MASTERING CLINICAL TRIAL MONITORING
Royal Sonesta Hotel, Cambridge, MA | June 24th & 25th, 2010

THE PREMIER EVENT FOR EXPERIENCED CLINICAL TRIAL MONITORS

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Featuring speakers from:

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Barnett International & Cambridge Healthtech Institute’s Mastering Clinical Trial Monitoring will address the evolving and expanding role of the clinical trial monitor. The conference will feature strategies, presentations, and case studies that specifically address the challenges faced by today’s experienced monitor. Monitoring thought leaders will present advanced monitoring strategies and best practices that will improve both the monitor’s job performance and the clinical research site’s performance. The conference will also include a review of and reaction to recent FDA monitoring-related citations, guidances, and inspection trends, and how these developments affect the overall strategy and the day-to-day activities of the monitor.

MONITORING IN 2010

More than Monitoring: The Changing Expectations of the Monitor’s Responsibilities
Darren Cowan-Bittner, Regional Team Leader, Clinical Research, Western Canada, Pfizer Canada, Inc.
Kathleen M. Recchiuti, Clinical Study Standards Lead, U.S. Clinical Operations, Clinical Study Operations, PGRD, Pfizer, Inc.

The Risk-Based Monitoring Plan
John Creech, CCRP, Clinical Research Associate, Clinical Operations, Abbott Vascular

Monitoring in an Era of Change
Barbara E. Tardiff, M.D., MBA, Corporate Vice President, Data Sciences, PAREXEL International

FDA AUDITS: PREPARATION AND FOLLOW-UP

What the FDA Warning Letters Tell Us about Clinical Monitoring: Diverse Perspectives on a Critical Process
Barbara van der Schalie, Contractor, Clinical Training Manager, Clinical Research Monitoring Program, SAIC-Frederick

Preparation for an FDA Audit
Michelle Noe, Senior Regulatory Operations Officer, Office of Regulatory Affairs, New England District, U.S. Food and Drug Administration
Patricia Murphy, Bioresearch Monitoring Specialist, Investigations Branch, U.S. Food and Drug Administration

What One Site Learned from Their First FDA Audit—Sharing and Learning from the Experience!
Nada Mlinarevich, Research Manager, Department of Neurosurgery, University of Illinois, Chicago

SITE RELATIONSHIP MANAGEMENT: BUILDING PARTNERSHIPS

Improving the Monitor’s Reputation: “Fixing” Site Misperceptions of the Monitor’s Role
Amy Adams, Clinical Project Manager, Regulatory Compliance and Human Subjects Protection Program (RCHSPP), SAIC-Frederick

Sponsor and Site Communication: A Framework for Developing an Effective and Rewarding Site-Sponsor Partnership
Deborah Lasher, RN, MPH, CCRC, CCRA, Senior Clinical Research Specialist, Diabetes Clinical Research, Medtronic, Inc.

MONITORING IN THE OUTSOURCED ENVIRONMENT

How to Go from Being a Good CRO Monitor to a GREAT CRO Monitor
Brenda Reese, Executive Director, West Coast Operations, Clinical Operations, DSP Clinical Research

Best Practices for the CRO Monitor: Managing Various Scenarios, Establishing Clear Communication, Developing SOPs, and Managing Staff Turnover
Amal Kumar, Team Lead—Research Scientist, Clinical Research and Pharmacology, Cadila Pharmaceuticals Limited

Connecting the Dots: Sponsor Strategy for Ensuring Quality and Integrity in Clinical Trials while Enhancing CRO-Site-Sponsor Relationships
Rebecca Darlington, Manager, Clinical Operations, Otsuka Pharmaceutical Development & Commercialization

GLOBAL VIEW ON MONITORING

Global Monitoring: Strategies for Managing Sites in Both Developed and Developing Regions
Rodrigo Crispim, Site Monitoring Manager, Brazil Regional Clinical Operations, Bristol-Myers Squibb

Creating a Collaborative Environment at Monitoring Visits: A Global Perspective
Carol Opalek, Clinical Research Associate, Abbott Vascular

Monitoring Informed Consent in India: Addressing Ethical, Regulatory, Sponsor, Protocol, and IRB Requirements
Rao Teki, Ph.D., Vice President, Clinical Operations, MakroCare

BEST PRACTICES FOR SITE MONITORING AND MANAGEMENT

Monitoring “Worst Practices”: The Impact of Bad Habits and Corner Cutting
Christine Sahagian, M.S., Associate Director, Clinical Compliance, Biogen Idec

Working with Clinical Sites to Implement Corrective Action Plans that Work!
BJ Guthrie, Manager, Clinical Operations, Clinical Research, Abbott Vascular

Troubleshooting Difficult Sites: Strategies for Achieving Compliance
Marsha (Toby) Johnston, RN, CCRA, Associate Director, Regional Study Managers with Global Site Management, Pfizer, Inc.

