursday 1:00-3:30 pm)

(SC5) Quality by Design for Success: QbD in the Design and Planning of Your Clinical Trial

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

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

Regulators are demanding a risk-based approach to managing quality in clinical trials and in particular monitoring as an oversight tool. Many have started to work on such an approach, however, they fail to be successful. The main reason for this failure is found in ignoring the Quality by Design (QbD) aspect of clinical trials in the first place. We have all seen studies with many protocol amendments that were necessary even before the trial started. This is only one example of wasting time and money, including extending the timelines of clinical studies unnecessarily. If you are not building your risk-based monitoring methodology on a sound foundation of a well-designed trial, even the smartest set up of risk-based monitoring will not live up to its expectations. In this workshop, you will learn what aspects to consider when designing a clinical protocol, when you plan for the study start up based on the approved protocol, and when you plan to use metrics to measure adherence to the protocol and support risk-based monitoring.

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Fifth Annual | June 2 - 3

Mastering Clinical Trial Monitoring

Optimizing Site Performance and Improving Efficiency with Risk-Based Monitoring

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

RBM IN THE ERA OF THE FDA FINAL GUIDANCE

The Brave New World of Risk-Based Monitoring
Susan Bosworth-Farrell, BSNMPH, CCRC, CCRP, Clinical Operations, Senior Clinical Research Associate, Abbott Vascular

Challenges and Solutions to Implementing a Risk-Based Monitoring Program within an Academic Research Institute
Gregory Staios, Research Monitor, Research Services, Centre for Addiction and Mental Health

Working Together to Implement Risk-Based Monitoring: A Pharma and CRO Perspective
Ben Dudley, Executive Director, Alliance Management, Clinical Development Services, Covance, Inc.

Institutional Risk-Based Monitoring: Three Years Later
Ina Abel, Manager, Clinical Research Monitoring, St. Jude Children's Research Hospital

THE TRANSCELERATE INITIATIVE

Piloting Risk-Based Monitoring: A TransCelerate Member Company Perspective
Ramil Abdrachitov, Clinical Research Director, Clinical Operations, AstraZeneca

BUILDING RELATIONSHIPS, INCREASING COMPLIANCE

Site Relationship Management: A CRA's Perspective
Sharon Sothern, BA, CCRP, CRA, Westat

Assessment Tools for Triggered Monitoring Visits
Lesli DeSimone, MSHS, RN, CCRA, CCRP, Clinical Monitoring Manager, Medtronic, Inc.

Principal Investigator GCP Training - Maybe It *Is* Rocket Science!
Shari Zeldin, BS, CCRC, Manager, Clinical Research Compliance Office, University of Wisconsin Carbone Cancer Center

FDA Investigation Preparation: The Do's and Don't's
Nancy S. Bakke, Manager, US Clinical Monitoring, Sorin Group CRM and Cardiac Surgery

Best Practices for Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA)
Speaker to be Announced

MEETING GLOBAL CHALLENGES

Cultural and Socioeconomic Variables in Global Clinical Trials and Its Effect on Risk-Based Monitoring
Vlad Bogin, M.D., CEO, Clinical Research, Cromos Pharma

Monitoring in the Electronic Environment: Electronic Data Capture (EDC), Electronic Medical Records (EMRs), and Electronic Storage Systems
Lee Truax-Bellows, President, CEO, Clinical, NCRA

MONITORING DEVICE STUDIES

What's the Difference? Pharma vs. Device Studies
Eddy Lyons, CCRP, Senior Clinical Research Associate, Biotronik, Inc.

QUALITY BY DESIGN AND MONITORING

Quality by Design: A Lean Six Sigma Approach to Risk-Based Monitoring
Erika Stevens, Senior Manager, Advisory Services Health Care, Ernst and Young LLP

Abstracts Are Still Being Accepted in These and Other Topic Areas:

- Monitoring High Risk Sites: Increased On-Site Monitoring vs. Remote Monitoring
- FDA's Final Guidance: Alternative Remote Monitoring Techniques
- Techniques for Optimizing Clinical Trial Site Performance
- The Physician Payment Sunshine Act: Practical Tips for Compliance
- Monitoring in Unique Environments: Academic Medical Centers, Medical Devices, and Clinical Resource Organizations
- Managing FDA Site Inspections and Their Consequences
- Site Relationship Management Techniques: From Site Selection, Management, Support, and Escalation Techniques
- Best Practices for Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA)
- FDA Inspection Trends: Expectations, Preparation, Documentation, Delegation, and Follow-Up
- Tools and Apps for Monitors: Making Monitoring More Effective and Efficient

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Third Annual | June 2 - 3

Vendor Management in Clinical Trials

Ensuring Quality Through Effective Assessment, Qualification, Auditing and Oversight

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

RISK-BASED VENDOR MANAGEMENT STRATEGIES

Risk-Based Approaches to Clinical Vendor Management
Ken Shitamoto, MS, PMP, CPRE, Kikai Consulting, LLC

How Risk-Based Approaches Affect Working with Your Service Providers
Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.

IMPROVING VENDOR PERFORMANCE

The Key Drivers of CRO Performance
Michael Howley, Ph.D., Associate Clinical Professor of Business, LeBow College of Business, Drexel University

Clinical Vendor Audit Logistics, Preparation, Conduct, and Reporting
Speaker to be Announced

Stop the Audit Treadmill: How Not Auditing Can Improve Your Vendor Management Program
Brandy Schenck, Manager, Quality, Cerulean Pharma, Inc.

OUTSOURCING MODELS

A Study of Outsourcing Models: Options, Approaches, and Impact
Mary Jo Lamberti, Ph.D., Senior Research Fellow, Tufts Center for the Study of Drug Development

VENDOR QUALIFICATION AND CONTRACTING

Strategies for Vendor Qualification: Strategies, Questionnaires, Pre-Qualification, and Risk Assessment
Treena Jackson, MS, CQA, RAC, CSSGB, Supervisor, Office of Quality Assurance, RTI Health Solutions
Norlonn A. Sturdivant, MT, RAC, Director, Office of Quality Assurance, RTI Health Solutions

Fundamental Processes for Optimizing Management of Contracts and Financials
Sally Teeters, CCRP, Senior Director, Legal and Business Management, CardioVascular BioTherapeutics, Inc.

The Sponsor/Clinical Research Organization Relationship: From Conception through Evolution
Speaker to be Announced

Abstracts Are Still Being Accepted in These and Other Topic Areas:

- Implementing a Quality Management Approach to Clinical Vendor Selection and Oversight
- The Sponsor/Clinical Research Organization Relationship: From Conception through Evolution
- Building a Partnership Relationship with Your Third Party Vendor
- Ensuring that Your Third Party Vendors Are Inspection Ready
- Effective Strategies for Ongoing Oversight of Third Party Vendor Oversight
- Clinical Research Sites as Vendors: Assuring Quality and Managing Relationships
- Addressing Quality Issues: Corrective and Preventive Actions (CAPA), Follow-Up, and Escalation Plans and Procedure
- Clinical Vendor Audit Logistics, Preparation, Conduct, and Reporting
- Strategies for IRB Evaluation, Selection, Compliance, and Regulatory Considerations
- Preparation and Oversight of a Vendor Partner's Regulatory Inspection

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Fourth Annual | June 4 - 5

Clinical Auditing Forum

Ensuring Audit Readiness and GCP Compliance Across Clinical Research Functions

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

RISK-BASED AUDITING TECHNIQUES

Implementing a Risk-Based Auditing Approach in Clinical Trials
Karine Julien, MBA, MSc, Disease Area Lead, Cardiovascular/Metabolic Disease, Pfizer Medical Quality Assurance
Federico Feldstein, J.D., Senior Director, Quality Assurance, Pfizer

Building Quality by Design (QbD) and Quality Risk Management (QRM) Systems into Clinical Site Operations: An Academic Clinical Research Site Perspective
Marina Malikova, Ph.D., CCRA, MA, Clinical Investigation, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

Auditing Third Party Vendors and Providers
Speaker to be Announced

THE CURRENT INSPECTION ENVIRONMENT: FINDINGS, TRENDS

Change at FDA Brings Challenge to Industry
Jerry B. Perkins, M.D., former Medical Officer, FDA

Regulatory Trends: Review of Recent FDA 483/Warning Letters Findings for Sponsors, IRBs, and Sites
Paul Papagni, Executive Director, Research, Holy Cross Hospital CHE

Comparing Drug to Device GCPs: ISO 14155 to ICH E6
Lee Truax-Bellows, President, CEO, Clinical, NCRA

IMPROVING OUTCOMES THROUGH COMPLIANCE

We're from Compliance and We're Here to Help – Really We Are!
Anne Adams, MS, J.D., Chief Compliance Officer, Emory Healthcare and Associate Vice President, Clinical Trials Compliance, Emory University