MONITORING IN THE ELECTRONIC ENVIRONMENT

EDC Training Requirements in Clinical Trials: A Monitor’s Role in EDC, CRA, and Site Activities
Tina Pagos, EDC Technology Project Leader, EDC Solutions, Chiltern International

Electronic Medical Records: Overcoming the Obstacles in Monitoring the EMR
Dana Haudek, Manager, Clinical Operations, Research/Vascular, Abbott Vascular

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Abstracts are Still Being Accepted in the Following Topic Areas:

- Global Monitoring: Strategies for Managing Sites in Both Developed and Developing Regions
- Optimizing Efficiency in the Budgeting and Contracting Process
- Strategies for Adverse Event Reporting and Compliance: Reconciling Adverse Event Data
- Strategies for Source Documentation Management: Regulatory Requirements, Best Practices, and Expert Interpretations
- Approaches to Site Training: Implementing, Following-Up, Documenting, and Evaluating the Effectiveness of Training Initiatives
- Knowing Your Training Responsibilities: The Monitor’s Role in and Responsibility for Training the Clinical Research Site
- Examining the Impact of the New FDA Guidance, “Investigator Responsibilities–Protecting the Rights, Safety, and Welfare of Study Subjects”

For questions about the meeting, please contact:
Rachel Meyers, Associate Director
Barnett International
a division of Cambridge Healthtech Institute
Email: rmeyers@barnettinternational.com
Phone: (413) 527-3056

Become a Sponsor

Your company has a unique opportunity to influence this major gathering of Clinical Trial Monitoring leaders.

Brand your company as a thought leader in providing clinical trial monitoring solutions and services by participating as an active Sponsor.

Presenting your solutions or services directly to our delegates can significantly impact their purchasing and collaboration decisions and help you achieve your sales and business development objectives.

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To discuss your objectives and participation options, please contact:
Arnie Wolfson
Manager of Business Development
Phone: 781-972-5431
E-mail: awolfson@healthtech.com
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HOTEL & TRAVEL INFORMATION

Conference Hotel:
Royal Sonesta Hotel
40 Edwin Land Boulevard
Cambridge, MA 02142
Phone: 617-806-4200
Fax: 617-806-4232
Discounted Room Rate: $199 s/d
Discounted Cut-off Date: May 24, 2010

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

Flight Discounts:
To receive a 5% or greater discount on all American Airline flights please use one of the following methods:
- Call 1-800-433-1790 use Conference code 6360AD
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- Contact Wendy Levine, Great International Travel 1-800-336-5248 ext. 137

Car Rental Discounts:
Special discount rentals have been established with AVIS for this conference. Please use one of the following methods:
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- Go online www.avis.com use our Avis Worldwide Discount (AWD) Number J868190

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HOW TO REGISTER: Online: www.healthtech.com/crm
Email: reg@healthtech.com
Phone: 781-972-5400 Fax: 781-972-5425

Yes! Please register me for the Mastering Clinical Trial Monitoring

Key Code CRM 106400P

REGISTRATION INFORMATION

Mr. Ms. Mrs. Dr. Prof.
Name
Job Title Div./Dept.
Company
Address City/State/Postal Code Country
Telephone

How would you prefer to receive notices from CHI? Email: Yes No Fax: Yes No

*Email is not a mandatory field. However, by excluding your email you will not receive notification about online access to pre-conference presenter materials, conference updates, networking opportunities and requested eNewsletters.

MAIN CONFERENCE PRICING

Commercial Academic, Government, Hospital-affiliated
Early Registration Deadline until March 26, 2010 $1245 $625
Advance Registration Deadline until May 14, 2010 $1395 $695
Registrations after May 14, 2010 and on-site $1595 $795

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. Please reproduce this registration form as needed.

GROUP DISCOUNTS AVAILABLE!

Special rates are available for multiple attendees from the same organization. Contact David Cunningham at 781-972-5472 to discuss your options and take advantage of the savings.

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Invoice me, but reserve my space with credit card information listed below.

Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availability.

Please charge: AMEX (15 digits) Visa (13-16 digits) MasterCard (16 digits)

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Each registration includes all conference sessions, exhibits, and food functions, and a copy of the conference proceedings link.

Group Discounts
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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.

Substitution/Cancellation Policy
In the event that you need to cancel a registration, you may:
- Transfer your registration to a colleague within your organization
- Credit your registration to another Cambridge Healthtech Institute program
- Request a refund minus a $100 processing fee per conference
- Request a refund minus the cost ($350) of ordering a copy of the CD

Note: Cancellations will only be accepted up to two weeks prior to the conference.

Program and speakers are subject to change.

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

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