Achieving Compliance in Research: The Implementation of Quality Improvement Systems
Johanna Stamates, RN, MA, CCRC, CHRC, Executive Director, Research Compliance and Quality Assurance, University of Miami

Utilization of a Risk-Based Compliance Audit Tool for the Conduct of Audits
Ken Schiff, BA, MBA, Quality Risk Management Associates, LLC

Site Inspection Readiness and Strategies
Speaker to be Announced

PERFORMING MOCK AUDITS

Performing Mock Inspections to Identify Strengths and Address Weaknesses
Michael G. Duncan, Program Manager, Global Systems, Quality Assurance, Johnson & Johnson
Swati A. Tendolkar, BPharm, MT(ASCP), MS, Program Manager, Global System Quality Assurance, Johnson & Johnson

Abstracts Are Still Being Accepted in These and Other Topic Areas:

- International Audits: Regulatory Requirements, Regional Considerations and Similarities and Differences from FDA
- Developing and Implementing a Process Improvement Plan or Continuous Improvement Plan
- Defining "GCP Inspection Readiness" in Today's Regulatory Environment
- Improving Auditing Processes Using Lean Six Sigma
- Auditing Vendors and Providers: Clinical Research Organizations, Academic Research Organizations, IRBs, and Core Labs
- Internal, Interdepartmental and Site Audits
- Auditing Sites for Fraud, Bioethics, or Serious Noncompliance
- Ensuring GCP Compliance in SOPs
- Auditing in Unique Environments: Medical Device, IVD, IIT, Academic, and Government Studies

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Fifth Annual | June 4 - 5

Clinical Project Management Forum

Risk-Based Approaches to Maximizing Trial Performance

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

RISK-BASED APPROACHES TO PROJECT MANAGEMENT

Risk Management and Implementation of Strategic Project Management Tools in Clinical Trials
Marina Malikova, Ph.D., CCRA, MA, Clinical Investigation, Executive Director, Surgical Translational Research Operations and Compliance, Boston University

Coverage Analysis, Budgeting and Pre-Award Practices Limiting Fiscal Risk in Clinical Research
Erika Stevens, Senior Manager, Advisory Services Health Care, Ernst and Young LLP

A Holistic Approach to Managing Clinical Trials
Peter Schiemann, Ph.D., Managing Partner, Widler & Schiemann Ltd.

Investigation Product (IP) Logistics: Domestic and International Challenges
Speaker to be Announced

GLOBAL CLINICAL TRIAL CHALLENGES AND OPPORTUNITIES

Multi-National Clinical Studies: The Good, The Bad, and The Ugly
Kenneth K. Kleinhenz, Vice President, Global Regulatory Affairs, Cytori Therapeutics, Inc.

Strategies for Success in Emerging Markets
Mauro Martinelli, Associate Director, Emerging Markets Specialist, Clinical Development, Quintiles

Overcoming the Challenges in Global Clinical Trials: A Clinical Trial in Asia
Larn Hwang, Ph.D., Vice President, Regulatory & Clinical Operations, Sorrento Therapeutics, Inc.

Optimizing Global Patient Recruitment: The Current Regulatory Environment, Challenges, and Opportunities
Speaker to be Announced

MANAGING SITES TO SUCCESS

Critical Factors to Develop and Maintain a Comprehensive Site Initiation Strategy
Victor M. Lucariello, Jr., BS, Associate Manager, Investigator Grants, Clinical Site Contracts, Celgene Corporation

Maximizing Site Performance from Start-Up to Close-Out
Musa Mutyaba, CCRA, Infinity Pharmaceuticals, Inc.

Mitigating Clinical Study Risks Utilizing a Robust Catalog of Targeted Reports
Rosanne Petros, Clinical Project Manager US – West, Global Clinical Trial Operations NA, Merck Research Laboratories

How to Be Agile Oriented in Managing the Clinical Site
Ahmed R Saleh, Ph.D. , MS, CCRP, Director, Clinical Trials, Laboratory of Viral Diagnostics, University of Maryland, Baltimore, School of Medicine

Putting a Price on Priceless: Establishing a Correlative Sciences Program at Your Research Centre
Vanessa Speers, MSc, BEd, CCRP, Manager, Correlative Studies Program & Clinical Trials Support Unit, Princess Margaret Cancer Centre

Abstracts Are Still Being Accepted in These and Other Topic Areas:

- Optimizing Global Patient Recruitment: The Current Regulatory Environment, Challenges, and Opportunities
- Managing the Effects of Social Media on Clinical Trials: Risks and Opportunities
- Utilizing Risk Management Tools to Improve Performance: Process Mapping, Study Activity Templating, Project Operating Guidelines (POG), and Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA)
- Applying Quality by Design When Setting Up Clinical Trials
- Effective Project Management of Clinical Research Organizations
- Effective Project Management of Other Third Party Vendors: Core Labs, Academic Research Organizations (AROs), Site Management Organizations (SMOs), Software Providers, Electronic Patient-Reported Outcomes (ePRO) Providers
- Investigation Product (IP) Logistics: Domestic and International Challenges
- Addressing Changes in Regulatory Requirements and Incorporating Them into Trial Management
- Decreased Funding and Increased Expectations: Remaining Effective When Budgets Decrease

SPONSORSHIP, EXHIBIT, AND LEAD GENERATION OPPORTUNITIES

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

Podium Presentations – *Within the Main Agenda!*

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

Breakfast & Luncheon Podium Presentations

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

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

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

Exhibit

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

Additional branding and sponsorship opportunities available!

Looking for additional ways to drive leads to your sales team? One move can make all the difference!

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

Opportunities include:

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

Advertising opportunities such as marketing and promotional emails are also available.

For sponsorship and exhibit information, please contact:
Ilana Quigley
Business Development Manager
781-972-5457 | iquigley@healthtech.com

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HOTEL & TRAVEL INFORMATION

Conference Hotel:
Hilton Boston Back Bay
40 Dalton St.
Boston, MA 02115
Phone: 617-236-1100

Discounted Room Rate: $245 s/d
Discounted Room Rate Cut-off Date: May 6, 2014

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 discounts have been established with American Airlines for this conference.

- Call American Airlines 800-433-1790 and use Conference code 7264AD.
- Go to aa.com/group and enter Conference code 7264AD in promotion discount box.
- Contact our dedicated travel agent, Rona Meizler, at 617-559-3735 or rona.meizler@protravelinc.com

Car Rental Discounts:
Special rental discounts have been established with Hertz for this conference.

- Call Hertz 800-654-3131 and use our Hertz Convention Number (CV): 04KL0004
- Go to hertz.com and use our Hertz Convention Number (CV): 04KL0004

TOP REASONS TO STAY AT THE HILTON BOSTON BACK BAY

- Free wireless internet in all guest rooms
- The Prudential Center is located directly across the street and features over 75 shops and restaurants including the panoramic Skywalk
- The newly expanded Museum of Fine Arts and the Gardner Museum are a ten minute walk away
- The hotel in downtown Boston is surrounded by the scenic and historic Back Bay, South End and Fenway neighborhoods including 18 miles of recreational trails along the Charles River and the Esplanade

Third Annual
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REGISTER BY JANUARY 24, 2014
SAVE up to $400!

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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 P when registering

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One short course	$495	$270
Two short courses	$795	$520
Three short courses	$1095	$770
Four short courses	$1395	$1020

Monday, June 2nd	Tuesday, June 3rd	Wednesday, June 4th	Thursday, June 5th
(SC1) Best Practices to Become a Preferred Site	(SC2) Metrics & KRIs: Study Oversight in a Risk Management Environment - How to Make It Work!	(SC4) Take Control of Your RCA and CAPA Activities to Achieve Clinical Excellence	(SC5) Quality by Design for Success: QbD in the Design and Planning of Your Clinical Trial
	(SC3) Managing the CRO Relationship: From Engagement through Delivery		

CONFERENCE PRICING

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

Special Early Bird Rate until January 24, 2014	$2195	$835
Early Registration until March 7, 2014	$2295	$935
Advance Registration until April 18, 2014	$2450	$1025
Registrations after April 18, 2014, and on-site	$2595	$1095

SINGLE CONFERENCE PRICING (Includes access to 1 conference, excludes short courses)

Special Early Bird Rate until January 24, 2014	$1445	$675
Early Registration until March 7, 2014	$1545	$775
Advance Registration until April 18, 2014	$1695	$875
Registrations after April 18, 2014, and on-site	$1895	$975

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

CONFERENCE DISCOUNTS

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

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

Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472

If you are unable to attend but would like to purchase the Clinical Trial Summit CD for $750 (plus shipping), please visit ClinicalTrialSummit.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

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

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

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